WIPO AND THE REINFORCEMENT OF THE NAGOYA PROTOCOL: TOWARDS EFFECTIVE IMPLEMENTATION OF AN ACCESS AND BENEFIT SHARING REGIME FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

by

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Abstract

Traditional knowledge associated with genetic resources (TKaGRs) is acknowledged as a valuable resource. Its value draws from economic, social, cultural, and innovative uses. This value places TK at the heart of competing interests as between indigenous peoples who hold it and depend on it for their survival, and profitable industries which seek to exploit it in the global market space. The latter group seek, *inter alia*, to advance and maintain their global competitiveness by exploiting TKaGRs leads in their research and development activities connected with modern innovation. Biopiracy remains an issue of central concern to the developing world and has emerged in this context as a label for the inequity arising from the misappropriation of TKaGRs located in the South by commercial interests usually located in the North. Significant attention and resources are being channeled at global efforts to design and implement effective protection mechanisms for TKaGRs against the incidence of biopiracy. The emergence and recent entry into force of the Nagoya Protocol offers the latest example of a concluded multilateral effort in this regard. The Nagoya Protocol, adopted on the platform of the Convention on Biological Diversity (CBD), establishes an open-ended international access and benefit sharing (ABS) regime which is comprised of the Protocol as well as several complementary instruments. By focusing on the trans-regime nature of biopiracy, this thesis argues that the intellectual property (IP) system forms a central part of the problem of biopiracy, and so too to the very efforts to implement solutions, including through the Nagoya Protocol. The ongoing related work within the World Intellectual Property Organization (WIPO), aimed at developing an international instrument (or a series of instruments) to address the effective protection of TK, constitutes an essential complementary process to the Nagoya Protocol, and, as such, forms a fundamental element within the Nagoya Protocol’s evolving ABS regime-complex. By adopting a third world approach to international law, this thesis draws central significance from its reconceptualization of biopiracy as a trans-regime concept. By construing the instrument(s) being negotiated within WIPO as forming a central component part of the Nagoya Protocol, this dissertation’s analysis highlights the importance of third world efforts to secure an IP-based reinforcement to the Protocol for the effective eradication of biopiracy.
Dedication

The grace of God and everything it represents to me.
Abisoye, Anjore, and Kamisore; you make it all worth it!

1 Corinthians 15.10, John 15.5
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The tangible output of the past four years of my doctoral study is contained in this volume. However, in completing this work, I owe a debt of gratitude to several individuals and institutions, without whom and which the completion of this work would not have been possible.

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All errors and ommissions contained within this work remain mine.
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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ABS</td>
<td>Access and Benefit Sharing</td>
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<td>ABSCH</td>
<td>Access and Benefit Sharing Clearing House</td>
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<tr>
<td>AML</td>
<td>African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (AML)</td>
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<tr>
<td>ASPAC</td>
<td>Asian and Pacific Countries</td>
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<tr>
<td>CACEES</td>
<td>Caucus of Asian and Eastern European States</td>
</tr>
<tr>
<td>CBD</td>
<td>Convention on Biological Diversity</td>
</tr>
<tr>
<td>CEBS</td>
<td>Central European and Baltic States</td>
</tr>
<tr>
<td>CEWIPO</td>
<td>Convention Establishing the World Intellectual Property Organization</td>
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<tr>
<td>CNA</td>
<td>Competent National Authority</td>
</tr>
<tr>
<td>COP-MOP</td>
<td>Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol</td>
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<tr>
<td>CSICH</td>
<td>Convention for the Safeguarding of the International Cultural Heritage</td>
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<td>CSIR</td>
<td>South African Council for Scientific and Industrial Research</td>
</tr>
<tr>
<td>ECOSOC</td>
<td>United Nations Council for Economic and Social Affairs</td>
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<tr>
<td>EMCA</td>
<td>Kenyan Environmental Management and Coordination Act</td>
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<tr>
<td>EMCR</td>
<td>Kenyan Environmental Management and Coordination Regulation</td>
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<tr>
<td>FAO</td>
<td>Food and Agriculture Organization</td>
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<tr>
<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
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<tr>
<td>GRIPS</td>
<td>Intellectual Property-Related aspects of Genetic Resources.</td>
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<tr>
<td>GRs</td>
<td>Genetic resources</td>
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<tr>
<td>GRULAC</td>
<td>Group of Latin American and Caribbean States</td>
</tr>
<tr>
<td>IBRD</td>
<td>International Bank for Reconstruction and Development</td>
</tr>
<tr>
<td>ICNP</td>
<td>Open-Ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol</td>
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ICSIR  Indian Council for Science and Industrial Research
IFPMA  International Federation of Pharmaceutical Manufacturers & Associations
IGC  World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
ILC  International Law Commission
ILO  International Labor Organization
IMF  International Monetary Fund
IP  Intellectual Property
IPC  Intellectual Property Committee
IPCS  International Patent Classification System
IRCC  Internationally Recognized Certificate of Compliance
ITO  International Trade Organization
ITPGRFA  International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN  International Union for the Conservation of Nature and Natural Resources
LMC  Like-Minded Group
LMMC  Like-Minded Megadiverse Countries
MATs  Mutually Agreed Terms
MTS  Multilateral Trading System
NAFTA  North America Free Trade Agreement
NEMA  Kenyan National Environment Management Authority
NFP  National Focal Point
OHCHR  Office of the United Nations High Commissioner for Human Rights
P&B  World Intellectual Property Organization Program and Budget.
PGRFA  Plant Genetic Resources for Food and Agriculture
PIC  Prior Informed Consent
PLT  Patent Law Treaty
R&D    Research and Development
S& Dt  Special and Differential Treatment
SASI   South African San Institute
SCP    WIPO Standing Committee on the Law of Patents
TAK    Traditional Agricultural Knowledge
TCEs   Traditional Cultural Expressions
TEK    Traditional Ecological Knowledge
TK     Traditional Knowledge
TKaGRs Traditional Knowledge associated with Genetic Resources
TMK    Traditional Medical Knowledge
TPP    Trans-Pacific Partnership
TRIPS  Agreement on Trade-Related Aspects of Intellectual Property Rights
TWAIL  Third World Approach to International Law
TWIP   Third World Innovations and Practices
UNDRIP United Nations Declaration on the Rights of Indigenous Peoples
UNEP   United Nations Environment Program
UNESCO United Nations Educational Scientific and Cultural Organization
USPTO  United States Patents and Trademarks Office
VCLT   Vienna Convention on the Law of Treaties
WCED   World Commission on Environment and Development
WG-ABS Working Group on Access and Benefit Sharing
WHO    World Health Organization
WIPO   World Intellectual Property Organization
WTO    World Trade Organization
The most pressing issues to challenge are not the gap between theory and practice, or the gap between politics and public interest. Fundamentally, we need to address the gap between where we are today and where we want to be tomorrow.¹

Chapter 1

Introduction

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity [Nagoya Protocol]\(^2\) is an international legal instrument which establishes an international regime on access and benefit sharing (ABS). The Protocol advances the Convention on Biological Diversity (CBD)’s broader objectives of biodiversity conservation and sustainable use\(^3\) by offering another approach, within the context of international environmental law, to the protection of traditional knowledge (TK). Significantly, the Protocol carves out an important subsection of TK for protection: TK associated with genetic resources (TKaGRs).\(^4\) The equitable sharing of benefits arising from the use of TKaGRs forms a core objective of the Protocol.

Adopted in 2010, the Protocol entered into force in 2014 and is currently the subject of implementation efforts both at the national and international level. Though not mentioned explicitly in its text, the eradication of biopiracy represents a central objective underlying the implementation of the benefit sharing mechanism of the Protocol. This is particularly from the perspective of developing countries, which presently account for 75 per cent of the total ratifications to the Protocol.\(^5\) In other words, the express

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\(^2\) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 29 October 2010 [no UNTS Volume Number has yet been determined for this record] (entered into force 12 October 2014) [Nagoya Protocol]. For the full decision by the Conference of the Parties (COP) adopting the Protocol, see Doc.: UNEP/CBD/COP/DEC/X/1 of 29 October 2010, annexed to this dissertation (Annex 1).

\(^3\) The Convention on Biological Diversity pursues three key objectives: the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources (GRs). See, Article 1, CBD, 5 June 1992, 1760 UNTS 79; 31 ILM 818 (entered into force 29 December 1993) [CBD]. For its part, the Nagoya Protocol identifies the fair and equitable sharing of benefits arising from the use of GRs as its singular objective, with the purpose, however, of ‘contributing to the conservation of biological diversity and the sustainable use of its components’ (See, Article 1). In other words, the Protocol singles out the sharing of benefits as a plan of action for the attainment of the CBD’s other objectives.

\(^4\) See Article 3, Nagoya Protocol, noting that the Protocol shall apply to traditional knowledge associated with genetic resources (TKaGRs) within the scope of the CBD and to the benefits arising from the utilization of such knowledge. A full discussion and contextualization of TKaGRs for this thesis is undertaken in chapter three.

\(^5\) This is current to October 19, 2016. With a total of 87 ratifications, the significant ratifications from developed countries come from the European Union (22), a factor which is attributable in large part to the direct compliance required within the Union pursuant to EC, Regulation (EU) No 511/2014 of 16 April 2014 on compliance
objective of the Protocol (the equitable sharing of benefits) is aimed at addressing an implicit objective (the eradication of biopiracy) which is of immense importance to developing countries.

Biopiracy is generally described as the uncompensated acquisition of the genetic resources (GRs) and/or TKaGRs of indigenous peoples by users, most of whom are usually located in industrialized countries. The most common users are located within the innovation sectors, and include pharmaceutical corporations, personal care manufacturing companies, biotechnology industries, and academic institutions, to name but a few. Biopiracy represents a major concern of developing countries and indigenous peoples. In this dissertation, I examine, through a conceptual, legal and institutional analysis, whether the Nagoya Protocol is able to meet this identified implicit objective of addressing the incidence of biopiracy. In analyzing the Protocol’s ability to address biopiracy, I particularly focus on biopiracy’s manifestation through the misappropriation and/or misuse of TKaGRs. To this end, the subject of TK receives prominence in my discussion of biopiracy.

To clarify this focus on TKaGRs, the biopiracy rhetoric bears within its scope concerns over two core subjects of appropriation: GRs and TKaGRs. It is recognized, particularly from a western analytical perspective, that the knowledge over GRs could be misappropriated without the actual GRs being misappropriated and vice versa. While most cases of misappropriation generally involve both subjects of appropriation (that is, the GRs and the TKaGRs), the legal recognition of the distinct possibilities regarding separate isolated instances of misappropriation has resulted in the Nagoya Protocol outlining parallel provisions to regulate the protection of TKaGRs and GRs respectively. The focus then, in this dissertation, is on the Nagoya Protocol’s efforts to articulate a protection mechanism for TKaGRs from the incidence of biopiracy.

Focusing on TKaGRs as a ‘subject of appropriation’ is extremely important in a world today where knowledge occupies the center of innovation and matrices of global competitiveness. Innovation, in turn,
sits at the heart of the intellectual property (IP) system and is seen as a major driver of economic
development. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), for
instance, provides:

> [t]he protection and enforcement of intellectual property rights should contribute to the
> promotion of technological innovation and to the transfer and dissemination of
> technology, to the mutual advantage of producers and users of technological knowledge
> and in a manner conducive to social and economic welfare, and to a balance of rights and
> obligations.\(^7\)

Indeed, the IP system has emerged as a system for development; one which industrialized countries
point to as the basis for their global competitiveness. They argue that the global implementation of its
mechanism will guarantee a fertile environment for rapid economic development, including in developing
countries. Empirical studies have failed to confirm the veracity of this claim.\(^8\) On the contrary, evidence
points to the negative effects which the globalization of the IP system has had on several developing
economies.\(^9\) IP broadly encapsulates creations of the mind. It includes within its ambit, for instance,
inventions, literary and artistic works, designs, symbols, names and images which are used in the fields of
commerce.\(^10\) IP law is widely justified as a system which exists to encourage and reward creative work,
promote technological innovation, ensure fair competition in the market space, guarantee the protection of
consumers, and facilitate the transfer of technology. Of central relevance to this dissertation is the patent
system. Patents are a form of IP. As a system designed to incentivize innovation, the patent system extends
protection to ‘knowledge’/innovation as determinable through three mutually inclusive criteria; knowledge
which is new, the product of an inventive step, and which is capable of industrial application.\(^11\) The
rationale underlying these criteria reflect an instrumental justification for IP; one which seeks to spur further

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\(^7\) See, Article 7, *Agreement on Trade-Related Aspects of Intellectual Property Rights*, being Annex 1C to the Final

\(^8\) See discussion in 6.1.2.5. *infra*.

\(^9\) Ibid.

\(^10\) The Convention Establishing the World Intellectual Property Organization, 14 July 1967, 828 UNTS (entered
into force 26 April 1970) [CEWIPO], notes that IP includes all rights resulting from intellectual activity in the
industrial, scientific, literary or artistic fields, including the rights relating to; literary, artistic and scientific
works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human
endeavour; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and
designations; and protection against unfair competition. CEWIPO Article 2 (viii).

\(^11\) See Article 27, TRIPS Agreement. A patent confers a minimum 20-year term of protection on the patent holder.
See, Article 33, TRIPS Agreement.
inventions while yet sharing the results of innovation with society. TK as an indigenous body of innovation does not meet these prescriptions for the privatization of knowledge as property and, as such, its protection is generally excluded from the modern IP system.12

TK is definable as the knowledge resulting from intellectual activity in a traditional context,13 and could be viewed as a form of IP. In making this statement, I am careful to clarify that its potential characterization as an IP form is more a conceptual one. This conceptualization is based on the fact that TK constitutes a creation of human minds, albeit indigenous minds. A representative system of governance in human creativity should, therefore, ordinarily include TK within its regulatory structure. Historically, however, TK as a body of knowledge, as well as its holders and owners, has been excluded from the protection mechanism contained within the formal IP system. This exclusion is traceable to the Eurocentric conceptions of knowledge which are foundational to the IP system. These conceptions of knowledge, including the regulatory indices for its creation, are reflected in the patentability criteria outlined above.

The prevailing regulatory standard for determining innovation and knowledge lends itself to suggestions of incompatibility between the IP system protection mechanism and the protection of TK.14 This incompatibility arises because of the peculiarities of TK which do not necessarily align with the general concept of knowledge recognized and catered for within the classical IP system.15 Sanjay Bavikatte notes four of such key anti-TK assumptions which underlie the IP system: the assumption that the owners or progenitors of knowledge are clearly identifiable; the assumption that new knowledge is clearly distinguishable from old knowledge; the assumption that knowledge creation and development is primarily motivated by the potential of future rewards and that creators would be willing to share their knowledge with society in exchange for such rewards; and, the assumption that IP rights adequately reward developers

13 See, WIPO Glossary of Key Terms Related to Intellectual Property & Genetic Resources, Traditional Knowledge & Traditional Cultural Expressions, WIPO IGCOR, 31 Sess, WIPO/GRTKF/IC/31/INF/7 (2016) at 40.
of new knowledge by guaranteeing their exclusive and time-bound use of such knowledge in exchange for sharing the knowledge with society.\textsuperscript{16}

The continued exclusion of TK from the IP system therefore constitutes a difficulty for the legitimacy of the IP system as we know it today. This is because a significant portion of human creativity, as contained within the indigenous experience, is unable to access protection from the IP system, purportedly designed to recognize, reward, and promote all of human creativity. Furthermore, in assigning IP rights over inventions based on TK, the IP system rewards inventors to the exclusion of holders of the underlying TK which lead to such inventions. In this sense, the IP system has been criticized as a facilitator of the misappropriation of TK as the historical innovative practices of indigenous and local communities, which constitute a significant driver of ‘modern’ innovation, are largely undermined.\textsuperscript{17} Consequently, the role of the IP system in further entrenching inequalities in the treatment of TK vis-à-vis knowledge categories which are eligible to receive IP protection, places the IP system in a precarious position particularly with TK holders and their sympathizers.

As noted, these foundational ideas about knowledge, creativity, and innovation as contained in the IP system were linked to European ideas of knowledge and thus excluded uncivilized forms of knowledge.\textsuperscript{18} In this dissertation, such uncivilized forms of knowledge are broadly categorized as third world innovation and practices (TWIP). A major part of this is TK. This foundational exclusion of TWIP from the IP system, as well as the entrenched institutional inequalities that have continued to define the narrative amongst the protectable and non-protected knowledge categories, has led writers like Ikechi Mgbeoji to suggest the IP system as being inherently racist.\textsuperscript{19} Ruth Okediji’s reflections on the IP system’s viewing of third world innovation also supports this conclusion.

\textsuperscript{16} Ibid.
\textsuperscript{17} Amani, “What’s Wrong with IPRs?”, supra note 12 at 21, noting a flaw of the IP system being its alienation of the contributions of TK preservers for the use of plant resources rendering same free for private taking.
\textsuperscript{19} Mgbeoji, Ikechi. Global Biopiracy: Patents, Plants & Indigenous Knowledge (Vancouver: UBC Press, 2006) [Mgbeoji, Global Biopiracy] at 56, noting that the early western scientific world was an elitist structure which emerged with a narrow construct on knowledge, thus alienating all that did not conform to such standards. This led to the assumption that there was no science or knowledge amongst the races and peoples of the South. See
[t]he key question about IP in Africa is not whether there is innovation and creativity on the African continent, but whether the IP system counts the innovation that exists. These IP categories are not static — they are political and social […] the inability of IP to deal with African innovation and creativity is not an issue of methodology, but one of systematic manipulation.20

For her, this points to a pressing need to challenge the regulatory capture of IP.21 An increasing awareness and acknowledgment of the need to address this inequity has been witnessed within international circles. It is now widely accepted, for instance, that the IP system is not sufficiently representative of knowledge holders and creators all around the world. Since the late 1990s, the World Intellectual Property Organization (WIPO) – the specialized agency of the United Nations tasked with the global administration, protection, and promotion of IP – has been invested in normative and policy efforts to make the IP system more representative by incorporating new beneficiaries of IP protection. Significantly, these efforts are directed at indigenous peoples and local communities, and their TK.

WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2000 as an IP-based policy forum for discussions relating to the protection of GRs, TK and traditional cultural expressions (TCEs). The IGC’s negotiations are structured across these three major themes (GRs, TK, and TCEs). Within this research, the IGC themes of GRs and TK bear direct relevance to the subject matter of TKaGRs and biopiracy. For this reason, my reference to the emerging IGC instruments, including arguments for their coherence with the Nagoya Protocol, is limited to significant aspects of the textual developments being undertaken under these two subject areas.

Participants within the IGC include WIPO Member States and accredited observers. These observers are drawn from indigenous groups, industry representatives as well as a wide range of public interest organizations. These participants have continued to debate on the text(s) of an international legal

also Pat Mooney, noting that the argument that IP is only recognizable when performed in laboratories with white lab coats is fundamentally a racist view of scientific development. (Ibid., at 140)

Farmers’ fields and forests are laboratories, farmers and healers are researchers. Every season is an experiment. (Ibid.).

21 Ibid.
instrument(s) for ensuring the effective protection of TK.\textsuperscript{22} These negotiations have been ongoing for about 16 years and still do not yet show signs that delegations are nearing consensus on core aspects of an IP-based protection system for TK. Specifically, efforts by developing countries to utilize the IP system to secure defensive reinforcements\textsuperscript{23} has continued to face stiff resistance from industrialized States. As part of this research, I was privileged to coordinate a total of six sessions of these IGC’s negotiations over a period of two years (2012 – 2014). In this role, I interacted closely with delegates to the IGC and engaged closely with the core issues, both political and substantive, which continue to inform the deliberations. This opportunity effectively served as a field study for this research and, to this end, several reflections from this experience inform this research and will be drawn on in the course of this dissertation.

This dissertation demonstrates that the IGC process is a central element in the Protocol’s efforts to address the protection of TKaGRs from the incidence of biopiracy. It contends that the Protocol cannot properly address biopiracy without the support of a coherent defensive protection outcome emanating from the WIPO IGC. This arises from the central assertion advanced that the Protocol’s ABS regime and the international legal instrument(s) which are emerging from the IGC negotiations, form elements of a \textit{single} regime complex aimed at addressing effectively the protection of TKaGRs from the incidence of biopiracy. To make this argument, this dissertation situates itself within the voices and struggles of third world actors concerning TWIP within this evolving area of international governance. It justifies its primary assumptions based on a third world approach to international law (TWAIL).\textsuperscript{24} A full discussion of this approach,

\textsuperscript{22} See, for example, the current mandate of the IGC for the 2016/2017 biennium in \textit{Assemblies of the Member States of WIPO: Fifty-Fifth Series of Meetings, Geneva, October 5 to 14, 2015: List of Decisions, A/55/INF/11, WIPOGAOR, 55\textsuperscript{th} Sess (2015) [IGC 2016/2017 Mandate]} at 10 – 12, with specific reference to para (a), providing, in relevant part, that

\begin{quote}
The Committee will […] continue to expedite its work, with a focus on narrowing existing gaps, with open and full engagement, including text-based negotiations, with the objective of reaching an agreement on an international legal instrument(s) […], relating to intellectual property which will ensure the balanced and effective protection of genetic resources (GRs), traditional knowledge (TK) and traditional cultural expressions (TCEs).
\end{quote}

\textsuperscript{23} By defensive reinforcements, I refer to complementary rules, principles or norms to the ABS regime, located within the IP system, and which prevent third parties from utilizing the IP system to illegally secure rights over GRs, TKaGRs, or inventions based thereon where compliance with the ABS regime has not been effected. The most significant normative defensive reinforcement which I point to within this thesis is the proposed mandatory disclosure requirement within patent applications discussed further in chapter 6 below.

\textsuperscript{24} The TWAIL scholarship is channeled towards a ‘…a commitment to centre the rest rather than merely the west, thereby taking the lives and experiences of those who have self-identified as Third World much more seriously than has generally been the case’. See Obiora Okafor, ‘Critical Third World Approaches to International Law
including its relevance to this dissertation’s analysis is undertaken in chapter two. It is worth clarifying here that by referencing the TWAIL scholarship, my intention is not to seek an exploration of TWAIL or its criticisms. Rather, the TWAIL reference here is provided as guiding light to the rationale underlying the choices adopted in the analyses undertaken in this dissertation. Specifically, it provides a rationalization for the emphasis on third world interests within the discussion of ABS.

A theoretical rationalization for this dissertation’s analysis is contained within a discussion of international regimes and their existential interdependence. This draws from an understanding that regimes are not negotiated in silos, neither are they implemented as independent structures of governance. Rather, international regimes are path dependent and are constantly influencing and being influenced by neighboring regimes which share a common connection within an issue area of concern. Such influences could have positive or detrimental consequences on the ability of respective individual regimes to attain their stated objectives. The potential of a regime to address the concerns for which it exists, must therefore be construed within the context of principal neighboring regime influences.

Furthermore, the idea of regime or institutional complexity is gaining prominence and exists as a complementary approach to viewing fragmented regulatory pieces of international law in support of effective international lawmaking. In other words, through a conceptualization of regime complexes, neighboring regimes are viewed as complementary elemental regimes addressing specific aspects of broader trans-regime concerns – concerns which could not ordinarily be addressed within single elemental regimes. The implication of this, is that in addressing specific issue areas within the context of regime complexes, several instruments must be read together as addressing differing aspects of a single issue of concern. The protection of TKaGRs from biopiracy is suggested as one of such trans-regime issue areas.

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which justifies a construing of the implementation of the Nagoya Protocol within the context of the emerging instrument(s) within the WIPO negotiations.

1.1 Research Background

To provide a contextual background to my central research question, three mutually inclusive pillars are of central significance. First, the Nagoya Protocol (including the justifications accompanying its negotiation); second, the phenomenon of biopiracy with a particular emphasis on its modern manifestations, and, third, the nature, status, rationale, as well as difficulties underlying the ongoing negotiations within the WIPO IGC. These three distinct, yet closely related paradigms are now introduced.

1.1.1 The Nagoya Protocol: A Benefit Sharing Institution

Parties to the CBD adopted the text of the Protocol in the early hours of October 30, 2010, in Nagoya, Japan. The Protocol is primarily aimed at implementing, in an effective way, the third objective of the CBD. The third objective of the CBD relates to the fair and equitable sharing of benefits which arise from the use of GRs. This objective also extends to the equitable sharing of benefits which arise from the use of TK of indigenous peoples associated with GRs. The adoption of the Protocol signified the climax to an intense era of multilateral negotiations that occurred under the auspices of the United Nations (UN), spanning over six years, for an international regime on ABS. In line with the above stated third objective of the CBD, the core negotiation of this international regime was focused, inter alia, on the legal clarification of standards which would facilitate the lawful access to GRs and TKaGRs located within provider countries. Furthermore, it was aimed at strengthening the institutional and regulatory mechanisms which would ensure that provider countries and indigenous peoples secured equitable returns from the benefits which may be realized where such TKaGRs and GRs are accessed for use.

About four years after its adoption, on October 12, 2014, the Protocol entered into force. This was exactly 90 days after the fiftieth country ratified the Protocol. A total of 87 ratifications and/or

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27 This is in accordance with Article 33, Nagoya Protocol.
accessions have so far been received to the Protocol,\textsuperscript{28} of which 75 percent are from developing countries. Canada, as well as several other industrialized countries including the United States, has not yet signed the Protocol and, as such, has no registered intent to be bound by the provisions of the Protocol. Two related implications of this neglect are worth highlighting here.

First, this ratification trend \textit{prima facie} suggests the primary importance of the Protocol and its implementation to developing countries, while yet revealing a corresponding nonchalance from several developed countries to the Protocol. Second, given that the majority of scientific users of GRs and TKaGRs are located in industrialized countries, an early potential hurdle regarding the implementation of the Protocol can be identified.\textsuperscript{29} Indeed, a major rationale for negotiating the Protocol was to offer political and legal support to the domestic regulatory efforts of provider states. This support was aimed at preventing misappropriation by ensuring that regulatory frameworks within user states provide for individual users of GRs within their territories to be in compliance with the ABS obligations of the provider countries. A significant achievement of the Protocol is consequently its requirement that all Parties to the Protocol develop legislation which ensures that users of GRs and TKaGRs within their own territories have complied with the existing ABS regulations in the foreign countries from which these resources were sourced.\textsuperscript{30} Where major user countries therefore refuse to sign on to the Protocol, early questions are raised as to the ability of the Protocol to achieve its objectives in monitoring the use of GRs and TKaGRs. Furthermore, the ability of the Protocol to ensure that the ABS regulations of provider countries are enforced within user territories, is thrown into doubt.

\textbf{1.1.2 Biopiracy: A Third World Law and Policy Concern}

Developing countries have shown a demonstrable support for the Nagoya Protocol. From their perspective, the Nagoya Protocol represents a major solution to the incidence of biopiracy. The remedial

\textsuperscript{28} For a full listing of the 87 ratifications and/or accessions, including the signatories to the Nagoya Protocol, see CBD: Parties to the Nagoya Protocol, \textit{supra} note 26 [current to September 30, 2016].

\textsuperscript{29} Daniel Robinson notes that the non-participation of countries like the United States is a central concern in foreseeable efforts (including through the Nagoya Protocol) to address the incidence of biopiracy. See Daniel F Robinson, \textit{Confronting Biopiracy: Challenges, Cases & International Debates} (UK: Earthscan Ltd, 2010) [Robinson, \textit{Confronting Biopiracy}].

\textsuperscript{30} See, for instance, Articles 5, 15 & 16, Nagoya Protocol.
implementation of an effective ‘benefit sharing’ solution to biopiracy, therefore, remains an issue of prime concern to the developing world. The case of the San Peoples of southern Africa, who have lived in the Kalahari Desert for thousands of years offers an excellent example of biopiracy and benefit sharing.31

The San tribes of the Kalahari Desert have historically occupied regions within Botswana, Namibia, South Africa, and Angola.32 They are among the oldest and poorest communities in Africa.33 The San have historically used the bitter flesh of the Hoodia plant (hoodia gordonii) – a leafless succulent plant endemic to the region – to effectively block feelings of hunger and energize themselves when hunting or on long trips across their inhospitable land.34 Based on their traditional collaborative lifestyle of uninhibited sharing, the San people often shared their TK associated with hoodia with outsiders in exchange for small gifts.35 Unbeknownst to them, much of this TK gradually filtered into the ‘public domain’36 as some


32 According to Roger Chennells, the legal representative for the San, the San presently comprise approximately 100,000 people, 55,000 of whom live in Botswana, 35,000 in Namibia, 8500 in South Africa and 4500 in Angola, with scattered populations in Zimbabwe and Zambia. See Roger Chennells, “The Hoodia Case: A Paper presented at the Seminar ‘Strengthening Partnership between States & Indigenous Peoples: Treaties, Agreements & other Constructive Arrangements’”, organized by the Office of the High Commissioner for Human Rights, Geneva, 2012, online: OHCHR <http://www.ohchr.org/Documents/Issues/IPeoples/Seminars/Treaties/RogerChennells.pdf> at 2. [Chennells, The Hoodia Case]. See also Daniel Robinson, who notes that the San have lived off the land in a region including Botswana, Namibia, South Africa and Angola for over 20,000 years. Robinson, Confronting Biopiracy, supra note 29 at 61.

33 Bavikatte et al attribute the poverty levels of the San to the increasing marginalization they experienced due to the influx of Bantu herders from the north, European immigration and the private appropriation of their lands. See Kabir Bavikatte, Harry Jonas & Johanna von Braun, “Shifting Sands of ABS Best Practice: Hoodia from the Community Perspective” (2009) UNU-IAS Traditional Knowledge Initiative: Guest Articles, 31 March, online UNU <http://www.unutki.org/default.php?doc_id=137>. (accessed August 7, 2015). Roger Chennells similarly attributes the extreme poverty of the San people to centuries of genocide and marginalization initiated by the colonial era, which has resulted in the loss of land and consequently loss of culture and identity. Today, they occupy an unchallenged niche as the poorest of the poor in these countries, living in conditions of relative powerlessness. See Chennells, The Hoodia Case, supra note 32 at 2 – 3.

34 Attesting to the potency and efficacy of the Hoodia Plant, Rudolf Marloth, A South African ethno botanist, remarked of his experience with the San people and the Hoodia plant: 

[the sweet sap reminds one of licorice and, when on occasion thirst compelled me to follow the example of my Hottentot [San] guide, it saved further suffering and removed the pangs of hunger so efficiently that I could not eat anything for a day after having reached the camp. 


36 The public domain is said to consist of intangible materials that are not subject to exclusive IP rights and which are, therefore, freely available to be used or exploited by any person. It is the universe of inventions and creative works that are not protected by IP rights and therefore available for anyone to use without charge. See WIPO IG C OR, 17th Sess, WIPO/GRTKF/IC/17/INF/8, 2010 at para 2. Bryan Garner A, ed, Black’s Law Dictionary 10ed (USA: Thomson Reuters, 2014) at 1424.
researchers published information on the hoodia based on their interactions with the San.\textsuperscript{37} The South African Council for Scientific and Industrial Research (CSIR) learnt about these TK practices of the San through documented bioprospecting records and commenced research into the properties of the hoodia. The CSIR was able to determine a specific molecule of the plant (dubbed “P57”) that could be commercialized into an appetite suppressant and anti-obesity drug.\textsuperscript{38} The CSIR promptly secured a patent on the plant’s chemical properties having appetite suppressant activity.\textsuperscript{39} The rights to further develop and commercialize this patent was licensed to major pharmaceutical companies located in industrialized countries by the CSIR in exchange for hefty sums. The CSIR negotiated, for example, in 1998, an exclusive license, which transferred the rights over the further research and commercial exploitation of the patent to a UK company (Phytopharm) for the development of hoodia products.\textsuperscript{40} In its effort at commercialization, Phytopharm entered into a short-lived licensing agreement with the global pharmaceutical giant, Pfizer, and thereafter, a short-lived joint-development agreement with the food multinational, Unilever.\textsuperscript{41} The mere

\textsuperscript{37} According to Chennells, the botanist Francis Masson, who visited the Cape from 1772 to 1774 and 1786 to 1795 was the first to record the uses of the plant. Later the naturalist Marloth (1855–1931) described how the plant was used by San as a substitute for food and water. Robinson notes that it was the documented colonial ethnobotanical accounts of Francis Masson from 1978 that sparked the interest of the CSIR in 1963, in further studying the edible wild foods, including the hoodia, in the region. Robinson, \textit{Confronting Biopiracy}, supra note 29 at 61. See also Olufunmilayo B Arewa, “Piracy, Biopiracy and Borrowing: Culture, Cultural Heritage & the Globalization of Intellectual Property” (2006) Case Research Paper Series in Legal Studies (working paper 04-19) [Arewa, “Piracy, Biopiracy & Borrowing”] at 14. It is however worth pointing out here that there is considerable evidence that the willingness of indigenous peoples to share their knowledge is not the equivalent of placing it in the public domain. See, Susy Frankel & Peter Drahos, ‘Indigenous Peoples’ Innovation and Intellectual Property: The Issues (2012) 2 Victoria University of Wellington Legal Research Papers 9. [Frankel & Drahos, “Innovation & Intellectual Property”].

\textsuperscript{38} See WIPO, “Leveraging Economic Growth” \textit{supra} note 35.

\textsuperscript{39} South Africa Patent no. 198/3170 (1995). The patent has 132 claims relating to the use of the active components of the plants which are responsible for suppressing appetite. Robinson, \textit{Confronting Biopiracy}, supra note 29 at 61.

\textsuperscript{40} In addition to the licensing to Phytopharm, CSIR also filed for additional patents in other countries. In 2010, the CSIR and Phytopharm agreed to cancel the exclusive license agreement, thus placing the future of the hoodia back in the hands of the CSIR. Robinson, \textit{Confronting Biopiracy}, supra note 29 at 61.

\textsuperscript{41} Phytopharm’s initial license and royalty agreement with Pfizer was short lived owing to the closure of Pfizer’s Natureceuticals group. Some commentators have argued that the negative press around the hoodia at the time had a direct bearing on the corporate decision of the Pfizer to withdraw from its involvement with hoodia. In 2004, Unilever negotiated a joint-development agreement with Phytopharm to develop active ingredients of the plant into a functional weight-loss food. Unilever has also since pulled out of this agreement. Robinson, \textit{Confronting Biopiracy}, supra note 29 at 62. See also, Frederik Joelving, “Would-be Fat-fighter Hoodia nothing but Side Effects”, \textit{Reuters} (28 October 2011) online: Reuters <http://www.reuters.com/article/us-hoodia-idUSTRE79R6AI20111028> noting that the reason behind Unilever’s abandonment of its $25 million investment in the hoodia was linked to confirmed results of a clinical trial (which Unilever had known much earlier), published in The American Journal of Clinical Nutrition, the results of which suggested that the hoodia extracts had no impact on appetite or food intake, but did have a lot of side effects, like vomiting, weird skin sensations and elevated blood pressure and heart rate. See the full study in Wendy Blom, Salomon Abrahamse,
potential of the hoodia plant within the context of the lucrative western market for diet control ensured that millions of dollars exchanged hands between these commercial interests that saw the huge possibilities in the hoodia. Though the patent was secured legally, the case stirred public controversy as the CSIR failed to consult, acknowledge, or share benefits of the P57’s commercialization with the San peoples from whom the initial knowledge of the hoodia plant’s properties had been obtained.

In response to the public outrage, a benefit sharing agreement was eventually concluded between the CSIR and the San peoples. On the basis of this benefit sharing agreement (which clearly emerged as an afterthought), the San peoples were expected to receive six percent of all royalties received by the CSIR for products and eight percent of milestone income when certain targets were reached. Though a truly inadequate arrangement, it probably represented the best of what could be remedially secured at such an

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44 Under the WTO rules prescribing minimum requirements for Member States’ patent regimes, an invented product or process is recognised for protection where it is shown to be new, capable of industrial application and the product of an inventive step. See Article 27.1, TRIPS Agreement.

45 Juxtaposing the poverty of the San peoples with the vast sums which were exchanged for the licensing agreements and the potential value a drug emanating from the hoodia promised for the CSIR, questions of injustice were grounded in ethical, moral and even legal persuasions.


47 See Wynberg, “Hot air over Hoodia”, supra note 42. For further details of the benefit sharing arrangement, see Wynberg et al, Indigenous Peoples, Consent & Benefit Sharing, supra note 31. The benefit sharing trust, into which the payments were to be made, comprised of three representatives appointed by the South African San Council, a CSIR representative, a non-voting observer from the South African Department of Science and Technology, three representatives appointed by WIMSA, a member of WIMSA, and a professional appointed by the San Council. This Trust was established to ensure that monies received were used for the general development and training of San communities including the purchase of lands, building clinics, and investing in education and development projects. See WIPO, “Leveraging Economic Growth” supra note 35.
advanced stage of the misappropriation. In any event, a difficult situation for the CSIR and other involved pharmaceutical firms was greatly assuaged through this benefit sharing agreement. As at 2010, Wynberg reports that only $100 000USD had been paid into this account; a meagre figure in the context of the estimated market value that a successful product would represent.47

Discernible from the example above, the problem of biopiracy shows three interconnected and exploitative strands relating to the utilization of TKaGRs. First, it highlights the non-recognition of the innovation of indigenous peoples (and the biodiverse states within which they are located), such as the San peoples’ knowledge of the hoodia and the contributions of such knowledge to formal innovation chains. Though valuable, TKaGRs is largely considered knowledge which exists in the public domain and, as such, knowledge to which no legal protection attaches. Explaining the implications of this in a reverse context, protectable knowledge, as noted above, is defined by the modern intellectual property (IP) system to include knowledge that is new, the product of an inventive step, and which is capable of industrial application.48 The TK of indigenous peoples does not fit within this criteria, and as such is often erroneously discarded as not forming a protectable part of the innovation chain. As a result, the inventive practices of indigenous peoples which constitute a major driver for modern innovations are preyed on.49 The connotation of theft

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47 The dietary control of obesity is valued at over $3billion per year in the US alone. See Rachel Wynberg, “Hot air over Hoodia”, supra note 42.
48 See supra note 43.
49 Innovation is used interchangeably with invention in the course of this work to describe new knowledge. Strictly, they are however clearly distinguishable. According to Christopher Freeman, ‘technical innovation or simply innovation is used to describe the introduction and spread of new and improved products and processes in the economy and technological innovation to describe advances in knowledge’, while inventions are considered to be ‘an idea, a sketch or a model for a new or improved device, product, process or system […] an innovation in the economic sense is accomplished only with the first commercial transaction. See, Christopher Freeman, The Economics of Industrial Innovation (Harmondsworth: Penguin Modern Economic Texts, 1974) at 18, 22. Bill Walker distinguishes the concepts on the basis of use, noting that while invention is about creating something new, innovation introduces the concept of ‘use’ of an idea or method. Consequently, an invention is usually a ‘thing’, while an innovation is usually an invention that causes change in behaviour or interactions. Bill Walker “Innovation vs. Invention: Make the Leap & Reap the Rewards” (2015) online: WIRED <https://www.wired.com/insights/2015/01/innovation-vs-invention/>. Inventions are therefore marked by discovery or a state of new existence, while innovation is marked by first use in a manufacturing context of in a market. Innovation includes the generation of an idea or invention, and the conversion of that invention into a business or other useful application. Edward B Roberts “What We Have Learned: Managing Invention & Innovation” online: <http://secure.com.sg/courses/ICI/Grab/Student_Presentations/A01_G02.pdf>. To help contextualize their interchangeable use within this dissertation, Dan Breznitz & Peter Cowhey note incremental and process innovation as an important oft overlooked aspect of innovation which encompasses the improvements in how goods and services are designed, produced, distributed and serviced. See Dan Breznitz & Peter Cowhey, “America’s Two Systems of Innovation: Innovation for Production in Fostering U.S. Growth” (2012) 7:3 Innovations: Technology, Governance, Globalization 127 at 129 – 133. Their analysis supports an understanding of TK as an important part of the ‘incremental and process innovation’ which is often tapped for the purpose of
within the biopiracy rhetoric serves to emphasize this. Though the CBD recognizes TK, its primary focus is GRs. The minute reference to TK in the CBD is contained in Article 8(j) which states that

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\text{[e]ach contracting Party shall, as far as possible and as appropriate: subject to national legislation, respect, preserve and maintain knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices.}
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The Nagoya Protocol expands on this provision and develops an entire set of parallel provisions which stipulate regulations governing access, benefit sharing, and monitoring of the use of TK, as a distinct subject of protection from GRs.

Secondly, biopiracy highlights the exclusion of indigenous peoples from the decision-making processes which result in the utilization and/or commercialization of their TKaGRs. In this regard, the San peoples were neither consulted nor acknowledged when decisions regarding the commercialization of the hoodia based on their knowledge were being pursued. This is significant as the exclusion of indigenous peoples in this regard violates their guaranteed right to maintain, control, develop, and protect their TK, as well as to participate in decision making over their affairs. It is in this context that the misappropriation


51 Article 8(j), CBD (emphasis added).


53 See Article 18, UNDRIP.
and/or theft of TKaGRs again features as a central theme underlying the biopiracy rhetoric. To counteract this, the Nagoya Protocol’s ABS regime requires that the prior informed consent (PIC) of indigenous peoples relating to the use of their TK is obtained.\textsuperscript{54} Furthermore, to ensure the participation of indigenous peoples, the development of mutually agreed terms (MATs), which govern the entire interaction of users with the resources and/or TK, is required.\textsuperscript{55}

Third, biopiracy highlights the inequitable distribution of economic resources which arise from the use and commercialization of GRs and TKaGRs. GRs are defined by the CBD as genetic material of actual or potential value. Consequently, the value inherent in GRs is a central part of its very definition. GRs are a potential source of income for biodiversity rich communities as well as biotechnology industries which rely on GRs as a major source of input for research into the development of a wide range of health, agricultural, and cosmetic products.\textsuperscript{56} The value of TKaGRs is similarly multifaceted. Significantly, however, the leads provided by TK, such as seen in the TK of the San peoples over the hoodia, save time, money, and investment of modern biotech firms into any research and product development by helping corporations to focus their research and development efforts.\textsuperscript{57} It is estimated, for example, that a hit-rate of 80 percent or more can be achieved in developing medical drugs where the screening of plants is limited to species used by indigenous communities.\textsuperscript{58} Again, outlining the value of TK, Crookshanks & Phillips draw on estimates suggesting that if the United States was forced to pay fair royalties on TK currently being used by corporations within its territory, it would owe developing countries US$302 million annually for agricultural products and US$5.1 billion annually for pharmaceuticals.\textsuperscript{59} UN estimates also show that poor

\begin{footnotesize}
\begin{enumerate}
\item See Article 7, Nagoya Protocol.
\item Ibid.
\item Biodiversity is often viewed by the local communities as possessing intrinsic value as well as high use value in itself, while commercial interests have often sought to downplay the value of GRs, rather discussing it as a raw material for the production of commodities and profit maximisation. It is through these final products that the economic value of biodiversity is, however, often determined. Vandana Shiva, \textit{Protecting our Biological & Intellectual Heritage in the Age of Biopiracy} (New Delhi: Research Foundation for Science, Technology & Natural Resource Policy, 1996) 1-30.
\item Ibid.
\end{enumerate}
\end{footnotesize}
countries lose $5 billion in royalties annually due to the unauthorized outside use of TK. The social, cultural, and economic value of GRs (including TKaGRs) thus render it a valuable component of human existence, livelihood, and wellbeing for which a protection mechanism is required. It is this value that has offered economic justification for a market based approach (benefit sharing) to support the conservation and sustainable use of GRs. The entire Nagoya Protocol and its international regime on ABS is aimed at advancing this third objective of the CBD by ensuring that users and providers receive an equitable share of benefits which arise from the utilization of GRs and TKaGRs. For third world actors, the Protocol’s implementation is therefore expected to address, amongst others, these three factors: the respect and recognition of TK, the enforcement of enhanced participatory models for transactions involving the use of TKaGRs, and the enforcement of benefit sharing based on mutually agreed terms (MATs) between users and providers.

Questions still remain as to whether the Protocol is able to provide a full solution to the incidence of biopiracy given the trans-regime nature of biopiracy. It is argued here, that as a trans-regime phenomenon, biopiracy’s articulation is made possible through the combined working of the principles of more than one international regime. In this regard, the appropriative strength of the IP system vis-à-vis the ineffective benefit sharing obligations within the CBD has fueled the injustice which is often highlighted in allegations of biopiracy. In this research, I examine the extent to which the trans-regime nature of biopiracy poses a challenge to the Nagoya Protocol’s efforts to successfully eradicate same. In addressing this aspect of the research question, this dissertation offers a useful and important contextualization of biopiracy within a contemporary frame. For the purposes of this thesis I have defined biopiracy as

the result of a commercial/non-commercial drive to utilize the IP system to acquire rights over inventions based on the experiences of indigenous peoples contained in GRs and/or its associated TK, without complying with existing obligations, national or international, governing the acquisition and use of such resources

By so doing, I seek to focus attention on the strict elements of the contemporary manifestation of biopiracy as distinct from its broad scope of possible, historically-based, expressions. The contemporary rendering of biopiracy reflects biopiracy as a phenomenon which occurs in individual transactions due to the strength

and dominance of the global IP regime within transactions involving the use of GRs. Again, the story of the hoodia above demonstrates this. The ability of the CSIR to secure the P57 patent on the chemical properties of the hoodia granted them proprietary rights over the hoodia. This translated to an ownership right to further license the P57 for further development. This pattern of appropriation through the IP system is particularly a common feature in modern instances of biopiracy. The literature reflects this and largely defines biopiracy in such terms, as the misappropriation and/or misuse through the IP system of GRs and/or TKaGRs of indigenous peoples, without adequate compensation being returned to such provider communities. This strict linkage between the ABS regime and the IP system in the articulation of biopiracy is developed in this dissertation as a restrictive interpretation of biopiracy. Two main significances of this restrictive definition must be highlighted to advance the central argument that the Nagoya Protocol will remain ineffective to attaining its objective of eradicating biopiracy without a corresponding IGC outcome.

First, is the important recognition of the interaction between international regimes and the effects that such interactions have on the actualization of prescriptions of individual regimes. By this, I refer to the fact that international regimes, such as the ABS regime, do not exist in isolation. Rather, they emerge and are implemented in a context of surrounding regimes which adversely or positively impact on the ability to attain outlined objectives. Indeed, international law is made up of normative and institutional fragments which interact in diverse ways. Not only do such normative fragments overlap at certain points, the interaction among ‘independent’ normative fragments underlie an entire universe of issues relating to the relationship between existing and emerging fragments of international law. The existence of normative

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61 See chapter four of this dissertation for a comprehensive discussion of biopiracy including its restrictive and inclusive approaches to definition.

62 Wilfred Jenks is attributed with providing the earliest background analysis on fragmentation of international law. See, International Law Commission, Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law: Report of the Study Group of the International Law Commission Finalized by Martti Koskenniemi, ILCOR, 58th sess, UN Doc A/CN.4/L.682 (2006) paras 5-6. He identified the international world’s lack of a general legislative body which resulted in multiple unrelated sources churning out international laws and the development of laws governing the revision of multilateral instruments as well as defining the effects of such revisions, as the two key reasons for the fragmentation of international law. Ibid. See also C. Wilfried Jenks, “The Conflict of Law-Making Treaties”, (1953) 30 Brit YB Int’l L at 403. See, Margaret A Young, “Regime Interaction in Creating, Implementing and Enforcing International Law” in Margaret A. Young, ed, Regime Interaction in International Law: Facing Fragmentation (Cambridge, UK: Cambridge University Press, 2012) [Young, “Regime Interaction”] at 91, noting the interaction of regimes during the making, implementation, and enforcement of international law.
fragments could serve, for instance, to provoke the emergence of counter-norms seeking to balance the effects of existing norms, or could serve as foundations for the emergence of strengthened norms aimed at the consolidation of existing norms. Yet again, normative fragments could emerge within an interpretive context, seeking to provide further clarification or explanation to existing norms. Fragments could yet be opportunities for actors within negotiations to shift across varied regimes in search of favorable conditions. The emergence of international norms, as with international regimes, may therefore be said to be path dependent, and are generally reactive to, or predicated on existing regimes.64

Another critical element of the ongoing interaction within regimes relates to the use of forum shifting as a strategy by regime actors to secure their best interests within complexities that define the issue area. Laurence Helfer discusses the public choice dimension65 of regime shifting in IP law making66 and describes regime shifting as an interest-based shifting of negotiations by States and NGOs from one venue to another within a single regime (intra-regime shift) or across regimes (inter-regime shift).67 Such an intra-regime vs. inter-regime distinction is easily recognizable where the boundary lines between regime ‘issue areas’ are clearly delineated – a feature which is becoming increasingly rare in global governance:

[i]n more recent times, the boundaries have become less rigid as international governance efforts have expanded their reach and become more interdependent. Such interdependence promotes the formation of networks among formerly disparate state, intergovernmental, and non-state actors and linkages among formerly discrete issue areas. The result is a “conglomerate type of regime” or a “regime complex” – a multi-issue, multi-venue mega-regime in which states and NGOs shift negotiations from one venue to another within the conglomerate, “selecting the forum that best suits their interests”68

64 See, for instance, Raustiala, who makes this argument, albeit within the context of international regime complexes. See, Kal Raustiala & David G Victor, “The Regime Complex for Plant Genetic Resources” in Beth A Simmons & Richard H Steinberg, eds., International Law & International Relations (UK: Cambridge University Press, 2006) [Raustiala & Victor, “The Regime Complex for Plant Genetic Resources”]. See also, Andreas Hasenclever, Peter Mayer & Volker Rittberger, Theories of International Regimes (Cambridge University Press: UK, 1997) [Hasenclever, Mayer & Rittberger, International Regimes] at 37, noting that ‘regimes do not emerge in a cognitive and institutional vacuum’, but are rather based on and influenced by earlier experiences of actors.

65 Public choice theory views government decisions as the product of interest group politics. It argues that concentrated interest groups with high individual stakes will devote significant resources to lobbying government officials if doing so allows those groups to acquire advantages through regulation that would be unavailable in the market. Because such interest groups face lower informational and organizational costs than more diffusely organized voters or consumers, they tend to be more successful in mobilizing resources and influencing legislative outcomes. Laurence R. Helfer ‘Regime Shifting: The TRIPs Agreement & New Dynamics of International Intellectual Property Lawmaking’ (2004) 29 Yale J. Int’l L. [Helfer, “Regime Shifting”] at 19.

66 Ibid. at 16 – 17.

67 Ibid.

68 Ibid.
Indeed, a restrictive interpretation of biopiracy places it within at least two international regimes of global governance (the IP and the ABS regimes) with an increased blurring of the differentiation within efforts at the joints of the various fora. This dissertation, in a slight departure from Helfer’s approach which is essentially focused on the process of international IP law making, reflects on how regime actors, particularly weaker actors of the developing world, have shifted regimes to the WIPO IGC in search of normative reinforcements for the normative victories gained within the Nagoya Protocol. It is in this context that the current efforts, to seek reinforcements within the IP regime (specifically through the WIPO IGC), by the Nagoya Protocol’s proponents is addressed. Susan Sell identifies vertical and horizontal aspects of forum shifting, and discusses the latter as a strategy which offers more benefits to weaker parties within regime complex negotiations. Indeed, the movement of Third World actors to the WIPO IGC supports Sell’s thesis and, as I argue here, offers the next best vertical (multilateral) option for developing countries to secure an effective reinforcement to the Protocol for reasons which I outline in the next section.

Summarily, therefore, international regimes are not isolated blocs, and an effort through this dissertation to analyze the potential ability of the Nagoya Protocol to address biopiracy must be undertaken within the context of the relevant influencing regimes. The interaction between regimes could be simply based on the contextual implementation or interpretation of normative elements of individual or intersecting regimes, or could be based on direct stakeholder movements across regimes. As noted earlier, the contemporary framing of biopiracy draws a strict connection between the ABS regime and the IP regime. For this reason, a second major significance of the restrictive conceptualization of biopiracy concerns the role of the IP regime in addressing biopiracy.

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69 I note that a major part of the defining elements of the struggle which are advanced within these two mentioned fora are drawn from the international human rights regime. A huge reliance will therefore be made to international human rights standards, particularly drawn from the UNDRIP, in advancing and justifying the dissertation’s analyses.

70 By vertical regime shifting refers to a top-down approach whereby parties shift negotiations to bilateral, regional or plurilateral in nature, thus affording stronger parties an opportunity to impose even higher demands within such agreements. Horizontal regime shifting however relates to the shifting across multilateral fora. This generally favours weaker actors. See Susan K Sell, “TRIPS: Fifteen Years Later” (2011) 18:2 Journal of Intellectual Property Law [Sell, “TRIPS”] at 5.
1.1.3 A Global System of Intellectual Property

The IP regime encompasses a broad range of international, regional, bilateral and domestic IP agreements, norms, policies, and institutions. In reviewing the IP system’s possible role in addressing biopiracy, my intention is, however, to approach the IP regime from an institutional and normative standpoint. The key IP institutions at the international level engaged with the governance of IP are the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). While the latter is the specialized agency of the United Nations system charged with the promotion and protection of IP worldwide, the former has assumed prominence in IP matters through the negotiation of the TRIPS. This dissertation’s analysis prioritizes WIPO’s present negotiations as the most important ongoing institutional development by and for third world actors geared significantly towards the effective implementation of the Nagoya Protocol. Before delving into the justification for this, as well as an overview of the WIPO negotiations, a few words on the significance of the WTO and its TRIPS Agreement are appropriate.

The TRIPS, concluded in 1994, significantly resulted in the consolidation as well as globalization of IPRs for all WTO Member States. Given its association with the multilateral trade regime, the TRIPS has significantly strengthened the IP regime and given it a further resilience and robustness due to significance of global trade to national economies, and further the dispute settlement mechanism of the WTO.71 In fact, this very idea of further strengthening IP rights formed the basic rationale for the TRIPS. The early push for the incorporation of IP rules into international trade was by industry representatives in developed countries, particularly the United States, that were concerned with the rising international trade in counterfeit and pirated goods.72 The existing international IP system, which was at the time administered solely by WIPO, was limited in addressing this concern for two main reasons. First, it lacked detailed rules on the enforcement of rights before national judicial and administrative authorities. Second, it lacked binding and effective dispute settlement mechanisms for disputes between states. An agreement within the framework of international trade was deemed the best solution by industrialized countries and their industry

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71 The resilience and robustness of a regime refers to the staying power of such a regime. Hasenclever, Mayer & Rittberger, International Regimes, supra note 64.
actors. The TRIPS which emerged at the close of the Uruguay Round addressed both of these concerns. In particular, it significantly enlarged the jurisdiction of the dispute settlement system of the WTO to resolve IP disputes between states. It is worth noting that the international trading regime, governed by the WTO, retains arguably the most effective system of enforcement in international law. Its dispute settlement system is designed as a central element in providing security and predictability to trade partners and, given its effectiveness and efficiency, is widely regarded as the ‘jewel in the crown’ of the multilateral trading system.

Developing countries have struggled with the implementation effects of the TRIPS. Multiple studies, even by the UN, have shown that the TRIPS has had major detrimental effects on developing countries. These have prompted calls for amendments to the TRIPS, several of which are being pursued within the TRIPS Council of the WTO. One of the significant areas of contention within the review of the TRIPS relates to the relationship between the TRIPS and the protection of TK. Developing countries have long contended that the TRIPS not only fails to recognize TK as a body of knowledge worthy of protection, but has also served to significantly facilitate the misappropriation of TK. In other words, the TRIPS has been identified by developing countries as a major catalyst for biopiracy, one which entrenches

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74 See, for instance, Petros C Mavroidis, “Raiders of the Lost Jewel (in the Crown)” (2015) 14.3 Journal of International Trade Law & Policy 106 at 107 noting that the ‘jewel in the crown’ talk only started post-1995 after the DSU had been put into place. See also Peter Van Den Bossche, The Law & Policy of the World Trade Organization: Text, Cases & Materials, 2ed (New York: Cambridge University Press, 2008) [Bossche, Law & Policy of the WTO] at 94, noting that the WTO dispute settlement system is usually referred to as the ‘jewel in the crown’ of the WTO given that is arguably the most prolific of all intergovernmental dispute settlement systems. This extreme validation often accorded to the WTO’s dispute settlement system (including terms such as the the DSU as ‘the core linchpin of the whole trading system’ etc., has yet been criticized by some authors. See, for example, John Ragosta, Navin Joneja & Mikhail Zeldovich, “WTO Dispute Settlement: The System is Flawed and Must Be Fixed” (2003) 37 Int’l L at 697.

75 See, for instance, UNDP, Making Global Trade Work for People (UK: Earthscan Publications Ltd., 2003) at 221 – 222 which notes, inter alia, ‘the relevance of TRIPS is highly questionable for large parts of the developing world’ and unequivocally recommends that the WTO begin dialogues at an intergovernmental level to replace TRIPs with alternate IP paradigms which are unrelated to trade sanctions.

76 Examples of current work within the TRIPS Council with respect to the amendment of the TRIPS Agreement includes the extension of the transition periods for least developed countries under Article 66, TRIPS, which has been extended to July 1, 2021. See Extension of the Transition Period under Article 66.1 for Least Developed Country Members: Decision of the Council for TRIPS of 11 June 2013, IP/C/64, WTOOR, 2013. Other ongoing work includes work on TRIPS and Climate Change, TRIPS and Public Health, Geographical Indications, Non-violation complaints (Article 64.2) TRIPS, Technology Transfer, and traditional knowledge and biodiversity (Article 27.3(b)) etc. See generally, WTO, “TRIPS [Trade Related Aspects of Intellectual Property Rights] Material on the WTO Website”, online: WTO <https://www.wto.org/english/tratop_e/trips_e/trips_e.htm>.
a global system of IP which alienates and misappropriates significant aspects of TWIP. Based on the insistence of developing countries, the 2001 Doha Ministerial Declaration requested the TRIPS Council to examine the relationship between the TRIPS and the CBD as well as its relationship with the protection of TK and folklore. Such discussions have remained stagnant over the past five years. However, the significance of this consideration of the relationship between the TRIPS and the CBD, especially within the context of the ongoing review of the TRIPS must not be lost. It points significantly to a developing country-led effort to initiate the amendment of the TRIPS through the promotion of greater conformity and complementarity between the TRIPS and the international biodiversity regime, contained in the CBD. Furthermore, addressing the issue of alienated TWIPs, the reference to TK and folklore, points to an effort to bring within the context of the TRIPS, major questions relating to the protection of TK. The last proposal submitted to the TRIPS Council by developing countries, regarding a suggested amendment to the TRIPS, must be mentioned here.

In 2006, a group of developing countries submitted a proposal for an amendment to the patent provisions of the TRIPS. This proposal for the insertion of an Article 29bis, entitled “Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge”, seeks to address the concern of misappropriation of TK by requiring that applicants for patent rights over inventions which make use of TK or GRs, disclose the source of their TKaGRs and/or GRs as well as show evidence of compliance with the ABS requirements of such provider countries. The most recent submission, representing a slightly amended version to the 2006 proposal and also a reflecting a wider support from the developing countries.

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77 This was the official resolution by members of the WTO at the end of the Fourth Ministerial Conference in Doha, Qatar November 2001. This Declaration was adopted on 14 November 2001. See Ministerial Declaration, WT/MIN(01)/DEC/1, WTOOR, 4th Sess (2001) at para 19, which provides in relevant part, We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore.

78 This proposal is contained in a communication from Brazil, India, Pakistan, Peru, Thailand & Tanzania to the Trade Negotiations Committee. See Doha Work Programme – The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Communication from Brazil, India, Pakistan, Peru, Thailand & Tanzania, WT/GC/W/564; TN/C/W/41, WTOOR (2006). See also, Tove Iren S Gerhardsen, Developing Countries Propose TRIPS Amendment on Disclosure (1 June 2006), online: Intellectual Property Watch (Geneva) <http://www.ip-watch.org/weblog/index.php?p=323>.

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within the TRIPS negotiations, was made in 2011. This proposal was significantly made shortly after the adoption of the Nagoya Protocol, and reflects an effort to ensure coherence between the TRIPS and the Nagoya Protocol. The first two paragraphs of the revised proposal provide:

For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, Members shall have regard to the objectives, definitions and principles of this Agreement, the Convention on Biological Diversity, and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, in particular its provisions on prior informed consent for access and fair and equitable benefit sharing.

Where the subject matter of a patent application involves utilization of genetic resources and/or associated traditional knowledge, Members shall require applicants to disclose: (i) the country providing such resources, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD; and, (ii) the source in the country providing the genetic resources and/or associated traditional knowledge. Members shall also require that applicants provide a copy of an Internationally Recognized Certificate of Compliance (IRCC). If an IRCC is not applicable in the providing country, the applicant should provide relevant information regarding compliance with prior informed consent and access and fair and equitable benefit sharing as required by the national legislation of the country providing the genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD.

This proposal arguably offers a clear ultimate vision of third world countries with respect to TK and the TRIPS’ role in addressing biopiracy: a defensive protection mechanism for TKaGRs and GRs within the TRIPS. Two significant proposed implications of the proposal include its stipulation that the disclosure requirement proposed in paragraph two should form a precondition for the processing of patent applications, and that stiff sanctions, including the possibility of revocation of the patent, should apply where applicants are found to be wanting in abiding with this disclosure requirement. The discussions on

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79 See Trade Negotiations Committee, Draft Decision to Enhance Mutual Supportiveness Between the TRIPS Agreement and the Convention on Biological Diversity: Communication from Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group, TN/C/W/59, WTOOR (2011).
80 Ibid. (Footnotes omitted).
81 See, in particular, Ibid. at para 9 of the preamble: “[a]cknowledging that a legal obligation establishing such a mandatory disclosure requirement in patent applications will contribute to prevent both misappropriation of genetic resources and the grant of erroneous patents and also enhance transparency about the utilization of genetic resources and/or associated traditional knowledge”.
82 Ibid. at para 4, which provides, inter alia, “[p]atent applications shall not be processed without completion of the disclosure obligations set out in paragraph 2 of this Article”.
83 Ibid. at para 5, noting in relevant part: “…[m]embers shall impose sanctions, which may include administrative sanctions, criminal sanctions, fines and adequate compensation for damages. Members may take other measures and sanctions, including revocation, against the violation of the obligations set out in paragraph 2”.

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This proposal have remained deadlocked with no progress whatsoever since 2011. This deadlock at the WTO with regard to the defensive protection of TKaGRs mirrors a deeper institutional challenge. In reality, the issue of TK protection does not represent an area of positive interest to the powerful actors within the multilateral trading system. The main actors that pushed for the negotiation of the TRIPS, for instance, were primarily the United States’ pharmaceutical, software, and entertainment industries. Till date, the pharmaceutical companies retain a strong aversion to disciplines around the protection of TK due to, as Andrew Jenner suggests, concerns around the impracticality and uncertainty that would necessarily arise around the implementation of such measures. Flowing from this logic, the long term effects of such protection mechanisms would result, inter alia, in a natural disincentive for pharmaceutical companies to continue investments within the field of natural product research. Investments require an environment of legal certainty and predictability which varying standards in provider countries would not necessarily support. These powerful lobbies remain a central driving force behind the Member State positions in the efforts to amend the TRIPS. This is all the more significant as the TRIPS Council negotiations, like all WTO negotiations, are purely carried out by States to the exclusion of NGOs, indigenous peoples, and private individuals. The WTO therefore has been driven on by powerful Member States to adopt an oppositional stance towards measures which seek to bring the trading system into closer alignment with the ABS regime. A significant example of this is the continued rejection of the CBD Secretariat’s request to be admitted as an observer within the TRIPS negotiations. This request continues to be blocked principally on the insistence of the United States.

84 See the latest summary of the issues raised and progress made in the Director-General’s Report. Issues Related to the Extension of the Protection of Geographical Indications Provided for in Article 23 of the TRIPS Agreement to Products other than Wines & Spirits & those Related to the Relationship between the TRIPS Agreement & the Convention on Biological Diversity: Report by the Director-General, WT/GC/W/633, WTOOR (2011).


86 Dr. Andrew Jenner is the past Director, Innovation, Intellectual Property and Trade, of the International Federation of Pharmaceutical Manufacturers Association (IFPMA). According to their website, IFPMA represents the research-based biopharmaceutical companies and associations across the globe. It has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health. See IFPMA in Brief, online: IFPMA <http://www.ifpma.org/>.

The above then suggests that the WTO offers an important, yet unfriendly, if not hostile, environment for non-state actors for thinking solutions to biopiracy. This hostile environment draws from factors including participation, issue acceptance and compatibility. In terms of participation, biopiracy’s key stakeholders are Member States (who have sovereignty over resources within their territories and have responsibilities towards indigenous peoples within their domain), industry representatives (who make use of GRs and TKaGRs), indigenous peoples (who continue to hold, maintain and develop TK in association with the GRs within their territories), and civil society (which continues to serve, amongst others, as a moral compass, drawing global attention to the injustices in issues surrounding biopiracy). Only one of these stakeholders – the Member States – has a direct platform within the WTO. The others are precluded from directly participating in negotiations at the WTO. Where then the interests of such groups, such as indigenous peoples, do not align with Member State interests, no recourse exists for their positions within the negotiations. Furthermore, in terms of issue acceptance, and compatibility, the fact that the Ministerial Council approved a resolution for a review of the relationship between the TRIPS and the protection of TK is no indication that the issue of TK protection sits comfortably with major players in the multilateral trading system. The majority of industrialized countries have continued to insist that the WTO is not the appropriate forum for discussions relating to the protection of TK. As a result, the issue of TK protection within the WTO has remained at an impasse. The director of the IP Division of the WTO, a former acting director and head of the Global Intellectual Property Issues Division at WIPO, Mr. Anthony Taubman, noted simply in response to an update on WTO developments with respect to the protection of TK, that no substantive developments have occurred since April 2011. A lot is however happening in WIPO and, given the central role played by third world actors in advancing the WIPO negotiations, this dissertation focuses on WIPO’s role and relevance in the fashioning of IP-based biopiracy solutions.

As the prime international institution solely charged with IP matters, WIPO has continued to play a central role in the development and global administration of the IP regime. Within the past four years

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88 This was based on a private exchange with Mr. Taubman in November 2016. See, also, however, Council for Trade-Related Aspects of Intellectual Property Rights: Minutes of Meeting, held in the Centre William Rappard on 7 – 8, June 2016, IP/C/M/82, WTOOR (2016) being the latest update on the most recent TRIPS Council meeting. The document notes, with respect to the protection of TK and Folklore, that members’ views had remained divided and as such no progress could be made. Ibid. at 5.
alone, its norm making activity has enabled the adoption of two major instruments within the field of IP; significant work continues in several other areas, including the protection of TK. WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2000 as a policy forum for the discussion of IP issues arising within the context of access to GRs and benefit sharing. It was also aimed at the discussion of protection for TK and TCEs.

The establishment of the IGC was effected shortly before the 2001 Doha Ministerial Declaration paved a way for the formal consideration of TK issues within the WTO’s TRIPS Council. The close timing of the twin developments suggest that the regulation of TK grew in significance within the IP regime at the turn of the millennium. The emergence of modern biotechnologies has been suggested by WIPO as one of the key factors for these developments. With biotechnology has come an increased economic, social, and cultural valuation of GRs and TKaGRs. As with the hoodia case earlier mentioned, the patent system has had a major influence on the rise of the biotechnology industry. Biotechnology inventions have been the subject of an increasing number of patent applications, yet the TKaGRs and the GRs which are utilized in

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92 See WIPO Document 26/6, supra note 90, at para 1.

93 See, for example, Esteban Burrone, “Patents at the Core: The Biotech Business”, online: WIPO <http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html>, noting that: [t]he strong growth of the biotechnology industry in recent years has been mirrored by a higher than average growth rate for patent applications and patent grants that relate to biotechnology inventions. According to the OECD, the number of patents granted in biotechnology rose 15% a year at the United States Patent and Trademark Office (USPTO) from 1990 to 2000, and 10.5% a year at the European Patent Office (EPO), against a 5% a year overall increase in patents. The growth in the number of patents in the field of biotechnology is largely due to the importance that life sciences and biotechnology companies attach to intellectual property, particularly patents (footnotes omitted).
several of these inventions are not properly accounted for. In linking the biodiversity regime, which regulates the use of GRs, with the IP system which seeks ownership rights over GRs, WIPO’s establishment of the IGC drew some justification. To this end, the IGC was established to examine the IP issues which arise within the context of access to GRs (and TKaGRs) and benefit sharing. Furthermore, the IGC was established to address the subject of TK which, in itself, is a form of IP, though not yet recognized formally as such. WIPO as a specialized UN agency was, however, driven by a desire to ensure the IP system evolved into a more inclusive and representative system, which accommodated all legitimate beneficiaries of IP protection. Indigenous peoples were identified early on as an excluded group that needed to be brought within the purview of the global IP system.\textsuperscript{94} To this end, the knowledge as well as the expressions of such knowledge are considered vital forms of ‘grassroots’ IP.\textsuperscript{95} As a result of the foregoing, three main thematic areas of inquiry are addressed within the IGC: GRs (including TKaGRs), TK, and TCEs. The IGC represents a developing country-led effort to address the exclusion of TK from the IP system. It is pursuing this by negotiating a \textit{sui generis} instrument(s) which ultimately seeks to recognize TK and its holders as beneficiaries of IP protection. The outcome of the IGC bears important implications for the IP system as well as for the implementation of the Nagoya Protocol’s ABS regime.

The rationales underlying the establishment of the IGC are varied. Three main justifications have, however, been put forward by WIPO: first, it was established to address the themes of GRs, TK and TCEs which were simultaneously regarded as the ‘common heritage of humanity’ and as intellectual valuables which required an appropriate form of IP protection; second, GRs, TK and TCEs were seen as the intellectual assets of new key players in IP policy-making (developing countries and indigenous and local communities); third, it was conceived as part of a larger and structured endeavor by WIPO to move towards a modern, responsive IP system that could embrace non-Western forms of creativity and innovation, be comprehensive in terms of beneficiaries, and be fully consistent with developmental and environmental

\textsuperscript{94} See, 6.2.2.1. \textit{infra}, noting the initial Roundtable discussions organized by WIPO as part of efforts to commence engagement with indigenous peoples, who were identified as the first of potential new beneficiaries to the IP system.

\textsuperscript{95} See, \textit{supra} note 49 above.
goals. Currently, the IGC is negotiating, albeit with much difficulty, the text of an international instrument(s) which will ensure the balanced and effective protection of GRs, TK, and TCEs.

The IGC has continued to advance in its work over the past 16 years and offers developing countries three critical advantages over the WTO, as a choice forum for securing IP solutions to biopiracy. First, it is a developing country led process. In this regard, unlike the TRIPS which is essentially an industrialized country construct, the IGC (and the emerging agreement) exists on the insistence of developing countries. This is important as it affords the developing countries the opportunity to design the agenda of a system of protection in line with their interests while yet navigating the tides of resistance by industrialized countries. Even though it is a developing country led process, it yet exists within a regime which is an industrialized country construct – the IP regime. Many have consequently questioned the very basis of seeking protection through a system that actually facilitates misappropriation. However, as I suggest next, the IGC’s precarious position in being located within the IP regime, while yet legitimately focusing its attention on issues largely contained within the ABS regime, places it as a middle point forum between potentially extreme ends of the IP regime and the ABS regime.

As a middle point forum, the IGC occupies a central position within the difficult relationship between IP and the protection of TKaGRs. Though this view of WIPO’s neutrality may be contested due to the fact that, in itself, WIPO is the specialized agency of the UN responsible for administering and enforcing IP globally, the nature of WIPOs sui generis project within the IGC, including issues of participation, methodology, and even subject matter, point to the opening up of WIPO, in this respect, as a central platform for the negotiation of issues which lie at the intersection of the two principal regimes. Furthermore, the delegates have generally prioritized principles relating to fairness, justice, and equity over slavish adherence to IP principles in the formulation of solutions. It thus offers a platform for indigenous peoples, and developing countries especially, to assert themselves in the formulation of a supportive system to the ABS regime albeit on the platform of IP.

Third, the methodology and the inclusive participation within the IGC highlights it as an accessible forum which draws legitimacy in matters relating to the protection of TK given the presence of the principal

96 WIPO Background Brief 2, supra note 91 at 2.
stakeholders to the negotiations. The *United Nations Declaration on the Rights of Indigenous Peoples* [UNDRIP] for instance stipulates that indigenous peoples have the right to participate in decision-making in matters which affect them. Indigenous peoples are well represented within the WIPO negotiations and enjoy a strong institutional support for the purpose of enhancing their participation in the negotiations. Examples of support for indigenous peoples include the WIPO Voluntary Fund designed to facilitate the participation of indigenous representatives and the WIPO Indigenous Fellowship which offers an indigenous person a chance to work on and contribute to TK-related issues within the WIPO Secretariat, to name but a few. Not only are indigenous groups present, but industry representatives, intergovernmental and non-governmental organizations as well as Member States participate fully within the negotiations. The methodology adopted also facilitates full engagement between all stakeholders in the design of solutions. Consequently, unlike the state-centric climate of the WTO TRIPS Council, the WIPO IGC offers an open, accessible forum for all stakeholders to the biopiracy debate to effectively engage towards mutual and inclusive solutions. These advantages outlined have also had major negative implications on the progress of the Committee’s work.

The IGC is currently engaged in text-based negotiations aimed at arriving at the text(s) of an international instrument(s) which will ensure the effective protection of TK. This IGC project has been ongoing for 16 years and still does not show conclusive signs of an end point. The uncertainty around the conclusion to the IGC’s work is largely attributable to a lack of shared objectives amongst the varied blocs of negotiators. Ultimately, the lack of shared objectives manifests as the inability of developing countries to convince their industrialized partners of the importance of a binding IP-based instrument which is coherent with, and supportive of, the ABS regime. The wide gap in perspectives is observable in several areas of the negotiations, both substantive (such as the disclosure requirement) and political (such as the nature of the instrument).

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98 Article 18, UNDRIP.
The disclosure requirement impasse, similar to what is being contended with in the WTO TRIPS Council, has been identified as the key normative hurdle holding up the negotiations till date.\textsuperscript{99} The disclosure issue has divided policy makers and negotiators across the North-South divide. While several developing countries contend that a disclosure requirement is a necessary component of any instrument emanating from the IGC process, most industrialized countries have continued to resist efforts to incorporate a disclosure requirement within the IP system. A political subtext has also defined most of the ongoing discussions within the IGC.

By reviewing the WIPO negotiations as well as the political and substantive difficulties that have continued to define its progress (or lack thereof), several lessons may be drawn for the implementation of the Nagoya Protocol in the fight against biopiracy. To highlight these, this dissertation draws on the TK-related negotiations within the 2012/2013 biennium and 2014/2015 biennium. This time period is chosen as it reflects deep seated efforts, including innovative strategies to seek and pursue positive outcomes within the negotiations. Furthermore, the climax of these sessions was the breakdown in negotiations for the latter part of the 2014/2015 biennium. Though the negotiations have resumed, some of the underlying problems remain. One of the central lessons that will be developed through this thesis, however, is that the effective implementation of the Nagoya Protocol requires a positive outcome from the WIPO IGC – positive in the sense that the outcome is one which is coherent with, as well as reinforces the gains secured, through the Nagoya Protocol. Developing countries continue to pursue this objective through the ongoing negotiations within WIPO.

In conclusion, an important question which naturally arises from the foregoing centers on whether a WIPO solution is sufficient to address the third world concerns with the IP system. While the proposed TRIPS amendment referenced earlier in this introductory chapter must be viewed as an ultimate goal in terms of reconciling the IP system with the ABS regime, the WIPO negotiations are central to a realization of this. It is worth clarifying here that the shift in focus to the negotiation within WIPO is by no means a

suggestion that the ultimate vision of developing countries regarding amendments to the TRIPS, can or ought to be resolved within the WIPO context. Rather, it seeks to channel a course to actualizing this objective; one which leverages the accessible forum provided within the WIPO IGC to take a major stride towards this goal of preventing biopiracy. In a sense, therefore, the WIPO negotiations which brings the biodiversity and the IP regimes under one single umbrella, represents a next important step towards the attainment of the ultimate objective of reinforcing the ABS regime through the IP regime.

1.2 Research Methodology

This research has been carried out through a library-based review of the history, nature, and significance of the Nagoya Protocol, using relevant literature, instruments, and jurisprudence from international and national sources. Further, a case review of selected biopiracy examples has been used to establish the inseparability of the IP regime and the ABS regime in both the conceptualization as well as development of solutions to biopiracy. Given the central emphasis on the WIPO negotiations, a two-year field study within the Secretariat of WIPO was undertaken with the task of coordinating the WIPO IGC for the period. The responsibility of coordinating the WIPO IGC during this period reflects in this study. This field placement provided a deeper and practical understanding of the political, institutional, and substantive nuances impacting on the IP negotiations and their relationship to the Nagoya Protocol. While underscoring the significance of WIPO’s role as an institution, these factors provide significant context and subtext to the emerging texts. Also, through this placement, careful attention was paid to the participation and role of the non-state actors, particularly industry representatives and the ultimate beneficiaries of protection (indigenous peoples) within the negotiations with a specific focus on their needs and expectations with respect to the protection of TKaGRs. The field study finally provided opportunities for direct engagement with the related process of the WTO TRIPS Council, the negotiations within which are equally important to this research.

It is worth further mentioning that this dissertation’s analysis is inspired by the methodological and theoretical approach generally referred to as the third world approach to international law (TWAIL), given the centrality of the ABS regime to the third world. For our purposes, indigenous peoples as well as developing countries are subsumed under the ‘third world’ umbrella, and as such, the placing of their
perspectives, concerns, and struggles, at the center of the analysis offers a distinct strength to this research’s analysis. While a detailed critique of this approach is not my intention, I rather utilize it to justify a primary focus on the central concerns of a disadvantaged category of beneficiaries within the analysis of the biopiracy discourse. A discussion of the relevance and importance of this distinct international law approach to the research is undertaken in chapter two. Drawing on the intersection between the IP system and the ABS system, this dissertation highlights the concerns and struggles of the Third World participants – States and indigenous peoples – in advancing an effective structure for the implementation of the ABS regime within the IP regime. This dissertation thus underscores the relational aspects of international regimes in that it reflects the development of norms within the IP regime which bear potential implications for the implementation of the ABS regime. Adopting a third world approach, the struggle within the IP regime is currently focused on the strategic push by developing countries to secure a set of reinforcing norms which align with the normative structure contained within the ABS regime. Of course, the emergent ABS regime could, in itself, be construed as outlining a set of counter-regime norms to the IP system – an argument which sits on all fours with the core of Helfer’s thesis. However, this thesis is concerned with the further development of pro-regime norms which seek to reinforce existing standards secured within the context of the ABS regime. In so doing, it addresses the key question of whether the international regime on ABS could be effective without a coherent, or positive, outcome within the negotiations of the IP regime.

1.3 Chapter Breakdown

This dissertation argues that the Nagoya Protocol’s efforts to effectively address the protection of TKaGRs from biopiracy requires a normative defensive reinforcement from the IP regime, and the ongoing discussions within the WIPO IGC are central to a realization of this. Seven chapters follow to this end.

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100 See, Helfer, “Regime Shifting”, supra note 65, at 10 – 13. A discussion on the relational aspects of international regimes is undertaken in chapter two below. See, infra 2.2.3.

101 ‘Coherent’ is used, not to necessarily imply “similarity”, but rather “mutual supportiveness” or “complementarity”. It is used to refer to a set of mutually supporting/reinforcing obligations created within the regime, in line with the primary objective and obligations of the Nagoya Protocol. In other words, coherence is used to refer to an internal consistency within the elements of a defined international regime. See Oran Young, International Cooperation: Building Regimes for Natural Resources & the Environment (New York: Cornell University Press, 1989) [O Young, International Cooperation] at 25.
Following this introductory chapter which has provided a broad overview and contextual background to this research, chapter two draws on aspects of international regime theory to establish a foundational understanding of the Nagoya Protocol as well as its efforts to address the protection of TKaGRs from biopiracy. The chapter significantly aims to situate this dissertation’s discussion of biopiracy within the center of an international regime complex. Given that the Nagoya Protocol was negotiated to establish an international ABS regime, the discussion in chapter two clarifies the formal nature of this regime and discusses the importance of issue areas to the very conceptualization of regimes. Chapter two identifies the issue of biopiracy eradication as representing an implicit area of governance within the framework of the ABS regime – one which lies at the heart of the developing world’s expectations regarding the implementation of the Protocol. Furthermore, chapter two introduces the theoretical and methodological school, known as the TWAIL. Inherent within this approach, is the centralization of the interests and concerns of the marginalized participants within the analysis of the international system. Through a reflection on the TWAIL, the concerns of the third world are placed at the heart of this dissertation’s critical examination of the Nagoya Protocol. To this end, a focus on the eradication of biopiracy as a core objective of the Nagoya Protocol is justified. This approach also permits the prioritization of the interests and importance of third world actors within efforts to fashion solutions for biopiracy, particularly within the WIPO negotiations, which I deal with later in chapter six.

Chapter three advances the thesis by examining the core subject of appropriation which forms the basis for this dissertation’s biopiracy analysis – TKaGRs. As mentioned above, biopiracy is a problem which manifests through the wrongful appropriation of the GRs and/or TKaGRs of indigenous peoples without adequate compensation being paid to, or conferred on them. Though two subjects of appropriation are thus involved in the discussion of biopiracy (GRs and TKaGRs), I narrow my focus within this dissertation to TKaGRs. A subset of TK, TKaGRs is the subject of intense debates in several multilateral and regional fora seeking solutions to its protection. The uncertainty around the definitions and conceptual discussions of TKaGRs warrants a clarification of its scope and use within analyses directed at its protection. The Nagoya Protocol significantly fails to define TKaGRs. For this reason, chapter three contributes to this thesis by generating an understanding and appreciation of TKaGRs, as well as the
showing the complexities and contestations that surround its definition, and efforts at its protection. This chapter’s analysis, provides an important introduction to the political context within which the efforts to address biopiracy are framed. Furthermore, by explaining TKaGRs as a lived experience of indigenous peoples which cannot be protected through western IP forms, chapter three highlights the significance and central importance of WIPOs ongoing efforts to develop a \textit{sui generis} system of protection for TK.

Chapter four progresses the dissertation’s analysis to an actual discussion of misappropriation of TKaGRs, termed biopiracy. Drawing from the analyses in the earlier chapters, chapter four reflects on biopiracy as the implicit issue area of global governance for an emerging regime complex. From the perspective of developing countries, the Nagoya Protocol primarily seeks to address this. Drawing on examples of biopiracy, chapter four places the discussion of biopiracy within a restrictive contemporary frame – one which in light of the discussions in chapter two forces an interpretation of biopiracy as a trans-regime problem. It achieves this by focusing on two \textit{sore spots of emphasis} which define biopiracy in contemporary terms: the inequitable sharing of benefits and the appropriative tendency of the IP system. The trans-regime nature of biopiracy thus presents biopiracy as a regime issue area which is articulated through, and which requires solutions from, the interaction of the IP and ABS regimes. This important conclusion in chapter four offers a useful platform for analyzing the proposed solution to biopiracy presented in the Nagoya Protocol, as well as the emerging complementary efforts being advanced within the WIPO IGC.

Chapter five drawing from the conclusions in chapter four, analyzes the relevance and limitations of the Nagoya Protocol’s benefit sharing mechanism as a solution to biopiracy. It examines the development of benefit sharing in international law. It argues that benefit sharing emerged within the context of sustainable development and must therefore be primarily advantageous to indigenous peoples (the beneficiaries of protection) if it is to attain the underlying justifications for its very existence. Against this backdrop of benefit sharing, this chapter discusses the Nagoya Protocol, the international instrument which seeks to implement this benefit sharing principle in international law. It argues that the Nagoya Protocol provides a useful positive set of rights, principles and obligations to addressing the problem of biopiracy. These rights, however, point to a “trans-border benefit sharing” solution to biopiracy, one which
is insufficient to address the trans-regime concerns of biopiracy as highlighted in chapter four. I, however, argue that a closer look at the evolutionary context of the Nagoya Protocol points to the Nagoya Protocol as providing the very needed basis for a trans-regime solution to biopiracy. This evolutionary context of the Protocol significantly lays the foundation for the incorporation of external regime instruments to complement its “trans-border benefit sharing” solution. The latter section of this chapter thus argues that WIPO’s ongoing negotiations are a central part of the future evolution of the ABS regime, and should be construed as complementary efforts to expand the solutions contained in the Nagoya Protocol.

Chapter six concludes the substantive analysis by portraying WIPO’s IGC, and the instruments being negotiated therein, as the missing part of the Nagoya Protocol’s ABS regime. It commences with an introduction to the IP system, tracing its historical development and importantly, highlighting its strength and resilience as a globalized regime based on Western preferences and justifications. Noting the IGC to be an IP forum it, however, discusses the IGC as a ‘middle point forum’; one which sits at the intersection of IP and ABS policy discussions and which, therefore, benefits from a wide array of relevant stakeholders and participants involved in the biopiracy problem. The legitimacy generated in this sense, places the IGC as a relevant forum for arriving at the much needed IP-based solutions to biopiracy – a balanced solution which significantly draws from the input of all concerned stakeholders. The chapter demonstrates the efforts of developing countries to secure a complementary defensive outcome to the Protocol – one which offers conceptual clarity to significant aspects of the problem of biopiracy, and reinforces the Nagoya Protocol’s trans-border solutions through a mutually supportive trans-regime solution.

Chapter seven concludes the thesis with a summary of the analyses made throughout the course of the dissertation. It also offers useful suggestions for future research directions.
Chapter 2

Situating Traditional Knowledge associated with Genetic Resources within a Regime-Complex Discourse

In this chapter, I set out to achieve three things within the context of this thesis. First, a clarification of what international regimes are and a contextualization of their usage within this dissertation. Importantly, this discussion of regimes offers clarity to the complex and open-ended nature of the international ABS regime which the Nagoya Protocol establishes. I argue that the Nagoya Protocol is actually an open ended regime complex, one which by design continues to evolve to accommodate complementary instruments. Within this evolutionary context, the Nagoya Protocol specifically identifies the developments within WIPO as instrumental to its implementation. This indicates a need to focus on the WIPO negotiations as conclussory efforts to the ‘incomplete’ Nagoya Protocol. Second, this chapter’s discussion of regimes provides clarity on regime issue areas. This is an important point within the context of the thesis for it underscores the political nature in which the issue areas for cooperation within regimes are defined. With respect to this dissertation, defining the core issue area of the ABS regime is a critical foundational task which this chapter addresses. I identify biopiracy as a core implicit issue area and justify this choice through a reflection on the underlying third world policy interests within the ABS regime. Third, this chapter introduces the Third World Approach to International Law (TWAIL) as inspiring the perspective through which this dissertation’s critical analyses are undertaken.

The chapter is broken down into three main parts. Part one introduces the TWAIL as the foundational approach which inspires the analyses within this dissertation. Part two clarifies and contextualizes international regimes and regime complexes as used within this dissertation. In part three, the designation of biopiracy as a regime issue area is considered, establishing the problem to which the remainder of this thesis speaks.
2.1 A Third World Approach to International Law

As initiated by a group of Harvard Law School graduate students in the spring of 1996, the concept of a TWAIL offers a distinctive way of thinking about international law. While, as a theoretical school, it does not necessarily offer a uniform self-consistent approach by which all its adherents are bound, its varied approaches retain ‘a unifying core, a centripetal force that pulls it together.’ Obiora Okafor characterizes this coordinated diversity within the TWAIL network, which is alluded to within its vision statement, as reflecting a ‘fragmented unity’ in the TWAIL – a characterization which underlies most other legal theoretical schools. Consequently, the diversity within the TWAIL scholarship does not

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102 For a historical account of the TWAIL as well as an updated TWAIL bibliography, see generally James Thuo Gathii, “TWAIL”, supra note 24 at 26. See also, Anghie & Chimni, “TWAIL & Individual Responsibility”, supra note 24 at 79 – 87, who distinguish between a TWAIL I and a TWAIL II, the latter aligning with the present assertions. For them, prior to the spring of 1996, TWAIL already existed, albeit with less analytical finesse, and remains foundational for all subsequent TWAIL scholarship.

103 TWAIL offers both theories of, and methodologies for analysing international law and institutions. Given its broad approach to theoretical propositions generated from its application, it is probably best viewed as a school of thought. See Okafor, “Critical TWAIL”, supra note 24 at 377 – 378.

104 Ibid. at 376. See also James Thuo Gathii, who argues that TWAILers have not sought to produce a single authoritative voice [approach], but have rather generated vibrant ongoing debate around questions of colonial history, power, identity, and difference, and what these mean for international law. Gathii, “TWAIL”, supra note 24 at 27. See also, Antony Anghie, “TWAIL: Past and Future” (2008) 10(4) Int’l Comt’y L. Rev. 479.

105 Gathii notes that TWAIL has never really been organized as a movement or association with a formal membership, but has rather operated as a loose network. Gathii, “TWAIL”, supra note 24 at 32.

106 The vision statement for the Third World Approach to International Law (TWAIL), crafted by participants at the first major TWAIL conference, titled “New Approaches to Third World Legal Studies Conference”, which took place from March 8 – 9, 2007 at the Harvard Law School, provides:

[w]e are a network of scholars engaged in international legal studies, and particularly interested in the challenges and opportunities facing ‘third world’ peoples in the new world order. We understand the historical scope and agenda of the dominant voice of international law scholarship as having participated in, and legitimated global processes of marginalization and domination that impact on the lives and struggles of third world peoples. Members of this network may not agree on the content, direction and strategies of third world approaches to international law. Our network, however, is grounded in the united recognition that we need democratization of international legal scholarship in at least two senses: (i) first, we need to contest international law’s privileging of European and North American voices by providing institutional and imaginative opportunities for participation from the third world; and (ii) second, we need to formulate a substantive critique of the politics and scholarship of mainstream international law to the extent that it has helped reproduce structures that marginalize and dominate third world peoples. Thus we are crucially interested in formulating and disseminating critical approaches to the relationships of power that constitute, and are constituted by, the current world order. In addition, we appreciate the need to understand and engage previous and prevailing trends in third world scholarship in international law


107 In making this point, he references the Marxist as well as feminist legal theories to demonstrate that within theoretical schools, members do not always agree on every single idea and/or issue. See, Fabien Tarrit, “A Brief History, Scope, and Peculiarities of ‘Analytical Marxism’” (2006) 38 Review of Radical Political Economy 595
negate the existence of the TWAIL\textsuperscript{108} as a contemporary theoretical and methodological approach to the study of international law.\textsuperscript{109} What then makes TWAIL distinct from other approaches to international law?

According to Gathii, TWAIL draws its distinctiveness on the basis of a historically aware methodology; one which challenges the simplistic visions of an innocent third world and a colonizing and dominating first world.\textsuperscript{110} More than any other scholarly approach to international law, TWAIL has placed the colonial encounter between Europeans and non-Europeans at the heart of its historical reexamination of international law, thus challenging the complacency in international law to treat the colonial legacy as dead letter, overcome by the process of decolonization.\textsuperscript{111} For many TWAIL scholars, international law carries forward the legacy of imperialism and colonial conquest.\textsuperscript{112} In this context, Okafor references a common ethical commitment of the TWAIL scholarship, which is channeled towards an intellectual and practical struggle to expose, reform, or even retrench those features of the intellectual legal system that help create or maintain the generally unequal, unfair, or unjust global order…a commitment to center the rest rather than merely the west, thereby taking the lives and experiences of those who have self-identified as Third World much more seriously than has generally been the case\textsuperscript{113}

For their part, Anghie and Chimni discuss TWAIL scholarship as bearing a contextual undertone which views international law from the perspective of the lived history of Third World peoples.\textsuperscript{114} In this respect, for them, the effects of colonialism and neo-colonialism on Third World peoples’ perception of

\textsuperscript{108} In making a case for the TWAIL, Karin Mickelson had observed, for instance, that conventional legal scholarship did not generally recognize any coherent and distinctive ‘third world approach’ to international law. Rather, third world approaches were generally classed as a series of uncoordinated reactionary attacks on the existing international system, borne out of the weak economic and political standing of underdeveloped countries within the international system. See, Karin Mickelson, “Rhetoric and Rage: Third World Voices in International Legal Discourse” (1998) 16:2 Wisconsin International Law Journal [Mickelson, “Rhetoric & Rage”] 353. See justifications for both strands of TWAIL as a theoretical approach as well as methodological approach in, Okafor, “Critical TWAIL”, supra note 24 at 371 – 378.

\textsuperscript{109} Gathii, “TWAIL”, supra note 24 at 34. It is based on the assumption that it is not possible to isolate modern forms of domination, such as governmentality, from the continuation of older modes of domination (colonial and pre-colonial). Ibid.

\textsuperscript{110} See, for instance, Anthony Anghie, Imperialism, Sovereignty and the Making of International Law (Cambridge, UK: Cambridge University Press, 2005) at 6 – 7, where he argues that the doctrinal and institutional developments in international law cannot be understood as logical elaborations of a stable, philosophically conceived, sovereignty doctrine. But rather, as being generated by problems relating to colonial order.


\textsuperscript{112} Okafor, “Critical TWAIL”, supra note 24 at 376.

\textsuperscript{113} Anghie & Chimni, “TWAIL & Individual Responsibility”, supra note 24 at 78.
proposed international rules and institutions, as well as the actual resistance to, or acceptance of, international rules and practices which affect the lives of Third World peoples provides strong evidence of the justice or injustice of rules and practices.\textsuperscript{115}

\begin{quote}

[b]y evaluating positivist rules through the lens of the lived experience of Third World peoples, TWAIL scholars seek to transform international law from being a language of oppression to a language of emancipation – a body of rules and practices that reflect and embody the struggles and aspirations of Third World peoples and which, thereby, promotes truly global justice.\textsuperscript{116}
\end{quote}

In sum, therefore, TWAIL pursues a rebalancing of the international legal system through a reflection on the Third World realities, experiences, struggles and aspirations in international law. Having clarified the TWAIL, an outstanding, yet, important, practical question remains, ‘what is the Third World?’

The coining of the term ‘Third World’ is often credited to Albert Sauvy, a French demographer, who, in an early article published in the national Paris daily (L’Observateur, August 14, 1952), sought to draw a historical analogy to the ‘tiers etat’ within the French society – the commonplace citizens who were generally marginalized and oppressed among the population.\textsuperscript{117} The term has arisen, not helped by a faulty translation from French to English, to bear a negative connotation to the laggard elements of the international system. Karin Mickelson describes the Third World as referring to entities which occupy a historically constituted, alternative, and oppositional stance within the international system.\textsuperscript{118} Her broad and inclusive categorization draws from a variety of approaches which have offered interpretive value to the term.\textsuperscript{119} She, however, observes, in reference to her chosen approach, that

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In advancing her understanding of the Third World, Karin Mickelson offers four useful angles that have offered interpretive value to the term. First, in a descriptive sense, the third world is often used interchangeably with terms like developed, developing, underdeveloped countries and the South, to describe countries in Africa, Asia and Latin America that are generally lagging behind the West, North, First World, or developed countries. Second, the Third World is often used to refer to the countries that are generally marginalized within the international system. Julius Nyerere for instance had contended that [t]he Third World consists of the victims and the powerless in the international economy. Together, we constitute a majority of the world’s population and possess the largest part of certain important raw materials, but we have no control and hardly any influence over the manner in which the nations of the world arrange their economic affairs. In international rule-making, we are recipients not participants. See, Julius Nyerere, “South South Option” in Gauhar Altaf & Attiga Ali Ahmed, \textit{Third World Strategy: Economic & Political Cohesion in the South} (New York: Praeger Publishers, 1983) at 10. Third, it could be used to identify a political coalition, similar to any other grouping of states in pursuit of common goals. Fourth, it
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\textsuperscript{115} Ibid.
\textsuperscript{116} Ibid 78 – 79.
\textsuperscript{117} See Mickelson, “Rhetoric & Rage”,\textit{ supra} note 108 at 356 (note 15).
\textsuperscript{118} Ibid at 360.
\textsuperscript{119} In advancing her understanding of the Third World, Karin Mickelson offers four useful angles that have offered interpretive value to the term. First, in a descriptive sense, the third world is often used interchangeably with terms like developed, developing, underdeveloped countries and the South, to describe countries in Africa, Asia and Latin America that are generally lagging behind the West, North, First World, or developed countries. Second, the Third World is often used to refer to the countries that are generally marginalized within the international society. Julius Nyerere for instance had contended that [t]he Third World consists of the victims and the powerless in the international economy. Together, we constitute a majority of the world’s population and possess the largest part of certain important raw materials, but we have no control and hardly any influence over the manner in which the nations of the world arrange their economic affairs. In international rule-making, we are recipients not participants. See, Julius Nyerere, “South South Option” in Gauhar Altaf & Attiga Ali Ahmed, \textit{Third World Strategy: Economic & Political Cohesion in the South} (New York: Praeger Publishers, 1983) at 10. Third, it could be used to identify a political coalition, similar to any other grouping of states in pursuit of common goals. Fourth, it
such an approach does not deny the existence of differences between and within Third World countries and does not underestimate the importance of such differences. It speaks of the Third World, not as a bloc but as a distinctive voice, or, more accurately, as a chorus of voices that blend, though not always harmoniously, in attempting to make heard a common set of concerns. From this perspective, the relative disadvantage experienced by Third World countries is seen not only in descriptive, but in normative terms, as an intolerable situation that demands a response. To self-identify as part of the Third World, then, involves a choice to take a stand in a struggle in which what is sought is not merely a more equitable distribution of resources, or a reshuffling of existing power relations. While such goals have been part of Third World demands, they do not capture the fully revolutionary nature of the alternative sought: a fundamental rethinking of international relations.

Anghie and Chimni make an important observation of the Third World which is relevant here. According to them, a distinction may be drawn between the Third World peoples and Third World states. Indeed, for them, the interests of the Third World States do not necessarily always align with the interests of the Third World peoples. This is an interesting observation given the nature of this dissertation’s focus on the third world’s approach to the international ABS system. It again highlights the importance of examining the role, and perspectives of non-state actors, even from the Third World, on the implementation questions surrounding the Nagoya Protocol. The historical exclusion, for instance, of third world innovations and practices (TWIP) from the dominant international regimes charged with the promotion and reward of human creativity, and the resultant efforts of third world actors to reclaim recognition, reward and/or respect for their role in global innovation through the ABS regime, provides an important subtext to the Nagoya Protocol.

Summarily, this thesis accords primacy to the perspectives drawn from the lived experience of the third world in unpacking and analyzing the Nagoya Protocol. As a first step, it is worth noting that the Protocol establishes an international ABS regime. The word ‘regime’ has, however, drawn a variety of loose and strict applications within the literature. It is therefore important to clarify from the outset what regimes are, and contextualize its application within this research. This understanding is particularly important as the development of an international ABS regime was specifically demanded by developing countries.

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120 Could be used to describe a form of social movement; an international protest of the weak against the strong, or the poor against the rich. See Mickelson, “Rhetoric & Rage”, supra note 108 at 356 – 357.
121 Ibid. at 360.
121 Anghie & Chimni, “TWAIL & Individual Responsibility”, supra note 24 at 78.
2.2 International Regimes

The concept of international regimes was developed and has been popularized by scholars of international relations to capture the diversity and complexity of the cooperative arrangements that states use to address trans-border issues of mutual concern. Stephen Krasner is attributed with the canonical definition of the term, which he defines as implicit or explicit principles, norms, rules, and decision-making procedures around which actors’ expectations converge in a given area of international relations. I will return to an elaboration of this definition later as this definition, including the concept of regimes, has continued to draw wide interest and use from scholars and policy makers. Mark Zacher observes that the scholarly interest in regimes is motivated primarily by a desire to understand the extent to which mutually accepted constraints or regulations affect states’ behavior. It is worth noting that across and within the fields of international relations and international law, the understanding and use of the international regime concept has differed. The resulting imprecision and wooliness of the term, arising from such diverse usage of the concept, is a factor often cited as a criticism against the study of international regimes.

Regime theories have, however, emerged to explain the global politics underlying state behavior within the fields of international relations and global political economy. International relations scholars have extensively pursued an elaboration of the various theoretical underpinnings underlying the formation,

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122 Helfer “Regime Shifting” supra note 65 at 10. See also, Hasenclever, Mayer & Rittberger, International Regimes, supra note 64 at 1.
123 This ‘consensus’ definition, as elaborated by Stephen Krasner in his introductory essay to international regimes, was one of the results of a conference convened to prepare the 1982 special issue of International Organization on international regimes. It has been widely criticized for its imprecision and the difficulty of distinguishing among its various components. According to Krasner, principles are beliefs of fact, causation, and rectitude. Norms are standards of behaviour defined in terms of rights and obligations. Rules are specific prescriptions or proscriptions for action. Decision-making procedures are prevailing practices for making and implementing collective choice. See Hasenclever, Mayer & Rittberger, International Regimes, supra note 64, at 8.
125 See Margaret Young, “Introduction: The Productive Friction between Regimes”, in Margaret Young, ed, Regime Interaction in International Law: Facing Fragmentation (UK: Cambridge University Press, 2012) [Young, “Productive Friction”] at 2. This difference is also closely linked to the difficult historical relationship between international relations and international law scholarship. See, John H. Currie, Craig Forcete & Valerie Oosterveld, International Law: Doctrine, Practice & Theory (Toronto, Canada: Irwin Law, 2007) 29 – 38, who describe a tense relationship stemming from the questioning by international relations scholars (particularly those of the realist and non-realist school) of the relevance of international law to international affairs. Ibid. at 29.
126 See, e.g., Susan Strange, “Cave! Hic Dragones: A Critique of Regime Analysis”, (1982) 36.2 International Organization, at 484 – 485, who argues that the problem with such woolly words like regimes is that, where they do not actually mislead and misrepresent, they only serve to disorient and confuse. See also, O.Young, International Cooperation, supra note 101 at 9, who notes that critics have reasonably questioned whether the concept of regimes is ‘anything but a woolly notion likely to produce more confusion than illumination’.
maintenance, and demise of international regimes. The international law scholarship is focused mainly on understanding how different branches of norms and institutions overlap on issues of global concern. As Margaret Young notes, this overlap is not merely a matter of international judicial tribunals seeking to interpret conflicting norms, ‘but is a constant feature in the setting of agendas for new negotiations, the ongoing norm elaboration within regimes and even the domestic policy coordination between state ministries and departments’.128

Indeed, international law is made up of normative and institutional fragments which interact in diverse ways. There really is no central international law – a homogenous instrument, negotiated centrally, which governs international relations from a unified perspective. Rather, international law has developed in response to specific needs, as a body of fragmented regulations governing various areas of state relations. The flurry of regulations governing specific areas continues to emerge independent of coordinated central approach. The inevitable consequence of this is the overlap of regulations governing specific areas of state relations. Not only do such normative fragments overlap at certain points, the interaction among ‘independent’ normative fragments underlie an entire universe of issues relating to the relationship between existing and emerging fragments of international law; issues ranging from the negotiation, rationale, interpretation, implementation, and enforcement of international law.131

International law is a legal system. Its rules and principles (i.e. its norms) act in relation to and should be interpreted against the background of other rules and principles. As a

127 See Young, “Productive Friction”, supra note 125 at 1.
128 Ibid.
129 See note 62 above.
130 A useful example is drawn here against the backdrop of an institutional analysis undertaken by Amir A Majid. He notes, with reference to formation of international institutions, that ‘...the international legal regime does not have a pyramidal organization converging its ultimate authority in a universal legislature or government which can set up regulatory procedures or criteria...’ See, Amir A Majid, Legal Status of International Institutions: SITA, INMARSAT and EUROCONTROL Examined (UK: Dartmouth Publishing Company Ltd., 1996) at 119. See also, Young, “Productive Friction”, supra note 125 at 2, noting that there has never been a single global legislature or appellate court to mould a unified body of international law. Nor has there ever been a uniform will for such a system by sovereign states.
131 See generally, for instance, Beth A Simmons & Richard H Steinberg, eds, International Law & International Relations (UK: Cambridge University Press: 2006), which covers a broad range of topics, authored by law practitioners as well as political scientists, dealing with international regimes, within the specific context of the interaction of international law and international relations. See generally also, Margaret A Young, ed, Regime Interaction in International Law: Facing Fragmentation (UK: Cambridge University Press, 2012). See also, Young, “Regime interaction”, supra note 63 at 91.
legal system, international law is not a random collection of such norms. There are meaningful relationships between them.\textsuperscript{132}

The existence of normative fragments could serve, for instance, to provoke the emergence of counter-norms seeking to balance the effect of existing norms, or could serve as foundations for the emergence of strengthened norms aimed at the consolidation of existing norms.\textsuperscript{133} In this context, the emergence of international norms, just like international regimes, could be seen as being path dependent, and are generally reactive to, or predicated on existing regimes.\textsuperscript{134}

In contextualizing regimes, Oran Young explains that international regimes are located within the discourse on international institutions and generally exist within the context of broad international orders.\textsuperscript{135} Therefore, for instance, within the framework of the international economic order, specific regimes, such as, the multilateral trading regime and several other financial and investment regimes may be said to exist. A regime, distinguished from the broad international order, usually involves a smaller number of the members of the international order and is designed, as a social institution, to address a specific issue area(s) of concern.\textsuperscript{136} Such regimes, which may be formal or informal, implicit or explicit, build on foundations laid by the order, and, as such, operate within the context of broader general institutions. For this reason, Young argues, international regimes cannot be properly analyzed without reference to the broader institutional orders operative in international society.\textsuperscript{137}

Within the context of this discourse, therefore, a constant reference to the underlying international environmental system as well as international intellectual property (IP) system provides relevant context to the analysis of the international regime on ABS. This is due to their central role in the shaping, design,
interpretation and implementation of solutions to the protection of TKaGRs. On the relevance of IP, Simon West has, for instance, argued that a textured interpretation of the Nagoya Protocol requires its interpretation to be within the context of the broader political economy of IP. This, he argues, is because the Protocol is imbued with obligations which are subservient to the IP system, thus leaving its beneficiaries in a state of dependence on the IP system for the actuation of their rights.138

The emergence of the Nagoya Protocol and the ABS regime, and the current efforts at its implementation, all within a timeframe when the IP system has struggled to conclude its discussions on the design of solutions within the same issue area, therefore offers a useful opportunity for the legal scholarship to analyze the Protocol within the context of neighboring norms and institutions which may overlap with the very areas of concern that the Protocol is designed to address. A primary neighboring regime in this regard is the global IP regime. Margaret Young’s point also indicates an important basis for this dissertation’s analysis: the important interaction, on the one hand, between international law that has been adopted, and the processes and mechanisms leading to the formation of related fragments of international law on the other. In other words, an important analysis may be made regarding the implications of the Nagoya Protocol and the ongoing negotiating process within the neighboring IP regime. In this dissertation, a specific focus is placed on the emerging related negotiations within WIPO.

An important question, however, which will aid the analysis, centers on the identification of international regimes. How are regimes identified, and what constitutes an international regime? Is the Nagoya Protocol an international regime, or is it merely an international instrument? On what basis can this determination be made?

2.2.1 The Identification of Regimes

Several approaches have emerged by which the concept of regimes may be construed. The International Law Commission of the United Nations (ILC),\textsuperscript{139} for instance, highlights the narrow, broad, and broader interpretations which may be used to identify international regimes.\textsuperscript{140} According to the ILC, [i]n narrow terms, the concept of regimes exists where violation of a particular group of (primary) rules is accompanied by a special set of (secondary) rules concerning breach and reactions to breach. In a broader sense, it exists where there is a set of special rules, including rights and obligations, relating to a special subject matter. Such rules may concern a geographical area (such as a treaty on the protection of a particular river), or some substantive matter. Such a special regime may emerge on the basis of a single treaty, several treaties, or treaty and treaties plus non-treaty developments (subsequent practices or customary law). In its broadest sense, a regime may also be seen to exist where all the rules and principles that regulate a certain problem area are collected together so as to express a 'special regime'. Expressions such as 'law of the sea', 'humanitarian law', 'human rights law', 'environmental law' and 'trade law', etc. give expressions to some such regimes.\textsuperscript{141}

Flowing from the above definition, the narrow or strict definition indicates that a regime exists where secondary remedial and/or enforcement rules are put in place to address an actual and potential breach of primary rules. In this sense, the existence of a regime is linked to an enforceable and effective enforcement standard contained within a set of rules which is reactionary to potential breaches of a primary set of laws. Based on this interpretation, the rules regulating the international trading system, as contained within the covered agreements of the World Trade Organization, may be said to constitute an international regime, given the existence of detailed rules concerning dispute settlement and effective remedies for the breach of the covered agreements.\textsuperscript{142}

The broader sense identified omits a reference to enforcement and/or remedies in case of breach, but merely states the existence of a special regime where a law(s) or practices exist, which gives rise to a set of rights and obligations, for the regulation of a special subject matter. In other words, the existence of

\textsuperscript{139} The International Law Commission of the United Nations in 2002 established a study group to look into issues surrounding the fragmentation of international law. Chaired by Mr. Martti Koskenniemi, the study group’s final report was issued in 2006. For the full report, see ILC Study Group, \textit{Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law: Report of the Study Group of the International Law Commission Finalized by Martti Koskenniemi}, ILCOR, 58th sess, UN Doc A/CN.4/L.682 (2006).

\textsuperscript{140} Ibid at paras 128 – 132. See also Young “Productive Friction”, \textit{supra} note 125 at 5.

\textsuperscript{141} Ibid. [italics and insertions mine]

\textsuperscript{142} For a detailed discussion of the trading system as an international regime, including a political and economic analysis of the evolution of its rules, see generally, John H Barton, Judith L Goldstein, Timothy E Josling & Richard H Steinberg, \textit{The Evolution of the Trade Regime: Politics, Law, and Economics of the GATT & the WTO} (Princeton, New Jersey: Princeton University Press, 2006) [Barton, Goldstein, Josling & Steinberg, \textit{The Evolution of the Trade Regime}].
an agreed binding standard for regulating a particular subject matter provides a basis for identifying a regime. Within this definition remains a direct link between the problem area and the regulations governing its management; that is, the rules emerged to address the problem area. Examples could include the *United Nations Declaration on the Rights of Indigenous Peoples* (UNDRIP), which lays the frame for a regime on the rights of indigenous peoples.

Within the broadest sense, the UNDRIP, however, would form a component part of a broad international regime on human rights, given that it constitutes one of the many instruments negotiated to address human rights. This broadest sense offers a loose conception of a regime’s existence by regarding it present where a pooling of all regulations relating to a particular problem area are utilized to express a special regime. The common thread in this context running through all such treaties is the fact that all are pointed towards a particular problem area. Importantly, this broad conception describes regimes through the lens of regime complexes.

### 2.2.2 Regime Complexes

The idea of a regime complex is an extremely important one in the context of this dissertation for it places the existence of special regimes at the intersection of multiple regulations which address a specific issue area. As Kal Raustiala and David Victor note, the existence of multiple, overlapping, elemental regimes is the defining characteristic of a regime complex. These elemental regimes overlap in scope, subject, and time, with events in one affecting those in others. In effect, regime complexes are marked by the existence of several legal agreements that are created and maintained in distinct fora with the participation of different sets of actors. This defining characteristic of a regime complex then reinforces Margaret Young’s views on overlapping norms and institutions in which she points out that the overlap could be seen in the elaboration of new norms within regimes as well as the setting of agendas for new negotiations. Consequently, regime complexes could also be seen in the context of the relationship between existing and emerging fragments of regulation which address particular issue areas.

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143 See, Raustiala & Victor, “The Regime Complex for Plant Genetic Resources”, *supra* note 64 at 703.
144 Ibid. at 686.
145 Ibid.
146 Young, “Productive Friction”, *supra* note 125 at 1.
A central implication of this regime complex discourse is that the Nagoya Protocol, though an instrument designed explicitly for the international regime on ABS, could yet serve as an elemental part of a broader regime, along with other instruments which overlap in scope, subject, and time. More importantly, as an instrument which addresses the protection of TKaGRs, the Protocol could be seen to form a part of a broader set of existing and emerging treaties which place the protection of TKaGRs at the center of their framework. Indeed, this interpretation offers a basis for juxtaposing the Protocol with the emerging current efforts to address TKaGRs on the platform of IP, and other regimes.

Summing up on the identification of regimes, two central points are worth highlighting. First, international law scholars consider the presence of explicit regulations governing a specific issue area as a critical factor in the identification of regimes. Second, the clarification of an ‘issue area’ forms a central consideration in the determination of regimes. A central focus must then be placed on the determination of issue areas for a reasonable conception of regime, and indeed a regime-complex to be made. In other words, a regime is as clear as its issue area is made out to be. So also, the articulation of a regime complex rises and falls on the clarity that is given to the issue area of regulation that the various complementary instruments purport to address. As I will later explain, this issue of regime areas is largely a political issue – one which, for our purposes, necessitates a clarification for our analysis. Given the centrality of these two points to the analysis within this dissertation, I will discuss these two points seriatim in the next couple of sections.

2.2.3 Of Rules, Principles, Norms, and Decision Making Procedures

International law scholars consider a fundamental basis for identifying the existence of regimes as the presence of explicit regulations governing specific problem areas. Such regulations could be secondary mechanisms addressing the breach of primary rules, a binding standard for a particular subject, or a broad pooling of regulations addressing a subject area. This rule-based approach to the identification of regimes finds alignment with aspects of the international relations scholarship. However, it constitutes a narrower
International regimes are commonly defined as social institutions around which expectations converge in international issue-areas. The emphasis on convergent expectations as the constitutive basis of regimes gives regimes an inescapable intersubjective quality. It follows that we know regimes by their principled and shared understandings of desirable and acceptable forms of social behaviour. Hence, the ontology of regimes rests upon a strong element of intersubjectivity.

See, Friedrich V Kratochwil & John Gerard Ruggie, “International Organization: A State of the Art on an Art of the State” (1986) 40 International Organization, 753 at 764. See also Hasenclever, Mayer & Rittberger, International Regimes, supra note 64 at 16. Arising from such communicative actions, such as, reproaches, excuses, justifications etc., proponents seek an appreciation of the intersubjective meanings and shared understandings existing within a regime community.

The third approach, popularly associated with Keohane, advocates a formal approach to construing regimes primarily in terms of explicit rules as agreed on by actors and pertaining to a specific issue area in international relations. Hasenclever, Mayer & Rittberger, International Regimes, supra note 64 at 17. Keohane views regimes as ‘institutions with explicit rules, agreed upon by governments that pertain to particular sets of issues in international relations’. See Robert Keohane, ‘Neoliberal Institutionalism: A Perspective on World Politics’, in Robert Keohane, International Institutions & State Power: Essays in International Relations Theory (Boulder:
Though fundamental differences exist amongst scholars in the elaboration of the regime concept, the canonical definition of the term, as mentioned above, is generally attributed to Krasner.\textsuperscript{150} He defines international regimes as

\begin{quote}
\[\text{[i]mplicit or explicit principles, norms, rules, and decision-making procedures around which actors’ expectations converge in a given area of international relations’}. \text{Principles are beliefs of fact, causation, and rectitude. Norms are standards of behaviour defined in terms of rights and obligations. Rules are specific prescriptions or proscriptions for action. Decision-making procedures are prevailing practices for making and implementing collective choice.}\textsuperscript{151}
\end{quote}

For the purpose of characterizing regimes, Krasner’s definition identifies four hierarchical components of international regimes. These components, which exist in all regimes are principles, norms, rules, and decision-making procedures. They essentially form the hub at which the expectations of actors within a given area of international relations converge – whether within a formal simple regime or in a broader complex interpretation. According to Krasner’s definition, regimes are therefore comprised of a specified issue area requiring international cooperation, and a shared expectation among all actors on the way to address this issue, as evidenced by a shared set of principles, norms, rules, and decision-making procedures.

Despite its wide acceptance, Krasner’s definition has faced severe criticisms.\textsuperscript{152} A major critique is the lack of precise meanings and mutual relationship existing among the suggested four regime

\begin{footnotes}
\textsuperscript{150} Westview Press, (1989) at 4. This approach, which rejects the possibility of implicit regimes, settles on an identification of a regime’s existence based on clearly agreed rules addressed at a specific issue area. Implicit in this formal conceptualization is a deference to an established and agreed formal normative framework as well as a clear identification of a specified issue area in the articulation of a regime. He suggests regimes to be identifiable by the existence of explicit rules that are referred to in an affirmative manner by governments, even if they are not necessarily scrupulously observed. See Hasenclever, Mayer & Rittberger, \textit{International Regimes supra} note 64 at 20. See also, Robert Keohane, ‘The Analysis of International Regimes: Towards a European-American Research Programme’ in Volker Rittberger, ed, \textit{Regime Theory and International Relations} (Oxford: Clarendon Press, 1993) at 28.

\textsuperscript{151} Helfer “Regime Shifting”, \textit{supra} note 65 at 10.

\textsuperscript{152} This ‘consensus’ definition, as elaborated by Stephen Krasner in his introductory essay to international regimes, was one of the results of a conference convened to prepare the 1982 special issue of International Organization on international regimes. It has been widely criticized for its imprecision and the difficulty of distinguishing among its various components. See Hasenclever, Mayer & Rittberger, \textit{International Regimes supra} note 64 at 8.

\textsuperscript{150} A major critic of this definition is Robert O Keohane. Keohane’s criticism of the Krasner’s definition is threefold. First, he contends that the definition is a mere list of elements which are hard to differentiate conceptually and which overlap in real world situations. Second, he argues that the definition reflects a disconcerting elasticity when applied to the real world of international relations. Third, the definition is conceptually thin as it fails to tie the concept into the larger system of ideas that would help solve ambiguities and would offer guidance in formulating key questions and assumptions regarding international regimes. Hansclever, Mayer & Rittberger, \textit{International Regimes, supra} note 45 at 11 – 12.
\end{footnotes}
components – principles, norms, rules and procedures.¹⁵³ In practice, the fine distinctions among these regime components could prove difficult and in some cases impossible to define. Again, the persisting ambiguity inherent within the phrase, ‘around which actors’ expectations converge’ has been singled out as another criticism.¹⁵⁴ Underlying this ambiguity is the need for clarity regarding when a regime component, i.e. principles, rules, norms or procedures, may be said to exist within an issue area.¹⁵⁵ Though, in response to these criticisms, alternate definitions¹⁵⁶ as well as a range of contextual definitions¹⁵⁷ of the concept have emerged, the analytical value of Krasner’s definition has kept it a firm favorite.

Not only have scholars aligned with this definition, but interestingly, even the terms of reference for the negotiation of the ABS regime was drawn directly from Krasner’s iteration of regimes, with a stipulation that this international ABS regime could consist of one or more instruments within a set of principles, norms, rules and decision making procedures.¹⁵⁸ It is worth pointing out here that the international ABS regime, established by the Nagoya Protocol, thus exists as a hub of norms, principles, and rules which advance a benefit sharing strategy to protect, amongst others, TKaGRs. The open ended nature of the ABS regime, which draws from this very mandate for its negotiation, suggests that the ABS regime’s principles, norms, rules and decision making procedures, could form the base for construing several instruments as a part of the regime it establishes. The WIPO IGC’s elaboration, therefore, from an

¹⁵³ Ibïd at 11.
¹⁵⁴ Ibïd.
¹⁵⁵ Ibïd.
¹⁵⁶ Keohane, for instance, in line with his formal approach to regime construction, proposes an ‘alternate’, ‘easier’, and ‘leaner’ definition of regimes as ‘institutions with explicit rules, agreed upon by governments that pertain to particular sets of issues in international relations’. This simplified definition notably eliminates the distinction between various components of a regime, and proposes to address the criticisms of Krasner’s definition, inter alia, through a general categorization of all components as ‘rules’. Furthermore, the definition rejects the view that implicit rules play a part in regimes and, third, conceptualizes regimes arising solely from the agreement of governments. The view that non-state actors could be a direct part of the decision making process within regimes is thereby questioned in this definition. A major criticism of Keohane’s definition is its limitations with respect to the comparative analyses of regimes owing to its simplified structure. The consensus definition, though complex, enables researchers to reflect thoroughly on the mutual relationship of the various injunctions in the issue area in question and also forces a structure upon the description of regimes which ease comparisons across issue areas. Hansclevler, Mayer & Rittberger, International Regimes, supra note 46 at 12 – 13.
¹⁵⁸ See Access and Benefit-sharing as Related to Genetic Resources (Article 15) COP 7 Dec VII/19, CBDOR, 2004, UNEP/CBD/COP/DEC/VII/19, [COP Dec VII/19] at 6 (para (b), Annex).
IP perspective, of a complementary set of rules, principles, and norms, also focused on the protection of TKaGRs, places an early rationale for its possible consideration as a part of the ABS regime. Drawing from Raustiala and Victor’s analysis referenced earlier, this possible viewing of the IGC’s emerging instruments as a part of the ABS regime, offers a basis for construing the ABS regime as more than a single regime, but rather as an ABS regime complex.

Laurence Helfer provides an elaboration of regime components (based on Krasner’s definition) in a way that both accounts for the substantive rules, principles and norms within individual regimes, as well as the interaction of several regimes within a regime complex. He does this by providing a useful disaggregation of these regime components into substantive, institutional, and relational aspects. It is worth mentioning that this is by no means the only approach to discussing the components of regimes. However, this elaboration by Helfer is germane to this dissertation and the specific articulation of regime complexes as is his discussion on regime shifting. For the purposes of clarity, these three aspects are briefly outlined below.

According to Helfer, the substantive components of an international regime are focused on the regime’s principles, norms, and rules. This relates to the foundational rationales underlying the regime’s existence as well as the guiding norms which the members of the regime have agreed to be bound by in addressing the regime’s issue area(s). These norms and principles are mostly codified within treaty text.

The substantive component of a regime provides definition to the regime and sets out the consensus approach to addressing the regime’s issue area(s), the clarity of which, more often than not, underlies the basis for the regime’s development and continued existence. The identification, therefore, of a formal ABS

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159 See section 2.3.1. above.
161 See, for instance, O. Young, International Cooperation, supra note 101 at 15 – 21. Oran Young in elaborating the standard components of regimes through an analysis of Krasner’s definition, discusses regimes as being composed essentially of substantive, procedural and compliance components. According to Young, all regimes possess a substantive component, made up of rules and rights (Ibid. at 16). A procedural component, which involves recognized practices for handling situations requiring social or collective choices (Ibid. at 18 – 19), while the compliance component involves mechanisms which are authorized to promote compliance with the substantive provisions of a regime or with the outcomes generated by its social choice mechanisms (Ibid. at 20).
162 Helfer “Regime Shifting”, supra note 65 at 10 – 11.
regime through the Nagoya Protocol suggests that the underlying principles, norms, and rules of the ABS regime are as contained within the Nagoya Protocol.

Second, Helfer identifies the institutional component of regimes. In discussing the institutional component, it is worth acknowledging that international regimes may be seen as international institutions.\textsuperscript{163} The differing schools of thought in the elaboration of international regimes\textsuperscript{164} merely differ on the extent to which they centralize institutionalism in their discussion of regimes.\textsuperscript{165} As elaborated by Helfer, the institutional aspect involves the reference to decision-making procedures. This encompasses the formal institutions, such as intergovernmental organizations, as well as the informal cooperative arrangements which states utilize to create principles, norms and rules.\textsuperscript{166} Helfer describes the institutional component as a wide ‘spectrum running from highly structured intergovernmental organizations with staffs, facilities and budgets at one end, to informal networks of government officials who exchange information and coordinate national policies at the other.\textsuperscript{167} This institutional component of regimes recognizes that international regimes lack the capacity to ‘act’ and respond to situations of themselves as they represent mere principles, rules, norms and procedures. Regimes, therefore, usually require an international organization (or secretariat) which provides it with an administrative base, enabling the regime to respond to events, establish a forum for reviewing state behavior as well as engaging in further negotiations on the central

\textsuperscript{163} According to Amir Majid, International institutions, which may either be Inter-Governmental Institutions or Non-Governmental Institutions, are defined as ‘an organized body which possesses the following minimum characteristics; (a) has a membership extending to three or more states (b) the performance of its functions, as enumerated in its Constituent Document, is for the benefit of or in the territories of more than one State (c) It has an institutional structure which is not transient in nature and which, if viewed from a distance, portrays a collective entity distinct from the entities of its individual members. Amir A Majid, \textit{Legal Status of International Institutions: SITA, INMARSAT and EUROCONTROL Examined} (UK: Dartmouth Publishing Company Ltd., 1996) at 119 – 120.

\textsuperscript{164} Three main schools of thought are identified in the discussion of international regimes. These perspectives are the power-based approach to understanding regimes, the interest-based and the knowledge-based approach. According to Hansclever at al, these three schools of thought constitute explanatory variables to the understanding of such issues as what regimes are, how regimes affect the behaviour of state and non-state actors in the issue areas for which they have been created, as well as the sustaining powers of institutions, amongst others. See Hasenclever, Mayer & Rittberger, \textit{International Regimes}, supra note 64 at 1 – 7. See also, Oran Young who identifies two main approaches to the understanding of regime formation – the utilitarian model and the power (realists) model. Oran R Young, “The Politics of International Regime Formation: Managing Natural Resources and the Environment” (1989) 43.3 International Organization, 349 at 350 – 352.

\textsuperscript{165} While the power-based theories are generally seen as borderline examples of institutionalism, interest based theories adopt an unequivocally institutionalist perspective. Cognitivists adopt the strongest form of institutionalism of the three schools.

\textsuperscript{166} Helfer, “Regime Shifting”, supra note 65 at 10 – 11.

\textsuperscript{167} Ibid at 11.
The prevalence of international organizations in a wide range of issue areas supports an understanding of this component. Relevant examples in the context of this dissertation include the secretariats of WIPO, with respect to the intellectual property (IP) regime, and the CBD, with respect to the ABS regime. For the ABS regime, another important institutional component is the Conference of the Parties sitting as Members of the Nagoya Protocol (COP/MOP) which serves in an administrative and supervisory role over the functioning and implementation of the Protocol. It is important to clarify that though international regimes may be accompanied by international organizations designed to support them, the terms ‘international regime’ and ‘international organization’ are not synonymous or co-extensional. Regimes could exist without formal organizational structures.

The third aspect which Helfer describes is the relational component of regimes. The focus of this aspect is on the converging expectations of actors within a ‘given area of international relations’. It describes the building of a consensus ad idem among actors regarding an issue area. Amongst others, this aspect has the effect of situating independent, yet dependent regimes within the wider scope of intersecting issue areas, including factors within related regimes which prevent or enhance the actualization of the particular regime’s objectives. It encapsulates the substantive areas included within regimes and the ways these intersect with the issue areas of other regimes. An important value of this relational aspect of regimes, as elaborated by Helfer, is thus the recognition that regimes do not exist in isolation. Rather, regimes exist and operate within a myriad of related regimes. Such related regimes could be used, positively or adversely, to affect the implementation of neighboring regimes. Neighboring regimes could, for instance, be used to develop counter-regime norms which run against the principles and/or norms of dominant regimes or could be used to consolidate gains within existing regimes. Usually, the key link between regimes is the issue area of concern which, with the increased fragmentation in the development of international law, has led to issue areas being linked (controversially or non-controversially) with several regimes. The resulting density within regimes, particularly where it involves a controversial packaging and

168 Furthermore, unlike regimes which are issue-specific institutions by definition, the sphere of activity of an international organization need not be restricted to a particular issue area. Ibid.
170 Helfer “Regime Shifting”, supra note 65 at 10, 12 – 13.
linking of issues within a regime,\(^{171}\) is recognized by scholars as a factor which tends to create state conflicts, if not competing interests, and ultimately serves as an engine driving regime change.\(^{172}\)

On the basis of Helfer’s analysis, regimes can be independently assessed on the basis of their substantive and institutional components. These components indicate regime components that may be viewed as being located within the regime. Consequently, one may, for instance, exclusively examine the principles, norms, and rules, as well as institutional structures supporting the ABS regime. However, the relational component of regimes forces a look beyond the single regime to the wider regulatory context within which issue areas exist. By examining the issue area and the convergence of expectations on that issue area, the relational aspect of regimes requires an examination of the regime within the context of related regimes. Within the context then of this dissertation, Helfer’s adumbration of a triune component-structure of international regimes offers a useful basis for examining the emergent international regime on ABS and its interaction with closely related regimes, most specifically the parallel emerging regime developments within the IP regime.

This relational aspect of regimes is also important in elaborating an important part of regime complexes – regime shifting. One of the central features of regime complexes is regime shifting.\(^{173}\) Regime shifting is an interest-based shifting of negotiations by States and NGOs from one venue to another within a single regime (intra-regime shift) or across regimes (inter-regime shift).\(^{174}\) As in this instance, the shift being considered is across two possible elemental regimes. Reiterating the link between regime shifting and regime complexes, Helfer suggests that ongoing interactions between separate regimes promot[es] the formation of networks among formerly disparate state, intergovernmental, and non-state actors and linkages among formerly discrete issue areas. The result is a conglomerate type of regime” or a “regime complex” – a multi-issue, multi-venue mega-regime in which states and NGOs shift negotiations from one venue to another within the conglomerate\(^{175}\)

\(^{171}\) In elaborating this aspect, Helfer distinguishes between the ‘uncontroversial’ and ‘controversial’ packaging and linking of issues within regimes, noting that their controversial nature tends to create state conflicts, which serve as an engine driving regime change.\(^{Ibid.}\)

\(^{172}\) Ibid. Regime change could be viewed in two main ways. There could be the change of a regime and there could alternatively be changes within a regime. The former occurs where the principles and norms of a regime are changed, while all other changes to a regime result merely in the latter.\(^{Hasenclever, Mayer & Rittberger, International Regimes, supra note 64 at 13.}\)

\(^{173}\) Raustiala & Victor, “The Regime Complex for Plant Genetic Resources”, supra note 64 at 686 – 687, noting that the distinct negotiating fora within the regime complex spurs forum shopping.

\(^{174}\) Helfer “Regime Shifting”, supra note 65 at 16 – 17.

\(^{175}\) Ibid.
Through regime shifting, actors strategically move across independent elemental regimes for the purpose of advancing their interests with respect to the issue areas. This is important in the context of this dissertation as the interaction between the ABS regime and the emerging developments within the IP regime highlight an interest-based move by developing countries to secure normative reinforcements within the IP regime for the gains secured within the Nagoya Protocol. This move aligns with a vertical approach at forum shifting,\(^\text{176}\) which Susan Sell identifies as a strategy offering more benefits to weaker parties within regime complex negotiations.\(^\text{177}\) Indeed, the movement of Third World actors, to fora within the IP regime, particularly the WIPO’s ongoing negotiations, supports Sell’s thesis and, as I argue here, is a deliberate strategy by developing countries to secure an effective reinforcement for the ABS regime.

I have so far focused on the identification, definition, and characterization of international regimes for the purpose of properly analyzing the international ABS regime. It is worth noting, however, that international regimes are political constructs and, as such, a political dimension to their identification and elaboration cannot be ruled out. In this context, actors within regimes tend to perceive regimes differently. This divergence in regime perception underscores the political nature of regime objectives, or more accurately, issue areas, and brings into sharp focus, the need to determine, for the sake of analysis, the central issue area within the ABS regime. This goes now to the second identified point from the definitional discussion of regimes – the importance of issue area clarity.

### 2.3 Biopiracy: An Implicit ABS Regime Issue Area

Hansclever et al have observed, that issue-area specificity is an essential attribute of regimes, and consequently, the concept of a regime can only be as clear as the concept of an issue-area has been made.\(^\text{178}\) In other words, the clarity of an actual regime rests on the clarity of the issue-area for which cooperation is

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\(^176\)By vertical regime shifting reference is made to a top-down approach whereby parties shift negotiations to fora which are bilateral, regional or plurilateral in nature, thus affording stronger parties an opportunity to impose even higher demands within such agreements. Horizontal regime shifting however relates to the shifting across multilateral fora. This generally favors weaker actors. See Susan K Sell, “TRIPS: Fifteen Years Later” (2011) 18:2 Journal of Intellectual Property Law at 5.

\(^177\)See Sell, “TRIPS”, supra note 70 at 5. See, for example, Veronika Hrbata, “No International Organization is an Island...the WTO’s Relationship with the WIPO: A Model for the Governance of Trade Linkage Areas?” (2010) 44:1 Journal of World Trade, at 6, noting the positive ease for developed countries in utilizing bilateral agreements to reinforce the TRIPS Agreement.

\(^178\)Hasenclever, Mayer & Rittberger, *International Regimes*, supra note 64 at 60.
sought. The concept of ‘issue area’, though largely overlooked, is thus another important aspect of regimes that is worth mentioning.\textsuperscript{179} An issue area consists of one or more, in the perception of the actors, inseparably connected objects of contention and of the behavior directed to them. The boundaries of such issue areas are determined by the perceptions of the participating actors.\textsuperscript{180} This definition, amongst others, highlights the political nature of the circumscription of issue areas given its reliance on actors’ perceptions, as well as emphasizes the conflictual nature of issue areas.\textsuperscript{181}

The perception-dependency of issue-areas deserves to be stressed: it has the important implication that issue-areas can change without any corresponding change taking place in the objective facts to which policymakers are responding. Moreover, analysis is complicated by the fact that perceptions of actors as to which issues are indeed ‘inseparably connected’ can diverge: typically, the formation of an issue-area is itself a highly political process.\textsuperscript{182}

The international ABS regime thus offers an interesting framework for which the determination of the issue-area may prove a challenge for reasons alluded to above. \textit{Prima facie}, as discussed above, the ABS regime seeks to ensure cooperation among Parties on the effective implementation of the CBD’s third objective – equitable sharing of benefits arising from the utilization of GRs and TKaGRs. The flip side to this issue of benefit sharing is the issue of access to the resources located in the Third World. Highlighting the conflictual nature of the two sides, the user-actors, mostly located within developed countries are primarily concerned with issues of legal certainty surrounding the access terrain to resources, while the provider-actors are principally concerned with ensuring compliance with the terms of access especially as regards the sharing of benefits arising from use.\textsuperscript{183} The European Union, a major user of biodiversity, stressed the significance of the Protocol upon appending its signature to the Protocol, in the following words:

\begin{quote}
[t]he Nagoya Protocol should create the opportunities for biodiversity rich countries to conserve and sustainably use their biodiversity opportunities for fair and equitable sharing of benefits from their use. At the same time, the Protocol should create a clear and transparent framework for user countries to use the same opportunities as a resource.
\end{quote}

\begin{footnotes}
\item\textsuperscript{179} Ibid., who note that little attention has surprisingly been paid to the concept of issue area by students of international relations despite its centrality to the regime concept.
\item\textsuperscript{181} Hasenclever, Mayer & Rittberger, \textit{International Regimes, supra} note 64 at 61. Conflict is not used to refer to hostilities or violence, but is rather used to refer to incompatible preferences or differences in issue positions. The actions of actors in relation to these, is discussed as conflict management.
\item\textsuperscript{182} Hasenclever, Mayer & Rittberger, \textit{International Regimes, supra} note 64 at 61.
\item\textsuperscript{183} It may probably have offered greater clarity if the term utilization was used in place of access, as the benefit sharing provisions are contingent upon utilization of the resources and not access.
\end{footnotes}
to increase scientific knowledge and understanding, or to develop commercial products.\textsuperscript{184}

From the perspective of developing countries, mostly providers of GRs and TKaGRs, the immediate issue area, however, draws from a broad historical ancillary context of unfair access to and use of resources by user-actors, coupled with an inadequate or non-existent sharing of benefits with provider-actors. As noted above, given that the construction of issue areas is linked to the perception of actors and is largely a political issue, it will be a mistake to fail to acknowledge the underlying political sensitivities which benefit sharing has emerged to address within the third world – the eradication of biopiracy. Indeed, for developing countries, addressing the incidence of biopiracy represents a central policy objective at the heart of the efforts to establish and implement the Nagoya Protocol’s international ABS regime. The Government of India, for instance, upon ratification of the Nagoya Protocol noted in its press release;

\begin{quote}
India has been a victim of misappropriation or biopiracy of our genetic resources and associated traditional knowledge, which have been patented in other countries…it is expected that the ABS Protocol which is a key missing pillar of the CBD, would address this concern.\textsuperscript{185}
\end{quote}

The Government of Mexico, also noted, upon ratification of the Protocol, that the Protocol

\begin{quote}
[w]ould provide legal certainty regarding the use of genetic resources to indigenous and local communities, industries, pharmaceutical companies and researchers, by establishing measures to avoid misappropriation and misuse\textsuperscript{186}
\end{quote}

\begin{footnotes}
\item[184] See, EU Press Statement on the Signature of the Nagoya Protocol (23 June 2011), The European Commission <eu-un.europa.eu/articles/en/article_11157_en.htm>. See also, the official response to the question of why a Nagoya Protocol by the European Commission. “Questions and Answers on Access and Benefit Sharing”, online: European Commission < http://europa.eu/rapid/press-release_MEMO-14-411_en.htm>. According to the EC, The entry into force of the CBD did not create sufficient legal certainty. Some provider countries started to act upon the text of Article 15 of CBD and established national access legislation, which in some cases was so strict that users no longer had access to genetic resources from those states anymore. Many other Parties, such as the Member States of the European Union, while recognizing the general principles of Article 15 of the CBD, did not consider it sufficiently clear to be implemented into national law. This need for a more specific agreement led to the opening of negotiations of an international agreement on the subject. This agreement – the Nagoya Protocol – was finalized and adopted in October 2010 in Nagoya, Japan.


\end{footnotes}
Again, in this context, the former Vice President of Indonesia, Prof. Boediono, in offering support for the ratification of the Protocol, noted that

with the [Nagoya Protocol], Indonesia will have a firm legal basis to protect and preserve its genetic resources and traditional knowledge related to genetic resources. In addition, the law will also lay a legal basis for the country to prevent theft and illegal utilization of biodiversity\(^\text{187}\)

What then these three megadiverse country\(^\text{188}\) views point to is an expectation that the implementation of the Protocol will significantly assist their respective governments in the quest to prevent the continued theft, misappropriation, or misuse of TKaGRs and GRs from within their respective territories. These concerns, as expressed, are generally subsumed within the biopiracy rhetoric. From the perspective therefore of several developing countries, the Protocol is a central instrument for addressing biopiracy. In other words, the eradication of biopiracy represents an underlying expectation of benefit sharing arrangements within the concluded text of the Nagoya Protocol and, by extension, the ABS regime. This implies that beyond explicit primary regime objectives, regime signatories could yet approach the implementation of specific regimes for the fulfilment of ancillary objectives. Indeed, the ability to address these ancillary objectives could serve to determine – negatively or positively, the potential effectiveness of the said regime. Understanding biopiracy as an ancillary Third World objective of the ABS regime, assists with an understanding of the ABS regime and effective measures for its implementation from the perspective of the developing world.

Characterizing biopiracy as the central aim and issue area of the Nagoya Protocol based on an ancillary interpretation may admittedly seem simplistic, especially given that the express objective of the Protocol, as noted earlier, relates to the fair and equitable sharing of benefits, aimed at ensuring the conservation and sustainable use of biodiversity. In making this characterization, however, I highlight biopiracy as an *implicit* issue area of global governance. In reality, as explained above, the definition of


\(^{188}\) The Like-Minded Megadiverse Countries (LMMC) was established by the Cancun Declaration of Like-Minded Megadiverse Countries, 18 February 2002 [Cancun Declaration]. The LMMC today is a group of 17 countries which hold more than 70% of all biodiversity and 45% of the earth population. See, <http://pe.biosafetyclearinghouse.net/actividades/2009/grouplmmc.pdf> 2. For a fuller discussion of the LMMC, see note 698 below.

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regime issue areas is based primarily on the perceptions of actors within regimes and thus constitutes a largely political issue. Andrew Lang, through an analysis of the international trade regime, argues that each international regime contains “inner principles of vision – particular implicit frameworks of visibility and invisibility – which reflect the politics of the regime above and beyond the regime’s expressed mandate.”

This suggests that beyond an express regime mandate, the politics of the regime could actually be connected to ancillary objectives. As evidenced above, several developing countries have consistently referenced the issue of biopiracy in expressing their hopes and expectations for the implementation of the Protocol. In other words, in adopting Andrew Lang’s analysis, third world actors consider the issue of biopiracy to be an ‘inner principle of vision’ underlying the express objective of the ABS regime. Consequently, while some countries, like the United States have struggled to even acknowledge the existence of a phenomenon called biopiracy, Third World countries have placed the eradication of biopiracy as a core justification underlying the very existence of the Nagoya Protocol’s international ABS regime.

Does this then suggest an ‘issue area’ shift in the core rationale of the ABS regime? Absolutely not. The ABS regime, founded on the principle of benefit sharing and aimed at conserving and using biodiversity in a sustainable way remains an intact shared regime objective by all its signatories. While, for instance, developed countries have sought to clarify the rules for access to GRs and TKaGRs, thus promoting legal certainty for research and investment through such a regime, Third World countries have rather sought to reclaim a terrain of exploitation, by which token their sovereign rights over their resources have historically been compromised. In reasserting the rights over resources located within their territories, the biopiracy

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190 Through an analysis of the international trade regime, Andrew Lang argues that each regime contains what he terms, ‘inner principles of vision – particular implicit frameworks of visibility and invisibility – which reflect the politics of the regime above and beyond the regime’s expressed mandate. Understanding how these principles of vision are produced, contested and sustained is a necessary part of unearthing the internal politics of a regime. See Lang, “Legal Regimes & Professional Knowledges”; supra note 189 at 116 – 117.

191 As summarized by the WTO Secretariat, the US observed, in response to the submission of India to the Committee on Trade and Environment, that ‘whilst there were often disputes about whether something was patent-worthy […] [it] was not sure it accepted that there was a phenomenon that could be termed biopiracy.’ For a summary of the exchanges, see Someshwar Singh, “US Not Sure What’s Biopiracy” (July 20, 2000) South North Development Monitor, online: GRAIN <https://www.grain.org/article/entries/2103-us-not-sure-what-s-biopiracy>. See also India’s submission that sparked the particular debate in, Protection of Biodiversity and Traditional Knowledge – The Indian Experience: Submission by India, WT/CTE/W/156; IP/C/W/198, WTOOR, 2000 [The Indian Experience].
rhetoric has offered a useful framework through which the implementation of the ABS regime is perceived and indeed received within the Third World.

2.3.1 The ABS Regime as an Open-ended Regime Complex

While the outcome of the negotiations of the international ABS regime is correctly cited as the Nagoya Protocol, the Protocol exists within the framework of the CBD and draws extensively from the Bonn Guidelines. In a sense, however, the status of the Nagoya Protocol could be viewed in two ways. On the one hand, it could be viewed as the actual international regime on ABS. Since it reflects the outcome of the direct negotiation for an international ABS regime, it could be viewed narrowly as the international regime on the basis of a formal conceptualization of regimes. This is, however, to the extent that it contains the principles, norms, rules, and decision making procedures which the ABS regime ascribes to. By this, the various instruments indicated as forming a part of the regime, draw their relevance to the ABS regime, based on their coherence with the central substantive prescriptions of the ABS regime. The decision adopting the Nagoya Protocol clarifies that this international ABS regime is made up of ‘…the CBD, the Nagoya Protocol, as well as complementary instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Bonn Guidelines’.

My suggestion then is that the above mentioned instruments exist in consonance with a series of principles, norms, rules and decision making procedures embodied within the Nagoya Protocol’s ABS mechanism. This complementarity with the central ABS objective is a golden thread running through all the instruments. Again, for this reason, the Nagoya Protocol could be viewed as the core international ABS law upon which the ABS regime is anchored.

It is particularly significant that, as mentioned above, part of the terms of reference for the negotiation of the international ABS regime stipulated that this international regime could consist of one or more instruments within a set of principles, norms, rules and decision making procedures. Importantly, inherent in this mandate is the foundation of a regime complex for the attainment of the proposed regime’s

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192 See para 6, Preamble to Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Tenth Meeting: Access to Genetic Resources & the Fair & Equitable sharing of Benefits Arising from their Utilization, COP 10 Dec X/1, CBDOR, 2010, UNEP/CBD/COP/DEC/X/1 [COP 10 Dec X/1] at 1.
193 COP Dec VII/19, supra note 158, at 6 (para (b), Annex).
objectives. Bearing in mind that regimes are social institutions which unite actors and/or participants towards common objective(s) with respect to specific international issue-area(s),194 the significance of the open-ended terms of reference draws from the diversity of the instruments which are mentioned as forming part of the regime. It also offers a platform for determining further instruments which could possibly be a part of this regime complex on the basis of the common issue area. In this vein, the ABS regime is rather more accurately construed as an open ended ABS regime complex, made up of a set of international agreements which are complementary to the principles, norms, and rules contained within the Nagoya Protocol. To further place this issue of complementarity in context, the relationship between the identified instruments in the ABS regime-complex could be described as one of harmony or complementarity towards the attainment of a set ABS objective.

The CBD as one of the component regime instruments, for instance, adopted the benefit sharing principle as a market-based strategy to achieve objectives linked to the conservation and sustainable use of biodiversity. It offers the foundation and context for the ABS regime-complex. The Bonn Guidelines adopted in 2002195 served as the first step of the evolution of measures to implement these benefit sharing objectives of the CBD.196 Interestingly, the idea of a binding ABS regime had already been considered at the time of the negotiation of the Bonn Guidelines.197 However, this idea had been jettisoned at the time in favor of a set of non-voluntary guidelines which set forth broad principles within which varying national

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195 The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits arising out of their Utilization, 19 April 2002 [Bonn Guidelines], were adopted pursuant to Decision VI/24 (2002) at the Sixth Session of the Conference of the Parties to the CBD (COP-6) held in The Hague. Its designation as ‘Bonn Guidelines’, was derived from the location of the intergovernmental meeting which held in Bonn, Germany in October 2001 and which prepared the first draft of the eventual agreement.

196 See, Access and Benefit-sharing as Related to Genetic Resources COP 6 Dec VI/24, CBDOR, 2002, UNEP/CBD/COP/6/20, [COP Dec VI/24] (para 6 at A), and para 7, preamble to COP Dec VII/19, supra note 158, at 4. This evolutionary approach to the Guidelines which forms one of its central features, envisaged a review, revision and improvement of the Guidelines based on experience from ABS. See I.A.7(f) of the Bonn Guidelines.

197 It had, for instance been discussed at the COP 4, where it was decided to set up an expert group on ABS which could discuss all the options for ABS arrangements (see CBD Decision IV/8). Further, it was discussed at the meetings of the CBD’s Panel of Experts on ABS in San Jose, Costa Rica (October 1999) and Montreal, Canada (March 2001). The discussion also took place within the CBD’s Scientific Body on Technology and Technological Advice (SBTTA) as well as in the final deliberations at COP-6 where the Bonn Guidelines were formally adopted. See, W. Bradnee Chambers, “WSSD & an International Regime on Access & Benefit Sharing: Is a Protocol the Appropriate Legal Instrument?” (2003), 12:3 Review of European Community & International Environmental Law [Chambers, “WSSD & an International Regime”] at 310.
approaches to the ABS challenge could be pursued.\textsuperscript{198} The Bonn Guidelines were therefore negotiated as an alternative to a binding regime as the consensus amongst the majority within the negotiations had been that ABS was an issue more contingent on national regulation than on international regulation.\textsuperscript{199} The Guidelines were thus designed to serve as voluntary non-binding inputs to national efforts to develop and draft legislative, administrative, or policy measures relating to ABS.\textsuperscript{200} Importantly, the Parties were of the view that the Bonn Guidelines merely represented a useful first step of an evolutionary process in implementing the ABS provisions of the CBD.\textsuperscript{201} Further developments to the Guidelines, arising from experience gained in the implementation of ABS provisions, were consequently envisaged.\textsuperscript{202} If anything, the Bonn Guidelines were therefore an international experiment in operationalizing the ABS principles of the CBD, given the limited experience available to negotiators and the international community in developing and implementing ABS provisions.

Both of these instruments (the CBD and the Bonn Guidelines) have, however, not enjoyed a successful implementation to date for differing reasons. While the CBD has often been cited as hard law characterized by a soft nature, evidenced by its lack of an effective enforcement mechanism,\textsuperscript{203} the weak implementation of the Bonn Guidelines has generally been attributed to the voluntary nature of its undertakings.\textsuperscript{204} Addressing the weaknesses of these prior instruments, the Nagoya Protocol is drafted in conformity with the Bonn Guidelines, introducing binding obligations, and is expected to further aid the implementation of the CBD, with a specific emphasis on its benefit sharing objective. While the

\begin{itemize}
\item \textsuperscript{198} Ibid.
\item \textsuperscript{199} Ibid.
\item \textsuperscript{201} See para 6, COP Dec VI/24, \textit{supra} note 196. See also, para 8, preamble Cusco Declaration on Access to Genetic Resources, Traditional Knowledge and Intellectual Property Rights of Like-Minded Megadiverse Countries, 2002 [Cusco Declaration].
\item \textsuperscript{202} This evolutionary approach to the Guidelines forms one of its central features. This approach envisaged a review, revision and improvement of the Guidelines based on experience from ABS. See I.A.7(f) of the Bonn Guidelines
\item \textsuperscript{203} This has been attributed to its strict natured provisions which use mandatory language to describe obligations of Parties, yet fail to accompany such mandatory obligations with requisite enforcement measures in case of breaches. See Stuart Harrop R, “Living in Harmony with Nature? Outcomes of the 2010 Nagoya Conference of the Convention on Biological Diversity” (2011) 23 Journal of Environmental Law 118 [Harrop, “Harmony with Nature”] at 117 – 128.
\end{itemize}
complementary relationship between the CBD, the Nagoya Protocol, and the Bonn Guidelines within the context of the international regime on ABS is clear, the ITPGRFA offers an interesting dynamic, from the perspective of the regime complex discourse especially because, as an instrument, it was negotiated on another platform and its benefit sharing structure slightly differs from that obtainable under the CBD. It suggests the regime complex element of the ABS regime.\(^{205}\)

The ITPGRFA was negotiated within the framework of the Food and Agriculture Organization of the United Nations. However, similar to the above mentioned instruments, the ITPGRFA pursues the objective of fair and equitable sharing of benefits arising out of the use of GRs with a focus on a specialized category of GRs – plant GRs relevant for food and agriculture (PGRFA).\(^{206}\) It seeks to ensure the conservation and sustainable use\(^{207}\) of PGRFAs, and pursues its objectives through harmonization with, and close linkage to the CBD.\(^{208}\) Despite the ITPGRFA being mentioned as constituting a part of the ABS regime, it is worth noting that it adopts a substantially different approach to benefit sharing from that obtainable under the above mentioned CBD-based instruments. Under the ITPGRFAs Multilateral System of Access and Benefit Sharing, the ITPGRFA pools a total of 64 crops which account for 80 percent of plant-derived food into an easily accessible global pool of GRs. It facilitates access to these resources for purposes of research, breeding, and training pursuant to a standard Material Transfer Agreement,\(^{209}\) and ensures that benefits arising from their commercial use are shared through four benefit-sharing mechanisms, under the guidance of the Treaty’s Governing Body, including directly or indirectly to farmers in all countries.\(^{210}\) With respect to TK, it requires Contracting Parties to take measures to promote and protect Farmers’ Rights, including the protection of TK relevant to PGRFA as well as the right to equitably

\(^{205}\) Recall, the defining element of regime complexes is the existence of multiple, overlapping elemental regimes which overlap in scope and subject, and are created and maintained in distinct fora with participation of different sets of actors. See, Raustiala & Victor, “The Regime Complex for Plant Genetic Resources”, supra note 64 at 686, 703.

\(^{206}\) See Article 1.1, ITPGRFA.

\(^{207}\) Ibid.

\(^{208}\) See Article 1.2, ITPGRFA.

\(^{209}\) See Article 12.4, ITPGRFA

\(^{210}\) See Article 13.2 – 13.3, ITPGRFA. The four benefit sharing mechanisms proposed relate to the exchange of information, access to and transfer of technology, capacity building, and the sharing of the benefits arising from commercialization. For the detailed framework of the IPGRFA’s Multilateral System of Access and Benefit Sharing.
participate in sharing benefits arising from the use of PGRFAs.\textsuperscript{211} It is important to note here that the benefit sharing mechanism of the ITPGRFA differs considerably from the benefit sharing mechanism of the Nagoya Protocol. I discuss this approach under the Nagoya Protocol extensively in chapter five.

Despite this difference in approach, the ITPGRFA is yet explicitly mentioned as forming a part of the international regime. This is also despite the fact that the ITPGRFA was not negotiated on the platform of the CBD, and despite the clear differences which exist between the FAO’s driving objectives and those of the CBD. On what basis is it then included as a part of the international regime? Its inclusion is on the basis of \textit{complementarity}. Noted in the decision adopting the Nagoya Protocol, ‘the international regime is constituted of […] complementary instruments, including the ITPGRFA…’.

Complementarity then does not necessarily indicate similitude, exactness of approach or overriding objectives, or even institutional framework, but rather implies coherence, and harmony among relevant international instruments in the operation of the regime’s principles, norms, rules and decision making procedures. It is again important to note that the decision adopting the Nagoya Protocol suggests that the above mentioned list of international instruments which comprise the ABS regime – the CBD, the Nagoya Protocol, the ITPGRFA, and the Bonn Guidelines – does not constitute an exhaustive or closed list. Rather, other relevant instruments are eligible for inclusion within this regime, also on the basis of complementarity. This potential of the ABS regime to further incorporate other instruments is important in what may be considered as the continuing evolutionary context of the ABS regime complex. In this vein, the inclusion of the ITPGRFA suggests that further possible constituents of this ABS regime are not limited to instruments negotiated on the CBD platform, nor are they limited to instruments which are similar or exact, or even share common objectives with the Nagoya Protocol. Rather, the ABS regime complex is evolving, from the perspective of developing countries, to incorporate a complementary set of ABS-related instruments which support the principles, norms, and rules contained within the Nagoya Protocol and are aimed at complementing the efforts of the Protocol with regard to the issue area of concern.

\textsuperscript{211} See generally Article 9, ITPGRFA.
2.4 Conclusion

This chapter has provided a useful introduction to the TWAIL as a distinctive approach informing the core assumptions and perspectives within this thesis, particularly around the elaboration of the Nagoya Protocol. This approach significantly pursues the centering of third world interests within the analysis of international law, thereby rethinking international law solutions from their perspectives, concerns and historical struggles. This chapter has also discussed international regimes as institutions incorporating explicit regulations for state cooperation with respect to an area of mutual concern. In particular, an emphasis has been placed on highlighting regime complexes which suggest multiple overlapping instruments addressing a central issue area of concern. In this context, the ABS regime, established by the Nagoya Protocol, has been suggested as laying the framework for an ABS regime complex. Finally, issue areas have been identified as being central to the formation and definition of regimes. Given the politicized nature of issue areas, perspectives of actors within regimes relating to the issue area may differ. I highlighted biopiracy as the core issue area of concern to developing countries within the ABS regime.

In the rest of this work, my analysis of the ABS regime will be pursued on the understanding that the law and politics of benefit sharing is a tool addressing the protection of TKaGRs from biopiracy while seeking to appease developed states interest to access such resources. This is in keeping with a centering of the rest, rather than the west, in the analysis of the ABS regime. I adopt the TWAIL in addressing the ABS regime because of the centrality of this ABS regime to the third world. Indeed, as mentioned in chapter one, the ratification dynamics for the Nagoya Protocol reveals a trend which is heavily skewed in favor of developing countries. Key industrialized countries, including the United States and Canada have neglected to even sign onto the Protocol. It is therefore logical to consider what informs developing country interests with the ABS regime. The TWAIL inspires such an approach.

In developing the thesis revolving around the intersection between the IP system and the ABS system, this dissertation highlights the struggles of the Third World participants – States and indigenous peoples – in advancing an effective structure for the implementation of the ABS regime through the pursuit of a conclusion, which I term ‘positive’, within the IP regime. Positive on the basis that it is able to secure

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212 See, Section 1.1 above.
a complementary set of principles, norms and rules to the Nagoya Protocol. Efforts to secure such a positive outcome underscores the relational aspects of international regimes in that it reflects the development of norms within the IP regime which bear potential implications for the implementation of the ABS regime. The struggle within the IP regime, and in particular the WIPO IGC, is currently focused on the strategic push by developing countries to secure an instrument(s) which contain a set of reinforcing norms to the normative structure contained within the ABS regime. Though the ABS regime could be construed as outlining a set of counter-regime norms to the IP system (an argument which sits on all fours with the core of Helfer’s thesis), this thesis is rather concerned with the development of pro ABS-regime norms for the purpose of reinforcing the existing standards within the ABS regime. In so doing, it addresses the key question of whether a failure of these efforts within the IP space to yield a positive outcome would be tantamount to the ABS regime being rendered ineffective. In other words, can the ABS regime still be effective without a coherent or positive outcome within the negotiations of the IP regime, specifically within the WIPO IGC?

Though the three Helferian components are important and will be referenced in articulating this dissertation’s thesis, the relational aspect of international regimes, which focus on the packaging of substantive issues and the ways such substantive issues within regimes interact and intersect with the issue areas of other regimes, is the regime component that applies most directly to the analysis undertaken in this dissertation. Significantly, this thesis considers the interactions between the ‘positivist rules’ – the core substantive and institutional elements of the IP and ABS regimes in advancing an effective ABS system. Through what Helfer terms regime shifting, this dissertation demonstrates that, from a Third World perspective, the current interactions between these regimes aimed at effectively protecting TKaGRs from biopiracy, are being used by developing countries to articulate, develop, and secure an expansive ABS regime complex, which incorporates the IP regime, and is being driven to address effectively the problem of biopiracy.

213 ‘Coherent’ is used, not to necessarily imply “similarity”, but rather “mutual supportiveness”. It is used to refer to a set of mutually supporting/reinforcing obligations created within the regime, in line with the primary objective and obligations of the Nagoya Protocol. In other words, coherence is used to refer to the degree to which the elements of an international regime are internally consistent. See O.Young, International Cooperation, supra note 101 at 25.
In chapter three, I focus on the core subject of appropriation which underlies the ABS regime-complex, TKaGRs. As noted earlier, the protection of TK is not an end in itself, but rather a means to an end. In characterizing biopiracy as the implicit issue area of concern, the essence has been to point to biopiracy as the broader policy objective to which the protection of TKaGRs is targeted. In other words, in pursuing the protection of TKaGRs, developing countries and indigenous peoples have sought to secure the protection of TKaGRs from biopiracy. The discussion of TKaGRs in chapter three is therefore important in explaining why biopiracy represents such an issue of concern for the Third World.
Chapter 3

Traditional Knowledge associated with Genetic Resources

In the previous chapter, I identified the eradication of biopiracy as the core policy objective informing the interest of third world actors in the Nagoya Protocol. The importance of this clarification made in chapter two derives from the central importance of issue area clarity to the analysis of regimes. In other words, as I explained in chapter two, a regime is only as clear as its issue-area has been made out to be.\(^{214}\) Therefore, the discussion within this thesis of the access and benefit sharing (ABS) regime, as instituted by the Nagoya Protocol, can only be as clear as the issue area of biopiracy is made out to be. For this reason, I devote chapters three and four towards advancing an understanding of biopiracy. As my analysis will show, understanding the underlying subject(s) of appropriation which offers definition to biopiracy is as critical as understanding the actual concern of biopiracy.\(^{215}\) It is for this reason that I devote the next two chapters to discussing traditional knowledge associated with genetic resources (TKaGRs) and biopiracy, respectively.

Biopiracy is of central importance to the developing world and highlights the inequity which arises when genetic resources (GRs) and/or TKaGRs are misappropriated or misused. These two key subjects of appropriation (GRs and TKaGRs) form a central part of the very understanding of biopiracy. A useful example from criminal law may be used to explain this. Where an offence of armed robbery is being distinguished from a case of stealing, a defining factor that must be established, amongst others, is that the accused, at the material time, was armed. It would be difficult to proceed in an analysis of the offence of armed robbery where precise clarity is not provided on what constitutes ‘arms’. In other words, an important aspect of unpacking the offence of armed robbery, must be the very discussion of what the law defines arms to be. In a relevant sense, in unpacking the biopiracy phenomenon, an important preliminary step must be a clarification of the very subject of appropriation, which is in focus within this dissertation.

\(^{214}\) See Hasenclever, Mayer & Rittberger, *International Regimes*, supra note 64 at 60.
\(^{215}\) Though biopiracy involves two key subjects of appropriation – GRs, and the TKaGRs, I have narrowed my discussion of biopiracy to its manifestation through the misappropriation of TKaGRs. My focus in the rest of this thesis is, therefore, on TKaGRs, and GRs, to the extent that it supports, elaborates or clarifies aspects of TKaGRs.
By devoting chapter three to a discussion of TKaGRs, I aim to achieve two main objectives in the furtherance of the biopiracy discourse. First, an important clarification and contextualization of the nature, characteristics, and definition of TKaGRs which supports this dissertation’s analysis of biopiracy as an injustice which indigenous peoples and their TKaGRs require protection from. This clarification is important due to the largely undefined scope and confusing nature of TKaGRs – a problem which draws chiefly from the varying perspectives through which TKaGRs is articulated. Discussing it as a key aspect of third world innovation in need of protection from biopiracy, this chapter highlights the significant difficulty of fitting TK within western paradigms of innovation. Its analysis contributes to providing further clarity to the need for an interaction of regimes, particularly the ABS and intellectual property (IP) regimes, to address the protection of this underlying subject of appropriation. Second, this chapter highlights the politics underlying the contestations with respect to the protection of TKaGRs. These contestations, which tend to place the interests of third world actors who hold and/or harbor TKaGRs against those of their industrialized actors, often accused of appropriating TKaGRs, importantly demonstrates a number of issues and concerns which any regime seeking to address biopiracy must take into account. By examining the justifications and criticisms of protection of TKaGRs, this chapter demonstrates the central importance of solutions to biopiracy which are derived from a variety of regime sources. This multi-regime approach to resolving biopiracy, places in relevant context, the discussions in chapter two of biopiracy as an issue area which defines a regime complex for efforts at its eradication.

The chapter is divided into three parts. Part one explores some conceptual and practical difficulties associated with fitting TK within western paradigms. It clarifies some fundamental misconceptions about TK and offers a helpful definition of TK as a basis for this dissertation’s analysis. It commences with a discussion of the binary challenge which often plays out in efforts to develop systems of protection for TK. As part of this analysis in part one, the concept of indigenous peoples is examined. Part two situates TKaGRs within the broader discourse of TK protection. It highlights TKaGRs’ key characteristics and discusses it as a subject of appropriation defining the biopiracy discourse. In part three, I proceed to justify the need for the protection of TKaGRs through an analysis of some key objections and corresponding justifications that have defined the debate regarding protection of TKaGRs.
### 3.1 Traditional Knowledge: Experience or Know-how?

The protection of traditional knowledge (TK)\(^{216}\) is an important issue which has divided policy makers, academics and a wide range of stakeholders. TK is considered a part of the cultural assets of indigenous peoples, and provides enormous cultural and economic possibilities for their daily lives. The importance of TK to modern society has been accentuated with an increased recognition of its role, *inter alia*, in modern innovation, biodiversity conservation, the sustenance and livelihoods of indigenous peoples, and even national prosperity.\(^{217}\) The protection of TK is not approached as an end in itself, but rather is pursued as a means to an end. In other words, a range of broader policy objectives and stakeholder needs are known to underlie national and international efforts to protect TK.\(^{218}\) Consequently, beyond the question


\(^{218}\) Some of such policy objectives, include, the prevention of misappropriation and unauthorized exploitation; recognition of value and promotion of respect for TK; prevention of false and misleading claims to authenticity and origin; wealth creation, preservation, safeguarding of cultural identities and values of communities, promotion of cultural diversity, amongst others. See, generally, *The Protection of Traditional Knowledge: Revised Outline of Policy Options & Legal Mechanisms*, WIPOOR, 9th Sess, WIPO/GRTKF/IC/9/INF/5 (2006). See also, WIPO “Developing a National Strategy on Intellectual Property, Traditional Knowledge & Traditional
of whether or not TK should be protected, questions rather relating to the what, how, where, and why of TK protection have dominated the discussions on the protection of TK and proved to be most difficult.

Several countries, especially developing countries, have taken on this important challenge of implementing regulations governing the protection of TK within their borders. Efforts to protect TK have also entered the domain of international law. Such efforts are presently being pursued in international fora, such as, the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the Convention on Biological Diversity (CBD), the World Health Organization (WHO), the Food and Agriculture Organization (FAO), to name a few. Furthermore, a wide range of international legal instruments, such as, the CBD, United Nations Convention to Combat Desertification (UNCCD),

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220 The Government of India, for instance, has adopted the Biological Diversity Act, 2002, which provides for the conservation of biological diversity, sustainable use of its components and the fair, and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith. It has followed this, more recently, with the adoption of the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations 2014, for the purpose of operationalizing the Nagoya Protocol within India. Kenya, another biodiverse state, has in place The Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006, developed to protect biodiversity. Most recently, the government of Kenya also passed into law the Protection of Traditional Knowledge and Traditional Cultural Expressions Bill, 2015 aimed at protecting holders of TK from infringement of their rights, against misappropriation and ensuring that communities receive compensation for the use of their cultural heritage.

221 For a review of international initiatives as well as debates on the protection of TK, see Verma, “Protecting TK”, supra note 57 at 771 – 786. See also, Bubela & Gold, “Indigenous Rights & TK”, supra note 217 at 7 – 21.

222 The CBD, for instance, requires Parties to respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities, promote their wider application with the approval and involvement of TK holders, and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices. See Article 8(j), CBD.

223 United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa, 17 June 1994, 1954 UNTS 3; 33 ILM 1328 (1994) (entered into force 26 December 1996) [UNCCD] <http://www.unccd.int/Lists/SiteDocumentLibrary/conventionText/conv-eng.pdf>. The UNCCD is aimed at addressing desertification within drought stricken areas. See Article 2(1). Article 16(g) of the UNCCD, however, provides for the exchange of information on TK among parties while yet ensuring adequate protection and providing appropriate equitable returns to local populations form the benefits it yields. Article 17(c) further requires Parties to support research activities which protect, integrate, enhance and validate TK, as well as ensure that the owners of the knowledge benefit directly from any commercial utilization of it or from any technological development derived from that knowledge. Under the UNCCD, protection and promotion of TK use is also supported through the documentation of TK, with Parties undertaking to make inventories of TK to this end of equitable benefit sharing (Article 18(2), UNCCD). Parties again undertake to support the improvement and dissemination of TK, as well as facilitate its adaptation and integration into modern technology. See Article 18(2)(d), UNCCD.
International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)\textsuperscript{224}, United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP),\textsuperscript{225} etc., have also, to varying degrees, addressed the issue of TK protection. Consequently, the issue of TK protection is one which cuts across a wide range of international policy areas including trade, health, human rights, intellectual property (IP), agriculture, biodiversity, and desertification, amongst others. Because varying broader policy objectives inform efforts at TK protection, a variety of approaches to TK protection have been considered within the above mentioned policy areas.\textsuperscript{226} It is in this context that the protection of TK from biopiracy, as prioritized within this thesis, must be viewed as one of several possible reasons which could inform a protection mechanism for TK. It is helpful, based on this understanding, to reiterate that this dissertation’s analysis of TK and its protection is aimed at defining a broader policy objective (the prevention of biopiracy) which is of central importance to the third world.

3.1.1 Traditional Knowledge and Binary Interpretations of Power in Knowledge Production

Before proceeding to a discussion of what TK is, I wish to start out with a preliminary observation of the difficulties inherent in conceptualizing TK through a binary lens. An underlying practical difficulty in the discussion of TK is simply termed here as the ‘binary challenge’.\textsuperscript{227} By this, I mean the conceptualization and mental perception of TK through a contrasting stance to modern everyday life.
knowledge. A common perception about TK is that it exists as an opposite to modern knowledge – an opposite in terms of the quality, nature and hierarchical standing of the knowledge; and, opposite in terms of the source of such knowledge, including the people responsible for its creation, the contexts and manners in which it is created, and the modes of its transmission across generations. In this context, TK is generally spoken of as traditionally-generated knowledge, innovations and practices of indigenous peoples and local communities. This suggests a fundamental distinction between knowledge generated in a local context and our everyday knowledge. So strong is this binary approach, Graham Dutfield observes that the normative presumption of a kind of knowledge which radically differs from everyday knowledge does in fact underlie the very discussion and modern conceptualization of TK:

[w]hat is traditional knowledge anyway? We only speak of traditional knowledge at all because there is knowledge in the world that we assume to be radically different from ‘our’ knowledge. The latter we prefer to label as ‘modern’ or ‘scientific’ knowledge. Holding to a traditional – modern epistemological dualism as if all knowledge is either all of one or all of the other is in fact simplistic, misleading and unhelpful.228

Indeed, this approach has formed the basis for several attempts at its definition. Conceptually, this may be understandable. However, in reality, as Dutfield rightly argues, the distinctions between such binary classifications of knowledge may prove extremely difficult, if not impossible to sustain. Take the example of my father.

My father is an accomplished professor of pharmacognosy at Nigeria’s premiere university – the University of Ibadan. A celebrated Commonwealth scholar and recipient of numerous awards arising from research and academic work in the area of drug discovery and research, his scientific achievements often mask his local roots. As a young boy, he grew up in Egbe – a local community in the central part of Nigeria, where he served as an assistant to his grandfather, the community’s recognized traditional healer. His apprenticeship to his grandfather exposed him, from an early age, to the healing properties and the uses of a wide range of plants. So great is my father’s knowledge of plants and their uses that I grew up believing, at some point, that he was simply making up unreal stories about the many plants and their uses which he confidently spoke of. However, when on occasion – which was more often than not – we had to make use

of his herbal remedies to treat illnesses, they always proved to be even more effective than western remedies. This knowledge possessed by my father about the properties and uses of plants forms a central component of what has been described above as TK – knowledge generated in and linked to a traditional setting, passed on from one generation to another, and often based on experience and observations relating to the environment.

Though his roots informed his foundational understanding of plants, he went on to acquire scientific knowledge relating to the uses of plants in drug discovery through the study of pharmacognosy. As a discipline, pharmacognosy is defined as the study of the physical, chemical, biochemical and biological properties of drugs, drug substances or potential drugs or drug substances of natural origin as well as the search for new drugs from natural sources. He thus possesses both the TK of plant uses acquired from his grandfather and has further acquired a scientific understanding of plants, their compositions and their uses, acquired in the context of his western education. Against this backdrop, a lot of his patentable contributions to drug discovery were significantly based on traditional remedies, justified through scientific analyses. In fact, I understood my father to know most of what he knew about plants based on his local roots, but also noticed that he had an added advantage of being able to explain, rationalize and justify his knowledge, and even protect it, through his western education.

His experiences significantly place him at the center of the problematic nature of a binary approach to the definition of TK vis-à-vis western, modern or scientific knowledge. On one hand, he represents a TK holder. On the other, he represents a scientific researcher, curious to identify potential drugs from natural products. From the binary view, what kind of knowledge does my father then possess – traditional or scientific knowledge? In the context of the ABS regime, does my father’s use of TK place him within the user or provider spectrum of the ABS mechanism? Must it be judged on a case-by-case basis, or has his exposure to the western education system and scientific community stripped him of his TK and the right

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229 The word pharmacognosy is derived from two Greek words: “pharmakon” – meaning drug or medicine, and “gnosis” – meaning knowledge. As a discipline, it is the branch of knowledge concerned with medicinal drugs obtained from plants or other natural sources. It forms a central part of the teaching content for pharmacists, and represents the underlying professional body of instruction underlying the pharmaceutical industry. See, N Shashikiran, “Pharmacognosy” (2016) 34:2 Journal of Indian Society of Pedodontics & Preventive Dentistry, at 103.
to be a beneficiary of protection, while potentially decorating him with the label of a biopirate? Is a binary approach even required? This is not a hypothetical concern but plays an important role in the understanding of biopiracy. The story of the Guyana-born, UK-trained chemist, Conrad Gorinsky places this issue into further perspective.²³⁰

Gorinsky was accused of stealing medical secrets from the tribe in which he grew up to profit from its unique knowledge of forest poisons. Born in Rupununi – the most remote part of Guyana rainforest on the northern edge of the Amazon basin, he was born to a Polish father (who had immigrated to Brazil and had become a local cattle rancher in Guyana) and a mother who was indigenous to the local Atorad tribe. He grew up in Guyana within the context of an indigenous childhood and was exposed therefore to the traditional practices of his people. He later trained as chemist and according to his testimony,

while at Barts Hospital in London in the 1960s and 1970s, I did a PhD studying the materials that I knew as a child – the natural drugs and poisons of the forest. I researched the products of the greenheart tree (Ocotea rodiaei), which only grows in Guyana. When I was young the women chewed the tree’s nuts as a contraceptive to control menstruation, and they made infusions of the bark to prevent malaria fevers. At Barts, I isolated an alkaloid from the tree that was the active ingredient, and called it rupununine after the area where I grew up.

Gorinsky was accused of biopiracy and ostracized by the peoples of his native land after attempting to secure patents on these traditional practices.²³¹

These questions within the context of the preceding paragraphs raise germane questions about binary perceptions to TK vis-à-vis modern knowledge in at least two main respects.

First, is there an actual real life separation between TK and modern knowledge? The common perception that TK exists as an opposite to modern knowledge²³² is traceable to the negotiations on the Convention on Biological Diversity (CBD).²³³ While clear differences exist between what is considered to be TK and modern knowledge, authors have warned of the danger of overdrawing the distinction between

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²³⁰ See full story at as well as interview with Conrad Gorinsky at “Hero or Zero” New Scientist (July 22, 2006), online: New Scientist <https://www.newscientist.com/issue/2561%20/>.
²³¹ Ibid.
²³² A general tendency within the literature as well as a lot of the discussions on the protection of TK is to assume a clear dichotomy between TK and modern or contemporary knowledge. See Alan Reid, Kelly Teamey & Justin Dillon, “Traditional Ecological Knowledge for Learning with Sustainability in Mind” (2002) 18:1 The Trumpeter, 113 at 115, who note that “[t]here is consensus amongst scientists using various terms that [traditional ecological knowledge] …contrasts with ‘modern’ or ‘western formal scientific knowledge’.
these camps of knowledge. As an opposite, it contrasts with modern knowledge in terms of the people responsible for its creation, the contexts and manners in which it is created and the modes of its transmission across generations. TK is thus generally spoken of as traditionally-generated knowledge, innovations and practices of indigenous peoples and local communities.

From my father’s experience, for instance, such a defined dichotomy may not be clear. Does his relocation from his local community and acquisition of a western education strip him of his TK? Would benefit sharing still be required given his ‘access’ and use of TK? Or is he entitled to switch hats between TK and modern knowledge, as occasion demands, on the assumption that he embodies two categories of knowledge? In a further analysis, does he possess a westernized form of TK, or does he operate in the context of a traditional form of modern knowledge? Inherent in these questions lie some difficult practical and policy consequences of a strict dichotomized approach to TK and modern knowledge.

Furthermore, as Jane Anderson observes, binaries uphold specific power relations. Contrasting TK with modern knowledge establishes a fallacious connotation that TK is what modern knowledge is not. It is in this context that a lot of negative assumptions are ascribed to TK. For instance, arising from its terminology, TK is often viewed as knowledge that is antique, outdated, barbaric, static, unscientific, old, non-innovative and in many instances, irrelevant to modern society. These negative connotations have however been refuted through evidence by several authors. As a body of knowledge that enables

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235 See Daniel Gervais, “Traditional Knowledge & Intellectual Property: A TRIPS Compatible Approach” (2005) Michigan State Law Review [Gervais, “TK & IP”] at 140 where innovation is identified as a major quality of TK in stark contrast to widely held opinions to the contrary. In response, however, to claims particularly of antiquity and a static nature of TK with particular reference to the use of the term ‘traditional’, Russel Barsh, like other authors who disagree with this position, observes that

What is traditional about TK is not its antiquity but the way it is acquired and used. In other words, the social process of learning and sharing knowledge, which is
indigenous peoples to constantly adapt to their changing environments, TK is in fact a living body of knowledge which constantly evolves in response to the environmental and social realities of its holders.\textsuperscript{237} It thus embodies a highly diverse and dynamic nature.\textsuperscript{238}

My father’s story is one of the doubtless many that demonstrate that knowledge is interwoven, a product of experiences. TK and modern knowledge could, therefore, actually refer to the same knowledge, differentiated only by the conceptions, modes of generation, holders, and holder experiences. Does this then suggest that there are no differences between TK and what is popularly referred to as modern or scientific knowledge? Certainly not. However, the nature of differentiation of the knowledge has to be drawn from the experiences of holders: marginalized peoples, often referred to as traditional (indigenous) people, and not necessarily from the type or class of knowledge. For in the final analysis, it is not the knowledge that is necessarily discriminated against, it is the people – the indigenous people and all they represent, including their knowledge. The discussion of the protection of TK is essentially, therefore, a discussion of protection for indigenous peoples and their living cultural experience.

The importance of this clarification is that it demonstrates right from this preliminary stage that a discussion of TK is a discussion of people and their real life experiences, and not a mere abstract conception. The discussion of TK involves the commitment of the global community to enable a category of equal peoples (indigenous peoples) to exercise their fundamental rights over their knowledge by guarding their experiential learnings, and their right to continually generate, relive, transmit, and enjoy such experiences. Indigenous peoples are indeed the intended beneficiaries of protection. Yet, the binary challenge, an illusory categorization of knowledge, may present an unnecessary impediment to the realization of fair and equitable outcomes for them.


\textsuperscript{238} WIPO, \textit{Fact Finding Mission, supra} note 216 at 32.
Second, a key element often highlighted in definitions for TK is the association of such knowledge to an indigenous group or community. How do we characterize such an indigenous group? Further, how do we define the linkage between group and the knowledge? A focus on the characterization of an indigenous group is important here. The first and most reflective definition of this concept of indigenous peoples is provided by Jose R Martinez Cobo, the Special Rapporteur of the Sub-Commission on Prevention of Discrimination and Protection of Minorities:

Indigenous communities, peoples and nations are those which, having a historical continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing on those territories, or parts of them. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral territories, and their ethnic identity, as the basis of their continued existence as peoples, in accordance with their own cultural patterns, social institutions and legal system [...] On an individual basis, an indigenous person is one who belongs to these indigenous populations through self-identification as indigenous (group consciousness) and is recognized and accepted by these populations as one of its members (acceptance by the group). This preserves for these communities the sovereign right and power to decide who belongs to them, without external interference.239

This widely accepted definition of indigenous peoples by Cobo suggests a number of elements which underlie the characterization of indigenous populations. First, it presupposes the coexistence, within one single political sovereign territory, of two kinds of societies (nations, peoples, or communities): societies based on a ‘pre-invasion/colonization society’ and societies arising on the basis of invasion/colonization. Indigenous communities, in this context, are based on the pre-invasion/colonization societies. In other words, the way that traditional societies were organized before European colonists entered their territories. Furthermore, indigenous societies within the context of the political sovereign territory in which they now exist, are non-dominant. By non-dominant, their culture and practices do not align with the prevalent trends, standards and practices within the society. It is for this reason that

239 See, Secretariat of the United Nations Permanent Forum on Indigenous Issues “Introduction” in, United Nations Department of Economic and Social Affairs, State of the World’s Indigenous Peoples (New York: United Nations, 2009) [UNPFII, SOWIP] at 6. Distinctions exist, in practical terms, between indigenous peoples and local communities. These distinctions, however, fall outside the ambit of the proposed analysis in this dissertation. This dissertation examines the underlying interests and struggles of indigenous peoples and local communities (which are basically similar and therefore does not draw distinctions between these two concepts) with respect to their TKaGRs. The concept of indigenous peoples emerged from the colonial experience whereby the aboriginal peoples of a given land were marginalized after being invaded by colonial powers whose systems continue to dominate over the lifestyles and cultures of the earlier occupants. Ibid.
indigenous peoples and their ways are very often viewed as primitive and unrefined. Furthermore, indigenous groups consider themselves distinct from the prevailing society on the basis of a historical continuity with the pre-invasion societies, and exhibit a continued commitment to the further continuity of their historical distinctive ways. Finally, membership of such indigenous groups is based on self-identification and group acceptance.

This interpretation of indigenous peoples, while widely accepted, generally accords with indigenous realities of countries within the Americas, Russia, the Arctic and many parts of the Pacific, owing to the clear separation of indigenous groups from mainstream society. These countries widely understand indigeneity in the manner described by Cobo. Take the example of Canada. Within the Canadian context, the concept of aboriginality draws a clear line between the mixed peoples who occupy the Canadian territory; a line traced on the basis of the pre and post-invasion inhabitants of the Canadian lands. It thus accords with Cobo’s natural conceptualization of indigeneity. This natural concept of indigenous peoples emerged as a way of describing the original owners of the land – those who existed on the lands before the advent of colonialism and who have persisted in guarding their traditional heritage and maintaining their traditional lifestyles. It sought to characterize societal groups that had remained ‘unblemished’, or rather, ‘minimally blemished’, by the prevalent societal lifestyle introduced through colonialism – often termed *civilization* – that was dominant in their societies.

However, most countries within continents like Africa and Asia often reject the notions that groups within them are more indigenous than others given the general sense of indigeneity prevailing amongst all nationals. Even though I therefore speak of my father as being a holder of TK, within some contexts, he wouldn’t even be considered to be an indigenous person. My father’s little village, Egbe, has presently developed into a miniature town. This transition is probably most reflective of a growing pattern of

240 In Nigeria, for instance, traditional medicines are generally classed as unorthodox, while western medicines are viewed as being orthodox. See Oluwatobiloba Moody, *Regulating the Sphere and Scope of the Re-emerging Tradomedical Treatment of Patients in Nigeria* (LLB Thesis, University of Ibadan, 2007) [unpublished].


242 See, UNPFII, SOWIP, *supra* note 239 at 6, noting that this definition by Cobo makes less sense to countries in Africa and Asia, where the colonial powers did not displace whole populations of peoples and replace them with settlers of European descent.
westernization observable over the decades in the community. The erection of a teaching hospital, a local church, a primary and secondary school, as well as the consequential development of some roads, electricity and a gradual shift in consumer preferences highlight some of the changes that have occurred over the past two decades. Nevertheless, it retains its strong communal core with patterns of living organized around a historical and traditional base, unified by a local native dialect, Yagba. In the Nigerian context, it represents an indigenous setting which offers a traditional reference for its indigenous members that have ventured into larger cities. Within several African states, like in Nigeria, the concept therefore of indigenous peoples being isolated from the mainstream society is quite alien. Rather, for the most part, all peoples tend to consider themselves indigenous due to a root connection with a ‘village’ like Egbe. A proportion of the society remains within the ‘rural’ areas, while a larger proportion aims at migrating to the urban areas. Though large proportions of citizens end up migrating to larger cities, they still self-identify as belonging to such local root communities within the country. So strong is this connection to ‘home’ [the root community] that the general allegiance of most Nigerians is first to their community of origin before the nation. In this regard, the efforts to maintain the historical practices, irrespective of where one is based, is a shared drive pursued by most citizens. Questioning, therefore, an average Nigerian on his indigeneity will be tantamount to questioning the very basis of his/her nationality and identity. This raises another possible context for viewing indigeneity, one that may be understood through one of the strands of the two possible definitions accorded to indigenous peoples by the ILO Convention 169. Article 1 (a) of the Convention defines indigenous communities as

Tribal peoples in independent countries whose social, cultural and economic conditions distinguish them from other sections of the national community and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulations

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243 Article 1(a), Convention (No. 169) Concerning Indigenous and Tribal Peoples in Independent Countries, 27 June 1989, 1650 UNTS 383 (entered into force, 5 September, 1991) [ILO Convention]. The second definition of indigenous peoples within the Convention aligns with the general conception of indigenous peoples earlier referenced. See Article 1(b) ILO Convention, which offers an alternative definition viz:

Peoples in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonization or the establishment of present state boundaries and who irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions.
The concept of indigenous peoples may thus also operate, not necessarily to distinguish indigenous societies on the mere basis of aboriginality, but also on the basis of rural marginalization. As suggested in the definition above, the social, economic and cultural marginalization of a group vis-à-vis the mainstream population could serve as a basis for defining an indigenous group. In elaborating this concept of marginalization, the Report of the African Commission’s Working Group of Experts on Indigenous Populations/Communities offered the following characteristics of ‘marginalized’ indigenous peoples in Africa viz:

[...] their cultures and ways of life differ considerably from the dominant society and their cultures are under threat, in some cases to the extent of extinction. A key characteristic for most of them is that the survival of their particular way of life depends on access and rights to their traditional land and the natural resources thereon. They suffer from discrimination as they are being regarded as less developed and less advanced than other more dominant sectors of society. They often live in inaccessible regions, often geographically isolated and suffer from various forms of marginalization, both politically and socially. They are subject to domination and exploitation within national political and economic structures that are commonly designed to reflect the interests and activities of the national majority. This discrimination, domination and marginalization violates their human rights as peoples/communities, threatens the continuation of their cultures and ways of life and prevents them from being able to genuinely participate in deciding on their own future and forms of development.

In understanding TK, therefore, specific reference has to be made to the context within which indigeneity is considered. This difficulty in developing an all-embracing conceptualization of the term has resulted in a preferred approach among stakeholders, including indigenous peoples, which tends to avoid the development of an all-encompassing definition. Rather, a favored approach, in line with Article 33 of the United Nations Declaration on the Rights of Indigenous Peoples [UNDRIP] is to accord indigenous peoples with the rights to self-identification and self-determination. By this, local communities retain an

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245 See, for instance, Secretariat of the Permanent Forum on Indigenous Issues, The Concept of Indigenous Peoples: Background Paper Prepared by the Secretariat of the Permanent Forum on Indigenous Issues, PFII/2004/WS.1/3, UNDESAOR (2004) at 4, noting that, [i]n the case of the concept of “indigenous peoples”, the prevailing view today is that no formal universal definition of the term is necessary. For practical purposes the understanding of the term commonly accepted is the one provided in the Martinez Cobo study.
ultimate right to self-identify and be regarded as indigenous groups. In other words, I am indigenous if I identify myself as such. Furthermore, I belong to an indigenous group if the group says so.

Still relevant, however, my father symbolically embodies a significant dilemma which international policy makers will necessarily need to combat in defining TK and establishing protection systems for same. In most cases, the holders of TK (largely portrayed as indigenous peoples), are not the same holders of scientific knowledge (the biotechnology industry, researchers, pharmaceuticals etc.). Questions thus arise when scientific research appropriates TK without acknowledging or compensating such indigenous communities for their role in discovery. On the one hand, the holders of TK are the indigenous peoples and members of local communities who on a daily basis are forced to adapt to their environmental realities through cultural innovations relating to their environments. On the other hand, researchers and scientists, which include the broad range of the biotech industry, are oftentimes drawn to the TK of indigenous peoples as this saves time and money as well as provides helpful pointers that facilitate research and development.246 This is not to suggest that scientific research is only useful for the purpose of understanding and explaining traditional knowledge, however, in practice there have been a wide range of examples in which scientific knowledge builds on the invaluable leads offered by existing TK practices to assist researchers in the development of drugs, etc.

3.1.2 Defining Traditional Knowledge

As a body of knowledge and innovative practices which has generated so much interest and intense debates, it is interesting to note that TK has proven extremely difficult to define. In fact, there remains no authoritative and internationally agreed definition for TK.247 Consequently, TK retains undetermined

246 See Verma, “Protecting TK”, supra note 57 at 768, noting that the valuable leads provided by TK save time, money and investment of modern biotech firms into any research and product development. It is estimated that a hit-rate of 80 percent or more can be achieved in developing medical drugs where the screening of plants is limited to species used by indigenous communities.

247 See Bubela & Gold, “Indigenous Rights & TK”, supra note 217 at 2 – 3, noting the varying approaches adopted at international fora with its definitions, and thus identifying that the concept of TK is used regularly to refer to different ideas, such as indigenous knowledge systems, innovations, customary laws or practices. See also, Deepa Varadarajan, “A Trade Secret Approach to Protecting Traditional Knowledge” (2011) 36 Yale J. Int’l L. [Varadarajan, “A Trade Secret to Protecting TK”] 371 at 373 (identifying the lack of a definition as a problem for its protection).
boundaries which leave its precise definitional scope unclearly delineated. Teshager Dagne suggests that the very definitional venture of TK poses theoretical and methodological dilemmas due to the complexity of issues surrounding the term. WIPO has attributed this complexity to the highly diverse and dynamic nature of TK. This factor, WIPO notes, will challenge any efforts to develop a single and exclusive definition of TK. I should clarify here that attempts at offering a definition of TK, particularly within the frame of IP law, are largely efforts to interpret and redefine the living experiences of indigenous peoples through western concepts. As I shall demonstrate, this is highly problematic. As a matter of fact, the very conceptualization of TK has been suggested to be a recent invention. What this preliminarily suggests is that while western paradigms may be useful to support the protection of TK, they may not possess sufficient tools to define or protect TK as an experience of indigenous peoples.

Exemplifying the definitional complexity of TK, delegates to the 24th session of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) continued, as lunchtime approached on Tuesday, April 23, 2013, an endless debate on the very question; what is TK? The Australian delegate, then spoke. He identified the dynamic and evolving aspects of TK as important factors in any definition of TK. To the amusement of other delegates, he rounded off his intervention by drawing inspiration from the dilemma of Justice Potter Stewart, who is reputed for the following quote:

‘[…] under the First and Fourteenth Amendments, criminal laws in this area are constitutionally limited to hard-core pornography. I shall not today attempt further to define the kinds of material I understand to be embraced within that shorthand description, and perhaps I could never succeed in intelligibly doing so. But I know it when I see it, and the motion picture involved in this case is not that.’

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250 WIPO, Fact Finding Missions, supra note 216 at 25.

251 Sunder, “The Invention of TK”, supra note 234 at 111.

According to the Delegate, Justice Potter’s dilemma in identifying a threshold test for obscenity is on all fours with the existing dilemma in defining TK. Though hard to define, he felt, it can’t be missed when seen! As delegates burst out laughing, with a majority from developing countries nodding vigorously in agreement, the deep seated implications of the Delegate’s resignation began to sink: can it be that we may never be able to define TK exhaustively? Can this elusiveness of definition for TK be a mere reflection of the character of TK, and not an indication of its non-existence? What is it that makes TK so difficult to define? Is it altogether even necessary to arrive at a definition for TK for the purpose of addressing its protection?

3.1.3 Is a Traditional Knowledge Definition Needed?

Due to TK’s definitional complexity, scholars and policy makers tend to avoid defining the term, rather opting for broad contextual interpretations and descriptions. A typical example is contained in the Swakopmund Protocol of the African Regional Intellectual Property Organization (ARIPO). The Protocol is primarily designed to protect TK holders within its member states in the African region. Its definition section describes TK as ‘referring’ to:

any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices, and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific

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253 See, for instance, Dagne, “The Protection of TK”, supra note 249, at 139. See also, Coenraad J Visser, “Making Intellectual Property Laws work for Traditional Knowledge”, in Michael Finger & Philip Schuler, eds, Poor People’s Knowledge: Promoting Intellectual Property in Developing Countries (Washington DC: World Bank & Oxford University Press, 2004) at 207, using TK in a broad sense to include traditional and tradition-based literary, artistic, and scientific works; performances, inventions, scientific discoveries, and designs; marks, names, and symbols; undisclosed information; and all other innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. Again, see Varadarajan, “A Trade Secret to Protecting TK”, supra note 247 at 373 adopting a broad definition of TK as referencing the agricultural, environmental, medicinal knowledge of indigenous peoples and local communities, developed communally over generations. See also Janewa Osei-Tutu “A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in intellectual Property Law (2010) 15:1 Marquette Intellectual Property Law Review, [Osei-Tutu, “A Sui Generis Regime”] 149 at 163 describing TK broadly as the result of intellectual activity, which is handed down through the generations, and which pertains to particular cultural groups. Additionally, most of the existing international treaties addressing TK, including the CBD, Bonn Guidelines, ITPGRFA, UNDRIP, while yet laying down prescriptions on TK, fail to define TK, rather leaving its definition to national authorities.

technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources.\textsuperscript{255}

The Swakopmund Protocol, however, places a caveat on the application of this definition by noting in Section 1, that ‘this Protocol shall not be interpreted as limiting or tending to define the very diverse holistic [conception] of traditional knowledge…’.\textsuperscript{256}

According to OseiTutu, this broad and open-ended approach to defining TK is one of its major frailties especially from a regulatory perspective.\textsuperscript{257} This is due to the wide legal uncertainty that would accompany its implementation. But, it is also a necessary approach for devising a comprehensive system of protection for TK,\textsuperscript{258} especially at the international level given the varying national approaches to indigenous peoples and the protection of TK that such an approach will need to accommodate. As mentioned above, WIPO is currently engaged in a definitional consideration of TK. As part of the preparatory work for the establishment of the WIPO IGC, WIPO had previously suggested that there may be no actual need to delimit the scope of the subject matter of TK through a single definition:

This approach has been taken in a number of international instruments in the field of IP. For example, article 2.1 of the Berne Convention for the Protection of Literary and Artistic Works (“The Berne Convention”), does not include an exclusive definition for the meaning of “literary and artistic works”, but rather provides a non-exhaustive enumeration of subject matter in order to demarcate the categories of creations which are protected under the Convention. Certain other international agreements [such as the Paris Convention and the TRIPS Agreement] in the field of IP do not define a singular term which describes the totality of protected subject matter\textsuperscript{259}

A difficulty with WIPO’s no-definition suggestion, however, was that it failed to take into consideration the highly contested nature of TK. Charles Kamau Maina, for instance, using a political economy framework, has undertaken a study on the protection of TK within three main fora; WIPO, WTO, and the

\begin{footnotes}

\begin{enumerate}
\item Section 2.1, Swakopmund Protocol.
\item Section 1.2, Swakopmund Protocol.
\item OseiTutu “A Sui Generis Regime”, supra note 253 at 163.
\item NS Gopalakrishnan, “Protection of Traditional Knowledge: The Need for a Sui Generis Law in India” (2002) 5:5 The Journal of World Intellectual Property, 725 at 741, noting that the concept of TK must be viewed in a broad context, including folk science and technology for the actuation of a comprehensive legislation for protecting TK.
\item WIPO, Fact Finding Mission, supra note 216 at 25. Also, see Carvalho, “From the Shaman’s Hut”, supra note 236 at 243, noting that patent laws similarly do not define inventions, but rather identify basic mandatory characteristics that inventions must meet in order to be patentable. Similarly, in Trademark Law, no piece of legislation on trademarks attempts a definition of what a sign is. Distinctive signs are simply registrable as trademarks.
\end{enumerate}
\end{footnotes}
As one of his key findings, he identified three major categories of stakeholders in the debate – indigenous communities worldwide, member states, and industry, noting that these three categories express divergent views on the issues of TK and its protection. These divergences give a divisive and contested nature to the character of TK, one which also plays out in the very efforts to define TK. Given that such divergences exist across and within these categories of stakeholders, the development of rights, obligations, and exceptions to the existing systems of protection in favor of the contested subject matter, requires clarity and, to the extent possible, precision.

Furthermore, this non-definition approach has major implications on the practical implementation of legal and regulatory frameworks. Manuel Muller contends that while such broad definitions facilitate legal drafting, they often complicate practical implementation. This is due to the nature of TK, which could be viewed from several contexts and could mean several things at the same time. Arising from the CBD’s approach to defining TK, for instance, as involving the knowledge, innovations and practices of indigenous peoples, TK could be viewed as an intangible (knowledge per se), a tangible (material products or material innovations), or a process or procedure (form of techniques adopted by indigenous peoples).

Without clarity to the concept of TK, therefore, its use could be subject to application in a variety of contexts and towards different ends.

Again, this approach to conceptualizing TK raises major legal questions with respect to definition and enforcement of rights and obligations relating to TK. Indeed, a major difficulty in the efforts to circumscribe TK to a single definition is the contestation around the large body of potential legal rights, privileges, liabilities as well as exclusions that would necessarily accompany such a legal definition. Drawing from the very nature of TK, in particular, its dynamic and evolving nature, the concern of several developing countries, including those agreeing with the Australian delegate, is the potential exclusion of rightful beneficiaries through a rigid definition that lacks capacity to evolve like its subject. This explains

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261 Ibid. at 153 – 154.
262 Muller, “Protecting Shared TK”, supra note 219 at 6 – 7. Noting that the lack of a precise definition to TK, including its unclear scope is a limitation that could affect the implementation of legal and regulatory frameworks.
263 Ibid. at 8.
the caveat around ‘limiting’ the holistic nature of TK, within the Swakopmund Protocol. It, however, leaves more questions than answers from the perspective of legal certainty and clarity.

In sum, an effort to analyze the misappropriation of TK as a central subject of appropriation within the emerging ABS regime complex requires clarity in its definition. However, as I suggest, such clarity must be drawn from the perspective of indigenous peoples who hold the knowledge. The effort, therefore, should not be so much to see how TK’s definition can be explained from the perspective of existing western institutions which, as mentioned in chapter one, were not developed to capture the unique nature of TK. Rather, the effort should center on developing institutions that are specifically tailored to TK.

3.1.4 An Emerging International Definition for Traditional Knowledge

On the international scene, an intensified effort to secure an internationally accepted definition of TK has been witnessed. Though the Nagoya Protocol sets out an important set of provisions addressing the protection of TKaGRs, it fails to define TK. For the purposes therefore of the ABS regime, the baseline definition of TK is as contained in Article 8(j) of the Convention on Biological Diversity (CBD). This Article broadly governs the in-situ conservation of GRs264 and contains a reference to the knowledge, innovations, and practices of indigenous peoples. Muller notes that this definition within the CBD evokes a lot of uncertainty. As the analysis below demonstrates, the practical implementation of TK obligations therefore remains unclear when issues surrounding the very definition of TK remain unsettled. WIPO has pursued the elaboration of a definition for TK; one which will definitely provide even greater clarity to the Nagoya Protocol’s ABS regime.

In a seeming departure from its earlier suggested position, relating to the dispensability of an exhaustive definition of TK, WIPO has taken the lead in the quest to develop an internationally agreed definition of TK. WIPO’s current normative work in this respect is focused, albeit with much difficulty, on the articulation of an all-inclusive definition of TK.265 This TK-related norm-building process within

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264 See the text of Article 8(j) at 15 above.
265 Two main challenges have plagued the efforts to arrive at an all-inclusive definition for TK. First, is largely political and is linked to the large body of potential legal rights, privileges, liabilities as well as exclusions that would necessarily accompany a legal definition of TK. Such an effort will definitely have broader implications on existing international legal systems, as well as commercial interests. Second, is due to the very ‘traditional’
WIPO is significantly a part of a wider project aimed at the design of an international *sui-generis* system of protection for TK. Negotiations by WIPO Member States and accredited observers – which include, indigenous representatives, industry representatives, non-governmental organizations, and other international and regional intergovernmental organizations – are being undertaken on the platform of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). A fuller discussion of the IGC is provided in chapter six of this work. My intention in referencing the IGC at this point is, however, to further the present discussion on the definitional challenges associated with TK by highlighting some useful lessons based on the present difficulties being encountered within these WIPO negotiations.

WIPO’s discussion of TK has progressed under three main headings – TK, GRs, and traditional cultural expressions (TCEs). Three separate and parallel texts devoted respectively to these three aspects of TK therefore contain the tangible in-progress results of the Committee’s current negotiations.\(^{266}\) The three texts are presently designated as, “The Protection of Traditional Knowledge: Draft Articles” [TK: *Draft Articles*],\(^{267}\) “The Consolidated Document Relating to Intellectual Property and Genetic Resources” [*Consolidated Document*],\(^{268}\) and “The Protection of Traditional Cultural Expressions: Draft Articles” [TCE: *Draft Articles*].\(^{269}\) Though these texts respectively exist as stand-alone texts, they overlap in several ways. Importantly, developments within individual texts could often have far reaching implications on the development of other texts. In fact, the possibility of merging the texts into a single document has not been

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\(^{266}\) Though the IGC negotiations commenced with its establishment in 2000, a formal mandate for the commencement of text-based negotiations was only formally adopted in 2009. See chapter six below for a further detailed clarification of this point. Despite this, it is fair to assert that right from the outset of the Committee, negotiations and preliminary analyses aimed at the development of an international instrument has continued to define the engagement of delegations within the IGC.

\(^{267}\) *The Protection of Traditional Knowledge: Draft Articles*, WIPOOR, 31\(^{st}\) Sess, WIPO/GRTKF/IC/31/4 (2016).


ruled out; a factor which explains why the Committee’s mandates have consistently referenced the work of the Committee as pursuing the objective of “reaching agreement on an international legal instrument(s)”.

The effort to define TK within the TK: Draft Articles is one of such developments identified as a core cross-cutting issue across the three texts. This means that in addressing the issue within one of the texts, in principle, the work is being progressed within the other texts, subject to the unique features of the subjects of the other texts. I will limit my discussion at this point to the developments in the TK text for this reason as an explanation of the developments within this text offers an applicable basis across the three subject areas. In the next part of this chapter, I will draw on some of these points in discussing TKaGRs.

Article 1 of the latest iteration of the TK: Draft Articles provides:

The subject matter of protection/this instrument is traditional knowledge

a. That is created, and maintained in a collective context, by indigenous peoples and local communities or nations, whether it is widely spread or not;
b. That is directly linked/distinctively associated with the cultural and/or social identity and cultural heritage of indigenous peoples and local communities or nations;
c. That is transmitted from generation to generation, whether consecutively or not
d. Which may subsist in codified, oral or other forms; and or
e. Which may be dynamic and evolving.

Protected traditional knowledge is traditional knowledge that is distinctively associated with the cultural heritage of beneficiaries as defined in Article 2 that is generated, maintained shared and transmitted in a collective context, is intergenerational and has been used for terms as has been determined by each Member State/contracting Party [but not less than 50 years].

This definition represents a work-in-progress within the WIPO IGC. Torn between a characterization of TK – one which leaves the eventual definition of TK to national authorities – and an actual prescriptive definition of TK, WIPO has seemingly opted for a middle approach. In doing so, it carves out the major features of TK, while yet leaving a flexible space for national authorities to determine practical

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270 See, for example, the IGC 2016/2017 Mandate, supra note 22 at 10 – 12, with specific reference to para (a) of the mandate, at 11.

271 See Article 1, The Protection of Traditional Knowledge: Draft Articles, WIPOOR, 31st Sess, WIPO/GRTKF/IC/31/4 (2016) at 7. (Being the latest draft text on the protection of Traditional Knowledge being negotiated within the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), current to September 1, 2016). As a definition-in-progress, the text remains heavily bracketed around contested areas of the draft definition. It however offers an indicative expression of the definitional proposals as well as areas of tension with respect thereto within the IGC.
aspects of TK within their borders. The evolution of the definition, however, continues to highlight a broad range of difficulties which exist in the conceptualization of TK.

3.1.5 Traditional Knowledge Deconstructed

To explain this, a denotative deconstruction of TK provides a useful segue into the critical elements relating to the nature of TK. The word ‘traditional’ is defined as ‘...belonging to, consisting in, or of the nature of tradition; handed down by or derived from tradition’.272 ‘Tradition’ is explained as

‘the action of transmitting or handing down, or fact of being handed down from one to another or from generation to generation; transmission of statements, beliefs, rules, customs, or the like, esp. by word of mouth or by practice without writing; that which is thus handed down; a statement, belief, or practice transmitted (esp. orally) from generation to generation’.273

‘Knowledge’, on the other hand, is defined as

‘...information, intelligence, notice, intimation’, ‘information and skills acquired through experiences [...], the fact of knowing a thing, state, etc. [...]; familiarity gained by experience.’274

A combined reading of these definitions of ‘traditional’ and ‘knowledge’ supports a basic understanding of TK as ‘a body of tradition-based knowledge’275 which is handed down or transmitted...

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273 Ibid. Tradition is defined as that which is handed down; a statement, belief, or practice transmitted (esp. orally) from generation to generation...a long established and generally accepted custom or method of procedure, having almost the force of a law...the body (or any one) of the experiences and usages of any branch or school of art/literature, handed down by predecessors and generally followed. Ibid.
275 WIPO in its fact finding mission conceptualizes the term tradition-based in reference to knowledge systems that have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment. WIPO, Fact Finding Mission, supra note 216 at 25. See also, Sumathi Subbiah, “Reaping what they Sow: The Basmati Rice Controversy and Strategies for Protecting Traditional Knowledge” (2004) 27:2 B.C. Int’l & Comp. L. Rev. [Subbiah, “Reaping what they Sow”] 529 at 532.
(orally) from generation to generation;²⁷⁶ a product of experience, generationally improved upon;²⁷⁷ a collectively owned heritage as against an individually owned right;²⁷⁸ an adaptive innovative lifestyle generated for survival;²⁷⁹ and a largely unwritten body of instruction and belief”.²⁸⁰

Drawing, therefore, from WIPO’s emerging definition, as well as the denotative interpretation of the terms, three key characteristics of TK are

1. Its creation and maintenance in a collective context, by indigenous peoples.

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²⁷⁶ With regard to the generational transmission of TK, Martha Johnson observes that in contradistinction to western scientific knowledge, TK: is recorded and transmitted orally; is learned through observation and hands-on experience; is based on the understanding that the elements of matter have a life force; does not view human life as superior to other animate and inanimate elements but that all life-forms have kinship and are interdependent; is holistic rather than reductionist; is intuitive rather than analytical; is based on data collected by resource users themselves rather than specialized group of researchers; is based on diachronic rather than synchronous data; is rooted in a social context that sees the world in terms of social and spiritual relations between all life forms and; derives its explanations of environmental phenomena from cumulative, collective and often spiritual experiences. See Martha Johnson, “Research on Traditional Environmental Knowledge: Its Development and Its Role” in Martha Johnson, ed, Lore: Capturing Traditional Environmental Knowledge (Ottawa: Dene Cultural Institute & International Development Research Centre, 1992) [Johnson, “Research on TEK”] at 7 – 8.

²⁷⁷ See Quinn, “Protection for IK”, supra note 216 at 292. See also Graham Dutfield, “Legal & Economic Aspects of Traditional Knowledge” in Keith E Maskus & Jerome H Reichman, eds, International Public Goods & Transfer of Technology Under a Globalized Intellectual Property Regime (UK: Cambridge University Press, 2005) [Dutfield, “Legal & Economic aspects of TK”] at 500 – 501, where the author discredits the view often widely held indicating that TK is antique, void of innovation and lacking in creativity. Rather TK is described as being progressive, highly innovative and involving a continuous reformation of knowledge handed down to meet up with the adaptive requirements of the present environmental realities by indigenous communities. ‘...In short, knowledge held and generated within “traditional societies” can be new as well as old...TK has been adaptive because adaptation is the key to survival in precarious environments...while TK is handed down from one generation to another, this does not mean that what each generation inherits is what it passes on...TK develops incrementally with each generation adding to the stock of knowledge’. See also Bubela & Gold, “Indigenous Rights & TK”, supra note 217 at 2 – 3; Srinivas, “TK and IPRs”, supra note 248 at 84.

²⁷⁸ This is despite general acknowledgement that a major limitation in the quest for increased protection for TK in the IP sense, lies in its nature of collective ownership; See Javier Garcia, “Fighting Biopiracy: The Legislative Protection of Traditional Knowledge” (2007) 18 Berkeley La Raza L. J. [Garcia, “Fighting Biopiracy”] at 7; Gervais, “TK & IP”, supra note 236 at 140; many authors are quick to point out that it amounts to a generalization fallacy to conclude that all TK is communally owned. See Graham Dutfield & Uma Suthersanen, Global Intellectual Property Law (UK: Edward Elgar, 2008) [Dutfield & Suthersanen. Global Intellectual Property Law] where the authors state that

   the idea that traditional property rights are always collective or communal in nature while notions of western property are inherently individualist is an inaccurate cliché

   Significantly, several communities have well defined and established customary law practices which regulate intellectual property rights. These are often similar, albeit not as developed as western IP systems.

²⁷⁹ See Consolidated Survey of Intellectual Property Protection of Traditional Knowledge, WIPOOR, 5th Sess, WIPO/GRTKF/IC/5/7 (2003), which describes the concept of TK as

   ideas developed by traditional communities and indigenous people, in a traditional and informal way, as a response to the needs imposed by their physical and cultural environments

   a definition which emphasizes in clearer terms the strong relationship between indigenous communities and their environments; their TK and their quest for survival.

2. Its direct link or association with the cultural and/or social identity of indigenous peoples

3. Its transmission from generation to generation

But, therein lie, *inter alia*, three major areas of contention within WIPO’s definition-in-progress, especially when the perspectives of indigenous groups are considered. First, the idea of TK as a collective body of knowledge is one which bears strong implications for a determination of the appropriate beneficiaries of TK protection. Can, for instance, individuals be beneficiaries of TK protection or is protection restricted to communities. How are such communities to be defined? Could a nation be viewed as a community for this purpose?\(^{281}\) The views being expressed within the negotiations may be classed into three main groups; those that consider that states should be made beneficiaries,\(^{282}\) those that insist on only indigenous peoples as beneficiaries,\(^{283}\) and those that consider it to be an issue which could be left for determination by national laws.\(^{284}\) No agreement yet exists on this issue.

Second, the nature of the link between the TK to be protected and the indigenous community that holds them has been contested in the definition of TK. For the purpose of determining beneficiaries, should the TK be ‘distinctively associated with’ the indigenous group\(^{285}\) or does a mere superficial or general link

\(^{281}\) For instance, the intervention by the Delegation of Egypt during the 27\(^{th}\) session of the IGC which, in arguing for the inclusion of state beneficiaries, noted that while the concept of ‘indigenousness’ had been developed within the context of several other countries which had experienced a different history of incoming cultures that coexisted with, and sometimes overshadowed, existing cultures, this was not the reality in Egypt. Egypt rather had millennia of unbroken history and had emerged as a nation from the idea of the Nation State as one inseparable entity; consequently, the notion of indigenous populations was not relevant. For the delegation, the generation of TK was a nationwide process. Even if certain TK had originated from a certain part of the country, it had virtually spread all over the country and developed further through subsequent interaction. There was thus no geographic exclusiveness among the population in Egypt, as it had been mobile throughout history and territory. TK in Egypt was therefore not traceable or confined to one single place or part of the population in Egypt due to the continuous social mobility and mingling which defined the Egyptian nation as ‘one people’. See Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Report of the Twenty-Seventh Session*, WIPO, 27\(^{th}\) Sess, WIPO/GRTKF/IC/27/10 (2014) [IGC 27, *Report of the Session*] at 62 (para 219).

\(^{282}\) Countries like Indonesia, Thailand, Barbados and Egypt have reiterated the need to include States as beneficiaries of protection. Ibid. at paras. 40, 171, 59 & 219 respectively.

\(^{283}\) Indigenous peoples as well as industrialized countries generally support this view. The Delegation of Canada for instance noted that it would continue to oppose attempts to make the state the beneficiary unless indigenous and local communities identified the State in a particular situation as the appropriate and legitimate custodian. Ibid. at para 163. In further support of this view, see the interventions by the Indigenous Caucus (para. 44), as well as the USA (para. 62), Japan (para. 65), Sweden (para. 76) & Republic of Korea (para. 78).

\(^{284}\) The thrust of this approach is best summed with the textual proposal by the Delegation of Peru. Ibid. at para. 60, proposing: “The beneficiaries of protection are local communities and indigenous peoples or others that the Member State/Contracting Party defines as a beneficiary in its national legislation”. This affords flexibility to state governments in making such determinations.

\(^{285}\) Canada, United States, Japan, and Sweden, amongst other developed countries have been strong proponents of this position. Ibid. at para. 115.
to the community suffice? For several developing countries like India, a link to the community – which requires a minimal threshold of proof, is important in accounting for cases in which widely spread and diffused TK is in issue. Developed countries, however, have pushed more intently for a tighter standard – one which requires a distinct association of such knowledge with the social and cultural identity of the indigenous group for it to be protected. Part of the difficulty with the use of the distinctive standard as articulated by the indigenous caucus, and supported by a number of delegations within the informal negotiations, relates to the fact that it could mean more than one thing. On the one hand, it could refer to the strength of a knowledge connection with a community. On the other hand, it could refer to the uniqueness of the knowledge to a particular community. The concern emanating from the latter interpretation is that no protection would arise for such TK which was associated with more than one community. Again, this issue continues to divide views.

Third, the utilization of standard of intergenerational transmission of knowledge as a criterion has also raised a number of practical and legal concerns. El Salvador is an example of a country that has consistently, within the WIPO negotiations, expressed concerns of exclusion in this regard. El Salvador has had a difficult history marred by major civil wars and periods of repression. For this reason, it has expressed concerns that the idea of knowledge being transmitted from generation to generation would exclude significant portions of TK in El Salvador given that historical generational gaps are a feature of its national experience. To address this, a solution proposed during the last session dealing with TK was the inclusion of the phrase ‘whether consecutively or not’ after the words ‘transmitted from generation to

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286 Several developing countries support this view. See, for instance, the Delegation of India. Ibid. at paras 107, 169. Ibid. at para 259. See for instance the delegation of El Salvador, noting that its history has involved periods of repression, civil wars and periods where TK has been lost; a problem which makes a ‘generation to generation’ requirement for TK one that would necessarily exclude some TK in El Salvador. Solutions in this regard include viewing TK as an intergenerational concept, as opposed to a generation to generation one. See Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Report of the Twenty-Fourth Session, WIPOOR, 24th Sess, WIPO/GRTKF/IC/24/8 (2013) [IGC 24, Report of the Session] at para. 143 and the response by the Delegation of Japan, Ibid. at para. 154. Furthermore, the concept of generation has evoked intense debate, with delegations calling for a minimum time frame to be accorded to TK in this regard and a 50-year proposal relating to the existence of the knowledge, presently included within the definition. The majority of developing countries have opposed this, with some indicating the disparities in life expectancies across the globe as one militating against a unified concept of a generation. See, for instance, the Delegation of Niger, Ibid. at para. 150.
generation’. This places TK as an intergenerational concept and not one that necessarily occurs from one generation to the next. The concept of ‘a generation’ has also evoked intense debate, with delegations calling for a minimum time frame to be accorded to TK in this regard. A 50-year proposal by Japan is presently included within the definition, suggesting that TK must be at least 50 years old for it to be called ‘traditional’. The majority of developing countries have opposed this, with some indicating the disparities in life expectancies across the globe as one militating against a unified concept of a generation.

In sum, this reflection has been used to show some inherent practical and implementation difficulties which continue to militate against a uniform international definition of TK. Importantly, the implementation of the Nagoya Protocol will encounter these difficulties for which a useful solution on the WIPO platform may serve as a final resort in implementation. Further characteristics of TK, which again add to the complexities around a uniform working definition for an international agreement, are its subsistence in oral, codified or other forms, as well as its dynamism and constant evolution in response to the needs and social realities of indigenous peoples. Again, Muller argues that as a general rule and feature, TK is mostly shared between communities and in many cases across countries rendering the identification of single beneficiaries a challenging prospect. Further adding to the complexity of the definitional challenge for TK are conceptual issues which are connected to the overriding perception of TK.

### 3.1.6 Intellectual Property and the Conceptual Challenge for Traditional Knowledge

An important characteristic of TK which adds a further layer of complexity to efforts to define it relates to the various ways in which it is expressed and the difficulty of fitting its varied, yet holistic nature within parallel western paradigms. Arising from the multiplicity of contexts within which the term may be understood, TK may generally be conceptualized in two main ways. First, TK may be construed in terms of the ‘knowledge’, as such. This involves ideas, skills, processes and the overall body of know-how.

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289 Ibid. paras 143 and 154.
290 Ibid. at para. 150.
291 Muller, “Protecting Shared TK”, *supra* note 219 at 8, noting that TK is all but static. It is continuously subjected to social and environmental tests to prove its effectiveness and relevance over time.
292 Ibid. at 9. He argues that the confining of TK to single Indigenous Peoples groups/communities occurs more as an exception than as a general rule.
293 See, Carvalho, “From the Shaman’s Hut” *supra* note 236 at 243.
developed by indigenous peoples in a traditional, formal, and informal way as a response to the needs imposed by their physical and cultural environments. This aligns with Muller’s conceptualization of TK as an intangible and is described as TK ‘stricto sensu’. Four basic elements of TK stricto sensu are: its creation through an incremental collective process, with knowledge-growth arising from experimentation and experience built by a community over the years; its informal creation through a process of trial and error; its holistic nature by which its spiritual and practical elements integrate the community with its environment, thus rendering TK inseparable from the environment and ways of life, cultural values, spiritual values, and customary legal systems of the indigenous communities which hold it; and its relevance as a means of cultural identification, reflecting a practical skill or method that bears a strong tie with the culture and values of the community.

Secondly, TK may be conceptualized through a focus on the manifestations of such knowledge. These are popularly described as expressions of folklore or expressions of traditional culture, musical expressions, or expressions by actions or performances etc. It could include traditional songs, dances, games, stories, crafts etc. This category is commonly referred to in contemporary literature as traditional cultural expressions (TCEs). These two categories combine under a single umbrella, TK ‘lato sensu’.

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294 Ibid at 243.
295 See Charles McManis, “Biodiversity, Biotechnology & Traditional Knowledge Protection: Law, Science and Practice” in McManis, Charles, ed, Biodiversity & the Law: Intellectual Property, Biotechnology & Traditional Knowledge (UK: Earthscan, 2007) [McManis, “Biotechnology & TK Protection] at 4. A community for this purpose must be identified as a separate group (this may be developed using criteria of lingua, ethnicity/religion or a combination of all) which mandatorily maintains a close relationship with its geographical environment (its biodiversity). See, Carvalho, “From the Shaman’s Hut”, supra note 236 at 243.
297 This implies that it is vital to sustain, not merely the knowledge, but also the social and physical environment of which it forms an integral part. See WIPO. Intellectual Property & Traditional Knowledge Booklet No2 dealing with Intellectual Property & Genetic Resources, Traditional Knowledge & Traditional Cultural Expressions/Folklore Publication no. 920(E). Also available online: WIPO <http://www.wipo.int>.
298 Carvalho, “From the Shaman’s Hut” supra note 236 at 243.
299 Ibid at 243. See also Srinivas “TK and IPRs”, supra note 248 at 84, where the author in analysing the categorisations of TK however, couches its broad classifications as being Traditional Cultural Expressions (TCE’s) and TK relating to medicines, plant GRs, crafts, etc. See also, Bita Amani, “Restitution, Repatriation, & Resistance: Reframing the Biopiracy Dialogue toward Women's Work & Traditional Indigenous Knowledge”, Paper presented at the annual meeting of The Law & Society Association, Hilton Hawaiian Village Resort, Honolulu, HI not available> (12 December, 2014) abstract online: allacademic <http://citation.allacademic.com/meta/p_mla_apa_research_citation/5/5/9/1/2/p559126_index.html>. [Amani, “Restitution, Repatriation & Resistance].
Though the broad interpretation of TK *lato sensu* relates essentially to TK and TCEs, TK *stricto sensu* is also often categorized in terms of its tangible and intangible aspects.

Several authors and policy makers have viewed GRs as constituting tangible aspects of the intangible TK. 300 This position lies at the heart of claims relating to the inseparability of the TK of indigenous peoples from their surrounding biodiversity, the GRs of which inspire their traditional practices or knowledge. 301 These intangible and tangible distinctions are important as they highlight the relationship between TK and GRs. In a tangible sense, it reflects GRs as an innovative output of the knowledge systems of indigenous peoples; a product. Thus reflecting the role of indigenous peoples in maintaining and conserving GRs over generations. In an intangible sense it draws attention to the categorization of TK associated with GRs (TKaGRs) and its various ‘know-how’ subdivisions, such as traditional agricultural knowledge (TAK), traditional ecological knowledge (TEK) and traditional medical knowledge (TMK). 302

It is these categorizations that have informed the discussion of TK within the WIPO IGC under its three identified headings: TK, TCEs, and GRs. Highlighting their distinctive qualities yet close relationship to indigenous peoples, the example of the bamboo flute has often been cited. 303 The bamboo flute which is traced to several indigenous cultures in countries such as China, Japan, and India, is made from naturally occurring bamboo – a component of biodiversity. It is therefore arguably an instrument which made from GRs. The making of the flute, including the carving of its tone holes, is achieved through the TK of the

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300 See, for instance, *The Indian Experience*, *supra* note 191 at para. 2. Geertrui Overwalle “Holder & User Perspectives in the Traditional Knowledge Debate: A European View” in McManis, Charles, ed, *Biodiversity & the Law: Intellectual Property, Biotechnology & Traditional Knowledge* (UK: Earthscan, 2007) [Overwalle, “Holder & User Perspectives”] at 357, for instance, categorizes TK under two broad headings; tangible and intangible components. The tangible components are the GRs, the intangible aspects are subdivided into Traditional Medical knowledge (TMK), Traditional Ecological Knowledge (TEK) and Traditional Agricultural Knowledge (TAK). See, however, Zamudio et al, who contend that, contrary to the legal definitions of the CBD, GRs are not tangible material. They are rather intangible, coded information – a fact well understood by scientists but less so by politicians. Teodora Zamudio, Joseph Vogel & Muller Ruiz, “Logic Should Prevail: A New Conceptual and Operational Framework for an International Regime of Access to Genetic Resources” Research Document; Initiative for the Prevention of Biopiracy (2010) cited in Muller, “Protecting Shared TK”, *supra* note 219 at 20, note 3.

301 See, para 22 of the preamble to the Nagoya Protocol, noting, *inter alia*, the interrelationship between GRs and TK and their inseparable nature for indigenous and local communities.

302 See Overwalle, “Holder & User Perspectives”, *supra* note 300 at 357. See also McManis, “Biotechnology & TK Protection” *supra* note 295 at 4, who, by contrast identifies TAK and TMK as the two categories of TK related to GRs.

303 See, for instance, the delegation of the United States utilizing this example to discuss the differences and interrelationship between GRs, TK and TCEs within the WIPO IGC. See IGC 27, *Report of the Session*, *supra* note 281, at para 212.
flute maker. A manufactured bamboo flute may therefore be said to embody GRs as contained within the bamboo, as well as the TK of indigenous individuals who have overtime developed this cultural instrument. The cultural significance and use to which this instrument is put, however, reflects a third distinct dimension of TK which the bamboo flutes exemplifies: the melodies and the performance by indigenous peoples on the flute reflect an entire universe of TCEs which arise from the same flute. To this end, the use of the flute within ceremonies, including as an accompaniment to dances and songs, reflects, beyond the TK and GRs, the literary and artistic cultural expressions of indigenous groups. This simplified example provides an illustration of the distinct, yet related components of TK. Though they are closely related, these various aspects raise differing concerns within the elaboration of TK as a subject matter.

This explains why TK as a concept is often broken further down into various categories to fit within the western paradigms. 304 Within WIPO’s negotiations, for instance, the above categorizations (TK, TCEs and GRs) reflect the three main aspects of the broad concept of TK. 305 According to WIPO, these categorizations are important for policy development and scholarship in the field of IP as the various categories raise distinct issues which require distinct solutions. 306 A discussion of TCEs for this reason falls outside the scope of this dissertation. Rather, drawing from the Nagoya Protocol, elements of TK and GRs are merged to describe the important subset of TK referred to as TK associated with GRs (TKaGRs). 307

Before discussing TKaGRs, it is worth noting here that indigenous peoples view their TK as a holistic concept which is inseparably connected to their indigenous culture, identity, spirituality, livelihood, their location, their environment, their association with their land, and the natural conditions in which they

304 From an indigenous perspective, this is often deemed inappropriate. Muller in this context observes, ‘…applying western legal concepts to a very distinct reality has often been deemed inappropriate, in as much as these concepts and approaches are very utilitarian and anthropocentric – excluding variables and elements, which in the view of indigenous peoples and communities have to be part of the whole and clearly reflected…’ Muller, “Protecting Shared TK”, supra note 219, at 9.

305 It is worth noting that this is not a universal view, with some scholars contending that TCEs should form the overarching categorization for other TK forms. See, for instance, Bita Amani, “Restitution, Repatriation, & Resistance”, supra note 299, who argues that TK and folklore should conceptually belong to the umbrella category of TCEs rather than TK.


307 Specifically, Article 3, Nagoya Protocol, defines the TK to which the Protocol applies as being that which is associated with GRs within the scope of Article 15 of the CBD. The scope offered by Article 15, CBD, may be conceptualised as referring to TK associated with GRs held by Contracting Parties which are either countries of origin of such resources or in valid acquisition of the GRs according to the Convention.
This connectionism, from the perspective of indigenous peoples, serves to link their skills and understandings with their medical remedies, plant, and animal products, technologies and cultural expressions. For them, TK is thus the totality of all knowledge and practices, whether implicitly or explicitly used in the management of all socio-economic and ecological facets of life. It constitutes a central component of their biocultural heritage. Consequently, from the perspective of indigenous peoples, the distinctions above merely represent an artificial and alien attempt to compartmentalize a singular experience of their knowledge. On this point, Muller observes,

applying western legal concepts to a very distinct reality has often been deemed inappropriate, in as much as these concepts and approaches are very utilitarian and anthropocentric – excluding variables and elements, which in the view of indigenous peoples and communities have to be part of the whole and clearly reflected

For indigenous peoples, this separation into distinct legal categories for protection simply cannot be done, as the various categories (TCEs, TK and GRs), including the further legal sub-categorizations developed, all combine for them within an integrated holistic heritage. Justifying this

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308 See, Frankel & Drahos, “Innovation & Intellectual Property”, supra note 37 at 13 – 23 who describe the concept of ‘connectionism’ to explain the holistic nature of indigenous innovation. This view is supported by Anderson who notes in her analysis, the holistic manner in which indigenous peoples experience their knowledge systems. Anderson, “TK & IP”, supra note 234 at 5.

309 Stephen Munzer & Kal Raustiala, “The Uneasy Case for Intellectual Property Rights in Traditional Knowledge” (2009) 27 Cardozo Arts & Entertainment Law Journal 37 at 48, defining TK as an understanding or skill which is typically possessed by indigenous peoples and whose existence typically predates colonial contact (typically with the West), that relates to medical remedies, plant and animal products, technologies and cultural expressions.


311 Biocultural heritage refers to the “Knowledge, innovations and practices of indigenous and local communities that are collectively held and are inextricably linked to: traditional resources and territories, local economies, the diversity of genes, species and ecosystems, cultural and spiritual values, and customary laws shaped within the socio-ecological context of communities”. See Graham Dutfield, Alejandro Argumedo & Krystyna Swiderska, “Designing an Effective Biocultural Heritage Indication Labelling System” (August 2015) at 4.

312 Muller, “Protecting Shared TK”, supra note 219 at 9.


See also, Anderson, “TK & IP”, supra note 234 at 5 who argues that the various categorizations must be understood as a bureaucratic product which are unable to represent the way indigenous people experience their knowledge systems as it does not capture adequately the complexity of Indigenous Peoples epistemology and ontology.
compartamentalization of TK, WIPO notes that for the purposes of policy development and scholarship in the field of IP, these distinctions are necessary as the various aspects of TK, though similar, raise distinct issues requiring distinct solutions.\(^3\) However, even though this justification from WIPO is important to assist non-indigenous observers conceptualize and explain indigenous experiences, it should not be utilized as a basis for redefining and recasting the experience of indigenous peoples.

In the next section, the relationship between TK and GRs is explored and its central significance and importance within the issue area of biopiracy is highlighted. This discussion is useful in two main respects. First, as the key subject of appropriation within the ABS regime-complex, TKaGRs represents a unique subcategory of TK which draws significance for its medicinal, social, cultural, and environmental value. This value places it at the heart of competing interests between indigenous peoples and western corporations. This discussion places this value in context, thereby offering an insight into the contested nature of TKaGRs; a central factor which underlies the very need for an ABS regime-complex. Second, this discussion identifies and sheds light on the varying interests and concerns of the key stakeholders, both state and non-state actors, which lie at the heart of the ABS regime-complex. Third, by highlighting the significant tensions between the IP system and the sustenance of indigenous experiences within efforts to protect TKaGRs, this discussion reinforces the central justification for a consideration of a third world interest in the protection of TKaGRs.

3.2 Traditional Knowledge associated with Genetic Resources

In the last section, an emphasis was placed on the current international efforts to develop a single definition for TK. As part of the discussion, the experiential element of TK, as a body of knowledge embodied within the traditional lifestyles of communities emerged. There is probably no subcategory of TK that better expresses the centrality of this experiential element of TK than TKaGRs. In fact, the simple definition of TKaGRs which I will like to adopt for advancing my thesis is, ‘the body of knowledge constituting the lived experience of indigenous peoples concerning genetic material within their territories’. As a subcategory of TK, TKaGRs emphasizes the learning which draws from the close association of

\(^3\) See WIPO Background Brief 1, supra note 306 at 2.
indigenous peoples with their environments and their lands, as well as their innovative adaptations to changes within the ecosystems in which they live. This close association of TK with the environment, and in particular the components of biodiversity, warrants a contextual detour into the field of biodiversity and genetic resources. Not only does this provide a greater appreciation of the concept of TKaGRs, it serves to highlight and problematize a whole range of interests which make TKaGRs such a contentious subcategory of knowledge especially within the biopiracy debate. It also sheds light on the important backdrop within which the ABS regime emerged.

3.2.1 Life’s Prerequisites: Biodiversity and Genetic Resources

Biodiversity, which plays a critical role in overall sustainable development and poverty eradication, is essential to our planet, human well-being and to the livelihood and cultural integrity of people… [it] is currently being lost at unprecedented rates due to human activities.\(^{315}\)

The actual notion of biodiversity, a contracted form of biological diversity, was coined in the 1980s.\(^{316}\) According to the authors of the Global Biodiversity Assessment,\(^{317}\) the notion of biodiversity arose in response to the increasing loss of species, populations, domesticated varieties and natural habitats, such as, tropical rain forests and wetlands as well as the central role of human activity in this alarming


\(^{316}\) Ibid. The coinage of biological diversity is generally attributed to Professor Thomas Lovejoy. As a contracted form of biological diversity, biodiversity was first coined by Walter G Rosen in 1985 for the first planning meeting of the 1986 National Forum on Biological Diversity organised by the National Research Council. The term was first published as the title of a book reflecting the Forum’s proceedings in 1988, by E Wilson & Peters, the use of which paved the way for the common acceptance and wide usage of the contracted word and concept. See Jose Luiz de Andrade Franco, “The Concept of Biodiversity and the History of Conservation Biology: From Wilderness Preservation to Biodiversity Conservation” (2013) 32:2 Historia (Sao Paulo) 21 at 22 – 26.

\(^{317}\) Commissioned by the United Nations Environment Program (UNEP) and funded by the Global Environment Facility (GEF), the Global Biodiversity Assessment project was an attempt to mobilize the global scientific community to analyze the present state-of-the-art knowledge and understanding of biodiversity and the nature of human interactions therewith. Significantly, it sought to fill a gap arising from the lack of any formal knowledge assessment being carried out prior to the negotiation of the CBD. In this regard, it provides scientific information to answer identified key questions relating to biodiversity conservation, questions which include: what are the values associated with biodiversity? How can benefits be generated from this resource? How can these benefits be shared in a fair and equitable manner? How do humans influence biodiversity? What are the underlying causes for this influence and what are their ecological consequences? How do the natural dynamics of biodiversity and the human-induced changes in biodiversity affect the values of goods and services provided by biodiversity to society? Chaired by Robert Watson, the outcome of this project is contained in a report of over 1000 pages. See, V.H. Heywood, ed, Global Biodiversity Assessment (Cambridge: Cambridge University Press, 1995) [Heywood, Global Biodiversity Assessment] vii – ix.
trend. Biodiversity thus relates to the variety of life; the varied expressions of life forms in varied life contexts. The CBD defines biodiversity as:

the variability among living organisms from all sources including, *inter alia*, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

The CBD’s definition alludes to ecosystems both on land and in water as well as to the dynamics of life variations that occur within their borders and which they support and make possible. Discernible from this definition are life variations of ecosystems, variations between species and variations within species. Biodiversity is thus intertwined with all we know about life and offers a platform for life to flourish. It is the foundation of life.

Biodiversity is valuable. The value and importance of biodiversity may be viewed from social, economic and cultural angles. The International Centre for Trade and Sustainable Development (ICTSD) notes that forty percent of the world’s economy depends directly or indirectly on biodiversity; the rural poor have depend on biodiversity for up to ninety percent of the their daily needs; and, natural goods and services provided by biodiversity are key sources of food, water, shelter, income and livelihoods for billions of people globally. In recent times, the biodiversity discourse has become mainstream as the world has witnessed its transformation from ‘a life-support base for poor communities to the raw material base for powerful corporations’. Indeed, the emergence of new biotechnologies has changed the meaning and value of biodiversity.

Biodiversity ordinarily draws major cultural, social and even spiritual significance to indigenous peoples who maintain and conserve it within their environments. Today, however, biodiversity represents

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318 Ibid. at 5.
320 See, Richerzhagen, *Protecting Biodiversity, supra* note 6 at 11.
323 Ibid. See also, WIPO Document 26/6, *supra* note 90 at paras 1 – 2, noting that the emergence of modern biotechnologies, has seen genetic resources assume an increasing economic, scientific and commercial value to a wide range of stakeholders.
an extremely valuable phenomenon, with some authors going as far as to draw parallels between the value of biodiversity and that of oil. While this could yet be an exaggeration, biodiversity’s importance in sustainable development and in the eradication of poverty amongst indigenous peoples deserves mention. Within biodiverse countries, indigenous peoples have played a significant role in the conservation and sustainable use of biodiversity. Indigenous peoples’ unique relationship with their surrounding biodiversity is often understood in terms of survival and adaptation to their harsh social and environmental realities.

This relationship is widely acknowledged by several authors and international instruments as being a central factor in the sustainable use and preservation of the earth’s rich GRs. The relationship could also, for instance, take the form of indigenous dependence on biodiversity for health needs (traditional medicines) as well as food (traditional agricultural practices). Importantly, this relationship is known to harbor unique practices and solutions, closely linked to GRs, which provide valuable pointers for innovation in the fields of modern science today.

324 See Shiva, Biopiracy, supra note 322 at 72 – 73, who in discussing the negative connotations of the term bioprospecting, notes that biodiversity is quickly becoming the green gold or green oil for pharmaceuticals. See also, Devinder Sharma, “Selling Biodiversity: Benefit Sharing is a Dead Concept” in Beth Burrows, ed., The Catch: Perspectives in Benefit Sharing (Washington: The Edmonds Institute, 2005) at 10 – 12.

325 See, Chidi Oguamanam, “The Convention on Biological Diversity & Intellectual Property Rights: The Challenge of Indigenous Knowledge” (2003) 7 Southern Cross University Law Review 97 [Oguamanam “The CBD and IPRs”] who argues that it is the marginalization, exclusion or discrimination of these peoples from mainstream society due to their ways of life, cultures and modes of production, which differ from the national hegemonic and dominant models that has often couch the indigenous peoples’ concept as one of survival and adaptation. See also, Report of African Commission, supra note 244, at 88 – 89.

326 See, for instance, para. 22 of the preamble to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity [the Nagoya Protocol]. See also para. 7 of the preamble, and Article 9.1 of the International Treaty on Plant Genetic Resources for Food and Agriculture [ITPGRFA]. See, Oguamanam “The CBD and IPRs” supra note 325, where he notes that the recognition of indigenous and local communities as crucial forces in biodiversity conservation is due to their close link with ecological and other natural forces. See also, Okediji, “The International Relations of IP”, supra note 18 at 354, where she argues that the skills developed by indigenous peoples have allowed them to survive and flourish in fragile ecosystems without causing depletion of resources or damage to the environment.

327 In estimates by the World Health Organization (WHO), for instance, over 80% of the developing world relies on traditional medicine for their primary health needs. Martins Ekor, “The Growing Use of Herbal Medicines: Issues Relating to Adverse Reactions and Challenges in Monitoring Safety” (2014) 4 Frontiers in Pharmacology at 1, noting that up to four billion people (representing 80% of the world’s population) living in the developing world rely on herbal medicinal products as a primary source of healthcare.

328 The agricultural dependence of indigenous peoples on biodiversity for their food is confirmed, inter alia, through the work of the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA). Through its discussion on Farmer’s Rights, the Treaty recognizes the close historical relationship between local indigenous farmers and the GRs within their domains. See, Article 9, ITPGRFA.
Researchers and scientists have increasingly explored the understanding of this relationship between indigenous peoples and their environments in search of information regarding the existence and possible uses of biodiversity. This is known as bioprospecting.\(^\text{329}\) Lorna Dwyer discusses bioprospecting as an ethnobotanical search for new cures and new crops within the earth’s remote regions, primarily motivated by the economic and social value of biodiversity.\(^\text{330}\) It is based on recognition of the importance of natural product discovery for the development of new crops and medicines, often based on TK.\(^\text{331}\)

Placing the significance of bioprospecting in perspective, Bavikatte and Robinson note,

in many developing countries, a large part of the population depends upon traditional medicines for their primary health care needs. In India, 65 per cent of the population has access to traditional systems of medicine, and in Africa 80 per cent of the population uses traditional medicines. Much of this knowledge has not been examined using the most advanced scientific methods […] natural products continue to play a dominant role in the discovery of new leads for the development of drugs. They contribute significantly to the bottom lines of large pharmaceutical companies: between January 1981 and June 2006, for example, 47 per cent of cancer drugs and 34 per cent of all small molecule new chemical entities for the treatment of all disease categories were either natural products or directly derived therefrom. Research into specific natural products is usually directed by existing knowledge, often directly from indigenous or local communities […]\(^\text{332}\)

The use of bioprospecting to appropriate GRs and/or TKaGRs for the purpose of gaining exclusivity over benefits through the IP system, and without sharing in the benefits with indigenous populations is actually a useful explanation of biopiracy.\(^\text{333}\) Three significant points underscoring the

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\(^{330}\) Lorna Dwyer, “Biopiracy, Trade, & Sustainable Development” (2008) 19 Colo J Int’l Envtl L & Pol’y [Dwyer, “Biopiracy, Trade, & Sustainable Development”] at 223 – 224, noting that bioprospecting refers to the work of ethnobotanists who search the plant’s remote regions, motivated mainly by the economic and social value of biodiversity, to find exotic plants and animals in hopes of finding new cures and new crops. See also, Liang, noting that the potential of bioprospecting has been long recognized; i.e. building on indigenous peoples’ knowledge of biodiverse resources and their use is a recognized drug discovery strategy. Bryan Liang A “Global Governance”, supra note 329.

\(^{331}\) Bavikatte & Robinson, “Towards a People’s History of the Law”, supra note 329 at 38.

\(^{332}\) Ibid.

\(^{333}\) Drawing distinctions between bioprospecting and biopiracy, Javier Garcia considers bioprospecting as the least piratical form of biopiracy. See Javier Garcia, “Fighting Biopiracy: The Legislative Protection of Traditional Knowledge” (2007) 18 Berkeley La Raza Law Journal at 7 – 8. According to Garcia, biopiracy is found in three
importance of biodiversity within the context of its association to TK, and indeed its protection from biopiracy, are worth noting here.

3.2.1.1 Biodiversity: Unevenness in Global Distribution

First, as Kate and Laird rightly note, the world’s biodiversity is distributed largely in inverse proportion to scientific and technological capacity. To explain this, scientists have observed biodiversity distributional trends associated with the world’s equator. The equator, or equinoctial line, is an imaginary line or circle drawn around the earth at an equal distance from the north and south poles. The equinoctial line is significant, amongst others, in the understanding of the distribution of the earth’s biodiversity. Biodiversity is characteristically concentrated in regions which are closer to the equator. It is laden with genetic resources (GRs), which represent the smallest functional units of life, and determine the unique variations within ecosystems and species. Based on the World Bank’s classification of the world’s economies, the majority of countries located around the equator are developing economies while most forms, varying by the extent to which they are piratical: bioprospecting; the discovery of unknown properties in known plants and organisms; and, the exploitation of TK. Bioprospecting is often considered a harmless activity. See, for example, Hanne Svarstad “A Global Political Ecology of Bioprospecting” in Susan Paulson & Lisa L Gezon, eds. Political Ecology across Spaces, Scales, and Social Groups (New Jersey: Rutgers University Press, 2005) [Svarstad, “A Global Political Ecology of Bioprospecting” at 247. Several scholars have, however, sought to remove this benign label by considering bioprospecting to be as harmful as biopiracy itself. See Shiva, Biopiracy, supra note 322 at 73 noting that bioprospecting hides the prior use, knowledge and rights of indigenous peoples relating to biodiversity. In fact, some have refused to draw distinctions between biopiracy and bioprospecting, with others yet considering bioprospecting to be the legalized form of biopiracy. See generally, Vandana Shiva, “Bioprospecting as Sophisticated Biopiracy” in Beth Burrows, ed, The Catch: Perspectives in Benefit Sharing (Washington: The Edmonds Institute, 2005), arguing that the impact of bioprospecting on biodiversity and indigenous cultures and local economies is the same as that of biopiracy.

Kate Ten Kerry & Sarah Laird A “Biodiversity and Business: Coming to Terms with the Grand Bargain” (2000) 76 International Affairs 241. [Kate & Laird “Biodiversity & Business”]. The uneven distribution of the world’s biodiversity reflects a major concentration of it occurring close to the equator due to factors such as climate, altitude, soils as well as the presence of other species within the ecosystem.


The World Bank classifies annually the world’s economies based on estimates of gross national income (GNI) per capita for the previous year. As of 1 July 2013, the World Bank income classifications by GNI per capita are as follows: Low income: $1,035 or less; Lower middle income: $1,036 to $4,085; Upper middle income: $4,086 to $12,615; and High income: $12,616 or more. Low and middle – income economies are otherwise often referred to as developing economies. For further information on the World Bank’s country classifications, see The World Bank, Country & Lending Groups, online: <http://data.worldbank.org/about/country-classifications/country-and-lending-groups>. The United Nations Department of Economic and Social Affairs (DESA), similarly publishes a regional classification of economies. See Department of Economic and Social Affairs, Composition of Macro Geographical (Continental) Regions, Geographical Sub-regions, and Selected Economic and other Groupings, online: United Nations <http://unstats.un.org/unsd/methods/m49/m49regin.htm#
developed (industrialized) countries are located further north from the equator. Biodiversity-rich countries, therefore, generally fall within the low and middle-income economy category, while the majority of biodiversity-poor nations fall within the upper-middle and high economy category. Consequently, most industrialized countries are located in biodiversity-poor regions in the Northern Hemisphere, whilst most developing countries are found in biodiversity-rich regions within the tropics. This characteristic distribution of developed and developing nations has led to the politicized use of the terms North and South in describing these groups of nations in the discourses on biopiracy and IP.338 The concentration of biodiversity in poorer countries of the South implies that rarer GRs (unique units of heredity) are located within these countries and thus make these countries fertile venues for bioprospecting and biopiratical activities. This fact is a basis for the frequent conceptualization of biopiracy as a North-South debate and explains the significant interest of developing countries as well as indigenous communities in the development of an effective protection regime for biodiversity. It also underscores the interest of entities within industrialized countries in bioprospecting activities. These divergent interests underlie the development of the ABS regime; developed countries seek assurances of certainty in accessing resources within biodiverse countries and developing countries seek assurances of profits or some kind of return of benefits from the grant of access. Again, this distribution of biodiversity importantly points to an entire body of third world innovation captured in TKaGRs which exists within marginalized sectors of the global systems of governance, namely indigenous communities (particularly those located in developing biodiversity-rich states).

3.2.1.2 Biodiversity: A Rapidly Declining Heritage

A second point regarding the importance of biodiversity is that due to human factors, biodiversity continues to decline at a steady and alarming rate. Describing the extent of the decline, Harrop notes that:

current observations verify that the diversity of genes, species and ecosystems throughout the globe is declining at speed within what is now recognized as one of the most rapid extinction spasms the world has ever known. One-quarter of the world’s plants are threatened with extinction, populations of vertebrates have reduced by one-third in the last 30 years, forests continue to fragment and degrade, and crop and livestock genetic diversity is reducing. These processes are driven by anthropogenic effects.

Iris Borowy more recently also describes this decline:

At present, the world is using the resources and waste absorption capacities of 1.5 planets per time unit. Fifteen out of 24 crucial ecosystem services, evaluated by the Millennium Ecosystem Assessment in 2005, were degraded or being used unsustainably, including fresh water, air and water purification, climate regulation and pest control. And the world is heading for a four-degree temperature rise promising inundated coastal cities, increased food insecurity, frequent high-intensity tropical storms and further irreversible loss of biodiversity.

The human activities in question, most of which remain today, include uncontrolled habitat destruction, through acts such as deforestation activities, agriculture, pollution, over-exploitation of natural resources through industries such as pharmaceuticals etc., as well as human-induced climate change. This declining biodiversity bears severe implications for the functioning of the ecosystem and for the maintenance of the life sustaining systems of the biosphere. Biodiversity’s components are the

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339 See Breazeale, “Sustainable Pathways”, supra note 319 at 2, where the author argues that the major human threats to biodiversity are: invasive species that out-compete and cause extinction of native species; climate change due to increased carbon dioxide in the atmosphere; results of industrialization; habitat change or destruction; over exploitation of ecosystems; and nutrient loading and pollution from nitrogen and phosphorus fertilizers.

340 See, Harrop, “Harmony with Nature”, supra note 203. See also ICTSD, “Navigating Nagoya”, supra note 321, where it is noted that species are currently facing extinction at 1000 times the natural rate.


342 Vandana Shiva identifies habitat destruction due to internationally financed megaprojects and the technological and economic push to replace diversity with homogeneity as the two main factors for large scale biodiversity destruction. See Shiva, Biopiracy, supra note 322 at 65. See also Pimm and Raven, who note that habitat destruction is the leading cause of species extinction. Stuart L. Pimm & Peter Raven, “Extinction by Numbers” (2000) 403 Nature, 843 – 844.

foundation for global food security and play a central role in sustaining mankind with fundamental needs such as fresh water, medicines and key materials required for survival. The significance of biodiversity to human existence makes the development of international instruments demonstrating a common consensus for protective measures and their effective implementation, imperative.

Furthermore, from the perspective of the fight against biopiracy, the decline in biodiversity is directly linked to the decline in TKaGRs. As noted in section 3.2.1.1 above, the uneven distribution of biodiversity has resulted in the endemic occurrence of biodiversity within specific regions of the world. Consequently, communities located around such endemic biodiversity possess cultural practices, which, depending on the properties of the resource, may be unique in global occurrence. A key feature of TKaGRs is its distinct connection to the land, or the resources that sustain the practice. Where, therefore, the very resources which inform the knowledge are depleted, it results in a loss of TK—a loss which could have far reaching effects on the sustainability of indigenous communities. It could for instance signal the loss of a culture, a social identity, a belief system and, in some instances, a livelihood. In the story of the Hoodia provided within the introductory chapter, the loss of the hoodia plant, for instance, would naturally result in the loss of cultural hunting practices which had defined the San peoples and their communal cohesion for centuries. Furthermore, such a loss could represent a missed opportunity to harness solutions derived from the experience of indigenous peoples with their biodiversity and which could potentially address some of the difficult global challenges which mankind faces due to the effects of globalization and industrialization. This suggests that the efforts to maintain and sustain biodiversity must be viewed as opportunities to maintain indigenous societies and their innovation associated with preserving biodiversity, both for the benefit of indigenous societies and also humankind at large.

3.2.1.3 Biodiversity: A Home for Genetic Resources

Third, biodiversity is made up of genetic resources (GRs), which represent the smallest units of life, and determine the unique variations within ecosystems and species. To arrive at a proper appreciation of where GRs fit within biodiversity, it is useful to speak of biodiversity as a multi-level structure,

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344 Ibid. See also Breazeale, “Sustainable Pathways”, supra note 265 at 2. See also Kate & Laird “Biodiversity & Business”, supra note 334 at 241.
encompassing three main structural levels; an ecosystem level, a species level, and a genetic level.\textsuperscript{345} At the ecosystem level, biodiversity is viewed as the variety of habitats, biological communities and ecological processes that occur in such habitats. It involves the variety of forests, deserts, grasslands, and aquatic ecosystems that occur within an area.\textsuperscript{346}

Ecological diversity refers to the numbers of species in given areas, the ecological roles that these species play, the way that the composition of species changes as we move across a region, and the groupings of species (ecosystems) that occur in particular areas (such as grassland or forest), together with the processes and interactions that take place within and between these systems. It also covers the diversity of ecosystems in landscapes, of landscapes in biomes and of biomes on the planet.\textsuperscript{347}

Closely linked to the ecosystem level is the species level. Species, the term of which is generally used to imply distinctiveness between organisms, are widely regarded as the basic units in biological classification and, as such, of biodiversity.\textsuperscript{348} Within the context of species diversity, emphasis is placed on the number and kinds of living organisms within a population, community or ecosystem.\textsuperscript{349} Species are considered to each have specific roles within the ecosystem, meaning that the addition or loss of a single species could have consequences for the ecosystem as a whole.\textsuperscript{350} The third level of biodiversity, is known as the genetic level. At the level of genetic diversity, a focus is placed on the variations within and variations existing between populations of species.\textsuperscript{351} It is within this level that an appreciation is best made of GRs, their relationship with biodiversity, and the understanding of TKaGRs as knowledge derived from an indigenous experience.
3.2.1.3.1 Genetic Resources

GRs are ‘biological resources’ (BRs)\textsuperscript{352} and are defined in the CBD as genetic material of actual or potential value.\textsuperscript{353} They are living components of plant, animal or microorganism species that possess functional units of heredity known as genes.\textsuperscript{354} A gene is a segment of deoxyribonucleic acid (DNA) that is responsible for the physical and inheritable characteristics or phenotype of any living entity.\textsuperscript{355} Therefore, genes contain information and/or instructions relating to characteristics of living organisms as well as the way such living organisms function. There is no simple way to place a finite price on the value of GRs or the TK associated with its use; neither can the potential benefits that may possibly arise from access to GRs be accurately determined. GRs are a potential source of income for biodiversity rich communities as well as biotechnology industries which rely on GRs as a major source of input for research into the development of a wide range of health, agricultural, and cosmetic products.\textsuperscript{356}

What makes differences appear within a population of species? What are the therapeutic preparations of plants used as foods and medicines? How do they relate to the land and environmental conditions within which they are found? The answers to these questions, as developed within an indigenous community, derives primarily from their experiences, whether or not proven through scientific methods, gained through years of trial, error, observation and repeated learnings. The following passage by Jones Moody offers an interesting example of the value of indigenous experiences informing research:

Our work on *Terminalia catappa* (Indian almond) indeed presents another example of how not to discard in one stroke the “nonsense” associated with traditional medical

\begin{footnotesize}\begin{enumerate}
\item Article 2, CBD defines biological resources as including GRs, organisms or parts thereof, populations or any other biotic component of ecosystems with actual or potential use or value for humanity.
\item See Article 2 CBD. Furthermore, the preamble to the CBD recognises biodiversity as possessing high intrinsic value and identifies the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic value of its components (including GRs). See para. 1 Preamble to the CBD. Article 2, CBD, defines genetic material to mean any material of plant, animal, microbial or other origin containing functional units of heredity.
\item Ibid. at 72.
\item Biodiversity is often viewed by the local communities as possessing intrinsic value as well as high use value in itself, while commercial interests often view it as possessing no value in itself. They see it merely as forming a raw material for the production of commodities and profit maximisation. It is through these final products that the economic value of biodiversity is, however, often determined. See Shiva Vandana, “Protecting our Biological and Intellectual Heritage in the Age of Biopiracy” (1996) New Delhi: Research Foundation for Science, Technology and Natural Resource Policy, at 1 – 30.
\end{enumerate}\end{footnotesize}
practice [...] a professional colleague, who was later to become one of my postgraduate students, noticed in her community pharmacy practice some years ago that a number of her sickle cell disease patients using the fallen leaves of this plant as prescribed by traditional healers were experiencing very much reduced monthly pain episodes. The condition for efficacy was that the leaves selected for the decoction must be ripe and fallen from the tree. We examined and compared the anti-sickling activities of the ripe fallen, ripe but not fallen, and the unripe and not fallen leaves. Results revealed that the ethanol extract of the reddish brown ripe freshly fallen leaves exhibited the highest anti-sickling activity (78% inhibition at 180 min incubation). Extracts of the other leaves harvested when still on the tree were in fact found to cause lysis of the red blood cells.

Arising from the genetic level, the consistent interaction and dependence of indigenous peoples on their environments offers them unique knowledge about the special properties and characteristics of plants within their domain. This knowledge, as shown above, could also extend to the methods and processes of GRs use. For, in the above example, the remedial use of almond leaves to treat sickle cell anemia could be fatal depending on whether the leaves were ripe and fallen from the tree, or actually plucked directly from the tree. As in this example, such learnings would regularly be entrenched within the customs, beliefs, and practices transmitted between generations. With certain predictability such communities are able to understand the medicinal and agricultural uses of plants, their benefits, and risks. As James Anaya points out, it is this knowledge about the genetic material within their domains that actually translates genetic material to GRs. This derives from the interpretation of the CBD’s definition of GRs as genetic material of actual or potential value. In essence, genetic material which is not valuable cannot be considered a GR. The value attaching to genetic material, however, is significantly derived from the knowledge of its use. By searching out GRs through bioprospecting activities, therefore, an acknowledgement of the TKaGRs in leading researchers to the actual and/or potential value of genetic material exists.

The association of TK with GRs speaks of a relationship and a defining connection between the knowledge of indigenous peoples and the genetic material within their environment. The differing nature

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357 Moody J ‘The Sense and Nonsense of Traditional Medicine in Africa: An Odyssey of a Herbalist’s Grandson in Nature’s Laboratory’ (2010). Excerpts from an inaugural lecture delivered by the Dean, Faculty of Pharmacy, University of Ibadan, Nigeria on 2 July 2010 reflecting his achievements in drug discovery and research.

of this relationship between indigenous peoples and the genetic material within their environment has been captured through two broad interpretations: TKaGRs and ‘associated TK’. WIPO’s emerging text on GRs seeks to make a distinction between these two concepts, noting that ‘associated TK’ relates to the entire body of knowledge of indigenous peoples that may be associated with GRs, including innovations, skills, practices, and learning. TKaGRs, however, relates to the substantive knowledge of the properties and uses of genetic material held by indigenous peoples.\(^\text{359}\) In practical terms, therefore, while associated knowledge may include, \textit{inter alia}, ceremonies, songs, handicrafts, and inventions that make use of GRs, TKaGRs would be limited to the know-how of indigenous peoples about the specific properties and uses of GRs – including medicinal, agricultural, and even environmental uses. The bamboo flute in the earlier example will therefore constitute ‘associated TK’, and not a TKaGR as the flute, though made with a plant, is not based on the knowledge of the properties of the bamboo. The knowledge of the hoodia plant by the San peoples, however, will constitute a good example of TKaGRs. It is this latter conception of TKaGRs that this dissertation refers to.

The interest over time in the TKaGRs of indigenous peoples draws from the acknowledgement of its relevance and importance in advancing solutions to global challenges. In this context, TKaGRs is important for a wide range of global needs, including the conservation of biodiversity and the sustainable use of its components,\(^\text{360}\) addressing the effects of climate change,\(^\text{361}\) food security,\(^\text{362}\) cultural sustenance of indigenous peoples,\(^\text{363}\) and pharmaceutical innovation, amongst others. Importantly, TKaGRs is a key underlying driver of innovation related to biodiversity. The simplified diagram below seeks to locate TKaGRs within the broad discourse of TK.

\(^{359}\) See, \textit{Consolidated Document Relating to Intellectual Property & Genetic Resources}, WIPOOR, 30\(^\text{th}\) Sess, WIPO/GRTKF/IC/30/4 (2016) at Annex, 2. (Being the latest formal negotiation draft text on genetic resources within the WIPO IGC).

\(^{360}\) See para 22, preamble to the Nagoya Protocol.

\(^{361}\) See, for instance, the cited relevance of TK contained within the UNCCD. See note 223 above.

\(^{362}\) See note 234 above, emphasizing the relevance of farmers’ rights to the attainment of food security goals through the ITPGRFA.

\(^{363}\) See, for instance, the UNDRIP.
Addressing the protection of TKaGRs is an extremely important yet contentious area of global regulation. Connected, amongst others, to the difficulties in articulating a precise definition for TK, as well as the peculiar nature of GRs, including its unequal global distribution and rapidly declining rate, TKaGRs poses a significant dilemma for policy makers and a wide range of institutions striving for law reform. The competing interests relating to the use of TKaGRs, also serves to heighten the North South dimension to the problem of TKaGRs protection. A conclusion to be drawn here is that despite the present difficulty in formulating a comprehensive or exhaustive definition of TK (top level in diagram), we can develop sufficient working definition of TK stricto sensu in association to, and limited by its connection to GRs for the purposes of moving forward with the discussion in this dissertation. As discussed above, TK stricto sensu relates to the knowledge as such; that is, the substantive know-how, skills, and learnings generated in a traditional context by indigenous peoples. Importantly, discussing TKaGRs as the experience of indigenous peoples relating to genetic material within their territories, challenges the legal structures, assumptions and westernized compartments through which this experience is sought to be defined.

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364 Further subcategories of GRs could be mentioned, such as, plant GRs, animal GRs, and even human GRs. In line with the scope of the Protocol, however, its use is aimed at capturing the scope of GRs as covered by the Protocol – i.e. GRs within the scope of Article 15 of the CBD. See Article 3, Nagoya Protocol.
3.3 Justifying a System of Protection for Traditional Knowledge

The contentious nature of TKaGRs manifests in the wide range of conflicting arguments which generally arise for and against its protection. For instance, objectors to TK protection have often argued that the protection of TKaGRs places a financial burden on society which may not be commensurate with the economic value and/or benefits derivable from a system of protection for TK.\(^{365}\) Given that TK constitutes a central part of third world innovation and practices (TWIP), the need to formally recognize and protect TK as a form of IP has defined a lot of the debates relating to its protection. In this context, the earlier reflections in this chapter, including the efforts to define TK, have been pursued within WIPO as part of a larger *sui generis* project to define, and ascribe positive and defensive rights to TK based on IP-like principles. Importantly, these efforts are being pursued through the lens of the formal system of IP.

In justifying this needed system of protection for TK, I will now turn to briefly highlighting some of the common objections and justifications which have been used to resist, or alternatively support, efforts to protect TK. Construing these within the perspective of the broader objective of protection is important, and as such, it is worth noting that the core underlying reason for which TKaGRs is in need of protection is for the purpose of preventing biopiracy. In effect therefore, the objections and justifications below, are reflective of arguments and counter-arguments for and against the protection of TKaGRs from the incidence of biopiracy.

### 3.3.1 Objections to the Protection of Traditional Knowledge associated with Genetic Resources

A wide range of objections to the protection of TK have consistently been espoused.\(^{366}\) Though not all are necessarily borne out of bad faith,\(^{367}\) it is worth noting that a number of objections point towards efforts by beneficiaries of the IP system to maintain the institutionalized discrimination by which categories

\(^{365}\) Carvalho, “From the Shaman’s Hut” *supra* note 236 at 245.

\(^{366}\) Okediji notes that opposition to IP rights in TK comes from a variety of sources, including foreign users who rely on these material to create new products and services for global consumption, from environmental scientists and civil society groups concerned about the potentially disruptive effects of western-style property rights on the traditional lifestyles of indigenous groups and local communities in the developing world, from IP scholars committed to an expansion of the public domain, and from those who view these demands for new entitlements as part of an unjustified expansion of IP rights. Some indigenous groups oppose conventional models of IP protection for TK, instead seeking distinctive or *sui generis* protection for the objects of their creativity. See, Ruth Okediji, “When Should We Invent International Intellectual Property Rights?” (2016) [Okediji, When Should We Invent IPRs?] at 1 – 2.

of knowledge and inventive activity are privileged over others. The objections below are therefore mostly centered on concerns which the protection of TKaGRs will have on the existing IP system.

### 3.3.1.1 Guarding the Public Domain

To IP scholars, the public domain is said to consist of intangible materials that are not subject to exclusive IP rights and which are, therefore, freely available to be used or exploited by any person.\(^{368}\) Innovation is cumulative. In other words, it builds on existing innovation. For this reason a disclosure element is built into the IP system requiring that, in return for exclusive time-bound rights over the commercialization of inventions, the IPR holder must make sufficient disclosure of the invention in the patent so that a person of ordinary skill in the art can replicate and build on such innovation at the expiration of the exclusive IPRs.\(^{369}\) To promote this system of progressive development, a key policy objective is ensuring that there is a right balance between protected knowledge and the public domain. A larger public domain, it is believed, will facilitate creativity and invention, while a smaller public domain arising from increased restrictions (both in terms of the length of protection being assigned to existing IPRs, and also in terms of the increasing of subject matter which qualify for IP protection) will stifle and frustrate innovation.\(^{370}\) This is because the public domain may be conceptualized as an open field from which innovators draw ideas and inspiration in advancing society. The public domain represents the broad universe of knowledge, inventions and creative works that are not protected by IP rights but necessary for generating IPRs from their available use by anyone without charge. The maintenance of a rich public domain is therefore often put forth by developed countries as an important policy goal.\(^{371}\) From the perspective of indigenous peoples and local communities, however, the “public domain” operates to exclude TK and TCEs from protection and is often used to justify their misappropriation.\(^{372}\) In line with these views held by indigenous peoples, antagonists of TK protection view TK as constituting a part of the

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\(^{368}\) See, WIPO IGCOR, 17\(^{th}\) Sess, WIPO/GRTKF/IC/17/INF/8, 2010 at para 2.

\(^{369}\) See, Article 29, TRIPS Agreement.

\(^{370}\) Dutfield & Suthersanen. *Global Intellectual Property Law*, supra note 278 at 335, noting that a larger public domain supports innovation and best serves global interests. It for instance, reduces the costs of essential products accruing from the use of the knowledge, and increases opportunities for greater options from knowledge products etc.

\(^{371}\) Ullrich, “TK, Biodiversity, Benefit-Sharing” *supra* note 248 at 30

public domain, with the implication that no one is harmed and no rules are broken when research institutions
and corporations use resources from the public domain freely. By ascribing IP rights to TK and placing
restrictions over their unfettered use for innovation, objectors have contended that this will result in a further
depletion of the public domain. In sum, the fear of further depletion of the public domain is a source of
objection to TK protection.

3.3.1.2 Legal Uncertainty

Closely linked with the preservation of the public domain, opponents of TK protection have raised
concerns with respect to the large uncertain and undefined scope of TK. As noted earlier, a precise
all-embracing definition of TK has remained elusive to policy makers and scholars. This, several
objectors note, is an indication of the futility of attempting protection for TK as protection cannot be
effectively accorded to an undefined concept. Though this argument has often been countered by
proponents of TK protection on the ground that several existing frameworks of protection, even within the
field of IP, relate to concepts that are not defined, the uncertainty around the possible nature of protection,
scope of protection, the beneficiaries of such protection, and even the possible criteria for protection have
continued to be linked to an inability to agree on a definition of the term TK. This difficulty as I suggested
earlier, however draws from a fundamental problem of seeking to use western concepts and tools to define
indigenous experiences. In this context, it is worth noting here that a decisive definition of TK may not
necessarily be needed to advance the discussion on the effective implementation of the Nagoya Protocol
with respect to the ongoing discussions within the WIPO IGC. This is especially because, as I suggest, the
IP system’s role in the protection of TK should be limited to the prevention of the IP system being used as
a vehicle for the misappropriation of TK. In this sense, a clarification of the problematic issue area of
biopiracy draws central significance, and is why chapter four is devoted to this purpose.

373 See Alvarez Nunez R 'Intellectual Property and the Protection of Traditional Knowledge, Genetic Resources &
“The Peruvian Experience”] at 497, noting that this view must however be regarded as being false.
374 Dutfield & Suthersanen. Global Intellectual Property Law, supra note 278 at 336. See also Ullrich, “TK,
Biodiversity, Benefit-Sharing” supra note 248, where the author argues that the definition of both TK and
indigenous peoples or local communities to whom it may be attributed remain vague.
375 See, generally 3.1.2 above.
376 See, note 259 above and accompanying in-text discussion.
Legal uncertainty is also held out as a major criticism of efforts to protect TK from the perspective of practicability. Under the ABS regime, for instance, users are required to secure the prior informed consent (PIC) of the indigenous knowledge holders, and establish mutually agreed terms (MATs) for the purpose of sharing benefits arising from the use of the knowledge. A wide range of unanswered questions have however accompanied the analysis of these obligations on users. First, how are cases of trans-border instances of TK addressed? In other words, how do users determine the rightful beneficiaries where several communities are able to lay claim to the same knowledge. Furthermore, the question of scope has continued to remain contentious. Should, for instance, the present efforts to address the protection of TK, be made retroactive in effect? If yes, when would be the appropriate cutoff date? It is for such uncertainties within the efforts to protect TK that concerns remain as to the possible negative effects that efforts to protect TK could have on the very motivation of industries to invest in natural product research and innovation. This concern is often discussed within the context of the disincentive theory.

3.3.1.3 The Disincentive Theory

The process of food and drug development is a long, capital-intensive, winding road; one which involves huge financial risks and expertise spanning several daunting stages for the purpose of innovation. Even where a product is successfully brought to the market, there are still risks and costs associated with the marketing and sales of the final product, including the monitoring and enforcement of the IP rights over the product. According to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), for instance,

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\text{[t]he research and development process is characterized by a high degree of scientific, regulatory, and economic risk. Enormous quantities of time, effort, and money are invested in the research and development process to bring a new medicine to the market. Typically, discovering and developing a new medicine takes an average of 10 – 15 years, and for every 5,000 – 10,000 compounds investigated, only one is approved and marketed. The cost of developing a new medicine now totals on average more than USD 1.2 billion. These investments in R&D have no guarantee of a return, with statistically far more failures than successes in the laboratory.}\tag{377}
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\[\text{See, International Federation of Pharmaceutical Manufacturers \\& Associations (IFPMA), “Data Exclusivity: Encouraging Development of New Medicines” (July 2011) at 5. See also, Richerzhagen, Protecting Biodiversity, supra note 6.}\]
This industry perspective is crucial to recognizing the important value-addition which industry contributes in its research and development (R&D) activities, even where TK is involved. Despite these risks, corporations remain incentivized to invest time and resources in natural product R&D due to the IP system, which provides a reliable mechanism for guaranteeing returns on such hefty investments. Through the patent system, corporations are granted a time-bound monopoly by the state – a minimum of 20 years – within which they retain the exclusive rights to promote and profit from their successful inventions.\(^{378}\) After this period, the knowledge about the product and/or process of its creation falls into the public domain. Without this incentive, in accordance with the underlying rationale of the IP system, industries and individuals would not be encouraged to take on the risk of innovation.

In this context, TK protection has been described as having an overall disincentive effect for industry innovation.\(^{379}\) Many pharmaceutical companies have indicated that they really have little or no interest in the rigorous nature of bioprospecting and the increasing antecedent risks of nature research, due to a combination of factors, including, new developments in alternative drug discovery strategies,\(^{380}\) as well as the resulting uncertainty and risks associated with the implementation of a legal regime for the protection of TK. The latter is chiefly identified as a possible disincentive to the willingness of multinationals and research institutions to invest time and money within indigenous communities.\(^{381}\) Based on these considerations, the IFPMA notes that a majority of its pharmaceutical partners and firms have already closed down their departments which deal with natural product research.\(^{382}\) Proponents of this objection argue that this could lead to a ‘knowledge’ loss, as well as a missed opportunity for indigenous peoples to leverage on their resources to secure economic benefits, and a missed opportunity for the global community to benefit significantly from natural product innovation. Leaving TK ‘unprotected’, according to this view,

\(^{378}\) See, Article 33, TRIPS Agreement, providing that ‘the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date’.


\(^{380}\) Ibid at 336.

\(^{381}\) Ibid at 337.

\(^{382}\) This information is based on an interview conducted by the author with Dr. Andrew Jenner, Director Innovation and Trade Policy, IFPMA on May 29, 2013. See, for instance, the closure of the natureceuticals group within Pfizer. See, Danielle Rossingh, “Pfizer Hands Phytopharm’s Drug Back” *The Telegraph* (31 July 2003), online: The Telegraph Group <http://www.telegraph.co.uk/finance/2859230/Pfizer-hands-Phytopharm-s-drug-back.htm>. 
promotes legal certainty and thereby serves as an incentive for multinationals to commit resources into exploring biodiversity located in indigenous or local communities for global solutions benefitting all.

While merits exist in this objection, to the extent that it highlights possible losses to indigenous communities and the global society, it however reflects a sad reality of the wrongful scenario which seeks to justify the determination of the ‘public interest’ through market forces. A need to promote legal certainty must be pursued, however, the public interest can only be advanced through inclusivity. In this sense, development which prevents other sectors of society from developing, or which preys on other vulnerable sectors of society cannot be viewed as sustainable. I address this in further detail in chapter five.

Protecting TK, therefore, must not be seen as a prevention of industries from accessing the resources and knowledge practices, but rather must be seen as an equalization, if not prioritization of the interests of indigenous communities within such relationships. The rules of engagement must be based on their wishes, and not the institutionalized standards which oftentimes are utilized as a means of redefining the public’s expectations of what indigenous peoples’ wishes should be. The right of indigenous peoples to consent to the use of their knowledge, as well as have a say in the establishment of equitable rules of engagement must define the relationship between industries and indigenous communities. The centering of the principles of prior informed consent (PIC) and mutually agreed terms (MATs) within the ABS regime offers a rationalization for its designation within this dissertation as a useful and central part of the solution to protecting TKaGRs.

3.3.1.4 Empirical Deficit

Another core objection to the protection of TKaGRs arises from the limited experience and evidence which exists on the protection of TKaGRs. Within the IP circles, protection of TKaGRs is largely being pursued within the context of reinforcing the system of ABS. In other words, normative proposals within the IP negotiations are towards the end of ensuring that inventors who make use of TKaGRs and are seeking IP rights over their inventions, do so in compliance with ABS regulations. Indeed, this objective lies at the heart of the proposal for the amendment of the TRIPS to incorporate an Article 29bis on the

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disclosure of origin, referenced earlier in this work.\textsuperscript{384} So also, the central point of contention within the WIPO IGC negotiations is the difficult consideration of incorporating a disclosure requirement within patent applications.\textsuperscript{385} The implications of such a measure within the IP system is unclear and industrialized countries have been reluctant to sanction any such normative amendments to the existing IP system without evidence of its implications in implementation. Some of the concerns raised by industrialized countries include concerns over the effect that such an amendment could have on efficiency and integrity of the IP system. For example, with respect to patent examiners, the concerns expressed have highlighted the non-suitability of patent examiners to ascertaining compliance with ABS systems given their lack of training and lack of infrastructure to take on this task. Imposing such an obligation on patent examiners would lead to an overburdening of the patent offices and overall inefficiency. To proceed in this regard, several countries, including Canada, have requested that empirical studies and evidence should be presented as a basis for informed policy making.\textsuperscript{386}

Adopting this evidence based approach, major players within the WIPO IGC have also continued to demand evidence and empirical studies to inform the ongoing negotiations. Most have contended that the efforts to protect TK have hitherto been based on exaggerated claims of misappropriation, as well as non-conclusive proof of the possible advantages of a TK protection system. To this end, a proposal continues to be co-sponsored by the Delegations of Canada, Japan, the Republic of Korea, and the United States of America, requesting a factual cost-benefit analysis on measures relating to the protection of TK.\textsuperscript{387} Furthermore, the European Union has recently submitted to the IGC a proposal for the terms of reference for a study on national experiences and domestic legislation and initiatives in relation to the protection of TK.\textsuperscript{388}

\textsuperscript{384} See, 1.1.3. above, at 26 – 27.
\textsuperscript{385} See, “GRs Informal Issues Paper”, supra note 99 at 3.
\textsuperscript{386} See, for instance, the Proposal for the Terms of Reference for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents & Compliance with Existing Access & Benefit Sharing Systems, WIPO IGCOR, 31st Sess, WIPO/GRTKF/IC/31/7, 2016 (being the latest resubmission of this proposal, first circulated at IGC 23 in 2013 as document WIPO/GRTKF/IC/23/6).
\textsuperscript{387} Ibid.
While these proposals, and the studies they propose will have a beneficial impact for policy making, the reality, as several scholars argue, is that studies have already been done. In fact, the initiation of the IGC was commenced with an empirical fact-finding study on the IP needs and expectations of TK holders with respect to protection. The concerns over the possible implication of their very needs and expectations with respect to the protection of TK on the IP system, should not deter policy makers from acting in the interest of justice. It is for this reason that the IGC has continued its deliberations despite these proposals, with the understanding that such requests for studies should not serve to delay the process – a caveat which suggests that such studies, while important for information purposes, should not be considered prerequisites for according protection to TK. In this sense, the continued requests are explained as a political objection to the development of IP-based protection for TK.

3.3.2 Justifications for the Protection of Traditional Knowledge associated with Genetic Resources

Having examined a range of objections that have been raised to the efforts to protect TK, I now turn to highlight some of the key justifications which support the necessity of protecting TKaGRs from biopiracy.

3.3.2.1 An Environmental Justification

Research has revealed a history, dating back countless thousands of years, of biological harmony between indigenous peoples and their environment. This benign balance of communal interaction with nature is grounded in use, spirituality, and in the interests of long term survival, and accounts for the maintenance and sustainable use through generations of the rich biodiversity occurring within and around indigenous communities. The environment thus offers a central justification for the protection of TK. Two aspects to this justification draw relevance here: First, is the prevention of biodiversity loss. As noted in the earlier discussion of TKaGRs, biodiversity is declining at a rapid and alarming rate. Biopiracy has

389 See WIPO, Fact Finding Missions, supra note 216.
391 Ibid. This was reflective of a total communal integration with nature. Spiritual beliefs, community survival, as well as dependence on nature for food and medicines, meant that the destruction of biodiversity was a destruction of indigenous communities whose survival was tied to same.
played a significant role in this decline.\textsuperscript{392} The decline in biodiversity has led policy makers to seek possible solutions to the dilemma of protecting the environment for future generations, while guaranteeing its optimal use for the present generation’s needs. In advancing a lasting solution to this decline of biodiversity, the World Summit on Sustainable Development (WSSD) proposed

\[\text{[t]his trend can only be reversed if the local people benefit from the conservation and sustainable use of biological diversity, in particular in countries of origin of genetic resources}\textsuperscript{393}\]

In effect, the proposal emanating from the WSSD was a proposal to ensure the protection of indigenous peoples whose knowledge plays an indispensable role in efforts to address the loss of biodiversity. The CBD and Nagoya Protocol acknowledge this fact.\textsuperscript{394}

Consequently, a regime which respects and protects TK will also contribute directly to the conservation of biodiversity by ensuring that the historical benign relationship through which indigenous peoples have sustained biodiversity through generations is maintained. Furthermore, it is worth restating that the protection of the environment also translates to the sustainability of indigenous livelihoods, innovations, cultures, and knowledge. Efforts to protect TK, in this light, may therefore be justified on the basis of a wider global need: environmental sustainability through indigenous sustenance.

\textbf{3.3.2.2 The Human Rights Justification}

Closely linked to the environmental sustainability, the protection of TK is justified on the basis of the need to protect the rights of indigenous peoples over their knowledge. The United Nations Declaration

\textsuperscript{392} See, for instance, Prabodh Maiti & Paulami Maiti, \textit{Biodiversity: Perception, Peril & Preservation} (Delhi: PHI Learning Private Limited, 2011) at 9.10.5, noting biopiracy to be responsible for the destruction of species and loss of biodiversity that impede the sovereign rights of the producer nations, thus leading to the decline of the economic status of indigenous communities. See also, Chathurika Akurugoda, “Biopiracy & Its Impact on Biodiversity: A Critical Analysis with Special Reference to Sri Lanka” (2013) 2:3 International Journal of Business, Economics and Law 48 at 49, arguing that the negative effective of biopiracy on biodiversity include the extinction of endemic living organisms, as well as depletion of biodiversity.


\textsuperscript{394} See Par. 22 of the Preamble to the Nagoya Protocol. According to the CBD [the] current understanding of GRs owes a great deal to the TK of ILCs. This valuable knowledge has been built up and handed down over generations. It is essential that the value of TK is understood and valued appropriately by those who use it, and that the rights of ILCs are considered during negotiations over access and use of GRs. Failing to do this can put the knowledge, the resources and the communities at risk See, CBD: \textit{ABS, Introduction to Access and Benefit Sharing} 2, online, CBD, <http://www.cbd.int/abs/infokit/all-files-en.pdf>.
on the Rights of Indigenous Peoples [UNDRIP] provides that the rights recognized within the UNDRIP constitute the minimum standards for the survival, dignity, and wellbeing of the indigenous peoples of the world. The majority of the earth’s biodiversity is found in regions inhabited by indigenous peoples and has constituted a source of their TK practices. Accordingly, the UNDRIP establishes that ILCs have the right to maintain, control, protect and develop their TK and the IP over such knowledge including that relating to GRs, the knowledge of fauna and flora. It places an obligation upon States to take effective measures to partner with indigenous communities in protecting these rights. This human rights justification is found within a variety of international human rights instruments, including the UNDRIP and the International Covenant on Civil and Political Rights, amongst others.

3.3.2.3 An Economic Justification

The protection of TK has further been justified on the basis of the potential benefits it provides to the knowledge holders (indigenous peoples, and by extension host countries). This is a rationale which underlies several calls for the protection of TK. TK is of immense value in itself to indigenous communities as such communities depend on TK for practically all facets of their lives, livelihoods, health, and general wellbeing. The majority of the communities and countries holding TKaGRs are poor and it is widely

395 See Article 43, UNDRIP.
396 See Article 31(1), UNDRIP. See also Par. 11 of the preamble to the UNDRIP, which recognized the direct relationship that the respect for indigenous knowledge, cultures and traditional practices bears with the sustainable and equitable development and proper management of the environment. Furthermore, interestingly, Article 25, UNDRIP recognises the right of indigenous peoples to maintain and strengthen their distinctive spiritual relationship with their traditionally owned or occupied and used lands, territories, waters and coastal seas and other resources, and to uphold their responsibilities to future generations in this regard. Obviously, the emphasis is on the right of indigenous peoples to take the lead in the sustainable use of the biodiversity falling within their territories. See Article 29 (1), UNDRIP.
400 Ibid at 329.
believed that the protection of TK could drastically improve the lives of TK holders and their communities fostering economic development due to TKs economic value.\textsuperscript{401} TK is a basic input, both as an intellectual resource and also as a product resource to the manufacturers.\textsuperscript{402} Increasingly, cases of market success are being recorded with end-products bearing significant TK footprints. Calls for sharing of benefits arising from the use of TK, as a possible form of protection, are based on the hope that such a market-based approach may contribute to the sustainable development of countries of origin as well as to the improved livelihoods of indigenous communities traditionally holding the resources and associated knowledge.\textsuperscript{403}

3.3.2.4 An Innovation-based Justification

One of the main underlying motivations for the development of IP law has been the promotion of innovation.\textsuperscript{404} This motivation is premised on the principle that knowledge creation is a sequential and cumulative process for which earlier contributors deserve fair compensation.\textsuperscript{405} By this principle, new

\begin{itemize}
\item \textsuperscript{401} Ibid. Such protection should not be seen as restricting its use, but a wider interpretation it must be noted involves a recognition, a respect for and an adequate compensation of TK holders in case of the use of their TK, and an overall integration of TK into the global IP system. This involves some of the value added being shared to indigenous societies.

\item \textsuperscript{402} Ibid.

\item \textsuperscript{403} See Elisa Morgera & Elsa Tsioumani “The Evolution of Benefit Sharing: Linking Biodiversity & Community Livelihoods” (2010) 19:2 Review of European Community & International Environmental Law [Morgen & Tsioumani “The Evolution of Benefit Sharing”] at 3. See also, Richerzhagen, Protecting Biodiversity, supra note 6 at 59, who argues that the protection mechanism of ABS represents a new income opportunity for poor countries over their TK and GRs which could can alleviate poverty where local resource providers (including knowledge holders) are included as partners. It has the potential to promote economic development. Dutfield & Suthersanen. Global Intellectual Property Law, supra note 278 at 331, however stress a note of caution in overestimating the possible impact of TK protection on developing country economies, as such must not be viewed as the final solution to prosperity of such countries. Its possible role in economic development however remains undeniable.

\item \textsuperscript{404} See Carlos Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options (London: ZED-Third World Network, 2000) 38. [Correa, IPRs, the WTO & Developing Countries]. Patents are arguably the most highly valued form of IP. IP systems generally provide that for an invention to be patentable, it must fulfil the three criteria of being new, of being capable of industrial application, and of being a result of inventive activity. See Article 27, TRIPS Agreement.


\begin{itemize}
\item [i]f the next innovation could not be invented without the first, then the social value of the first innovation includes at least part of the incremental social value provided by the second. If the first innovation merely reduces the cost of achieving the second, then the cost reduction is part of the social value provided by the first. If the first innovation accelerates development of the second, then the social value includes the value of getting the second innovation sooner. The problem introduced for incentive mechanism is to make sure that earlier innovators are compensated for their contributions, while ensuring that later innovators also have an incentive to invest

Innovative TK practices, which contribute to these foundational innovation chains, and upon which so many present western advancements are built, has, however, remained largely uncompensated. This has been attributed
inventions derived from prior art (earlier insights, discoveries and inventions) are protectable. Inventions based on TK have therefore generally been treated as protectable; however, the underlying TK, which constitutes a prior art, is not protected. Protection therefore is often justified for TKaGRs on the basis of its role as a foundational element in several global inventive chains. An effective regime for protection of TK could also serve to address the suspicious nature by which several indigenous communities view bioprospectors, thereby facilitating the legal diffusion of TK into the wider society in accordance with the preferences of indigenous peoples.

The development of a protection framework for TK has also been argued as being capable of offering incentives for the further development of TK amongst indigenous communities. This argument is quite problematic and undermines the very basis for which protection of TK from biopiracy is being considered within this dissertation. In itself, the underlying assumption of the IP system that incentives make people innovative, represents an alien ideology within the context of indigenous innovation. It would therefore represent a challenge to place this justification, without more, as a policy objective within efforts to design a TK protection framework. This is because such an objective for protection may inadvertently result in a failure to acknowledge TKaGRs as body of knowledge that emerges through an indigenous experience borne in a close adaptive relationship between communities and their environments. Rather, such an objective may end up measuring TKaGRs through criteria which is alien to indigenous experiences and which becomes contained within the very regulatory structures from which protection is being sought.

The justification for innovation, however, can be supported within the context of maintaining the conditions within which indigenous peoples innovate. In other words, a protection strategy for TKaGRs

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to the weak link between IP systems and the local innovative processes taking place in developing countries. See Correa, IPRs, the WTO & Developing Countries, supra note 404 at 39.

The development of TK as well as its evolutions is linked to the quest for survival by indigenous communities. The dynamism of TK has been based on its evolving responses to needs imposed by the natural environments and as such, a new mechanism for the protection of TK, particularly an IP-based mechanism, would not have the dynamic efficiency of promoting the creation of new TK. See Carvalho, “From the Shaman’s Hut” supra note 236 at 245. See also Correa, IPRs, the WTO & Developing Countries, supra note 404 at 39 noting inter alia; that the patent system as an incentive to local innovations is unlikely to work. Again, see also Shubha Ghosh, “Globalization, Patents, & Traditional Knowledge” (2003) 17 Colum J Asian L [Ghosh “Globalization, Patents, & Traditional Knowledge”] at 75; noting that the use of IP as a tool of incentivizing IP amounts to a ‘strange use of IP’, given that the production of TK does not need to be incentivized due to the fact that the knowledge and its artifacts already exist.
which, in accordance with the UNDRIP, guarantees indigenous peoples access to their lands, security of their communities etc., could serve to sustain an indigenous experience which lies at the heart of indigenous innovation. Importantly, as I shall emphasize in chapter five, maintaining the indigenous knowledge experience means that benefit sharing as a protection mechanism must contribute to the sustainability of indigenous communities and not the destruction thereof. It is within this context, that indigenous communities are able to remain innovative.

3.3.2.5 A Development Justification

The protection of TK is cited as a central and critical mechanism for the harnessing and integration of knowledge systems for national and global development. TK is valuable and largely scientific.\textsuperscript{407} Due to the mistrust of the western institutions and researchers, holders of TK often resort to secrecy for the purpose of protecting their art.\textsuperscript{408} This has unfortunately resulted in the loss of such TK practices which pass on with the holders of the knowledge where such knowledge is not shared. A challenge, for instance, identified by several indigenous peoples has been that increasingly, younger generations have not imbibed wholly the knowledge practices of the older generations due, in part, to increasing western influences.\textsuperscript{409} A lot of knowledge is consequently being lost with the older generations. The result is a loss to the local communities and the global community. The possibility exists that solutions to global challenges (though developed in a local context) which probably had been secretly held by custodians of TK, are lost. Though this may seem a speculative basis for justifying TK protection, the efforts of countries like India in documenting and recording TK provides a practical example of its importance. India in 1999 established the National Innovation Foundation (NIF),\textsuperscript{410} one of its goals being the strengthening of research and development linkages between excellence in formal and informal knowledge systems so as to create a knowledge network.\textsuperscript{411} To this end it has embarked on the development of several initiatives for the purpose

\textsuperscript{407} Ibid at 335.
\textsuperscript{408} Alvarez Nunez, “The Peruvian Experience”, supra note 373 at 520.
\textsuperscript{409} See WIPO, \textit{Fact Finding Missions}, supra note 216 at 214.
\textsuperscript{410} Gupta, “The Conundrum of Creativity”, supra note 49 at 327. Dutfield & Suthersanen. \textit{Global Intellectual Property Law}, supra note 278 at 331, describe this as the greatest official commitment of any government to harnessing traditional technologies into modern systems for sustainable development.
\textsuperscript{411} Established under its Ministry of Science and Technology, the other goals of the NIF are; To help India become an inventive and creative society and a global leader in sustainable technologies; To ensure evolution an diffusion of green grassroots innovations in a time-bound and mission-oriented manner; To support scouting, spawning,
of formally integrating local innovation into the mainstream knowledge economy. Furthermore, India embarked on a massive project through which it undertook the documentation of TK around the country and compiled the results in its Traditional Knowledge Digital Library (TKDL). This initiative, which has assisted patent examiners with prior art searches, has also served the purpose recording, and preserving for future generations, the current TK practices within India. This effort has been a huge success and underscores the significance of building of an accessible global knowledge network as a fundamental justification for the protection of TK.  

3.4 Conclusion

As the search for a conclusive solution to the protection of TK continues to divide policymakers, academics and stakeholders, uncertainties still exist around such questions as; what constitutes protectable TK? What objectives should guide the protection of TK? What should be the scope of protection? Who should be the rightful beneficiaries of TK protection? What kind of rights should accrue to the identified beneficiaries of protection? Which alternative approaches to protecting TK are available and how can plausible approaches be effectively implemented? Given the wide range of questions relating to the protection of TK, as well as the varying angles from which such questions are often viewed the issue has been taken up in different fora and international legal instruments. The number of instruments and/or multilateral fora addressing this issue reflects the relevance of TK to a wide variety of regimes and policy discussions. An important consequence of the proliferation of discussions on TK across several regimes is the divergence in approaches employed to conceptualize and develop solutions for the protection of TK. This points to the fragmented regulatory nature of the terrain for the protection of TK.

This chapter has clarified that the protection of TK being considered is as against the incidence of biopiracy, a phenomenon which I argue represents an implicit issue area defining third world concerns sustaining and scaling up of grassroots green innovations and link innovation, enterprises and investments; To promote wider social awareness and possible commercial and non-commercial applications of innovations. Dutfield & Suthersanen. *Global Intellectual Property Law*, supra note 278 at 331.

Gupta, “The Conundrum of Creativity”, *supra* note 49 at 327. A further discussion of the TKDL, including some of its major achievements is undertaken in chapter 4 below.
within the emerging ABS regime complex. The examination of biopiracy as an issue is undertaken in chapter four.

In discussing TKaGRs within this chapter, I have reflected on it as a subject of appropriation, requiring protection from biopiracy. By isolating the prevention of biopiracy as the core policy rationale of protection within this dissertation, an important inference regarding the contextual nature of TK protection is made. This means that the conception of protection varies with use and forum; consequently ‘protective measures’ within the context of one forum may not be considered as ‘protection’ within others. For instance, under the UNESCO Model Law, the protection of TK is considered from the perspective of ‘safeguarding’ and preservation.\(^{413}\) It defines protection as ‘the adoption of measures aimed at the preservation, safeguarding and enhancement of the diversity of cultural expressions’.\(^{414}\) This approach does not align perfectly with the approach being taken, for instance, within the IP space. WIPO is considering protection in the context of IP-based protections and the ascribing of proprietary rights over TKaGRs. This involves both defensive and positive approaches to protection, but is primarily based on a construction of TKaGRs as IP. Positive protection is defined as protection which assigns positive rights to beneficiaries, while defensive protection entails measures which prevent third parties from appropriating and illegitimately acquiring rights over the knowledge and practices of indigenous peoples. My arguments in this chapter have suggested that the IP system is unable to address the protection of TK positively. In fact, seeking to ascribe proprietary rights to TK is an effort to redefine an indigenous experience which cannot be adequately placed within western paradigms. I have, rather, suggested that the IP system’s relevance in addressing the protection of TK should be focused on the development of defensive measures which ensures

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\(^{413}\) The Convention conceptualizes TK as ‘intangible cultural heritage’, which it defines as ‘the practices, representations, expressions, knowledge, skills […] that communities, groups and, in some cases, individuals recognize as part of their cultural heritage. This intangible cultural heritage, transmitted from generation to generation, is constantly recreated by communities and groups in response to their environment, their interaction with nature and their history, and provides them with a sense of identity and continuity, thus promoting respect for cultural diversity and human creativity […].’ Article 2.1, *Convention for the Safeguarding of the Intangible Cultural Heritage*, 17 October 2003, 2368 UNTS 1 [entered into force 20 April 2006] (CSICH). See also, Article 2.2., CSICH for a prescriptive list of the various forms in which intangible cultural heritage may be manifested. See Article 4.7, *Convention on the Protection & Promotion of the Diversity of Cultural Expressions*, 20 October 2005 online: <http://en.unesco.org/creativity/sites/creativity/files/article_18en.pdf> [entered into force 18 March 2007]. Safeguarding, being the central theme in its approach, is defined as ‘measures, aimed at ensuring the viability of the intangible cultural heritage, including the identification, documentation, research, preservation, protection, promotion, enhancement, transmission, particularly through formal and non-formal education, as well as the revitalization of the various aspects of such heritage’. See, Article 1, CSICH.
that the IP regime takes responsibility for preventing its mechanism from being used as a tool of TK appropriation.

This suggested need within the IP system is advanced as an important way of supporting the maintenance of the indigenous experience which facilitates indigenous innovation. This indigenous based standard of protection draws on the principles underlying the Nagoya Protocol. In other words, a standard which is based on an interpretation of the ABS mechanism through the principles of respect, equality and sustainability which run through the core of the indigenous rights regime. The UNDRIP stipulates, for instance, that indigenous peoples ‘have the right to maintain, control, protect, and develop their cultural heritage [and] traditional knowledge…’. Furthermore, it establishes that indigenous peoples are equal and have a right to be distinct, without being forced to give up their culture through a forced system of assimilation. As an instrument primarily designed to address the incidence of biopiracy, the Nagoya Protocol incorporates central principles based on these foundational indigenous rights alluded to. For instance, the obtaining of prior informed consent (PIC) establishes a sense of respect regarding the external use of TKaGRs. Furthermore, it supports the rights of indigenous peoples to maintain and control the uses of their TKaGRs. Also, the requirement of mutually agreed terms (MATs) establishes a platform of equality and respect through the entirety of third party transactions with indigenous peoples over their TKaGRs. Third, the principle of benefit sharing provides a sustainable angle to protection, and must be construed as an important tool for preserving culture and associations of indigenous peoples with their lands, territories, as well as ensuring their right to development.

The defensive reinforcement of the Protocol’s protection mechanism through the IP system, serves an important function of completing this protection strategy outlined within the Protocol. While I consider the IP system and the ongoing work of the IGC an important element in the implementation of the ABS regime, my recommendations, as earlier noted, are nevertheless biased towards a limitation of the IP aspect of protection to the defensive elements of the protection strategy. In other words, while the positive rights

415 See Article 31, UNDRIP.
416 See Para 2, preamble, UNDRIP. See also, Article 2, UNDRIP.
417 Article 8, UNDRIP.
and principles for the protection of TKaGRs are drawn from the Nagoya Protocol, the exercise of these rights require a corresponding defensive buffer drawn from the IP regime.

It is important to highlight that this chapter has importantly laid the frame for locating TKaGRs as a central element within two principal regimes of regulation – the biodiversity regime and the global IP regime. Underscoring the centrality of regime interaction in the framing of solutions to the protection of TKaGRs, this again reinforces the central thesis by rationalizing the importance of viewing the solutions to the protection of TKaGRs through a regime complex analysis. TK, an unprotected intellectual creation of indigenous communities, significantly sits at the core of the ongoing efforts within WIPO to expand the IP system in favor of indigenous innovation. WIPO, which is the designated specialized agency of the United Nations for administering and promoting IP worldwide, has continued to play a central role in the articulation of TK, including TKaGRs, as part of a drive to further its representativeness and legitimacy within the field of global innovation.

Yet, as the lived experience of indigenous peoples with respect to the genetic material within their territories, TKaGRs again sits at the heart of the biodiversity regime anchored in the CBD. It is particularly worthy to note, in this regard, that the Nagoya Protocol, the subsidiary instrument to the CBD being considered within this dissertation, specifies TKaGRs as being covered within its scope of regulation.\textsuperscript{418} This draws from the inseparable nature of TK and GRs for indigenous communities that hold them, as well as its recognized role in locating the actual and/or potential value in genetic material within indigenous territories. In other words, the holistic nature of TKaGRs, by which both the intangible TK and the tangible GRs form a part of a single biocultural experience for indigenous peoples, and warrants a regulation of TKaGRs as a central element of a biodiversity regime. The identification therefore of TKaGRs as a category of knowledge which is centrally linked to both the IP and biodiversity regimes, importantly highlights a subject of appropriation which necessarily draws regulatory significance from more than one regime.

Finally, this conclusion is again observable on the basis of the review of some objections and justifications to the protection of TKaGRs. A perusal of these justifications and objections demonstrates

\textsuperscript{418} See Article 3, Nagoya Protocol.
the central relationship between two principal regimes in the regulation of TKaGRs. While the biodiversity regime offers environmental and economic justifications for the protection of TKaGRs, the key objections to the protection of TKaGRs are largely based on innovation and IP concerns. This suggests a tussle between the proponents of the biodiversity regime in protecting TKaGRs and the proponents of the IP regime. Objections, such as the guarding of the public domain, legal uncertainty, disincentive implications, and even the empirical deficit, are all driven by key users of the IP system. Significantly, industry representatives, and industrialized states, are at the heart of such concerns. It is thus imperative to view efforts within the IP framework which seek to effect a protective strategy for TKaGRs as important aspects of any effective strategy to protect TKaGRs. The need for a complementary IP-based regulatory framework which serves to address these concerns is hereby emphasized. Without such corresponding outcomes within the IP forum, the efforts to advance a mechanism of protection as contained in the Nagoya Protocol will continue within a context of unresolved IP issues, which are just as important as the seemingly resolved regulatory issues within the Protocol.

In the next chapter, I shift from the current discussion on the subject of appropriation to discuss the identified regime-complex issue area of biopiracy. As noted in chapter two, issue area clarity is a fundamental element of regime definition. By taking a closer look at the incidence of biopiracy within the context of its definition as an issue area of governance, its resolution through a regime complex which incorporates benefit sharing principles, as well as an IP defensive mechanism is firmly established. The importance of this next chapter within the overall thesis, is that it lays out clearly the basis for examining the Nagoya Protocol and the IP regime as complementary elements within a single regime complex designed for biopiracy. It achieves this by casting biopiracy within a needed restrictive and contemporary frame; one which emphasizes biopiracy as a trans-regime issue area requiring of a trans-regime (or a regime complex) solution.
Chapter 4

Biopiracy: A Contemporary Expression of Regimes and Borders

In the last chapter, I dealt extensively with the subject of traditional knowledge associated with genetic resources (TKaGRs), which I defined operationally as the body of knowledge constituting the lived experience of indigenous peoples concerning genetic material within their territories. The chapter clarified that the protection of TKaGRs as utilized in this dissertation’s analysis of the Nagoya Protocol’s international access and benefit sharing (ABS) regime, is primarily within the context of biopiracy. In other words, preventing biopiracy forms the major incentive, challenge, and underlying rationale for the efforts of third world actors to protect the biocultural heritage of indigenous peoples, as embodied within their TKaGRs, through the ABS regime. While the concept of biopiracy was introduced in chapters one and two as part of a preliminary effort to offer a background and conceptual framing to this thesis, this chapter undertakes a deeper examination of what is meant by the term “biopiracy” towards a greater understanding of its trans-regime nature and thereby seeks to emphasize why, as an issue area, its prevention significantly requires a regime-complex solution.

Biopiracy is a contentious issue. While some scholars and policy makers altogether deny its existence, others have yet continued to place it at the forefront of demands for reforms to the international systems governing human innovation (the intellectual property system) and global biodiversity (within the frame of the Convention on Biological Diversity (CBD)). Interestingly, amongst the demandeurs for the protection of TKaGRs from biopiracy, an undefined variety of suggestions are advanced as providing scope and actual determination to the activities that constitute biopiratical acts. This is all the more significant where the legality of bioprospecting as a benign form of biopiracy is placed into perspective. As a consequence, biopiracy has remained the subject of a multitude of definitions. The imprecision around its definition has been one of the factors which have resulted in biopiracy being considered an emotive rhetoric.

What an operational definition of TK requires is the designation of its essential elements, and not an exhaustive description of its concept which, as identified in the previous chapter, might prove an impossible elusive task. See Carvalho, “From the Shaman’s Hut”, supra note 236 at 243.
which, though gratifying a ‘sense of moral worth, can offer only ‘utopian longings that ultimately have no critical edge.’

In this chapter, I challenge this viewing of biopiracy as a redundant emotive concept by advancing a distinct way of viewing biopiracy – one which supports the analysis of the ABS regime as an evolving regime complex seeking to address the problem of biopiracy. By drawing on what I term the ‘sore spots of emphasis’ in the biopiracy debate, I provide a contemporary discussion of the problem of biopiracy through an interpretation of biopiracy as a trans-border and trans-regime concept. As a trans-border concept, biopiracy exists as an international problem for which an international solution, as contained in the Nagoya Protocol, is required. An analysis of its trans-regime element however reveals the need for further defensive measures from the intellectual property (IP) system within efforts to effectively address the problem of biopiracy. This analysis places biopiracy within the mix of a myriad of competing international regimes, most notably, the ABS regime and the global IP regime. For an effective solution, therefore, my contention is that biopiracy requires a solution which draws from these two core regimes. This chapter analyses biopiracy as an issue area for state cooperation and strengthens the argument advanced for viewing the ABS regime as an emerging anti-biopiracy regime complex – one which is based on complementary and incremental normative advancements in these two regimes as its pillars, and which is principally being driven by Third World actors.

In part one of this chapter, I examine biopiracy as a significant problem for the third world. By drawing on its stylized manifestations which support its contemporary viewing, I argue that biopiracy is an issue which must be viewed within the context of a third world struggle to reclaim a territory of exploitation within the field of global governance. It therefore exists and must be interpreted as developing a counter-discourse to the globalized system of IP. The increasing awareness about biopiracy and the efforts to address its inequities are efforts being driven and sustained principally by actors; including states, indigenous peoples, and organizations from and/or sympathetic to the Third World. An emphasis on the literature from

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such activists is thus justified. In this connection, the analysis of biopiracy draws heavily on the third world approach to international law (TWAIL).

In part two, I discuss biopiracy as a contemporary problem which transcends single borders and regimes. In other words, it is fundamentally an international problem but also an inter-regime problem. Part two forces a restrictive interpretation of biopiracy within the context of its modern manifestation. As I clarify, this is not an effort to redefine a history of biopiracy (which significantly exists beyond the terminology of biopiracy we know today), but rather is an effort to recognize the modern institutions which continue its present day facilitation and to which solutions today must also address. Indeed, biopiracy fits both within a historical and a contemporary frame. As a historical problem, its foundations may be traced to early contact between explorers and new ‘discovered’ lands. Today, however, a contemporary set of factors and stakeholders serve to offer a redefinition for its articulation: a definition drawn from the increasing strength of the IP regime in the face of a weak ABS system in regulating the exploitation of GRs. These contemporary factors are central to defining the problem of biopiracy today and effectively addressing its occurrence through the combined efforts of the Nagoya Protocol and the ongoing work of the WIPO IGC, discussed in chapters five and six, respectively.

4.1 Biopiracy and the Third World

Biopiracy is the result of a commercial/non-commercial drive to utilize the IP system to acquire rights over inventions based on GRs and/or its associated TK, without complying with existing legal obligations, national or international, governing the acquisition and use of such resources. Principally, the regulations governing the acquisition and use of GRs and TKaGRs are contained within the access and benefit sharing (ABS) framework, which, at the international level, is comprised of the Nagoya Protocol, the CBD, the ITPGRFA, the Bonn Guidelines and other complementary instruments. Not only do international regulations govern the use of GRs, but importantly, the domestic regulations of States form a core component of such regulations governing the acquisition and use of resources. Evading such regulations, while yet securing legitimate IP rights over inventions based on GRs and TKaGRs, lies at the heart of biopiracy’s conceptualization.
Biopiracy is stylized in a north-south context. Schuler’s offering of the *stylized* story of biopiracy involves a three-step process whereby researchers (in the North) learn of a traditional herbal remedy or food crop (from a region or group in the South), perform only a limited amount of laboratory testing or selective breeding to determine how the remedy works or how to produce it in an industrial setting, and then receive a patent on what is little more than the traditional product.\footnote{Philip Schuler, “Biopiracy & Commercialization of Ethnobotanical Knowledge” in J Michael Finger & Philip Schuler, eds, *Poor People’s Knowledge: Promoting Intellectual Property in Developing Countries* (Washington, DC: 2004, The World Bank & Oxford University Press) [Schuler, “Biopiracy & Commercialization”] at 160.} David Castle and Richard Gold present the typical “wrongful exploitation scenario” of biopiracy:

> [a]n indigenous group has traditional knowledge. Another group, typically but not necessarily members of an industrialized country, recognizes the potential utility of the knowledge and exploits it. When the latter does so, it gains access to and control over the benefits arising from the knowledge to the exclusion of the indigenous group. As a result, an objection is raised that this is an inequitable outcome [...] the situation is made more egregious when the industrial party asks for compensation from developing country consumers for goods and services incorporating the exploited knowledge\footnote{David Castle & Richard Gold, “Traditional Knowledge & Benefit Sharing: From Compensation to Transaction” in Peter WB Phillips & Chika B Onwuekwe, eds. *Accessing & Sharing the Benefits of the Genomics Revolution* (The Netherlands: Springer, 2007) [Castle & Gold, “TK & Benefit Sharing”] at 67.}

Paul Heald, in his analysis of biopiracy, similarly offers two interesting hypothetical examples of the facts of a typical biopiracy case. In the first example, a pharmaceutical company in collaboration with a University in the North, seeks a new treatment for sickle cell anaemia. The company sends researchers to a remote rain forest where the inhabitants suffer an unusually low incidence of the disease. After many interviews with local residents, the researchers identify an enzyme in a variety of squash cultivated by them which seems responsible for the low rate of the condition. The researchers return home, isolate the gene that codes for the enzyme and mass produce a successful and valuable patented drug. The pharmaceutical company never compensates any of the local residents. In the second example, he references an agricultural corporation that is developing a smut-resistant strain of corn. The corporation sends researchers around the world to identify varieties of plants worth studying. In the highlands of a biodiverse developing country, the researchers interview farmers who for hundreds of years have maintained a strain with significant smut-resistant characteristics. The researchers acquire several of the plants and embark on a successful cross-breeding program when they return home. The information acquired during the interviews saves them...
thousands of research hours. They, however, do not share any of the profits earned from sales of their new patented hybrid seed with the local farmers.423

In addition to the three interconnected and exploitative strands which I identified in the introductory chapter as underlying the biopiracy challenge, *viz* the non-recognition of indigenous contributions, the exclusion of indigenous peoples from decision-making, and the inequitable distribution of economic resources arising from the use of TKaGRs),424 a common denominator in the above depictions and examples of biopiracy is the role of multinationals and/or individuals based in the North that utilize the existing legal terrain to secure rights over resources and/or knowledge acquired from communities located in the poorer South. This dynamic on the use of GRs and TKaGRs, coupled with the fact that most of the earth’s biodiversity is located within and/or endemic to developing countries of the South, while the users are largely located in the technologically advanced countries of the North,425 has often supported the consideration of biopiracy as a North-South issue – i.e. one in which the interests of the North are diametrically opposite to, and disparately impact on, the interests of the South. This is not always the case.426 However, natural product research and development is driven principally by the innovation

423 These two examples were slightly modified and have simply been adapted for use here. The originals are found in Heald “The Rhetoric of Biopiracy”, supra note 420 at 520 – 521.
424 See 1.1.2 above.
425 Kate and Laird note that the world’s biodiversity is distributed largely in inverse proportion to scientific and technological capacity. Kate & Laird “Biodiversity & Business”, supra note 334 at 241.
426 The “user” versus “provider” conceptualizations within the ABS regime have often generated confusion and debate with respect to their application. As regularly stated in the international ABS discussions, all countries may both be users and providers, and, as such, both victims and facilitators of biopiracy. See, for instance, Chidi Oguamanam, “Canada: Time to Take Access & Benefit Sharing Over Genetic Resources Seriously” (2009) 60 University of New Brunswick Law Journal at 141, noting thus far, the politics surrounding ABS have pitted developed countries as the users, against developing countries as the providers of genetic resources […] the positions of user and provider of genetic resources are not mutually exclusive. That understanding is necessary for progress on a credible global ABS regime.

This is because, depending on each particular ABS transaction, countries assume different roles. A distinction may also be drawn between parties to the ABS agreements and countries involved in the ABS transaction. For clarity, a user is described as an individual, company, university, agency, government or other entity which is “utilizing genetic resources,” acquiring genetic resources with the intention to utilize them or generating benefits from that utilization while a user country refers to the country with jurisdiction over a user in a given ABS transaction (either due to nationality of the user or due to the user’s activities (utilizing the GRs) occurring within that country’s jurisdiction). A provider is one who provides those resources to the user by giving him the legal right to utilize them. The exact nature of the provider depends on national law. In some countries, the provider will be any individual who can legally collect/sell/give anyone biological material including genetic resources. In other countries, rights in biological material are separate from rights to GRs within it, suggesting that the government is the provider of the GRs, even if an individual owner provides the biological material. A provider country (sometimes referred to as a source country) is the country in which the GRs in question were originally taken from in-situ conditions (or if the GRs are agricultural varieties, where their unique properties were
industry which is concentrated mainly within the industrialized world. The main relevant user actors within the innovation industry, including pharmaceutical corporations, biotech companies, agricultural companies etc., play a major role in the shaping of government policies. Therefore, there is analytical value in viewing the struggle as one of indigenous peoples within biodiverse developing countries for the protection of their TKaGRs from powerful corporations, states, and systems which seek to exploit the actual/potential value inherent in such TKaGRs.

In support of this point, Ikechi Mgbeoji places biopiracy within a broader frame of appropriation by describing biopiracy as a characteristic system of mutually reinforcing factors. First, from a sociocultural perspective, biopiracy involves the cultural and engendered denial of the intellectual input of traditional farmers and breeders, particularly women, in the improvement of biodiversity and development of associated TK practices. Second, biopiracy involves the established mechanisms by which powerful states have set up international agricultural research centers as research institutions and gene banks for the appropriation of GRs from the biodiversity-rich South. Third biopiracy involves the use of the IP system, particularly the patent system, to facilitate the ownership interests of western corporate seed merchants and pharmaceutical and biotech industries over the GRs and TKaGRs. For him, biopiracy is an institutional system of appropriation, enabled by regime protection for IP rights, which victimizes and ignores the contributions of indigenous peoples and the countries of the South. Biopiracy thus remains a problem of central concern to the developing world.

In an attempt to capture the rate of biopiracy in the region, for instance, the Edmonds Institute commissioned a study on biopiracy in Africa. The report, prepared by Jay McGown, was published in 2006 and reported over 35 active cases of biopiracy across the continent. In 2013, Edward Hammond compiled

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427 Richerzhagen, Protecting Biodiversity, supra note 6.
428 See Mgbeoji, Global Biopiracy, supra note 19 at 87 – 117
429 Ibid.
430 Ibid.
431 Ibid. See also, Bita Amani, noting this alienation of the contributions of indigenous communities through the formal Western IP system. Bita Amani, State Agency & the Patenting of Life in International Law: Merchants & Missionaries in a Global Society (UK: Ashgate Publishing Limited, 2009) [Amani, State Agency] at 40.
432 For the full report, see Beth Burrows, ed, Out of Africa: Mysteries of Access and Benefit Sharing – A Report by Jay McGown (Washington, USA: The Edmonds Institute, 2006) [Burrows, Out of Africa].
an extensive series of biopiracy cases in which again he demonstrated that some of the 2006 cases reported by McGown had continued to exist. In addition, a global range of new identified cases of biopiracy cutting across industry uses of GRs and TKaGRs in cosmetics, medicines, agriculture, microbes etc. were identified. For example, within the cosmetic industry, he reports of US giant, Avon’s active patenting of Asian plants which have traditionally been used to treat skin disorders across Asia, as major ingredients for its cosmetics. All this has been without any evidence of benefit sharing. Placing this exploitation in context, he notes that the skin cream market (which Avon operates in) is the largest segment of the global personal care products industry and was projected at $333 billion USD in 2015 annual sales. The skin care industry is worth roughly $90 billion USD per year. Avon is known to draw in about $11 billion in annual sales. What this kind of analysis succeeds in providing, is an early indication, from the perspective of the developing world, of the economic injustice captured within instances of biopiracy. In others words, the exploitative nature of biopiracy on which basis industries, and economies in the North continue to profit disproportionately from the use of resources located in the developing world.

In a 2014 study commissioned study by the United Nations Permanent Forum on Indigenous Issues (UNPFII), the former Chair of the UNPFII, Mr. Kanyinke Sena, similarly identified a range of biopiracy cases on the African continent. A prominent instance he cited was the case of the Endorois people in Kenya who had their GRs from the Lake Bogoria, taken by university researchers at the University of Leicester. This was subsequently patented by Genencor International Inc., which cloned the microbes on an industrial scale for textile companies, and detergent manufacturers with no economic returns being made to the

433 Such as the efforts of Rutgers University, based on funding received from the US Agency for International Development (USAID), to patent and profit from kombo butter – an extract of the African nutmeg tree (Pycnanthus angolensis) which has a wide variety of traditional medicinal uses in Central and West Africa. Hammond, Biopiracy Watch, supra note 50 at 17.
434 Ibid.
435 Such as the false daisy (Eclipta prostrata), elephant foot yam (Amorphophallus campanulatus), agate (Sesbania grandiflora), Pouzolzia pentandra, and soap nut (Sapindus rarak) Ibid. at 14.
436 Ibid. at 8.
437 Ibid. at 15.
438 Ibid. at 9.
Endorois. Estimates place the total value of the resource (now popularly used to bleach jeans) at $600 million USD per year.\textsuperscript{440}

In the hoodia case which I discussed in the introductory chapter, patents were secured on the hoodia plant based on the knowledge of the San Peoples. The projected market for dietary control in the United States alone was worth well over $3 billion USD. Though a benefit sharing agreement was eventually concluded, it was drawn up with terms which, unfortunately, given the late stage at which it was concluded, contained arrangements which were so disproportionate in value that nothing near an equitable sharing of benefits could have been suggested on the basis of a reasonable man test.\textsuperscript{441}

The flurry of instances of biopiracy within the African context has led Jay McGown, a renowned biopirate hunter, to the following conclusion:

\begin{quote}
[i]t's a free-for-all out there, and until the parties to the Convention on Biological Diversity (CBD) solve the problems of access and benefit sharing, the robbery will continue. They've got to declare a moratorium on access until a just protocol on access and benefit sharing is finished and implemented. Until they slog through that terrible work – and that includes all the hard questions indigenous peoples and local communities are asking and all the hard questions about the sources of biodiversity mentioned in patent applications – until that work is done, the biopirates will keep on shouting in the ears of their victims, "There's no such thing as biopiracy!" And, at the rate discussions are going, the biopirates and their associates may just be able to access everything there is before an agreement is finalized. If that happens, of course, there really may be no such thing as biopiracy. There will only be patent and trade secret transgression\textsuperscript{442}
\end{quote}

This conclusion was significantly made in 2006, at a time in which the negotiations for the Nagoya Protocol had just begun. McGown’s reflections suggest that the solution to biopiracy lies in the CBD’s ability to make the ABS system effective – an effort which culminated in the Nagoya Protocol. Indeed, it is this view that is challenged within this dissertation’s analysis as it places a coherent IP solution – coherent with the Nagoya Protocol – as a necessary element of any lasting solution to biopiracy. The above reflection also suggests that a gradual appropriation of resources through the mechanism of the IP system is ongoing – one which, if unchecked, will result in the complete privatization of global resources and their regulation through the IP system (as against the ABS regime). As I will establish in this chapter, the need for the IP

\begin{footnotes}
\item[440] Ibid. at 10 – 11.
\item[441] See, 1.1.2. above.
\item[442] Burrows, \textit{Out of Africa}, supra note 432 at iii.
\end{footnotes}
system to implement defensive measures that counter this appropriation of resources through the IP system is important as a complementary aspect to the Nagoya Protocol’s fight against biopiracy.

Africa is not alone in the discussion of biopiracy. Asia and South America have also been prominent victims of biopiracy. Thailand, for instance, has had to contend with the misappropriation of the Kwao Krua (*Pueraria mirifica*), a local herb whose medicinal use was first documented in Thai scriptures as far back as 1931, as well as the Plao Noi, another medicinal herb with early local documentation records. In South America, Mexico has had to contend with biopiracy cases such as the misappropriation of its Yellow Enola Beans, while Peru has contended with several cases including patents on the Maca and the Camu Camu. In the Amazon, the Ayahuasca (*Banisteriopsis caapi*), a native plant has been used by many indigenous groups for sacred and religious healing ceremonies through a hallucinogenic experience derived from the Ayahuasca. Again, this plant was the subject of biopiracy claims arising from the grant of a patent by the US Patent and Trademark Office for a purported ‘new and distinct’ specie of the plant (‘Da Vine’). India is however noted for some of the highest profile biopiracy cases, a prominent one of which involves the Neem tree.

The Neem tree is a popular indigenous tree in India. Dubbed by the United Nations as ‘the tree of the 21st century’, it has regularly been referred to as ‘the village pharmacy’, ‘the curer of all ailments’,

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444 Ibid. at 63 – 66.
448 See Robinson, *Confronting Biopiracy*, supra note 29 at 68 – 70.
449 See, for example, the controversial patents granted on Basmati Rice varieties, see Subbiah, “Reaping what they Sow”, *supra* 275, see also Ghosh “Globalization, Patents, & Traditional Knowledge, *supra* note 406 at 97 – 102. The controversy over the patent granted on the Turmeric Plant is another high profile case emanating from India. Ibid. at 93 – 96. See also Robinson, *Confronting Biopiracy*, supra note 29 at 47 – 49; again, see Schuler, “Biopiracy & Commercialization”, *supra* note 421 at 166 – 169.
and ‘the blessed tree’\textsuperscript{453} due to its amazingly wide range of uses. For centuries, its properties have been well known and utilized in India for purposes as diverse as pesticides, spermicides, and even toothbrushes!\textsuperscript{454} Its scientific name, the \textit{Azadirachta indica} literally translates as “the free tree of India”\textsuperscript{455} reflecting its free availability and use, and so it had been without doubt a practice that dates to over 4000 years in India, and as a result of which the tree has often been described as the village dispensary.\textsuperscript{456} Within the community, its use is noted as a cure for leprosy, malaria, cancer, respiratory disorders, sexually transmitted diseases as well as birth control, ulcers, infections like eczema, neuromuscular pain and inflammation, air purification, pest control etc.\textsuperscript{457} More recently, researchers seeking a cure for AIDS have taken a special interest in the neem given its antiviral and immune boosting qualities.\textsuperscript{458} The value of the Neem tree is therefore not in doubt.

With the exposition of some of its properties into the public domain, the privatization of the hitherto ‘free tree’ through IP rights began. Scientists believe that no other plant yields as many strange and varied products or has as many exploitable by-products as the neem.\textsuperscript{459} According to the Food and Agriculture Organization (FAO),

\begin{quote}
the wood is used to make carts, farm tools or even furniture. The heart-wood is very rich in tannin and in inorganic salts of calcium, potassium and iron. Nimatone, a turpentine-like liquid, and also a glossy resin, may be extracted from it. Many Neem extracts are effective against a large range of crop pests. Various insect-repellent products are extracted from the oil. The active principal in those products is Azidarachtine. The bark, leaves and fruit have been, from time immemorial, part of the Hindu pharmacopoeia; used for treating all sorts of ailments, from syphilis to leprosy to rheumatism. Neem leaves are sometimes consumed
\end{quote}

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\textsuperscript{453} See, Jere-Malanda, “Biopiracy”, supra note 452 at 18. Other names given to the Neem within India highlighting its potency include, ‘Divine Tree’, “Heal All”, “Nature’s Drugstore” and “Panacea for all Diseases”. In Sanskrit it is referred to as ‘Arishtha’, which means ‘reliever of sickness.’ See Rajesh Arora, Shikha Singh & RK Sharma, “Neem Leaves: Indian Herbal Medicine” in Ronald R Watson & Victor R Preedy, eds., \textit{Botanical Medicine in Clinical Practice} (UK: CAB International, 2008) [Arora et al, “Neem Leaves”] at 85 – 86. Given its immense potential it has also been described by some authors as ‘green gold’. Ibid. noting that its leaves represent a virtual gold mine for the industry as well as the common man.

\textsuperscript{454} See, Jere-Malanda, “Biopiracy” supra note 452 at 18, noting that the neem could be used as a toothbrush without the need for toothpaste given its antiseptic properties.


\textsuperscript{456} See Arora et al, “Neem Leaves”, supra note 450 at 86.


\textsuperscript{458} See, Jere-Malanda, “Biopiracy” supra note 452 at 18

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by livestock [...] It has been suggested that livestock browse Neem from time to time as a cure for some diseases.460

One of the most significant features of the Neem is its ability to protect itself from pests through a multitude of pesticide ingredients.461 When a massive plague of locusts attacked every tree and plant in Sudan in 1959, the neem tree alone stood untouched.462 During this onslaught by billions of locusts, the German entomologist Heinrich Schmutterer noticed that neem trees remained green and standing. Though the locusts settled on the trees in swarms, they always left without feeding. His inquiry and publication into this phenomenon sparked international attention on the neem’s unique qualities.463 Over 135 compounds have since been isolated from the Neem tree till date.464

W.R. Grace & Co., with its corporate headquarters in Columbia, Maryland, is described as a globally integrated product development and manufacturing company. According to its website,

[its] high-performance specialty chemicals and materials improve the products and processes of [its] customer partners around the world...in partnership with [its] customers, [it] develop[s], manufacture[s], license[s] and support[s] industry-leading technologies through [its] Catalysts Technologies and Materials Technologies business segments.465

W.R. Grace is specially noted as a world leader in the agrochemical industry. The neem tree was thus of extreme interest to the company. Alongside the United States Department of Agriculture (USDA), W.R. Grace secured a number of US patents on products and processes related to the neem tree.466 In particular, it filed for a patent on a process for making neem-based bio pesticides (including Neemix) with a shelf life of two years, for use on food crops in 1992. Neemix suppresses insect feeding behaviour and

463 Ibid. at 3. This is not to suggest that Schmutterer was the first to notice this, for Indian farmers had known this for centuries as well as Indian scientists who had published as far back as the 1920s information to this effect. It was however Schmutterer who drew international attention to its qualities. Ibid.
466 See, for instance, United States Patent Nos. 5,298,251 (A process for preparing fungicides derived from neem seeds or expressed neem oil), 5,372,817 (granted for a novel insecticide compositions prepared from neem seeds), 5,397,571 (An improved method of extracting neem seeds), 4,946,681 (a process for improving the shelf stability of the active pesticidal compound azadirachtin in neem seed extracts by selectively removing water from the extracts), etc. A quick preliminary search of the USPTO Patent Full-Text Database, returned over 25 neem-based patents held by WR Grace.
growth in more than 200 species of insects.\textsuperscript{467} Given the international scope of its operations, the company applied for and was issued patent protection by the European Patent Office (EPO).\textsuperscript{468} The patent disclosure described a method for controlling fungi on plants using a hydrophobic oil extracted from the seeds of the neem tree.\textsuperscript{469}

This patent was opposed by activists\textsuperscript{470} who contended that the patent lacked novelty due to prior public use of the process in India. This opposition claim was backed up with documentary and oral evidence of field trials of similar products conducted in India in the 1980s, as well as references to the scientific literature.\textsuperscript{471} In May 2000, the EPO’s opposition division found for the opponents, leading to a revocation of the patent.\textsuperscript{472} An appeal to the EPO Technical Appeal Board was similarly rejected in 2005.\textsuperscript{473} According to Shiva, ‘denying the patent [meant] upholding the value of ‘traditional' for millions of [people] not only in India but throughout the South. The free tree will stay free’.\textsuperscript{474}

Despite this grim picture of biopiracy, authors have been quick to caution against elaborated claims which lack empirical substantiation. Indeed, several of the cases of biopiracy are based on unclear evidence of benefit sharing (or the lack thereof). Hanne Svarstad thus suggests that biopiracy cases, and indeed, the biopiracy discourse, is largely based on knowledge that is external to individual cases and as such, ‘the

\textsuperscript{468} Patent number 436,257, issued on September 14, 1994.
\textsuperscript{470} Leading the campaign in the neem case was the European Union Parliament’s Green Party, India-based Research Foundation for Science, Technology and Ecology (RFSTE) and the International Federation of Organic Agriculture Movements (IFOAM). Fritz Dolder, (professor of IP at the University of Basel), Vandana Shiva (Indian anti-biotechnology activist), Magda Aevolet (then president of the Green grouping the European Parliament), and Linda Bullard (then vice president of the International Federation of Organic Agriculture Movements) were some of the leading figures in this quest. See Sheridan, “EPO Neem Patent Revocation”, supra note 469 at 511. See also BBC News, “India Wins Landmark Patent Battle” (March 9, 2005), online: BBC <http://news.bbc.co.uk/2/hi/science/nature/4333627.stm>.
\textsuperscript{471} Indian scientists had, for instance, published descriptions of the neem seed as far back as 1928. Also, in the 1960s, the Indian Agricultural Research Institute had found Neem’s potential use of pesticides.
\textsuperscript{473} BBC: India Wins Patent Battle, supra note 467.
\textsuperscript{474} Ibid. Summing up the import of this case, Jeremy Rifkin, president of the Foundation on Economic Trends noted, [w]hat many Americans have not realized is that the anger, frustration, and resentment in the developing countries against what they regard as piracy of their heritage is every bit as intense as the outrage that has been drummed up by the United States over the violation of our intellectual copyrights in the developing world

narratives produced are often based on rather weak empirical knowledge’.\textsuperscript{475} Furthermore, in suggesting that more positive (win-win) cases of bioprospecting exist, she observes that these success cases are less accessible as they are usually contained in anthologies and academic journals.\textsuperscript{476} Biopiracy, however, in which bioprospectors are portrayed as biopirates, occupies the populist stand given the ease of dissemination through NGO newsletters and electronic listervs.\textsuperscript{477} Indeed, for her the biopiracy narrative, as a counter narrative to the bioprospecting win-win narrative,\textsuperscript{478} supports the need for caution in overgeneralizing instances of misappropriation. In fact, a growing number of scholars have considered the issue of biopiracy to be out rightly exaggerated and not worthy of the attention that it continues to generate, including, in some instances, a rejection of its existential claims altogether.\textsuperscript{479}

While a cautious approach need be taken so as not to overgeneralize or exaggerate the problem, the reality of biopiracy to developing countries cannot be denied. It is telling that the majority of scholars and policy makers that reject the idea of biopiracy are based in and/or situated in the industrialized world. Giving primacy, however, to the views and efforts of developing countries, it is clear that biopiracy remains a serious issue of concern. On adopting the Nagoya Protocol, for instance, statements credited to some of the world’s most biodiverse countries suggest the centrality of eradicating biopiracy to the policy direction of several developing countries. Though mentioned in chapter two, I restate them below for emphasis. On the expected impact of the Nagoya Protocol, the Government of India pointed out that;

\begin{quote}
India has been a victim of misappropriation or biopiracy of our genetic resources and associated traditional knowledge, which have been patented in other countries…it is expected that the ABS Protocol which is a key missing pillar of the CBD, would address this concern.\textsuperscript{480}
\end{quote}

The Government of Mexico, also noted, upon ratification of the Protocol, its expectation that the Protocol

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\textsuperscript{475} Svarstad, “A Global Political Ecology of Bioprospecting, supra note 333 at 247.
\textsuperscript{476} Ibid.
\textsuperscript{477} Ibid.
\textsuperscript{478} Ibid.
\textsuperscript{479} See, for instance, James M Chen “There’s No Such Thing as Biopiracy…& it’s a Good Thing Too” (2006) 37 McGeorge Law Review 1 at 5.
\end{flushright}
A legal certainty regarding the use of genetic resources to indigenous and local communities, industries, pharmaceutical companies and researchers, by establishing measures to avoid misappropriation and misuse.\(^{481}\)

Again, in this context, the former Vice President of Indonesia, Prof. Boediono, in offering support for the ratification of the Protocol, noted that,

[\textit{\textbf{w}ith the [Nagoya Protocol], Indonesia will have a firm legal basis to protect and preserve its genetic resources and traditional knowledge related to genetic resources…}][\textit{\textbf{i}n addition, the law will also lay a legal basis for the country to prevent theft and illegal utilization of biodiversity}^{482}\]

These views underscore the centrality of the biopiracy concern to developing countries. It also shows that several developing countries view the Protocol as a beacon of hope in the fight to address biopiracy. Not only have developing countries expressed views around the eradication of biopiracy, a number of policy, administrative, and legislative approaches to addressing the incidence of biopiracy have been witnessed in developing countries which reflect the seriousness of the biopiracy issue to developing countries. In the next section, the experience of the government of Peru, is examined by way of example.

### 4.1.1 Peru’s Anti-biopiracy Commission

Peru is one of the world’s megadiverse countries, known for its rich biological and cultural diversity.\(^{483}\) Consequently, Peru represents a fertile ground for incidences of biopiracy both in terms of the

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\(^{483}\)Home to approximately 28 million people, it possesses a significant indigenous population – about nine million, which represents one-third of the country’s inhabitants. See \textit{Combating Biopiracy – The Peruvian Experience}, WIPO/GRTKF/IC/11/13, WIPOOR, 2007 \textit{[The Peruvian Experience]} Annex at 1. According to the recorded statistical data on the indigenous Peruvian population, current to 2007, there are 8,793,295 natives, of whom 97.8 per cent are Andean (of whom 90.9 per cent are Quechuan and 6.9 per cent Aymara) and 2.1 per cent are Amazonian. According to these figures, the indigenous population represents one-third of the country’s inhabitants. This indigenous population lives mainly in the country’s rural area, grouped together in 5,812 rural communities (Andean) and 1,315 native communities (Amazonian). Regarding the wealth of biodiversity, there are thought to be around 20,000 higher plant species in Peru (10% of the world’s total), of which 5,509 are endemic (approximately 27%) (Leon, B., 2006). It ranks fifth in the world for number of species, first for number of plant species with properties known and used by the population (4,400 species) and first for native domesticated species (128). It has 182 domestic native plant species, with hundreds or even thousands of varieties, of which 174 are of Andean, Amazonian and coastal origin and 7 are of American origin, having been introduced centuries ago. In addition, it has the wild forms of these plants…[t]he number of species with a current or potential industrial application is high at 2,642. Of those species, 682 are sources of food, 1,044 are medicinal, 444 provide timber resources, 86 are forage plants, 55 are used to obtain fertilizers, 60 are used in oils and fats, 46 in aromas and perfumes, 75 in cosmetic products, 22 in tanning products, and 128 in dyes and colorants. The country ranks very highly in terms of fruits (623 species), medicinal plants (1,408 species) and ornamental plants (1,600 species). Ibid.
resources available and the TK associated with use of such resources held by the population. In response to the incidence of biopiracy within Peru, the National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples (National Anti-Biopiracy Commission) was established in 2004. Since its inception, the National Anti-Biopiracy Commission has been engaged in ‘the [identification] and follow up [with] patent applications filed or patents granted abroad that relate to Peruvian biological resources or to collective knowledge of the indigenous peoples of Peru’. Based on a description of the work of the National Anti-Biopiracy Commission, the following requirements have served to guide the work of the Commission in its identification of cases of biopiracy: the volume of internal and external commercialization of the resources, the endemism of such GRs, as well as consideration of pending and/or granted patent applications. Consequently, a main driving force prompting the Peruvian government’s intervention in the issue of biopiracy is the concern over the appropriative and predatory prescriptions of the IP system over the resources and knowledge of peoples within its territories. The Peruvian government thus argues that,

> [t]here is an urgent need to rethink the patent system and to consider how to make it more balanced. The current intellectual property system does little to ensure fair and equitable compensation for benefits derived from the use of genetic resources and traditional knowledge. Although it is true that the patent system does not have the function of guaranteeing compensation for benefits and regulated access to genetic resources, it is necessary to create synergies between these needs and the functionality of the system in order to make it a fairer system.

The creation of synergies between the ABS regime and the IP regime (particularly the patent system) thus constitutes a critical practical requirement in national efforts to address the problem of biopiracy. Other administrative measures which have been taken by developing countries in response to the incidence of biopiracy (also forming part of efforts to promote the synergy between the ABS and the IP regime), include India’s defensive approach, through which it has embarked on the successful development of a Traditional Knowledge Digital Library (TKDL). The TKDL is a massive project which compiles

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484 Ibid. at Annex at 2.
485 Ibid. at Annex at 4.
486 Ibid. at Annex at 11.
existing traditional medical knowledge (TMK) practices in India within a single database for the purpose of preventing third party IP claims to India’s TK; it is discussed next as yet a different national response.

4.1.2 India’s Pioneering Documentation System

The Indian Council for Science and Industrial Research (ICSIR) cites the TKDL as a ‘pioneer initiative of India to prevent misappropriation’ which was inspired by significant incidents of biopiracy between 1990 and 2000. It is a dynamic database, rather than a comprehensive one, where formulations are constantly being added and updated according to inputs from users. The features of the TKDL give an idea as to the size of the project: the database contains over 1200 formulations; includes information on over 291 plants which are used as ingredients in these selected formulations to treat over 186 diseases; and contains information in over 34 million pages. The TKDL is made accessible and searchable through a unique and innovative classification system – Traditional Knowledge Resources Classification (TKRC) – which is a sui generis classification system based on the International Patent Classification system (IPCS). The ICSIR estimates that prior to the TKDL, about 2000 patents based on Indian systems of medicine were wrongly being granted annually, facilitated by the inability of international patent

487 Saikat Sen & Raja Chakraborty, “Traditional Knowledge Digital Library: A Distinctive Approach to Protect and Promote Indian Indigenous Medicinal Treasure” (2014) 106:10 Current Science [Sen & Chakraborty, “TKDL"] at 1341, who note that the instances of biopiracy witnessed between 1990 and 2000, particularly patents on the turmeric (No.5,401504 in 1995), basmati rice (No. 5663484 in 1997) by the USPTO, and the neem (No. 436257) by the EPO, led to the formulation of a collaborative and multi-agency task force to prevent misappropriation of Indian TK at international patent offices. The TKDL was the outcome. See also, WIPO Magazine, “Protecting India’s Traditional Knowledge” (June 2011) online: WIPO <http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html> [WIPO Magazine, “Protecting India’s TK”], noting that though the challenge of the cases were successful, they proved extremely costly and time-consuming. The TKDL was therefore a mechanism which would also promote efficiency in addressing instances of biopiracy.

488 Ibid.

489 Ibid. See also, WIPO Magazine, “Protecting India’s TK”, supra note 487.

490 Ibid. at 1342. Established by the Strasbourg Agreement Concerning the International Patent Classification, 1971, the International Patent Classification (IPCS) provides for a hierarchical system of language independent symbols for the classification of patents and utility models according to the different areas of technology to which they pertain. A new version of the IPCS enters into force each year on January 1. The IPCS divides technology into eight sections with approximately 70,000 subdivisions. Such classification is indispensable for the retrieval of patent documents in the search for ‘prior art’. Such retrieval is needed by patent-issuing authorities, potential inventors, research and development units and others concerned with the application or development of technology. See, WIPO, “International Patent Classification (IPC)” online: WIPO <http://www.wipo.int/classifications/ipc/en/>. Prior art refers to the references which prove that an invention is ineligible for patent protection. See, Vincent M Smoczynski “Willful Patent Filing: A Criminal Procedure Protecting Traditional Knowledge” (2010) 85:10 Chicago-Kent Law Review, 1171 at 1180.

examiners to access and/or comprehend the locally documented traditional medical knowledge of the Indian people.\textsuperscript{492} The TKDL addresses this challenge by making the documented records (over 0.29 million medicinal formulations) available upon request to patent offices in five international languages: English, Japanese, French, German, and Spanish.\textsuperscript{493} It is based on 359 books of Indian Systems of Medicine and serves as a bridge between these books and international patent examiners. Through an access and non-disclosure agreement, patent offices are granted access to the contents of the TKDL, as evidence of prior art.\textsuperscript{494} It is presently available to nine international patent offices\textsuperscript{495} and constitutes an example of a defensive mechanism to prevent biopiracy.

It has recorded tremendous success in this regard in its years of operation.\textsuperscript{496} Emphasizing the success of the TKDL, the ICSIR notes, “TKDL is proving to be an effective deterrent against biopiracy and is being recognized as a global leader in the area of traditional knowledge protection”.\textsuperscript{497}

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\textsuperscript{492} Sen & Chakraborty, “TKDL”, \textit{supra} note 487 at 1341, noting the documentation of ancient literature contained in Sanskrit, Hindi, Arabic, Persian, Tamil etc. See also, WIPO Magazine, “Protecting India’s TK”, \textit{supra} note 487, explaining:

\begin{quote}
when patent examiners assessed these applications for patentability, the claimed inventions did not feature in the prior art searches carried out. They were, therefore, deemed patentable. At that time, however, much of India’s traditional medicinal knowledge only existed in Sanskrit, Hindi, Arabic, Urdu and Tamil. These languages were neither accessible to nor understood by patent examiners working in the major patent offices to which the applications had been submitted.
\end{quote}

\textsuperscript{493} It is expected that it will be available in 20 foreign languages in the future, as well as in all Indian languages. Ibid.

\textsuperscript{494} As part of the access agreement, patent offices are obligated to make use of the TKDL for only patent searches and examination, and unless such is required for patent search and examination, are not permitted to make any third party disclosure of TKDL contents. Ibid.


\textsuperscript{496} See generally, Sen & Chakraborty, “TKDL”, \textit{supra} note 487 at 1342 noting its role in the successful prevention of biopiracy. According to WIPO, since July 2009, 215 patent applications relating to Indian medicinal systems for which third party TKDL evidence has been filed have been identified. In two such cases the EPO has already reversed – on the strength of TKDL evidence – its earlier intention to grant the patents. In one case the applicant modified the claims submitted and, in 33 other cases, the applicants themselves withdrew their four to five-year-old applications upon presentation of TKDL evidence. WIPO Magazine, “Protecting India’s TK”, \textit{supra} note 487. A recent study by a TKDL expert team at the EPO shows a sharp decline (44 percent) in the number of patent applications filed concerning Indian medicinal systems, particularly in relation to medicinal plants. Ibid.

\textsuperscript{497} See, “Traditional Knowledge Digital Library”, online: CSIR <http://www.csir.res.in/external/heads/TKDL/main.HTM>. According to WIPO, summing up the success of the TKDL:

\begin{quote}
[t]oday, thanks to its TKDL, India is capable of protecting some 0.226 million medicinal formulations and at zero direct cost. Access to the database helps patent examiners root out those applications that clearly do not satisfy the novelty requirement at an early stage. Without a TKDL database, the process of revoking a patent can be a costly and time-consuming affair. It takes, on average, five to seven years and costs between 0.2-0.6 million US dollars to oppose a patent granted by a patent office. Multiply this by India’s
\end{quote}
it has taken a pioneering role in the defensive protection of TK. Indeed, this leadership role has witnessed the endorsement, at the international level, of its standards and specifications as a model for setting up of TK databases round the world. Furthermore, its innovative classification system, the TKRC, has led to changes in the IPCS and a corresponding improvement in the quality of the search and examination of TK based prior-art.

The documentation of TK through databases, such as the TKDL, has however not gone without criticism. While, as in the Indian example, the TKDL is being heralded as an important defensive mechanism securing the interests of the indigenous peoples, counter arguments and concerns have been raised with regard to databases constituting vehicles for misappropriation. Indeed, concerns have been raised about documentation and its potential effects on the rights, culture, and livelihoods of indigenous peoples. Such concerns include the potential placing of TK within the public domain through the very act of documentation; the possible loss of control for indigenous communities arising from third-party access to databases in which TK is stored; the range of IP rights, particularly copyright and other related rights, that would accrue to third parties who may participate in the process of documentation; the loss of the secret nature of some TK practices; amongst others. Possible instances of the unwarranted disclosure of the

0.226 million medicinal formulations and it is clear that the cost of protection, without a TKDL, would be prohibitive [emphasis added].

WIPO Magazine, “Protecting India’s TK”, supra note 487.

498 See, “Traditional Knowledge Digital Library”, online: CSIR <http://www.csir.res.in/external/heads/TKDL/main.HTM>. See also, Sen & Chakraborty, “TKDL”, supra note 487 at 1343 noting that the TKDL has been chosen for a pilot study by 170 member states of WIPO. Having organized several study visits for interested participants, a number of countries and organizations, such as South Africa, Mongolia, Nigeria, Thailand, Malaysia, have expressed their eagerness in replicating the TKDL in their home countries. The attendant costs of compiling and maintaining such a database however serves as a deterrent for many.

499 As WIPO notes, the TKRC, which is modelled on WIPO’s IPCS, has prompted the reform of the IPCS as it relates to TK. Until 2005, only one subgroup existed for medicinal plants, meaning that patent examiners were ill equipped to examine traditional medicine-based patent applications. India took up this matter, and following the establishment of a five-nation “Traditional Knowledge Classification Task Force” – comprising China, the European Union, India, Japan, and the United States – the number of IPCS subgroups relating to medicinal plants rose to 207, bringing about a fundamental reform of the IPCS. In 2004, it was agreed to link the TKRC’s 27,000 subgroups to the IPCS. See, WIPO Magazine, “Protecting India’s TK”, supra note 487.

500 See, WIPO, The World Intellectual Property Organization Traditional Knowledge Documentation Toolkit: Consultation Draft November 1, 2012, online: WIPO <http://www.wipo.int/export/sites/www/tk/en/resources/pdf/tk_toolkit_draft.pdf> at 6 – 7. Noting, for instance, concerns raised by the Venezuelan Indigenous Council at the 5th Sess of the WIPO IGC, who pointed out that the indigenous peoples of Venezuela felt that cataloguing of their TK ran counter to their culture and also that it would fragment their vision of the universe where there could be no separation between knowledge of the earth and knowledge of religion. Importantly, they considered that they would lose control over their TK if it were to be catalogued.

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database’s contents through system hacks, leaks, or even court injunctions in cases of disputes, has underlined security concerns regarding the consequences and irretrievability of hitherto secret TK and practices which could be exposed to the public through system failures. Within the context of the developing world, where a lack of strong infrastructure exists, such concerns cannot be overlooked. Even where infrastructure could be said to exist within industrialized countries, the recent instances of system hacks within the developed world continue to point to the vulnerability which will necessarily accompany the documentation of TK practices as the sole method of protection.501 Worse still, is that in several of the instances of system hacks, it is a common outcome that the hack is not discovered for lengthy periods of time – periods within which major information could be taken away and utilized to the advantage of any person privileged to gain access to such.502

Another key criticism of the database is that it presents an extremely difficult system to replicate within developing countries, especially given the dearth of human, financial, and technological capacity needed develop, manage, maintain, and advance such a project domestically. It could therefore result in a government/indigenous peoples’ over reliance and dependence on technological experts from developed countries for the guarding of their heritage. Third, the documentation of TK through databases and registers

501 See, for instance, Tim Greene, “Biggest Data Breaches of 2015: From Ashley Madison to VTech It Has Been a Nasty Data Breach Year” (December 2, 2015) online: Network World <http://www.networkworld.com/article/3011103/security/biggest-data-breaches-of-2015.html> identifying some of the top hacks of databases in 2015 Examples of hacks considered fool proof, include, those of Ashley Madison, a secret extra marital affair website, where over 37 million customer records including passwords were compromised; the United States Office of Personnel Management also suffered hacks to personnel records on over 22 million current and former federal employees; the second largest health insurer in the United States, Anthem Inc. also had its database hacked in 2015, the consequence of which was that personal information for 80 million people, including 60 – 70 million of its own current and former customers and employees, was compromised. See, Anna Wilde Mathews, “Anthem: Hacked Database Included 78.8 Million People” The Wall Street Journal (February 24, 2015): online: The Wall Street Journal <http://www.wsj.com/articles/anthem-hacked-database-included-78.8-million-people-1424807364> noting the severity of the hack.

502 According to Kelly Jackson Higgins, “it takes the average attacker less than 10 seconds to hack in and out of a database -- hardly enough time for the database administrator to even notice the intruder. So it’s no surprise that many database attacks go unnoticed by organizations until long after the data has been compromised See Kelly Jackson Higgins, “Hacker’s Choice: Top Six Database Attacks: It Doesn’t Take a Database Expert to Break into One” (August 5, 2008) online: Information Week <http://www.darkreading.com/risk/hackers-choice-top-six-database-attacks/d/d-id/1129481/>. In most instances, the periods within which the hacks had gone unnoticed, ranged from days, to months, to even years. In some cases, it remains unclear how long the systems had been hacked for. Tim Greene, “Biggest Data Breaches of 2015: From Ashley Madison to VTech It Has Been a Nasty Data Breach Year” (December 2, 2015) online: Network World <http://www.networkworld.com/article/e3011103/security/biggest-data-breaches-of-2015.html>. 

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cannot stand alone as an effective strategy for protecting TK.\textsuperscript{503} Even the TKDL is considered only a first step within the comprehensive TK protection policy of India. According to Dr. V. Gupta, the Chairman of the TKDL of India,

\begin{quote}
[d]efensive measures must be supplemented by positive measures, such as benefit sharing, in order to provide adequate protection for TK holders. Therefore […] a positive legal protection framework should complement TKDL systems, in order to safeguard the interests of TK holders. At national and regional levels, work is under way for \textit{sui generis} protection frameworks, which will protect TK, whether disclosed or undisclosed, against misappropriation in form of commercial use without benefit sharing.\textsuperscript{504}
\end{quote}

This point underscores the central importance of effective legal and policy developments which support such administrative documentation measures. The development of legislation on the protection of TK has however remained a challenge within the developing world. Consequently, taking on the documentation of TK could result in more harm than good where the development of legislative frameworks is not principally addressed.

In this context, several developing countries have sought to address biopiracy through the enactment of legislation targeted at preventing the misappropriation of TKaGRs and GRs by spelling out conditions for access and benefit sharing. Ethiopia, Uganda, Zambia, Kenya, South Africa, Brazil, and India, to name a few, are some of the developing countries that have taken the lead in this regard.\textsuperscript{505} Major difficulties encountered to this end have been the lack of capacity by several developing countries to develop legislation implementing ABS obligations arising from the complexity of the ABS mechanism, lack of relevant institutional frameworks, poor coordination between government departments, and, in some cases, the incessant political cycles. Kenya offers an excellent example such difficulties faced in the development of relevant legislation.


\textsuperscript{505} For an up to date overview of legislative and regulatory efforts with respect to the protection of TK and GRs, see the Access and Benefit-sharing Clearing-house (ABSCH), which serves as an accessible platform established by the Nagoya Protocol for exchanging information on ABS. Online: CBD \texttt{<https://absch.cbd.int/>}. 151
4.1.3 Kenya’s Legislative Example

In August 2016, the Kenyan parliament finally passed into law the *Protection of Traditional Knowledge and Traditional Cultural Expressions Bill, 2015* [Kenya TK Law 2015]. The Constitution of Kenya obliges the State to protect the indigenous knowledge relating to biodiversity and the GRs of communities, as well as encourage the participation of indigenous communities in the management, protection and conservation of the environment.\(^{506}\) Based on this, the *Kenya National Policy on Traditional Knowledge, Genetic Resources, and Traditional Cultural Expressions, 2009* [Kenya National TK Policy] was developed by Kenya’s Taskforce on Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources.\(^{507}\) The policy, it should be mentioned, emerged within a broader environmental regulatory context for GRs in Kenya. Pursuant to the 1999 *Environmental Management and Coordination Act* (EMCA),\(^{508}\) the *Environmental Management and Coordination Regulation* (EMCR) was promulgated in 2006.\(^{509}\) This EMCR was significantly, the effort of the Kenyan National Environment Management Authority (NEMA), an administrative and policy body established by the EMCA.\(^{510}\) These regulations provide a detailed regulatory framework for the access to, as well as protection and conservation of, GRs. The regulations are not explicit on the protection of TK, focusing primarily on GRs. However, the regulations consistently make reference to the ‘intangible components’ of GRs, defined as ‘...any information held by persons that is associated with or regarding genetic resources within the jurisdiction of Kenya’.\(^{511}\) This notably incorporates TK, though the provision does not limit the category of ‘intangible components’ of GRs to TK alone.

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506 See Section 69(1)(c) – (d), Constitution of Kenya.
510 The EMCA establishes the Kenyan National Environment Management Authority [NEMA] (See Section 7 EMCA) with responsibility to issue guidelines and prescribe measures for the sustainable management and utilization of GRs of Kenya for the benefit of the people of Kenya (See Section 53(1) EMCA).
511 See, Section 2 EMCR 2006.
The lack of clarity in principles governing the regulation of TK led NEMA to set up a task force for the development of laws for the protection of TK, GRs, and folklore within Kenya. The outcome of this initiative was the 2009 Kenya National TK Policy referred to above. Placing the protection of TK at the heart of its long term development vision, the policy provided a ‘national framework for recognition, preservation, protection, and promotion of sustainable use of TK, GRs, and TCEs for the purpose of enhancing the mainstreaming of such knowledge systems into national development planning and decision making processes at all levels. Its policy strategy sought a comprehensive system of TK protection which addressed past, continuing and future uses of TK, and underpinned its approach with ten guiding principles, which included, amongst others, prior informed consent, equitable benefit sharing, compensation, sustainable development, and respect. Based on the National TK Policy, the conclusion of a draft bill was pursued and eventually passed into law in August, 2016. The comprehensive Act establishes criteria for the protection of TK and importantly provides for the establishment of a national TKDL, ‘in the interests of transparency, evidence, and the preservation of TK’. As part of this venture, it provides that the TKDL shall be

a collaborative program between agencies responsible for copyright, industrial property rights, the Ministry responsible for culture, sports and performing arts, Ministry responsible for education, science and technology, the National Museums of Kenya, the National Commission for Science, Technology and Innovation, the Kenya Plant Health

512 See Kenya Gazette Notice No. 1415 of 2006.
513 See, Kenya National Policy, supra note 504 at 5 (para. 1.1.8), noting that the Policy has been informed by the Vision 2030 of the country, which aims to create a ‘globally competitive and prosperous country with a high quality of life by 2030’.
514 Ibid. at 5 (para. 1.1.10).
515 Ibid. at 3.
516 Ibid. at 7 – 8.
517 With the adoption of the Policy, the mandate for the Taskforce was taken over by the Kenyan Copyright Board (KECOBO). It quickly identified, in collaboration with the Kenya Industrial Property Institute (KIPI), a central objective of concluding a draft bill on TK based on the policy. An Inter-Ministerial Expert Working Group, was established for the purpose of elaborating this draft bill. In May 2013, the draft bill was presented at a National Validation Seminar, organized and hosted by the KECOBO for the purpose of receiving stakeholder commentaries on the draft provisions. Indigenous peoples, community leaders, government officials and, civil society representatives were in attendance. The Validation Seminar incorporated a session for grouped thematic discussions by participants of the substantive provisions, with opportunities given at the end for responses and observations. Suggestions were incorporated into the draft bill by a local consultant engaged for this purpose. Three years later, in 2016, the draft bill was passed into law. It remains to be seen at this early stage, the impact which this will have on the protection of TK within Kenya.
519 See, Section 6(2), Kenya TK Law, 2015.
Drawing from Gupta’s earlier point, therefore, the pursuit of the TKDL in Kenya is importantly being centered within a broader legislative strategy. While this legislative effort by Kenya must be commended, and does reflect the extent to which developing countries are pursuing legislative solutions to biopiracy within their territories, it also highlights the difficulties which have accompanied the legislative process.

A significant difficulty is the internal complexity which makes biopiracy legislation difficult to enact. There is, for instance, the difficult issue of multiple government agencies seeking to take the lead on issues of TK protection. The compromise approach by which the law will be a ‘collaborative program’ between several ministries reflects on the difficult terrain within which biopiracy-related legislation emerges within national contexts. Importantly, this also reflects the international landscape wherein, as I will show in the next section of the chapter, biopiracy is an issue which transcends any single or singular regime. While my focus in this thesis has been the analysis of the international dimension of these regimes, this point also reflects in the national experiences, where ministries across the environment, culture, tourism, IP etc., often jostle for prominence in efforts to secure administrative rights over the protection of TK. This interest by several ministries often gives rise to a complex terrain within which anti-biopiracy

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520 See, Section 6(4), Kenya TK Law, 2015. I was privileged to assist the government of Kenya in the development of this legislation, including chairing and facilitating a group discussion within the validation seminar, as well as engaging and supervising the local consultant who worked on the finalization of the bill. A significant point from the legislative process should be mentioned here. The difficult road to the finalization of the Law, evidenced, amongst others, by the prolonged period for the passage of the bill into law highlighted major overlaps within the governmental departments, and agencies which sought to stake claims of central relevance in the development and eventual implementation of the law. Probably one the most visible areas of this contestation was in the establishment of the National Competent Authority (NCA) for the administration of provisions of the Act. [See, Section 4, Kenya TK Law, 2015]. While in the final Act, the provisions relating to the establishment of an NCA were omitted, it had played a significant part in the discussions of the draft bill, including at the validation seminar. The difficulties in clarifying roles and levels of involvement for respective agencies posed a significant challenge. In the final Act, as a way of addressing these significant administrative responsibilities are distributed within the NCA, and a team of “lead agencies”.
laws emerge.\footnote{521} This complexity has been highlighted as one of the reasons for which ABS laws have been difficult to develop, particularly in developing countries.\footnote{522}

**4.1.4 Regional Approaches**

At the regional level, regions have adopted measures to counter the regional incidence of biopiracy. The Andean Community of Nations Common Regime of Access to Genetic Resources came into force in 1996 and constitutes one of the most elaborate regional framework yet formulated to address ABS.\footnote{523}

Within Africa, the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (AML) was adopted by the Africa Union in 2000 and entered into force in 2003.\footnote{524} The AML provides a legislative model for African States, especially with regard to the protection of TKaGRs.\footnote{525} Also in Africa, albeit on a regional IP platform, the Swakopmund Protocol\footnote{526} was enacted in 2010 to address, inter alia, the incidence of biopiracy through a regional protection mechanism for TK holders.\footnote{527} A central underlying concern which prompted the negotiation of the Protocol is the ‘unlawful exploitation and misappropriation of traditional knowledge’ and the recognition of the rights of TK holders to ‘effective and efficient protection against all acts of misuse, unlawful exploitation or misappropriation of their knowledge.’\footnote{528}

\footnote{521} Often times, the ability to increase the portfolio of a ministry is associated with its potential viability and reflects in government decisions regarding allocation of funding, merging of ministries based on redundancy, etc. In effect, therefore, the protection of TK from biopiracy is one of those issues which, given its trans-regime nature, is also at the centre of struggles across government departments.

\footnote{522} Morten Tvedt & Tomme Young, *Beyond Access*, supra note 423 at 1 (especially note 3) & 16.


\footnote{525} See Garforth K, Noriega I, Medaglia J, Nnadozie K & Nemoga G *Overview of the National and Regional Implementation of Access to Genetic Resources and Benefit-Sharing Measures* (2005) 26 3ed. Centre for International Sustainable Development Law (CISDL). Significantly the terminology employed in the African Model Law slightly differs from that used under the Nagoya Protocol. In attempting to draw parallels though, TK is accorded a communal meaning as Community Knowledge (CK), while genetic resources are viewed within the larger scope of biological resources. Though differences exist in the strict definition of these terms (especially as CK refers to a collectively held TK, and genetic resources merely form a part of biological resources), for the sake of this research, they are construed in interchangeable terms. The point must be made though that this use of terms implies a wider scope in the African Model Law than under the Protocol.

\footnote{526} See, *supra* note 254.

\footnote{527} See Article 1.1. (a).

\footnote{528} See paras 7 – 8, preamble, Swakopmund Protocol
What the above discussion demonstrates is that biopiracy indeed continues to exist as a challenge for the developing world. A range of approaches, including positive and defensive approaches, through a range of measures, including administrative, policy, and legislative measures, have been developed to address this problem. It is in the context of estimated losses to developing countries arising from the commercial exploitation of their resources in foreign jurisdictions, without adequate compensation, that authors like Crookshanks & Phillips suggest estimates of the United States indebtedness to developing countries pegged at approximately US$302 million annually for agricultural products and US$5.1 billion annually for pharmaceuticals, were the US required to pay fair royalties on biopiracy by users within its territory.529

4.2 Two Sore Spots of Emphases

While these foundational discussions on biopiracy, including the important contexts of its occurrences are critical and must remain close through this analysis, it is worth noting that four key actors are generally implicated within the biopiracy debate: industry (including academic researchers involved in natural product research), indigenous peoples, sovereign states and civil society. The fractious yet important relationship between these camps continues to serve as a source of allegations and counter-allegations around the occurrence of biopiracy. In framing these allegations of biopiracy, the above case discussions, including the stylized renditions of biopiracy and the national efforts to address the problem of biopiracy, seemingly place emphasis on two critical contentious points: the benefit sharing challenge and the IP challenge. These critical points which I would like to describe as biopiracy’s ‘sore points of emphases’ are briefly discussed next.

4.2.1 A Benefit Sharing Failure

First, within cases of biopiracy is the social and legal emphasis on a failure to share benefits. Within the case of the hoodia which I discussed in chapter one,530 the significant problem which defined the

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530 See, 1.1.2. above.
biopiracy allegations was the concern that benefits arising from the use of the hoodia had not been shared with the San peoples. Indeed, confirming this point, the ability of the South African CSIR to eventually work out a benefit sharing arrangement, was a significant factor which served to greatly assuage the biopiracy allegations. In this context, the failure of the benefit sharing mechanism to adequately compensate the historical efforts, role, and contributions of indigenous groups in the maintenance and development of biodiversity serves as a foundation for biopiracy. This emphasis, which is seen in the moral outrage arising from the reports of several biopiracy cases, focuses on the economic exploitation of indigenous groups. Within the context then of global market possibilities, the non-compensation or inequitable compensation of providers is often flagged as an indicator of biopiracy.

On the one hand, this inequitable compensation is largely a social conceptualization, driven by activists and NGOs sympathetic to indigenous rights, which are able to arouse public interest based on an appeal to moral and ethical sensitivities. The realization, for instance, that a corporation could potentially fetch over a billion dollars in global market sales while the community from whom its ideas and resources were obtained remain trapped in poverty is a story that is definitely bound to evoke public sympathy for indigenous groups and could, in extreme cases, lead to a blacklisting of indicted corporate actors within the global markets. It underscores a desire to ensure ‘fairness’ and ‘justice’ to indigenous groups and providers who are typically victims of larger corporations who seek to exploit their knowledge and resources. The idea of benefit sharing is a mechanism that arose to address this inequitable compensation concern.

This benefit sharing conceptualization is, however, not only based on moral or ethical foundations. The 1992 adoption of the CBD and indeed the more recent adoption of the Nagoya Protocol, provide legal foundations in international law for the sharing of benefits. Furthermore, the rights of indigenous peoples, as enshrined within the UNDRIP, offers a legal platform for expectations around the implementation of the principles underlying the ABS regime – notably, the principle of prior informed consent (PIC), and that of mutually agreed terms (MATs). Concluding this thought, the benefit sharing emphasis on the problem suggests a resolution for the problem of biopiracy could lie in an improved mechanism of benefit sharing; one which ensures that indigenous peoples are adequately compensated whenever their resources and knowledge are appropriated. Developing countries have thus sought ways of ensuring the effective
implementation of benefit sharing mechanisms as solutions to biopiracy. The conclusion of the Nagoya Protocol as an instrument to implement the benefit sharing objective of the CBD, was pursued in this context.

4.2.2 Intellectual Property as a Channel of Appropriation

A second sore point of emphasis in the conceptualization of biopiracy, which is of equal importance, is the repeated emphasis on the IP system as a tool of appropriation. This is extremely important as it goes beyond a recognition of the historical stewardship role of indigenous peoples, but rather centers the question of ownership and property rights. Within the literature, a lot of emphasis has typically been placed on the IP system within discussions on biopiracy. As noted earlier in chapter one, the IP system through its ingenious mechanism of reward directed at spurring innovation, assigns legal rights of ownership for inventions that are new, capable of industrial application, and are the product of an inventive activity. The IP system therefore bears a social obligation to identify and assign in a fair manner private exclusive rights to inventors. In the context of biopiracy then, and as seen in Schuler’s stylized story of biopiracy, the IP system is seen as a vehicle of biopiracy where it assigns private rights over knowledge, and or resources which do not fulfill this criteria – especially which do not reflect something new. The above-discussed story of the neem tree is useful in explaining this. Similarly, the novelty of the patent held on the P57 in the story of the hoodia was also raised, even though it was never challenged. What these examples show are concerns around the working of the IP system, and how its appropriative mechanisms serve as a central indication of biopiracy. Particularly, the seemingly limited ability of the IP system to distinguish between inventions that are actually new, and those that constitute mere (re)discoveries of

531 Indeed, it is worth pointing out that this problem of ‘bad’ patents is not limited to cases relating to GRs. See, Amani, State Agency, supra note 431.

532 Viviana Munoz Tellez of the IP-NGOs Project within the School of Law, Queen Mary, University of London, notes that the validity of the patent granted to the CSIR was questioned for lack of novelty. It, however, was never legally challenged, as the priority of most NGOs involved in the Hoodia case was to ensure that the San people enjoyed a significant amount of the benefits derived from its commercialization and obtained proper recognition within the South African legal framework of the rights of the San indigenous people concerning their TK of the properties and use of Hoodia. See, Viviana Munoz Tellez, “Recognizing the Traditional Knowledge of the San People: The Hoodia Case of Benefit-sharing”, online: IPNGOS <http://www.ipngos.org/NGO%20Brie fings/Hoodia%20case%20of%20benefit%20sharing.pdf> [Tellez “The Hoodia Case of Benefit Sharing]. Arewa however explains that the requirement of inventive step within the patentability conditions meant that the Hoodia cactus as used by the San wasn’t patentable. Isolation of the P57, however represented an inventive step which made the knowledge about the P57 patentable. Arewa, “Piracy, Biopiracy & Borrowing”, supra note 37 at 15.
ancient indigenous practices has placed the proprietary mechanism of the IP regime in a negative spotlight vis-à-vis the protection of TKaGRs.533 Indeed, several authors have adopted instances of bad patents based on existing TK as a useful standard for analyzing the existence of biopiracy. As shown as in the examples of the Peruvian Anti-biopiracy Commission, and the Indian TKDL, developing countries have also placed this consideration at the center of their conceptualizations of biopiracy.

Two implications of IP’s role in facilitating biopiracy vis-à-vis the developing world are worth noting. On the one hand, this interpretation places the IP system in a precarious position within the developing world where it is considered a tool of oppression, designed for institutionalizing the transfer of rent from developing countries to industrialized countries.534 The consequence of this narrative is an outright rejection of the IP system and the continued viewing of its mechanism with palpable suspicion by third world actors. Several indigenous authors and activists adopt this position.535 Alternatively, however, the appropriative tendency of actors utilizing the IP system to secure rights on discoveries based on existing indigenous experiences can be viewed within the context of the limitations of the IP system being exploited by the dubious acts of innovators. In this regard, knowing the limitations of patent offices in investigating claims of novelty arising over TK, some western innovators have sought to exploit this loophole, hence biopiracy. The effect of this latter conception, has witnessed indigenous groups and developing countries adopt a cooperative stance to the possibility of utilizing the IP system as a preventive mechanism against the incidence of biopiracy. Indeed, the thrust of my analysis of the WIPO negotiations in chapter six addresses this effort by developing countries.

What the above discussion then shows is that biopiracy could broadly be viewed within the context of a weak benefit sharing system and an appropriative IP system. Though the extent of their respective emphases may differ at several points, the interplay of these two factors offers an interesting basis for discussing biopiracy in contemporary terms – contemporary, because the existence of biopiracy as a

534 Okediji, “The International Relations of IP”, supra note 18 at 336.
phenomenon predates the regimes that offer definition to these factors. Highlighting their interplay, Janet Bell thus notes that the CBD goal of benefit sharing is a difficult goal if the bio-prospector can secure IP rights over whatever he/she finds.\footnote{536 Svarstad, “A Global Political Ecology of Bioprospecting, supra note 333 at 246.} Indeed, this remains a central underlying basis for defining biopiracy: the inability of the benefit sharing regime to actualize its objectives in the face of the working of the IP regime, particularly the patent system. It is in the context then of bringing the IP system into ‘cooperative’ alignment with the ABS system as part of a larger regime complex built around the core issue of biopiracy, that this dissertation identifies a plausible solution to the protection of TKaGRs from biopiracy.

As the above discussions have served to highlight, these two key mechanisms are of central importance for the articulation of the problem and, by extension, the solutions to biopiracy. The interaction of the ABS regime and the IP regime in addressing the problem of biopiracy is therefore critical to solutions designed for resolving biopiracy. Importantly, the discussions also show that given the varied emphases that could be attributable to particular instances of biopiracy, \textit{interim} remedial (national) solutions to biopiracy could both emanate from a benefit sharing scheme and/or an IP scheme. While solutions advanced on the former platform could, for instance, support respect, compensation and an acknowledgment of the rights of indigenous peoples to determine the uses of their TKaGRs, the latter scheme has a key role, \textit{inter alia}, in the defensive protection of TKaGRs from biopiracy, i.e. in the prevention of the wrongful appropriation of rights over TKaGRs through the IP system. An effective and sustainable solution must however be drawn from both regimes as part of a coherent regime with reciprocal and reinforcing mechanisms dedicated to the issue of eradicating biopiracy.

Again, this supports the underlying premise of this dissertation – the need to view the Nagoya Protocol’s attempts at addressing biopiracy as well as the ongoing WIPO IGC negotiations within the context of an evolving regime complex against the incidence of biopiracy. In the next section, I place this regime complex in further perspective by articulating in clearer terms the contemporary trans-border and trans-regime nature of the underlying issue area – biopiracy.
4.3 Biopiracy as a Contemporary Expression of Borders and Regimes

From the outset, it is worth clarifying that this section does not attempt to redefine, in contemporary terms, a history of institutionalized acts of biopiracy. Rather, it attempts to focus the spotlight on the contemporary manifestation of a historical problem. Though there may be limits, understanding the present manifestations of a problem through a reflection on its histories provides a useful fulcrum to holistically address its continued occurrence. In this quest, a working definition of biopiracy as a basis for a solution design is essential. Furthermore, given that this chapter is essentially examining biopiracy as an issue area to which state cooperation towards its prevention within the context of a regime is being driven, clarity in its conceptualization is critical. Indeed, this was the essence of the discussion of regime issue areas in chapter two above, which emphasized that regimes are only as clear as their issue areas are made out to be. In this section, I try to bring some substantive clarity to the term “biopiracy” for the purposes of this dissertation.

The often cited argument that conceptual definitions of issue areas are not prerequisites to the establishment of effective protection frameworks, is often based on a compromise approach arising from the inability to effectively strike a definitional balance between the competing needs for legal certainty and clarity on the one hand, and the need to ensure sufficient flexibility in definition on the other. Flexibility is often required to accommodate the evolving nature of the intended subject of protection as well as guarantee that diverse interests find accommodation within the unifying standard. Biopiracy’s present lack of an all-embracing definition reflects these unresolved aspects of its definitional dilemma, much like the concept of TK does, discussed in the previous chapter.

Unlike several other concepts which could probably benefit from this flexibility compromise, biopiracy as an issue area reflects an anthropogenic ‘labeling’ of a specific series of infractions which are deemed unfair, or illegal and are traceable to specific identifiable factors. From a legal standpoint, therefore, the failure to provide a practical and workable definition for this term exposes its usage to the covering of a never-ending inclusive scope of acts on the one hand, or, its limitation to a restrictive scope which fails to acknowledge the root source of the problem on the other hand. A first step, therefore, in

situating biopiracy as a regime issue area of the ABS regime, and to which solutions may be advanced, is a clarification of the parameters which this dissertation outlines to define biopiracy. This clarification is made all the more important given suggestions of its weak and emotive use, lacking some may say in critical edge, which continues to define the common perception of biopiracy today.538

4.3.1 The Emergence of Biopiracy

As a terminology, biopiracy was coined in 1993 by Mr. Pat Mooney of the Canadian NGO, Rural Advancement Foundation International (RAFI), now known as the ETC Group.539 Its labeling as such was a response to the legal acceptance of bioprospecting540 as a lawful standard governing the utilization of GRs.541 Two initial points deserve mention here. First, the emergence of the biopiracy rhetoric did not serve to establish the problem of biopiracy, but rather merely sought to capture, define, and highlight, through a representative terminology, a history of unjust biopiratic acts. These early efforts to promote and draw attention to this injustice have been carried out by a group of NGOs, sympathetic to indigenous peoples and Third World concerns.542 Second, the biopiracy terminology problematizes its issue area of concern through a combination of contemporary factors. In other words, in defining a history of unfair resource appropriation, the terminology is based on modern ideas, institutions, and indeed, a contemporary challenge in the frame of biopiracy. What this suggests is that through a focus on the factors that have led to the emergence of the terminology, biopiracy is placed within a contemporary frame for its present manifestations. It is through this viewing, that I suggest a holistic international law solution may be formulated.

538 Robinson, Confronting Biopiracy, supra note 29 at 15.
539 Ibid. at 14. See also Dutfield “TRIPS-Related Aspects of TK”, supra note 236 at 237.
540 As mentioned in chapter three, bioprospecting involves the exploration of biodiversity for new cures and new crops primarily motivated by the economic and social value of biodiversity. See footnotes 330 & 333 above. Bioprospecting takes place largely within tropical third world countries found to be rich in biodiversity and is widely portrayed as a win-win example of North South cooperation in the utilization of GRs. Svarstad, “A Global Political Ecology of Bioprospecting, supra note 333.
541 Ibid. at 245, noting that the emergence of the term biopiracy was a direct response to Walter V Reid et al’s (1993) positive presentation of bioprospecting. Bioprospecting is an economic activity which has received considerable attention since the early 1990s even though, as Svarstad notes, the search for new uses of biological materials may be as old as humanity itself [Ibid. at 240]. Key advocates of the biopiracy discourse have essentially wrestled with efforts to entrench bioprospecting as a legitimate standard of resource appropriation. See, for instance, Mgbeoji, who identifies bioprospecting, including the institutions and systems designed to facilitate the transfer of plants, as a central element of biopiracy. Mgbeoji, Global Biopiracy, supra note 19 at 87 – 117.
542 Examples of these civil groups are, the ETC Group, the Third World Network, GRAIN, etc.
4.3.1.1 A Historical Perspective

Despite the seemingly recent labeling of biopiracy, as such, acts of biopiracy have existed for centuries. Vandana Shiva, for instance traces the origins of biopiracy to the conquering of ‘discovered’ lands by Columbus.\textsuperscript{543} Mgbeoji, on the history of biopiracy, posits that

\[\text{[f]or historical convenience rather than exactitude, the origins of the appropriation of plants may be traced to the “Columbian Exchange” of 1492, when Christopher Columbus’s forays into the Americas with some plant germplasm marked the introduction of “exotic” plant species. Since then the face of the earth, in the spread and distribution of human populations as well as in the realignment of geopolitical power, has radically changed. In 1493 Columbus returned to Europe with maize, and in 1494 he returned to the Americas with wheat, olives, chickpeas, onions, radishes, sugar cane and citrus fruits (for scurvy) in the hope of supporting a European colony.}\textsuperscript{544}

Consequently, the conquering of discovered territories, the acquisition of exotic resources therefrom, and the transferring of same to Europe marked the first instances of biopiracy. Noting that plants have formed the foundations through which human civilizations and development have evolved, Mgbeoji further argues that this early history of biopiracy played a significant role in redefining and reconfiguring the present global balance of power.\textsuperscript{545} Caloustus Juma argues that colonization could have been meaningless without access to GRs and demonstrates that the introduction of GRs into the economic system and the institutional reorganization to accommodate this was a core component of the colonial experience.\textsuperscript{546} This asymmetrical transfer of resources from colonies and colonialists was largely viewed an ‘internal affair’ of the colonial empires on the principle that acquired territories were simply outposts of

\textsuperscript{543} Often described as the discoverer of the New World, Christopher Columbus was an Italian-born navigator and explorer, who sailed the world in the service of Spain. He was granted by the Queen Isabel and Kind Ferdinand of Spain, the privileges of ‘discovery and conquest’. Shiva, Biopiracy, supra note 322 at 1 – 5. This view is also expressed by indigenous rights activists. See generally, for instance, Harry, “Biocolonialism & Indigenous Knowledge”, supra note 535. In their view, the modern system of IP is a mirror of the ancient colonial system through which foreign lands were acquired. She argues that today, the project of colonization is continued through the mechanics of patents and IPRs – the targeted subjects now being life forms and species manipulated by modern biotechnologies. On this concept of bio-colonialism, see also, Bita Amani & Rosemary Coombe, “Human Genome Diversity Project” (2005) 27:1 Law & Policy 152 at 175, noting that biocolonialism highlights contestations within the ‘links between Western exploitative practices, and the production of diversity as a site of informational and commercial value’.

\textsuperscript{544} Mgbeoji, Global Biopiracy, supra note 19 at 96.

\textsuperscript{545} According to Mgbeoji, plants have always formed the substratum upon which diverse human civilizations have prospered. Consequently, the asymmetrical movement of plant life forms from the South to the North largely underpinned and indeed redefined the structure and configuration of the global economy, human population distribution and the cultural, scientific and international legal order. Mgbeoji, Global Biopiracy, supra note 19 at 95.

the colonizing state. Against this backdrop, the appropriation of resources was seen as a natural right of the colonizer, and was fueled by a sense of entitlement by the European colonialists over the earth, its peoples and resources. This historical element of biopiracy reflects the international nature of biopiracy and lays foundations for a North-South framing of the biopiracy discourse. In this early context, biopiracy existed as a territorial problem, which involved the expropriation and/or transfer of resources across jurisdictional borders. In other words, biopiracy emerged in an international context. The trans-border element of biopiracy, through which resources are fraudulently utilized abroad without due regard to the existing standards obtainable in the source countries, contends with the independence of sovereign states, particularly developing countries from which resources are widely sourced. This important discussion serves to explain the historical trans-border nature of the biopiracy problem which still yet exists today.

The early trans-border occurrences of biopiracy were not entirely cases of unjustified fraudulent actions across borders, however. Rather, the early history of biopiracy alludes to an era in which the international law concept of state sovereignty over resources had not been established, neither was benefit sharing an established principle of the international law framework. Consequently, GRs were largely viewed as constituting a part of the common heritage of mankind (CHM) which was freely available for the benefit of mankind. This CHM principle over GRs was eventually laid to rest with the adoption and entry into force of the CBD. By this instrument, the international community offered clarification to the international law principle of state sovereignty over GRs which occur within their territories as well as set out standards for the equitable sharing of benefits arising from the utilization of GRs. Inherent within the biopiracy rhetoric thus remains a reminder of the limitations which provider countries face in restricting and controlling the established terms of access to resources located within their borders, even to date.

In casting biopiracy within a trans-border frame, I am aware of instances of domestic cases of misappropriation of resources, including, for instance, government agencies as well as private entities.

547 Mgbeoji, *Global Biopiracy, supra* note 19 at 96.
548 Shiva, in describing this state of affairs, remarks that the Pope as the vicar of God commanded the world, as if it were a tool in his hands and thus considered the world as his property to be disposed according to his will. He was thus able to ‘legitimately’ grant discovered and yet to be discovered portions of the earth to whomsoever he deemed fit. In effect, Christian monarchs of Europe were considered rulers of all nations, ‘wherever they may be found and whatever creed they may embrace’. Shiva, *Biopiracy, supra* note 322 at 1 – 2.
549 See Article 15.1, CBD.
located within national borders. The case of the Arogyapacha (*Trichopus zeylanicus*) offers an example of this which continues to divide opinion between those who contend that it represents an example of good benefit sharing practice and those who suggest it to be biopiracy.\(^{550}\) In 1987, a government ethnobotanical expedition to Western Ghats stumbled on the herb.\(^{551}\) The team observed that the Kani guides who accompanied the scientists were continuously munching the black fruits of some plants and did not feel tired.\(^{552}\) According to Dr. Pushpangadan (the team lead), “upon eating the fruits, [the] team felt immediately charged and full of energy and vitality”.\(^{553}\) Though the indigenous guides were initially reluctant to reveal the identity of the plant as it was an honored tribal and sacred secret,\(^{554}\) they agreed after much persuasion from the scientists. Clinical tests of the plant were undertaken and led to the production of the Jeevani drug, widely marketed as an energizer, adaptogen and immune stimulator. The Jeevani has become an international brand and as part of its commercialization strategy, a benefit sharing arrangement was concluded between the Kani tribals and the Tropical Botanic Garden and Research Institute (TGBRI) – a governmental agency established to study plant genetic resources and their sustainable use.

These kind of instances are an important feature within the discussion of biopiracy. In the example of the hoodia plant which I discussed in the introductory chapter, the South African Council for Scientific and Industrial Research (CSIR) was also at the heart of the initial appropriation of the knowledge and resources of the San peoples. In fact, the P57 patent was held by the CSIR. What these kind of examples

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\(^{550}\) The Arogyapacha is a perennial herb which grows in Sri Lanka, Southern India and Malaysia. In India, it is endemic to the region of the Western Ghats within the states of Kerala and Tamil Nadu. This region is the home to the Kani tribe; an impoverished nomadic tribe with an estimated population of about 18,000. For a detailed discussion of this case, see Anil K Gupta, *WIPO-UNEP Study on the Role of Intellectual Property Rights in the Sharing of Benefits arising from the Use of Biological Resources and Associated Traditional Knowledge* (2004) available online: WIPO <http://www.wipo.int/edocs/pubdocs/en/tk/769/wipo_pub_769.pdf>. [Gupta, *WIPO-UNEP Study*]. The story of the Arogyapacha has, for instance, been held out as a useful example of benefit sharing. Ibid. at 111. On the other hand, however, the story has emerged as an example of biopiracy. See, for instance, Schuler, “Biopiracy & Commercialization”, *supra* note 421 at 195 – 196.

\(^{551}\) This was an ethnobotanical expedition conducted by the All India Coordinated Research Project on Ethnobiology (AICRPE). Gupta, *WIPO-UNEP Study*, *supra* note 550 at 109.

\(^{552}\) Schuler, “Biopiracy & Commercialization”, *supra* note 421 at 195.


\(^{554}\) Ibid.
however point to is a weakness of domestic legislation to address instances of internal appropriation of
resources. As Viviana Munoz Tellez notes of the hoodia case,

[a] central problem in seeking an agreement with the CSIR to ensure fair and equitable
sharing of benefits derived from the P57 patented Hoodia products was the deficiencies
in South African legal framework for the protection on biodiversity and traditional
knowledge. In the Hoodia case it was difficult to assert the claims of the San people
regarding the P57 patent and the future commercialization of Hoodia products because of
the lack of a clear regulatory framework establishing their rights.\footnote{See, Tellez, “The Hoodia Case of Benefit-sharing”, supra note 529.}

The responsibility in such instances thus lies with the government to define rights and obligations
of users and providers within its borders, as well as set up appropriate machinery for addressing instances
of breach. I therefore exclude such national cases of appropriation by entities located within national
borders as these do not necessarily challenge the sovereignty of states over resources within their borders.
These are issues which are principally addressable through national regulation. In the wake of the hoodia
case, for instance, the backlash on the South African government for being complicit in the alleged
misappropriation, led to the enactment of domestic regulation forestalling such a recurrence.

Distinguishing instances as these from the examples of biopiracy being considered within this
dissertation, reflects those instances where domestic regulation is insufficient to address the cross-border
misappropriation due to the lack of cooperation from user states. The need for state cooperation through a
regime in addressing the incidence of biopiracy therefore suggests that biopiracy as a problem transcends
national regulation. In this work, I focus on biopiracy therefore as a trans-border phenomenon. To make
clear, the core significance of this trans-border conceptualization which shall be further developed in the
next chapter, is the fact that biopiracy is a problem which requires a trans-border cooperative solution to its
eradication.

4.3.1.2 A Contemporary Context

Despite the continuity of appropriation of resources through generations, the nature of biopiracy
has changed over time. In fact, the very emergence of a biopiracy rhetoric, served the purpose of providing
a contemporary expression to this historical dilemma. The majority of attempts to define the biopiracy
terminology since its coinage have placed emphases on various aspects of the problem. Two main
definitional approaches are, however, noticeable. I categorize them here, based on their renditions of the scope of biopiracy, as the ‘inclusive’ and ‘restrictive approach’.

4.3.1.2.1 An Inclusive Approach to Biopiracy

The inclusive approach views biopiracy within its broad parameters. In effect, biopiracy is used loosely to incorporate practically all acts of unpermitted appropriation of GRs and/or TK (with inequitable, or without any form of compensation being returned to the providing country). In this category, the reference for an alleged biopiratical act is generally linked to the perception of injustice arising from appropriative acts. Furthermore, the inclusive approach to biopiracy serves to incorporate the above referenced instances of domestic appropriation of resources by entities located within national borders, including national authorities. Jay McGown and the Edmonds Institute, for instance, developed an inclusive definition of biopiracy framed around the broad language of theft viz:

where there is access to or acquisition of biodiversity (and/or related TK) without PIC, including PIC about benefit sharing, on the part(s) of those whose biodiversity (or TK) has been ‘accessed’ or ‘acquired’, there is biopiracy -- i.e., theft.

At least two definitional implications are identifiable from the inclusive approach. First, the unpacking of biopiracy from this perspective offers an opportunity to view it within its broad context, involving its historical antecedents, which may have occurred without the IP system and/or benefit sharing system in place. Mgbeoji’s broad iteration of biopiracy alluded to above offers an excellent example of this. In identifying three mutually reinforcing factors which define biopiracy, Mgbeoji places biopiracy within the mix of historical as well as contemporary factors which lend to its inclusive definition. The inclusive approach, however, poses challenges linked to the emotive manner in which the term emerged. In this context, the deployment of the biopiracy rhetoric as a tactical, political, economic, and diplomatic tool has witnessed it being utilized to label a wide range of possible activities. The ultimate effect of this is the weakening of the biopiracy rhetoric, a weakness arising from an inability to focus on a core central and contemporary problem as well as factors which continues to entrench a historical injustice. A clear

556 See the full biopiracy report in, Burrows, Out of Africa, supra note 432.
557 Subbiah, “Reaping what they Sow”, supra note 275 at 539. See also Shiva, Biopiracy, supra note 322 at 10 – 11. Robinson, Confronting Biopiracy, supra note 29 at 14 in like manner, highlights the political nature of the term biopiracy.

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expression of this is observable when discussions regarding the solutions to biopiracy are taken on. Of the proposals for instance to develop a new set of property rights as a solution to biopiracy, Heald observes the futility of such an approach arising from a perceived unconvincing nature of the broadening biopiracy rhetoric, and notes that while it may gratify ‘our sense of moral worth, [it] can offer only ‘utopian longings that ultimately have no critical edge.’”

4.3.1.2.2 A Restrictive Approach to Biopiracy

On the other hand, the restrictive approach includes definitions which involve a strict linkage between the violation of ABS obligations and the IP system. This is in keeping with the literal analysis of biopiracy as a concept which links the exploitation of biodiversity with the IP system. To clarify, the restrictive approach always includes a reference to the IP system as a tool of appropriation. Bryan Liang, for instance, describes biopiracy as occurring when bioprospecting is used to appropriate knowledge and biodiversity resources to gain exclusivity over benefits using IP rights without sharing with indigenous populations. The ETC Group also defines biopiracy restrictively as

the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions that seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge.\footnote{560}

Ikechi Mgbeoji, using this restrictive approach, defines biopiracy as

the unauthorized commercial use of biological resources and/or associated traditional knowledge, or the \textit{patenting of spurious inventions based on such knowledge, without compensation}.\footnote{561}

Vandana Shiva similarly notes;

Biopiracy refers to the use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized cultures\footnote{562}

\footnotetext{558}{Heald “The Rhetoric of Biopiracy”, \textit{supra} note 420 at 543.}
\footnotetext{559}{See Bryan A Liang, “Global Governance” \textit{supra} note 329 at 248}
\footnotetext{560}{See ETC Group, “Patents & Biopiracy”, online: ETC Group <http://www.etcgroup.org/issues/patents-biopiracy>}
\footnotetext{561}{Mgbeoji, \textit{Global Biopiracy, supra} note 19 at 13.}
This restrictive approach is widely used in the literature\textsuperscript{563} and interestingly, several authors oscillate between both approaches in their conceptualizations of biopiracy.\textsuperscript{564} Within the restrictive context, however, it is impossible to construe biopiracy without a reference to the IP system as well as the core elements of the ABS system. It is worth noting that a third combined approach of defining biopiracy, involving both restrictive and inclusive elements is also observable. Dutfield, for instance, seems to adopt this combined approach, by noting ‘biopirates’ to be individuals or companies accused of \textit{one or both} of the following acts: (a) misappropriation of GRs or TK through the patent system; or (b) unauthorized collection of GRs or TK for commercial ends.\textsuperscript{565}

For legal certainty and definitional clarity, and in line with the focus of this dissertation on the contemporary manifestations of biopiracy as an issue area for state cooperation, this dissertation views the term biopiracy in its ‘restrictive’ context. Two main reasons are adduced below for this.

First, it promotes certainty for the regime analysis by lending itself to a definable scope. A definable scope for biopiracy provides a framework within which analyses can be conducted. An analysis of biopiracy is not complete without a reference to the IP system. In fact, without a reference to IP, biopiracy cannot be properly defined and/or analyzed, neither can real solutions be adduced. Interestingly, the use of an IP-based descriptor to describe the infraction (piracy) centralizes the IP concerns within the very conceptualization of biopiracy. The importance of this assertion is linked to the recognition that the working of the IP system lies at the heart of biopiracy’s emergence (as a terminology) as well as its continued existence. Cases of biopiracy have most commonly been linked with the patent system though,

\textsuperscript{563} Though Robinson also conceptualizes his discussion of biopiracy within a restrictive context, he goes a step further to distinguish ‘patent-based biopiracy’ from ‘non-patent biopiracy’. He adds a third typology which he terms misappropriations. The first two typologies reflect definitions within the restrictive scope while the third category of misappropriations, includes the definitions which could be considered inclusive. Robinson, \textit{Confronting Biopiracy, supra} note 29. See also Edward Hammond, defining biopiracy as the misappropriation of GRs and knowledge through IP claims. Hammond, \textit{Biopiracy Watch, supra} note 50 at 5.

\textsuperscript{564} Mgbioji, \textit{Global Biopiracy, supra} note 19.

as Daniel Robinson rightly points out, trademarks as well as plant varieties protection systems have also played a major role in several biopiracy cases.\footnote{Robinson, *Confronting Biopiracy*, supra note 29 at 77 – 78. See also, for instance, Jay McGown’s report on biopiracy, where, of the over 36 reported biopiracy cases and investigations, only three cases did not involve the patent system. One of these dealt with trademarks while the other 2 involved plant variety protection. Edward Hammond’s compilation of recent biopiracy cases similarly identifies nine cases of biopiracy all of which are linked to the patent system. Hammond, *Biopiracy Watch*, supra note 50.}

Not only does this restrictive interpretation promote certainty, it also underscores the importance of regime interactions by implicating the IP and ABS institutions in the articulation of biopiracy. By wedding the regimes of ABS and IP within the same definition of biopiracy, the spotlight is placed on the underlying tensions which have highlighted the power dynamics between the two systems. Indeed, as several restrictive definitions demonstrate, the predatory nature of the IP system on the knowledge and resources of indigenous peoples, as well as its granting of property rights with/without compliance with the ABS system, characterizes the biopiracy rhetoric.\footnote{The predatory nature of the IP system is not limited to the indigenous context. See, Amani, *State Agency*, supra note 431 at 40, but is certainly highlighted by it.} In this sense, biopiracy is presented as a trans-regime concept; one which principally merges two core regimes in its articulation.

The emergence of the biopiracy terminology is, therefore, a codification, through one word, of a history of practice as well as a modern occurrence of patterns engaging the IP system in biopiratical acts. Since 1993, the term’s significance has rapidly grown within and beyond the context of discussions to address its continued existence. On the strength of the prevailing context within which the term emerged – a context which reflected above-described perceptions of IP’s predatory tendencies – Mooney’s conceptualization of biopiracy was not a random term selection. Rather it bore within it a calculated expression of defiance to the unfair *status quo* which had hitherto characterized the strengthening of IP rights to protect rights holders from pirates at the expense of the rights of indigenous peoples and communities over their resources and knowledge.\footnote{Robinson, *Confronting Biopiracy*, supra note 29 at 14, who, inter alia, notes that the term was developed due to growing frustrations about the appropriation and monopolization of long-held medicinal and agricultural knowledge about nature, as well as the related physical resources (plants animals and their components).} Understanding this reasoning behind the conceptualization of biopiracy offers a strong indication of the contemporary ambit within which biopiratical acts can be viewed. It also provides a platform from which a holistic assessment of biopiracy cases through
time may be undertaken, and facilitates a better understanding of the contemporary manifestations of biopiracy. In all these instances, the IP system plays a significant role in the conceptualization of biopiracy. As mentioned above, it also demonstrates why an inclusive approach to biopiracy could overshadow a proper assessment of the actual concerns underlying its contemporary occurrence.

While it is important to acknowledge that biopiracy is not an issue which, in totality, may fully be addressed solely by the IP system, the recognition of the indispensable role of the IP system in conceptualizing biopiracy is important in seeking viable solutions to biopiracy, nationally and internationally. It is through the incentives of the IP system that researchers, multinationals etc., are driven and/or encouraged to invest in the utilization of resources for the development of innovations aimed at the global market. Furthermore, the wrongful grant of rights over inventions based on GRs and TKaGRs through the IP system has played a major role in facilitating the occurrence of biopiracy. A bold assertion in this regard is that we probably would have no biopiracy, as we know it today, if the IP system as well as its incentives did not exist. In other words, there is a direct causal link between biopiracy and the prevailing Western frameworks designed to promote human inventive activity. Furthermore, as an institution that has served to appropriate excluded forms of creativity such as TKaGRs, an emphasis on IP solutions, particularly defensive solutions must be made.

In sum, the restrictive context provides insight into the nature of a relationship between IP and the appropriation of TKaGRs – a relationship which is politicized and reflects disparities in power, thrives on the vulnerability of GRs and TK to exploitation, and highlights the predatory tendencies of ‘individuals, global systems and institutions’ involved in their commercial use. The IP system, its institutions, and its major users are, in this regard, portrayed as the main culprits, while indigenous groups and Third World countries are typically viewed as the victims of biopiracy. Little wonder Schuler, in summing up on biopiracy, notes that the central criticism in the biopiracy literature is that businesses in industrial countries

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570 Western IPRs are based on a theory of exclusion […] in the politics of excluding specific forms of works culturally incongruent with western normative legal prescriptions such as traditional knowledge of plant genetic resources. Amani, State Agency, supra note 431 at 40.
are getting rich off of poor people’s knowledge at developing countries’ expense.\textsuperscript{571} Arising from the above analyses, a suggested restrictive definition for biopiracy, which I adopt is

\textit{the result of a commercial/non-commercial drive to utilize the IP system to acquire rights over inventions based on the experience of indigenous peoples relating to GRs and/or its associated TK, without complying with existing legal obligations, national or international, governing the acquisition and use of such resources.}

\textbf{4.3.2 Biopiracy as a Counter Discourse: A Transition from Borders to Regimes}

For our purposes, biopiracy in its restrictive context importantly describes a contemporary expression of a historical problem by drawing attention to the trans-regime nature of biopiracy. As a terminology, biopiracy’s coinage in 1993 aligned with an important year in which global attention was focused on two main novel introductions to the international regulatory system; the CBD\textsuperscript{572} and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).\textsuperscript{573} I offer a detailed examination of these developments, respectively, in the next two chapters. Suffice it to say here, however, that the CBD’s entry into force in 1993 ushered in the firm entrenchment of benefit sharing principles in international law.\textsuperscript{574} Its emergence also played a central role in clarifying the principles of state sovereignty over GRs.\textsuperscript{575} On the other hand, within the sphere of international trade, agreement was reached on virtually all the issues, including the text, of the TRIPS in 1993.\textsuperscript{576} The adoption of the TRIPS in 1994, signified that the efforts of industrialized countries (driven by major industry representatives) to incorporate IP rules within the multilateral trading system as a way of addressing concerns of counterfeit (pirated) goods in international trade, had been successful.\textsuperscript{577} Significantly, however, TK is not covered under the Agreement.

\begin{thebibliography}{9}
\bibitem{schuler2011} Schuler, “Biopiracy & Commercialization”, \textit{supra} note 421 at 160.
\bibitem{cbd1992} CBD, 5 June 1992, 1760 UNTS 79; 31 ILM 818 (entered into force 29 December 1993) [CBD].
\bibitem{tripsnegotiations} See Article 1, stipulating that the fair and equitable sharing of benefits arising from the utilization of GRs constitutes one of the objectives of the CBD. Article 15.7 further requires states to take legislative, administrative or policy measures with the aim of ensuring benefit sharing. With respect to TK, the CBD in Article 8(j) lays out this benefit sharing obligation. See also para 12, preamble to the CBD.
\bibitem{tripsnegotiations2} Article 15.1, CBD.
\bibitem{wtounderstanding2} See full discussion of the globalization of IP through the TRIPS Agreement at 6.1.2.6. below.
\end{thebibliography}
Rather, the existing foundational standards of the IP system which had hitherto served to exclude TK, were

globalized. I deal extensively with this in chapter six. I note however that as part of the globalization of IP

through the TRIPS, the scope of patentability was extended to include life forms, notably GRs.578 Through

the TRIPS, an era of globalization for IP rights emerged, one in which obligatory minimum standards of

protection for IPRs were exported to all Members of the trading system.579

For activists, like Pat Mooney, this strengthened regime of IPRs was in fact hypocritical as it failed
to acknowledge that piracy was also perpetuated by several corporations that acquired the resources and/or
knowledge of indigenous peoples without due permission, recognition or even acknowledgment.

Explaining this point, Graham Dutfield observes that the term biopiracy was developed as

part of a counter attack strategy on behalf of developing countries that had been accused
by developed countries of condoning or supporting ‘intellectual piracy’, but who felt
that they were hardly as piratical as corporations which acquire[d] resources and
traditional knowledge from their countries, use[d] them in their research and
development programs, and acquire[d] patents and other intellectual property rights –
all without compensating the provider countries and communities.580

The difficult relationship between the IP system and the conservation of biodiversity thus underlies the
biopiracy rhetoric. On the basis of the above, three important points are worth noting regarding the
emergence of the biopiracy terminology:

First, it was principally designed for uptake by developing countries and their local and indigenous
communities. Though the victims of biopiracy cases are not limited to this identified category, its use has
grown to define a problem which, till date, portrays developing countries and their indigenous groups as
the significant biopiracy victims; Second, it emerged as a counter-attack. In other words, it emerged as a
defensive strategy against the allegations of piracy which, at the time, were principally channeled towards
the developing world. These allegations were widely regarded as justifications for the need for a globalized
and strengthened regime of IP through the TRIPS. In a wider sense, therefore, the biopiracy terminology

578 See Article 27, TRIPS. This is subject to allowances within the TRIPS Agreement for state discretion with
differentiation under Article 27.2 and 27.3(b). See, Amani, State Agency, supra note 431 at 172 – 173.
International IP system”].
580 Dutfield “TRIPS-Related Aspects of TK”, supra note 236 at 237 to 238.
emerged as an attack on the core rationale and expansion of the global IP system; and third, it bore within it, an effort to expand the standard conceptualization of piracy – the commercial violation of legally sanctioned IP\(^{581}\) – to include acts which centered on the uncompensated commercial exploitation of biodiversity and related knowledge.

In sum, a calculated response on behalf of the developing world to the unilateral attack on developing countries by the developed world for failing to hallow the western-styled IP system \(viz-a-viz\) the protection of GRs and its associated TK, embodies the context within which biopiracy emerged, and, till date, within which it continues to thrive. From its humble beginnings, in 1993, of a privately developed rhetoric, biopiracy has today grown into a widely accepted public and diplomatic tool, occupying a sensitive place in modern discourse, particularly within the ABS and IP regimes. It today stands as a recurring theme within these multilateral discussions – one which generally pitches the developing world against the industrialized world. In practice, its use has also been aimed at securing political leverage within several related and unrelated negotiations.\(^{582}\) Through its use, several developing countries as well as indigenous groups continue to advocate for reform in a global state of affairs within which they remain disadvantaged.\(^{583}\)

### 4.3.2.1 The Trans-Regime Connection

As noted earlier, acts of biopiracy have long preceded the emergence of the terminology. The early expropriation of resources was seen as a natural right of the colonizer, and was fueled by a sense of entitlement by the European colonialists over the earth, its peoples and resources.\(^{584}\) The idea that GRs were

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\(^{581}\) See Adrian Johns, *Piracy: The Intellectual Property Wars from Gutenberg to Gates* (University of Chicago Press: 2009, USA) [Johns, *Piracy*] at 6. Though he identifies this definition of piracy as “the standard definition”, he notes that it falls short of what piracy is in that it fails to recognize cases of piracy which occur without IP being in issue pointing out that cases of piracy had existed before the IP system as we know it emerged.

\(^{582}\) Robinson describes biopiracy as a ‘discursive tool that both describes an injustice and is used for political leverage. Daniel Robinson, “Biopiracy and the Innovations of Indigenous Peoples and Local Communities” in, Drahos, Peter & Susy Frankel, eds. *Indigenous People’s Innovation: Intellectual Property Pathways to Development* (Canberra: ANU E Press, 2012) at 78.

\(^{583}\) Robinson contends that the biopiracy discourse has emerged as a powerful counter to the perception of new hegemonies imposed by IP rules with global reach such as the TRIPS Agreement. Ibid.

\(^{584}\) Shiva, in describing this state of affairs, remarks that the Pope as the vicar of God commanded the world, as if it were a tool in his hands and thus considered the world as his property to be disposed according to his will. He was thus able to ‘legitimately’ grant discovered and yet to be discovered portions of the earth to whomsoever he deemed fit. In effect, Christian monarchs of Europe were considered rulers of all nations, ‘wherever they may be found and whatever creed they may embrace’. See Shiva, *Biopiracy, supra* note 322 at 1–2.
part of the common heritage of mankind overtime served to justify the continued exchange with GRs being viewed as global resources which were freely available and to which no country could claim exclusive rights. This historical element of biopiracy reflects biopiracy as an international problem involving the expropriation of resources across jurisdictional borders. This thesis highlights the trans-border nature of biopiracy – as a problem which transcends single state borders and which requires solutions that effectively monitor the trans-border appropriation of resources.

By focusing, however, on the restrictive explanation of biopiracy, the historical phenomenon is given a contemporary frame. In this context, beyond a mere trans-border problem, biopiracy sits at the intersection of two major regimes: the ABS and IP regimes. Acts of biopiracy are facilitated by the working of the IP regime in disregard for standards of resource use laid out in the ABS regime. In other words, the ability of users to secure private IP rights over inventions which make use of GRs and/or TKaGRs, while yet failing to secure the prior informed consent (PIC) of providers of TKaGRs, as well as establish mutually agreed terms (MATs) for benefit sharing with providers, explains a challenge of biopiracy which most developing countries have had to contend with. Consequently, while the content of appropriation of resources has continued through generations, the nature of biopiracy has changed over time. Notably, the mechanisms facilitating the appropriation of resources, as well as the motivations underlying such appropriations have gradually changed. The conquering of foreign territories underscored the early

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585 Schroeder and Pogge argue that the idea of the common heritage of humankind entered into the canon of international law in the late twentieth century with the conclusion of two UN treaties: The Agreement Governing the Activities of States on the Moon and Other Celestial Bodies (1979) and The Convention on the Law of the Sea (1982). See Doris Schroeder & Thomas Pogge, “Justice & the Convention on Biological Diversity” (2009) 23:3 Ethics & International Affairs [Schroeder & Pogge, “Justice & the CBD”] at 268. In explaining the common heritage principle within the context of GRs, Brush points out that ‘common heritage refers to the treatment of genetic resources as belonging to the public domain and not owned or otherwise monopolised by a single group or interest’. Brush maintains that, reference to crop genetic resources as a common heritage appeared in the 1980’s in association with the establishment of the Commission of Plant Genetic Resources at the Food and Agricultural Organisation of the United Nations (FAO Commission) and the launching of the International Undertaking of Plant Genetic Resources. The 1983 conference establishing the FAO Commission and International Undertaking affirmed a resolution stating that ‘Plant genetic resources are a heritage of mankind and consequently should be available without restriction’. See Stephen Brush “The Demise of ‘Common Heritage’ & Protection for Traditional Agricultural Knowledge” in Charles McManis, ed, Biodiversity & the Law: Intellectual Property, Biotechnology & Traditional Knowledge (UK: Earthscan, 2007) 298 – 299. See also Srinivas “TK and IPRs”, supra note 248 at 89. Srinivas argues that though in the 60s and 70s, there had been a debate in the UN and elsewhere on the ‘Common Heritage of Mankind’ and the ‘National Sovereignty over Natural Resources,’ and though the UN General Assembly recognised the idea of National Sovereignty over natural resources, the principle was only firmly established in international law for the first time in 1992 with the adoption of the CBD. Ibid.
appropriation of resources. In more recent times, however, the institutional structures that have risen to reward and stimulate innovation have entrenched and perpetuated this expropriation of resources.

According to Daniel Robinson,

> [a]lthough the colonial enterprise of plant and animal collecting has been ongoing for centuries, the biopiracy discourse was generated to illustrate that more recent technological and institutional changes have encouraged new inequities and compounded old ones. In the context of the new global intellectual property rules, biopiracy has essentially been wielded as a counter-discourse to intellectual property piracy.

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In essence, moving away from a strict trans-border problem of resource expropriation, the problem of biopiracy today is closely linked to a similar trans-border problem, located within the context of international regimes. For this reason, we can conclude that biopiracy today represents a trans-regime issue area; one which finds its articulation and manifestation within the overlap of independent regimes. As such, biopiracy must also draw cooperation from such independent regimes in the design of solutions. In a contemporary rendition of biopiracy, the IP regime thus provides a modern shadow of the historical problem of borders. While it does not replace the historical problem, it offers an additional layer to the trans-border problem of biopiracy and thus provides another basis for examining the solutions to biopiracy within the context of a regime complex. Given that its articulation is made possible due to the constant interaction between the ABS regime and the international IP regime with respect to the use of TKaGRs, biopiracy poses both trans-border and trans-regime questions to efforts for its eradication. The latter of these questions reveals a major limitation of the text of the Nagoya Protocol (as a single regime approach) which draws centrally from a single biodiversity regime (the CBD) in the articulation of its solution to protecting TKaGRs from biopiracy. Yet, it also reveals why the open-ended ABS regime which the Nagoya Protocol establishes offers an important regulatory basis for the protection of TK – one which sets out a template for a regime complex approach to addressing biopiracy. Of importance here, the Protocol particularly sets out to coordinate amongst other international efforts, including those within the WIPO. It also explains why, as I show in chapter six, developing countries have continued to probe the foundations of the IP system for adequate reinforcements to the ABS regime.

586 Robinson, Confronting Biopiracy, supra note 29 at 14.
While arguments may be made about the overt narrowing of the concept of biopiracy through this restrictive conceptualization, my argument essentially is that though biopiracy has existed through time, the perfect marriage of institutional and legal frameworks which could provide a basis for its articulation only emerged in 1993. The piracy terminology itself shares a similar historical basis which places its contemporary interpretation within the contemporary institutions that have supported its articulation and offers some further elaboration to my point.

In his authoritative book on piracy, Adrian Johns, a Professor of History at the University of Chicago, makes the case that piracy denunciations had been going on for over 150 years before the emergence of the IP system. It is thus erroneous to presume, as is the norm with policy makers and jurists, that piracy is a mere derivative of the IP system. The rise of the IP system has witnessed the term being used largely to describe the commercial violation of legally sanctioned IP. However, as a subject, piracy has existed long before the IP system. The IP system has, however, led to a change in the nature and understanding of piracy over time. Today, therefore, piracy is generally understood as the commercial violation of legally sanctioned IP. An alternative and interesting definition of piracy, developed in an official study for the European Union, defines piracy as whatever the knowledge industries said they needed protection from. Within the context of a counter-discourse to IP piracy, biopiracy has significantly emerged to expand these conceptions of IP piracy by focusing the spotlight on the piracy which is inherent within some practice areas of the IP system. In so doing, it has offered developing countries, which generally bear the brunt of piracy attacks, both a moral justification and defense to IP piracy by highlighting the inherent hypocrisy in such allegations of IP piracy.

Vandana Shiva in this context thus discusses the IP system as well as the international trading system as constituting modern forms of colonialism through which biopiracy continues to be perpetuated.

587 Johns, Piracy, supra note 581 at 7.
588 Ibid. at 7.
589 According to Johns, the history of piracy has never really been examined for two main reasons. First, is the modernist approach of conceptualizing it merely in terms related to the present. Secondly (providing a rationale for the first reason), piracy is viewed as not being a subject at all. It merely reflects the rise of the IP system, and as such the real subject would be IP itself. Understanding IP would translate to an understanding of piracy. Johns, Piracy, supra note 581 at 5 – 6.
590 Ibid. at 6 – 7.
591 Ibid. at 6.
and the grip of the North over resources and the knowledge of peoples in the South remains entrenched.\textsuperscript{592} In doing so she draws comparisons between the early Columbus expeditions and the modern IP system, querying its incursion into the realms of indigenous life.\textsuperscript{593} Johns, in this context provides a depiction of biopiracy as a reverse form of piracy. Based on this expose, everyone could be seen as a pirate, depending on which side you stand:

[p]irates, in all too many cases, are not alienated proles. Nor do they represent some comfortingly distinct outsider. They are [all of] us. Biotechnology companies certainly complain about seed piracy, for example – but also find themselves confronted by protests at their own alleged “biopiracy”. The same charge is liberally hurled at high-tech “pharmers” in the West – the word here referring not to unscrupulous forgers of Web sites but to highly credentialed bioscientists and ethnobotanists traversing the tropics in their search for new medicines. In such cases, the institutions of scientific and medical research on which we depend are being denounced as pirates not for destroying intellectual property, but precisely for introducing it to places where it did not previously exist\textsuperscript{594}

In defining biopiracy, we are therefore essentially defining piracy from the perspective of developing countries and indigenous peoples; piracy in which the subject is not legally sanctioned IP, but rather the knowledge and biological resources of indigenous peoples; piracy as what indigenous communities, and not necessarily knowledge industries, require protection from. As used in this restrictive sense and, as Johns suggests above, this protection could even be from the IP system itself.

Truly, like piracy, the nature of biopiracy has similarly changed over time and though, as Shiva and Debra Harry have tried to show, historical traces may be gleaned from the existing manifestations of biopiracy,\textsuperscript{595} biopiracy’s contemporary expression offers an interesting framework with which to examine the concept. The existence for centuries prior to its conceptualization did not suggest that piracy was regarded with indifference before then, however, the combination of commercial and cultural ingredients that would produce a concept of piracy only emerged in the 17\textsuperscript{th} century.\textsuperscript{596} Similarly, though the biopiracy phenomenon had existed for centuries [as depicted above], the emergence of the commercial and cultural ingredients that would sustain a conceptualization of biopiracy only led to the emergence of its terminology

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\textsuperscript{592} See Shiva, \textit{Biopiracy}, supra note 322.
\textsuperscript{593} Ibid.
\textsuperscript{595} Harry, “Biocolonialism & Indigenous Knowledge”, \textit{supra} note 535.
\textsuperscript{596} Johns, \textit{Piracy}, \textit{supra} note 581 at 19.
\end{flushright}
in 1993. An examination of these contemporary factors, leads to a contemporary understanding of biopiracy. It is the emergence of the contemporary manifestation of biopiracy that this dissertation focuses on. This is in full acknowledgment of the fact that there exists a history of phases through which biopiracy has evolved over the years and does not represent an attempt to, as Adrian Johns suggests, ‘disrespect historical meanings’ by imposing a current interpretation of biopiracy on our ancestors. However, in seeking to unpack the Nagoya Protocol as a regime established to address biopiracy; one which, as the government of India noted, would address the concerns arising from the victims of the IP system’s grant of private rights over genetic resources and knowledge, attention needs to be paid to this contemporary manifestation of biopiracy.

4.4 Conclusion

Summing up the discussions so far, biopiracy therefore is a form of piracy. It bears a history which precedes its nomenclature. It, however, also bears a contemporary expression; one which is understood essentially within the context of a counter-discourse or counter-attack to the IP system given the IP system’s role as a modern institutional structure that supports biopiracy’s articulation. Due to the fact that the ABS regime has been negotiated by the international community to address the incidence of biopiracy – as it is known today – a contemporary viewing of biopiracy is justified in this work. A significant implication of its contemporary rendition, expressed through a restrictive interpretation of biopiracy is the importance of viewing solutions to biopiracy through the lens of multiple regime interactions. In particular, the design of a biopiracy solution must draw from a cooperative stance between the ABS regime on the one hand and the IP regime on the other. These separate regimes together hold the respective solutions to the respective sore spots of emphases which I identified as define the contemporary biopiracy dilemma. Through an expansive reading of the ABS regime, therefore – one which considers emerging related developments in the IP regime as part of a single struggle to address the holistic problem of biopiracy through fragmented pieces – further strength is provided to the idea of an emerging regime complex for the purpose of addressing biopiracy.

597 Ibid. at 7.
Biopiracy is indeed an issue of concern to the developing world, and of genuine importance to developing countries. Through efforts, such as policy measures, administrative measures, and even legislative measures, several developing countries have taken on the important task of combating biopiracy. The Nagoya Protocol represents the latest international effort concluded to address biopiracy, and as seen through the statements of several developing countries, an expectation exists that the Nagoya Protocol will further contribute to the national and regional efforts to combat biopiracy.

In the next chapter, I review the Nagoya Protocol, its provisions and limitations, as an ABS regime. In doing so, I highlight the unmistakable links between the concluded Nagoya Protocol and the present developing country-led efforts to design a coherent system incorporating the IP system as part of an emerging regime complex reinforcing the Protocol’s objectives against the incidence of biopiracy.
Chapter 5

Benefit Sharing and Biopiracy

In the last two chapters, I have taken considerable effort to set out the problem of biopiracy both by reviewing its subjects of appropriation, and also reflecting on ‘biopiracy’ as a phenomenon and as an articulated wrong in search of remedy. On this basis, chapter three outlined the nature of traditional knowledge associated with genetic resources (TKaGRs) – which constitutes one of the key subjects of appropriation within the biopiracy discourse. It also discussed some of the central problems warring against a unanimous definition for TK, as well as its protection from biopiracy. In chapter four, I discussed biopiracy as a contemporary problem which draws strength from two core sore spots of emphasis – a failed benefit sharing mechanism, and an appropriative intellectual property (IP) system. The interplay of these factors continues to define the problem of biopiracy today. This chapter examines the Nagoya Protocol as a potential solution to the problem of biopiracy. It argues that while the Nagoya Protocol is a necessary component of the solution (with a particular emphasis on the benefit sharing failure), it is insufficient given the broader trans-regime nature of biopiracy.

The Nagoya Protocol was adopted in 2010 and entered into force in 2014. A subsidiary instrument to the Convention on Biological Diversity (CBD), the Protocol contains a 27-paragraph preamble, 36 substantive articles and an Annex. The Nagoya Protocol was negotiated in response to a call by the World Summit on Sustainable Development (WSSD) which took place in Johannesburg, 2002. The call was to negotiate within the framework of the CBD, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources (GRs). As a direct consequence of this call, the CBD mandated its Ad Hoc Open-ended Working Group on Access and Benefit Sharing to negotiate and elaborate, in collaboration with its Ad Hoc

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598 The singular annex of the Protocol relates to the monetary and non-monetary benefits which could form the basis of negotiations in benefit sharing agreements.

599 See, United Nations, Report of the World Summit on Sustainable Development: Johannesburg, South Africa, 26 August – 4 September 2002 (New York: United Nations, 2002) at 36. This call was contained in para 44(o) of the Johannesburg Plan of Implementation; a 65-page document which set out in more detail the action that needs be taken in specific areas, including gaps in the implementation of Agenda 21.
Open-ended Intersessional Working Group on Article 8(j) and Related Provisions, an international regime on access to GRs and benefit sharing. The mandated negotiations were to be aimed at adopting an instrument/instruments to effectively implement the provisions of Article 15\textsuperscript{600} and Article 8(j)\textsuperscript{601} of the Convention, as well as the Convention’s objectives.\textsuperscript{602} The result of this negotiation is contained in the Nagoya Protocol.

This chapter advances the thesis in three key ways. First, this chapter provides a historical account of benefit sharing as a solution to biopiracy in international law. By doing this, I present benefit sharing as a mechanism driven primarily by the broader objective of sustainable development and argue that its implementation within the context of addressing biopiracy must be construed as one which guarantees the sustainability of the indigenous experience, and not the ultimate destruction thereof. Next, the chapter traces the development of the Nagoya Protocol. It introduces the legal nature, content and scope of the

\begin{itemize}
\item \textsuperscript{600} Article 15, CBD, which deals with access to GRs, provides:
\begin{enumerate}
\item Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
\item Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
\item For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
\item Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
\item Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
\item Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
\item Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.
\end{enumerate}
\item \textsuperscript{601} Article 8, deals with the in-situ conservation of GRs. Of relevance here, Article 8(j) provides, \texttt{subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices}
\item \textsuperscript{602} See COP Dec VII/19, \textit{supra} note 158 at 5 (para D.1)
\end{itemize}
Nagoya Protocol. The examination of the Protocol’s provisions offers a useful introduction to the key principles, rule, norms, and decision making processes of the international ABS regime it establishes, and how these regime components interact with other regimes. Third, this chapter points to the evolutionary context of the Nagoya Protocol. This evolutionary analysis significantly establishes a basis for the examination of the World Intellectual Property Organization’s (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) as a central element in the very design of the Nagoya Protocol – a discussion which I undertake in chapter six. I reiterate, in making this point, the earlier argument made in chapter two regarding the Nagoya Protocol as an open-ended elemental regime which is best characterized as an evolving regime complex bound by ‘complementary’ instruments of which WIPO forms an important part.

This chapter is divided into two main parts. In part one, I review the direct events which led to the emergence of an international regime on access and benefit sharing (ABS). Furthermore, the justifications for this international regime are outlined and emphasis is placed on the user-compliance deficiency. I then briefly outline the steps that led to the direct adoption of the Nagoya Protocol, while yet providing an overview of its ABS provisions with a specific focus on TKaGRs. In part two, I review the evolutionary context of the Protocol in support of a rendering of the Protocol as an emerging regime complex defined by the problem of biopiracy and incorporating in a significant way, the IP regime (particularly, WIPO). Part three offers conclusions to the chapter.

5.1 The Emergence of an International Dispensation on Access and Benefit Sharing.

The Nagoya Protocol’s negotiation was commenced with a call for the negotiation of an international regime on ABS within a discourse on biodiversity conservation and management. This call was contained in one of the principal outcomes of the WSSD which took place in Johannesburg, South Africa in 2002. The Summit was organized to afford the international community another opportunity to adopt concrete steps and identify quantifiable targets for better implementing Agenda 21, which had been adopted by over 178 governments at the United Nations Conference on Environment and Development (UNCED) otherwise referred to as the ‘1992 Earth Summit’, which was held in Rio de Janeiro, from 3 – 14 June, 1992. It is a comprehensive plan of action to be
adopted 10 years earlier. Three key outcomes were produced at the Summit. Of these three, the Johannesburg Plan of Implementation (JPI) contained the call for the negotiation of an international regime on access and benefit sharing (ABS). It is worth noting that this call for the negotiation of an international regime was driven primarily through the lobbying of megadiverse countries who sought a firm solution to the problem of biopiracy within their territories. A further elaboration of this important point regarding the role of the developing countries in securing the WSSD outcomes is made in my discussion of the Bonn Guidelines below. The call for the negotiation of the international regime offers a useful preliminary understanding of the demands of developing countries in the foundational articulation of a firm biopiracy

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604 According to Doran, the three main outcomes from the WSSD were, the Johannesburg Declaration on Sustainable Development, the Johannesburg Plan of Implementation and the Type II Commitments by Governments and other stakeholders. For a full assessment of the WSSD, see generally Peter Doran, “World Summit on Sustainable Development (Johannesburg) – An Assessment for IISD”, Briefing Paper, (October 3, 2002), online: <http://www.iisd.org/pdf/2002/wssd_assessment.pdf>, at 1 – 2.

605 The Like-Minded Megadiverse Countries (LMMC) was established by the Cancun Declaration of Like-Minded Megadiverse Countries, Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela, 18 February 2002 [Cancun Declaration]. The LMMC today is a group of 17 countries which hold more than 70% of all biodiversity and 45% of the earth population. See, <http://pe.biosafetyclearinghouse.net/actividades/2009/grouplmmc.pdf> 2. These countries are; Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela. The LMMC acts as a mechanism for cooperation to promote the interests of the members on matters relating to the protection of TK, access to GRs and the fair and equitable sharing of benefits derived from their use. The LMMC was established with 15 primary objectives. See Declaration 1(a) – (o). While recognising the importance of TK in biodiversity conservation (Par. 6 of the Preamble), as well as the limitations of the various existing international instruments to protect effectively the legitimate interests of the countries of origin of biodiversity (Par. 7 of the Preamble), the Group was established as a mechanism for consultation and cooperation for the promotion of interests and priorities related to the preservation and sustainable use of biodiversity (See Declaration 1). Significantly, the Cancun Declaration was made just about 6 months prior to the WSSD. As Peria notes, this was an independent move, premised on the fears that no substantial agreement would be made with regard to the international regime later that year. Elpidio Peria ‘Benefit-Sharing from the Use of Genetic Resources: Real Myths or Mythical Realities?’ in Burrows, Beth, ed, The Catch: Perspectives in Benefit Sharing (USA: The Edmonds Institute, 2005) 166. [Peria, “Benefit Sharing from the Use of Genetic Resources”] at 166. Since the formation of the Group though, its tremendous impact has been felt in all areas of negotiations on biodiversity conservation and TK protection (see Par. 8 of the preamble to the Cancun Declaration). Significantly, the effect of the Declaration and the presence of the LMMC at the WSSD gave a greater platform to the calls by the developing biodiversity rich countries for an international regime on ABS. This group was extremely active at the WSSD in pushing forward the case of biodiversity rich countries especially with the need to negotiate an international regime. With the support of the G77, these efforts resulted in the decision to negotiate an international regime. (See Joseph Reji “International Regime on Access and Benefit Sharing: Where Are We Now? (2010) 12:3 Asian Biotechnology & Development Review 77 [Reji, “International Regime on ABS”] at 80).

606 See, section 5.1.2.3. below.
solution through benefit sharing. In relevant part, the Plan of Implementation adopted by the Summit provides,

[b]iodiversity, which plays a critical role in overall sustainable development and poverty eradication, is essential to our planet, human well-being and to the livelihood and cultural integrity of people. However, biodiversity is currently being lost at unprecedented rates due to human activities; this trend can only be reversed if the local people benefit from the conservation and sustainable use of biological diversity, in particular in countries of origin of genetic resources, in accordance with article 15 of the Convention on Biological Diversity. The Convention is the key instrument for the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising from use of genetic resources. A more efficient and coherent implementation of the three objectives of the Convention and the achievement by 2010 of a significant reduction in the current rate of loss of biological diversity will require the provision of new and additional financial and technical resources to developing countries, and includes actions at all levels to […] negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources’ [emphasis added].

This call was thus contained within the context of a chapeau which recognized the danger of ignoring the continued loss of biodiversity. The chapeau also recognized the central role of biodiversity in eradicating poverty and contributing to sustainable development. Three main premises for the Nagoya Protocol, which support this dissertation’s analysis, are embedded within this call. First, the central importance of biodiversity to our very existence and the corresponding threat emanating to life and TKaGRs arising from its rapid loss. Having dealt extensively with the issue of biodiversity within the discussion of Traditional Knowledge associated with Genetic Resources (TKaGRs) in Chapter three, I will not repeat the discussion here. The second premise, which I will now turn to address, however, is the idea that enabling local people to benefit from biodiversity is the only way to address the problem of biodiversity loss. Indeed, this represents a useful premise for the effectiveness of benefit sharing as a solution to biopiracy – the ability of indigenous peoples and developing countries to benefit from benefit sharing. I now turn to address the foundational basis for the regime anchored within the mechanism of benefit sharing.

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608 See 3.2.1. above.
5.1.1 Benefiting from the Sharing of Benefits

This trend [of biodiversity loss] can only be reversed if the local people benefit from the conservation and sustainable use of biological diversity, in particular in countries of origin of genetic resources⁶⁰⁹

This second key premise contained within the call for the ABS regime relates to the importance of the benefit sharing mechanism. It is interesting to note that the entire concept of benefit sharing as contained within call for an ABS regime is mentioned as being the only solution to the rapid loss of biodiversity. I should note here, however, that the call does not necessarily speak of ‘benefit sharing’ as the solution, but rather indicates the solution being that local people are able to benefit from the conservation and sustainable use of biodiversity. In other words, the strength of the rhetoric ‘benefit sharing’ should not lie so much in the perceived distribution of benefits, but rather should focus on the realization of actual benefits to the indigenous peoples when biodiversity and associated knowledge is used. Where therefore the systems being designed do not result in actual benefits to indigenous peoples and societies, the concept of benefit and the corresponding obligations of conservation and sustainable development cannot be attained. A helpful interpretive reading of the phrase will then be that biodiversity loss can only be reversed if the conservation and sustainable use of biodiversity is made advantageous to indigenous peoples and/or biodiverse countries.

A simple hypothetical illustration can be used to describe this. A local county X is noticing a rapid decline in the quality of results produced by its local primary school. It considers that the only way to address this trend is to incentivize the primary school teachers. In thinking of ways around this, the local council decides to raise the salaries of its primary school teachers. To realize this salary raise, the Council also raises the tuition costs for the students and imposes a development levy on the teachers. As soon as the salary raise takes effect, market prices of goods and services within the community begin to rise as parents seek ways to meet up with the new tuition rates. In addition to the increased cost of living, teachers are beginning to contend with the additional levies they are required to pay. Eventually, the excitement amongst the teachers generated by the new salary scale is quickly replaced by frustration as teachers begin

to consider themselves actually worse off with the new salary scale. Consequently, though the policy led to a perceived benefit (or incentive) for the teachers, it did not actually benefit the teachers. In a similar way, when the discussions around benefit sharing are being held, the focus must actually be on the extent to which the mechanisms place indigenous peoples in an advantaged position to benefit from their stewardship. This understanding has not necessarily guided the evolution of the benefit sharing concept due to its varied applications and uses. I will take a step back here to highlight some of the ways the term ‘benefit’ is commonly used or conceptualized.

5.1.1.1 A Benefit as an Advantage

According to Doris Schroeder, benefit sharing involves the action of giving a portion of advantages/profits derived from the use of genetic resources or traditional knowledge to the resource providers, in order to achieve justice in exchange.\(^{610}\) As with this interpretation, a benefit is generally construed as an advantage, profit, or privilege.\(^{611}\) However, the idea of a benefit could assume differing meanings within the course of differing transactions.\(^{612}\) A relevant iteration of the concept could include, for instance, its reference to an eventual advantage or sustainable privilege something gives. For instance, the benefit of a good education could be the opportunity to ultimately secure and excel in a professional work environment. From this perspective, a benefit is explained in terms of a desired effect or ultimate outcome. This, I believe, is the literal context in which the framers of paragraph 44(o) considered this term and which guides my argumentation around the benefit sharing system. For the conservation of biodiversity to be made possible, it must be pursued within the context of an advantageous ultimate prospect to indigenous peoples and developing countries. Indeed, this is the interpretation that is being advanced from my description above. The term benefit sharing has, however, been subjected to differing conceptual interpretations, some of which are highlighted here, as they also reflect how benefit sharing is often conceptualized within various analyses.

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612 Ibid.
A benefit could alternatively be explained as the immediate profit or gain (consideration) which moves to a promisee, whether or not such is adequate, and whether or not such holds ultimate advantages for the recipient. For example, direct or indirect payments made in return for a good or service. In this context, it assumes the status of a consideration – a price paid for something valuable. In the hypothetical example portrayed above, the salaries of the teachers fit this explanation. This is a popular way in which the benefit sharing system is often implied. By this, biodiversity as well as the knowledge of indigenous peoples about its uses is seen as a valuable and price-determinable commodity for which the sharing of benefits represents a consideration for access. A danger of this interpretation is that it wholly discusses biodiversity within a proprietary context while yet failing to account for the cultural and spiritual elements of biodiversity, most importantly the fact that biodiversity is part of a holistic cultural heritage. Furthermore, deriving from this interpretation, immediate benefits could actually represent ultimate disadvantages for indigenous groups and/or biodiverse countries. It is in this context that activists like Vandanda Shiva, Martin Khor, and Beth Burrows discuss benefit sharing as a hoax aimed at plundering the wealth of indigenous peoples through false benefits.

Yet again, benefits could be explained as a privilege or a dispensation which the state or individual is not constitutionally required to provide. For instance, describing a benefit as a favor or a gratuitous act – a direct or indirect economic advantage on the beneficiary, which it would not have obtained in the

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613 See, for example Article 25, UNDRIP, providing that Indigenous peoples have the right to maintain and strengthen their distinctive spiritual relationship with their traditionally owned or otherwise occupied and used lands, territories, waters and coastal seas and other resources and to uphold their responsibilities to future generations in this regard.

614 See, for instance, Devinder Sharma, “Selling Biodiversity: Benefit Sharing is a Dead Concept” in Beth Burrows, ed. The Catch: Perspectives in Benefit Sharing (Washington: Edmunds Institute, 2005) 1 – 14. See also, Silvia Ribeiro, “The Traps of Benefit Sharing” in Beth Burrows, ed. The Catch: Perspectives in Benefit Sharing (Washington: Edmunds Institute, 2005), who summarizes the legitimation of the concept of benefit sharing in the following words:

[r]obbery of resources is a fact of life, like progress and science; it can’t be stopped, so let’s face the inevitable and try to get something out of it. Let’s become merchants instead of victims, and do it before our neighbor’s do
ordinary course of business – explains this point.\textsuperscript{615} Again, this erroneous interpretation\textsuperscript{616} is sometimes adopted and reflected in discussions around benefit sharing. Based on this view, benefit sharing exists as a moral obligation; one which is not premised on any contribution or ownership rights of indigenous peoples over their knowledge and resources. Rather, it is linked to the moral duty of companies to help the poor indigenous communities by extending ‘beneficial hand outs’ to them. Again this iteration is highly problematic as establishes a power relationship which places the sharing of benefits as the ‘good of a user’ and not in any way the ‘right of the provider’. It fails to acknowledge the role of indigenous peoples in the maintenance of biodiversity over time. The broader idea of state aid or development aid, and the concerns thereof around neocolonialism in international discourse, provides the context for this usage of the term.

Finally, a fourth explanation could yet be ‘benefits’ as a financial assistance that is received from an employer or insurance company in times of sickness, disability or unemployment. This is often understood in terms of a compensation for losses or misfortunes suffered.\textsuperscript{617} Interestingly, this interpretation has been widely developed into the fabric of the biopiracy rhetoric as a justification for benefit sharing. By this, benefits are viewed as ‘compensation’ for the appropriation of resources. Indeed, biopiracy is often defined or spoken of as the ‘uncompensated acquisition of resources and/or knowledge of indigenous peoples”. From this perspective, biopiracy is technically addressed where such acquisitions are ‘compensated’. However, as Goodin notes, “it would […] be wrong to presume that we as a society can do anything we like to people, just so long as we compensate them for their losses.”\textsuperscript{618} An unfortunate implication of this interpretation is that benefit sharing is actually then the very endorsement or legitimization of a continued state of misappropriation. Shared benefits become a part of the running costs


\textsuperscript{616} Doris Schroeder for instance, notes that the concept of benefit sharing ‘has no charitable overtones’. See Doris Schroeder “Benefit Sharing: From Obscurity to Common Knowledge” (2006) 6:3 Developing World Bioethics, at ii.

\textsuperscript{617} See Bryan A Garner, ed, \textit{Black’s Law Dictionary} 10ed (USA: Thomson Reuters, 2014) at 188.

for achieving broader corporate ends irrespective of the wishes of knowledge and resource holders. It is in this context that Argumedo’s reflections makes a little more sense:

benefit sharing is like waking up in the middle of the night to find your house being robbed. On the way to the door, the thieves tell you not to worry because they promise to give you a share of whatever profit they make selling what used to belong to you.\textsuperscript{619}

Compensation then reads ultimately as an agreement to justify a system of misappropriation in return for an established mechanism of receiving benefits. The popular quote often attributed to Rear Admiral Grace Murray Hopper; “it is better to beg forgiveness than ask permission” comes to mind. In this case, compensation through benefits is seen as an answer to appropriation of resources.

These four perspectives manifest in various ways in the way the term benefit sharing is utilized in the ABS regime. Drawing extensively from the Bonn Guidelines, the Nagoya Protocol’s outlines a series of possible monetary and non-monetary benefits which could form a part of benefit sharing contracts. With respect to monetary benefits, it specifically lists a non-exhaustive total of ten possible monetary benefits which include; access fees/fee per sample collected; up-front payments; milestone payments; payment of royalties; license fees in case of commercialization; special fees to be paid to trust funds in support of conservation and sustainable use of biodiversity; salaries and preferential terms where mutually agreed; research funding; joint ventures; joint ownership of relevant IP rights.\textsuperscript{620} For non-monetary benefits, a total of 17 possible benefits are suggested, including, sharing of research and development results; participation in product development, collaboration in education and training; admittance to ex-situ facilities of GRs and databases; strengthening of capacities for technology transfer; human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

The importance of this clarification is that for a proper discussion around justice to indigenous peoples from benefit sharing as well as a full realization of the objective of biodiversity conservation, the perception and realization of benefits must be exclusively construed in terms as defined and accepted by indigenous peoples. Beyond a mere protection of biodiversity, benefit sharing is a protection system for the sustainability of indigenous peoples and their experiences. The benefit then is not a question of how


\textsuperscript{620} See Annex 1(a) – (j), Nagoya Protocol.
corporations or users understand it, but rather how indigenous peoples understand it. Preston Hardison, a leading indigenous representative within the ABS circles, offers the following example of the tension arising from the differing interpretations of benefits from user and provider perspectives:

[i]ndigenous people are striving to live in their cosmo-vision and have their dignity. Access and benefit-sharing is a contractual approach focused on the active access and some immediate benefits, but it is not looking at whole ways of life and ways of being and not really holistically protecting indigenous peoples in their culture in the long run.  

Explaining and justifying an interpretation of benefit sharing through the lens of an ultimate and sustainable advantage for indigenous peoples requires an understanding of the demands and expectations of indigenous peoples.

5.1.1.2 The Indigenous Advantage

For centuries, Indigenous Peoples all around the world have suffered discrimination and exclusion. Their oft forced and yet characteristic self-separation from mainstream society has typically placed them in precarious positions vis-à-vis the respective dominant state cultures within which they exist. Though the very concept of indigenous peoples continues to be debated among scholars and even indigenous groups themselves — a reflection of the divergent historical experiences of various indigenous populations that claim representation under this terminology, several common denominators serve to

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622 The term ‘indigenous’ is often used interchangeably with other terms, such as “aboriginal”, “native”, “original”, “first nations”, “tribal” or other similar concepts. See, Rodolfo Stavenhagen, Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous People, document E/CN.4/2006/78/Add.2. [Stavenhagen, Report of the Special Rapporteur].

623 In his report on Human Rights and Indigenous Issues, Rodolfo Stavenhagen notes that there is no internationally agreed upon definition of indigenous peoples. Different states generally adopt different definitions in terms of their particular contexts and circumstances. Ibid. See also Arewa, “Piracy, Biopiracy & Borrowing”, supra note 37 at 12 – 13 (noting the context-dependent nature as well as fluidity – susceptibility to change – of the indigenous peoples’ terminology). Within multilateral negotiations, TK holders and indigenous peoples have generally sought to avoid being bound by all-embracing definitions of the concept. See, for instance, Document DESAO, 2004, PFII/2004/WS.1/3 (2004). In line with Article 33 of the UNDRIP, indigenous peoples have preferred to self-identify themselves as such in line with their rights to self-identification and self-determination. Frankel & Drahos also cite self-identification as the core principle within the United Nations system for determining the application of the ‘indigenous’ concept. See, Frankel & Drahos, “Innovation & Intellectual Property”, supra note 37 at 10.

624 See, for instance, para 23 of the Preamble to the UNDRIP which recognizes the differences in the situations of indigenous peoples in various regions and various countries round the world. Within this context, continents like Africa and Asia, for instance, often reject the notions that groups within them are more indigenous than others. This is in stark contrast to the Americas, Russia, the Arctic and many parts of the Pacific. Similarly, within the African context, unlike other regions, indigenous peoples are not typically distinguished on the basis
unite the general experience of indigenous peoples globally. Some of these common denominators include their discrimination and exclusion from economic and political power, their displacement from ancestral lands, their loss of cultural and physical resources for survival, their poverty, illiteracy, and malnutrition, amongst others. Of these common denominators, a central concern for all indigenous peoples relates to the misappropriation of the GRs and TKaGRs held within their communities. This is especially with respect to the uncompensated and unauthorized acquisition of GRs and/or TKaGRs which indigenous peoples have maintained and developed over generations. For them, as discussed in chapter three, these resources form a part of their integrated biocultural heritage, bearing cultural, spiritual and social significance. It is this misappropriation that I have discussed extensively as biopiracy. Indigenous peoples are the ultimate victims of biopiracy.

Several sources may be referenced in advancing an argument on what would really be advantageous to indigenous peoples within the context of appropriation of resources and their knowledge. The most notable instrument codifying the hopes and aspirations of indigenous peoples, is the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), adopted in 2007 by the UN General Assembly. The UNDRIP has developed as an important document on the rights of indigenous peoples within the international legal framework. It contains both the stated rights for indigenous peoples as well as a range of corresponding duties of States in supporting and enforcing these rights. Importantly, though it is not a binding legal instrument, its importance in ascribing legitimacy to the processes and outputs of other international legal frameworks which deal with the rights of indigenous peoples cannot be underestimated. According to James Anaya,

\[\text{n]o international standard-setting process [...] should lead to an instrument that goes below or undermines the standards articulated in the Declaration and other established\]

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626 For the concept of [collective] biocultural heritage, see supra note 311.

627 See, for instance, Bavikatte & Robinson, “Towards a People’s History of the Law”, supra note 329 at 37, noting the central use of UNDRIP by indigenous peoples as a means of advancing their rights within the Nagoya Protocol negotiations.

The UNDRIP thus represents ‘the minimum standard for the survival, dignity and well-being of the indigenous peoples of the world’\footnote{See Article 43, UNDRIP.} and, as such, is consistently held out as a measure within negotiations that deal with indigenous peoples. For this reason, it has appeared severally within the discussion of ABS.\footnote{Bavikatte & Robinson, “Towards a People’s History of the Law”, supra note 329 at 45 – 46.} It is suggested here that any construed benefit for indigenous peoples must align with the spirit and purpose of the UNDRIP.\footnote{Ibid.}

Anaya asserts that the contemporary indigenous rights regime of which the UNDRIP forms a central part, is guided by three core principles.\footnote{See, Anaya, “What is at Stake for Indigenous Peoples”, supra note 358 at 2.} These principles are important in determining the very spirit and purpose underpinning the UNDRIP. First, indigenous peoples should be able to exercise meaningful control over the future development of all those aspects of collective human interaction that define and constitute their distinct societies.\footnote{Ibid.} The central distinctive factor of indigenous peoples is their culture which is generally regarded as the totality of attitudes, beliefs, practices, values, experience etc. which serves to distinguish peoples. International law has established a right to culture\footnote{See Article 27, International Covenant on Civil & Political Rights 1966 (entered into force on 23 March 1976) . <http://www.ohchr.org/Documents/ProfessionalInterest/ccpr.pdf>, which contains an elaboration of the ‘right to culture’ by the United Nations Human Rights Committee, suggesting that indigenous peoples shall not be denied the right to enjoy their own culture.} and the maintenance of this right must be taken into account when the ultimate advantage of benefits is being considered. In protecting the right to culture, it is suggested that benefit sharing should not have the effect of dispossessing indigenous peoples of their future ability to maintain their distinct culture. In other words, benefit sharing should not operate to render the culture of indigenous peoples unsustainable. The UNDRIP expresses this concern as a right of indigenous peoples not to be subjected to forced assimilation or destruction of their culture, and as such, States are required to provide effective mechanisms to prevent
actions which have the *aim or effect* of depriving them of their integrity as distinct peoples, or of their cultural values or ethnic identities.\(^{635}\)

Closely tied to the discussion above, a second principle of the contemporary indigenous rights regime as noted by Anaya, is that indigenous peoples’ cultures and societies are deeply rooted in the lands, waters and natural resources that they have traditionally used.\(^{636}\) Article 26, UNDRIP notes that ‘indigenous peoples have the right to the lands, territories and resources which they have traditionally owned, occupied or otherwise used or acquired’\(^{637}\) as well as the right to maintain and strengthen their distinct spiritual connection with such territories\(^{638}\) Of significance within this context of benefit sharing and culture is that the lands, territories and resources of indigenous peoples are known to be a rich source of conserved biodiversity. Indeed, their knowledge about the genetic material within their territories is what transforms same into resources with actual and/or potential value.\(^{639}\) In effect, therefore, the culture of indigenous peoples and its association to their lands and resources is a major pointer to the value of genetic material contained therein. The deprivation of indigenous peoples’ access to their lands and/or resources, is an indirect deprivation of the right to culture, and should therefore not be a direct or ultimate outcome of benefit sharing arrangements.\(^{640}\)

Third, Anaya notes the principle of equality.\(^{641}\) Based on this, the UNDRIP suggests the idea of equality in differentiation. In other words, it affirms that indigenous peoples are equal to all other peoples, while recognizing the right of all peoples to be different, to consider themselves different, and to be respected as such.\(^{642}\) Article 2 of the UNDRIP also provides that

[i]ndigenous peoples and individuals are free and equal to all other peoples and individuals and have the right to be free from any kind of discrimination, in the exercise of their rights, in particular that based on their indigenous origin or identity.

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\(^{635}\) See Articles 8.1 & Article 8.2(a), UNDRIP
\(^{636}\) See para 7, preamble to the UNDRIP.
\(^{637}\) See Article 26, UNDRIP.
\(^{638}\) See Article 25, UNDRIP
\(^{639}\) Anaya, “What is at Stake for Indigenous Peoples”, *supra* note 358 at 4.
\(^{640}\) Article 8.2(b), UNDRIP provides that states shall provide effective mechanisms for the prevention of actions which have the aim or effect of dispossessing indigenous peoples of their lands, territories or resources.
\(^{641}\) Anaya, “What is at Stake for Indigenous Peoples”, *supra* note 358 at 2.
\(^{642}\) See, para 2, preamble to the UNDRIP.
Indigenous peoples are thus entitled to have their customs and practices respected, are entitled to equal protection over their IP and innovations, and are entitled to an equal (or equitable) share of proceeds arising from the use of their resources. The important implication of this to benefit sharing is that equality between the parties must form a core part of the entire negotiation and implementation of benefit sharing arrangements, including the right of indigenous peoples to fully participate as equals in the decision making processes which address the sharing of benefits. This is an important point and has led to an increased emphasis on capacity building initiatives for indigenous communities to ensure that they are well informed and empowered to take complex decisions on benefit sharing arrangements which affect them. Again this principle of equality serves to underscore the importance of respecting the existing customary laws which indigenous groups have defined for themselves relating to the use and conservation of their resources.

In sum therefore, the concept of an ultimate advantage for indigenous peoples presupposes that benefit sharing arrangements should be based on principles of respect, and not serve to destroy the distinctive characteristics of indigenous groups, nor their associations with their resources and heritage. In effect, benefits should support the sustainability of indigenous existence and experience. Interestingly, the emergence of the benefit sharing principle within international law was made prominent within the context of a discourse on sustainable development. In reviewing the emergence of benefit sharing as a central tenet of the ABS regime below, I seek to emphasize the primacy of the interests and actual needs of beneficiaries within the Third World in the equitable and just conceptualization of benefits.

5.1.2 A History of Benefit Sharing in International Law

Within the context of the ABS system and the third objective of the CBD, the phrase benefit sharing continues to attract popular usage today.643 The idea of benefit sharing has, however, been in existence even before the adoption of the CBD.644 The earliest identified references to benefit sharing in international law have been contained within the context of development. The 1986 Declaration on the Right to

643 See Morgera & Tsioumani “The Evolution of Benefit Sharing” supra note 403 at 2.
644 Ibid. This view is also supported by Peria, “Benefit Sharing from the Use of Genetic Resources”, supra note 605 at 166.
Development for instance utilized the idea of benefit sharing in connection with the right of states to formulate development policies aimed at improving the well-being of their populations. The participation of the citizens in the actualization of such development initiatives entitled them to enjoy a ‘fair distribution of benefits resulting therefrom.’ A year later, in 1987, the World Commission on Environment and Development (WCED), also known informally as the Brundtland Commission, submitted its final report to the United Nations General Assembly and also included a reference to benefit sharing, albeit, for the first time, from the perspective of solving a deeper problem; the Report, entitled ‘Our Common Future’, offered the issue of benefit sharing as a critical element to attaining present development objectives without compromising the future – sustainable development. Its inclusion was seen as a way of correcting faulty notions of development while yet advancing a more responsible idea of development; i.e. one that is sustainable. The prominence and significance of the Commission’s work in the area of sustainable development, including its endorsement of benefit sharing as a viable solution to the problems it had identified, was such that it is often still credited with the first international reference to benefit sharing.

The effects of the Brundtland Commission Report still resonate today within the discourse of ABS and an understanding of the foundations of the Commission explains why this is so.

5.1.2.1 The Brundtland Commission

According to Iris Borowy the need for a normative definition of human conduct which delineated the direction and range of acceptable policies, laws, investment, and private behavior was the underlying need which necessitated the 1983 formation of the Brundtland Commission. From the perspective of the

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646 See Article 2.3 and preamble para. 2. Article 2.3 provides:

[states have the right and the duty to formulate appropriate national development policies that aim at the constant improvement of the well-being of the entire population and of all individuals, on the basis of their active, free and meaningful participation in development and in the fair distribution of the benefits resulting therefrom.

647 Peria, “Benefit Sharing from the Use of Genetic Resources”, supra note 605 at 163.

648 Informally, and yet more commonly, the WCED is often referred to as the Brundtland Commission, a reference to the name of its Chair; Ms. Gro Harlem Brundtland, the former Prime Minister of Norway. The Brundtland Commission was established by the United Nations General Assembly in 1983 and its final report was presented on 27 April 1987 to the UN General Assembly. For a full and detailed discussion of the origins, rationale and progressive work of the Brundtland Commission, see, generally, Borowy, Defining Sustainable Development, supra note 341.

649 Ibid. at 3
international community, the Commission’s work constituted an important political follow on to the earlier works of the Brandt Commission on North South Issues,650 (considered to contain the most comprehensive and solutions-oriented analysis of critical global economic issues)651 and Palme’s Commission on Security and Disarmament Issues which was established to examine international security issues.652 For its part, the Brundtland Commission sought to look into the future of the planet within the context of development. The establishment of the Commission was also based on a need to address the real concerns regarding the unsustainable development drives and their negative impacts on the environment. Its report was focused on an integrated and responsible approach to the understanding and pursuit of development. In carrying out its work, the Commission significantly drew on the two concepts of the environment and development as cardinal references.

With respect to the environment, the Commission attempted to correct the notion that environmental issues could be isolated from human actions, ambitions and needs. Instead, it reiterated, amongst others, the inseparability of these factors. The Commission was wary of the narrow focus of

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650 German Chancellor Willy Brandt was asked to preside over a commission of experienced, respected politicians and economists – an idea floated in 1977 by the then president of the World Bank, Mr. Robert McNamara. The underlying objective of the Commission was to make recommendations on ways of breaking through the existing international political impasse in North-South negotiations for global development. Brandt therefore established an ‘Independent Commission on International Development Issues’ in September 1977 with the purpose of influencing public opinion to help change government attitudes, as well as to make proposals for revitalizing North-South negotiations. The Brandt Commission’s work culminated in the release of two reports; North-South (1980) and Common Crisis (1983) which gave primary emphasis to the international issues of food and agricultural development, aid, energy, trade, international monetary and financial reform, and global negotiations, amongst others. They called for a ‘full-scale restructuring of the global economy, along with a new approach to the problems of development, including an emergency program to end poverty in developing nations’. See the updated Brandt Report: James B Quilligan, *The Brandt Equation: 21st Century Blueprint for the New Global Economy* (Philadelphia, USA, 2002) at 1. See also Centre for Global Negotiations, “The Brandt Equation: 21st Century Blueprint for the New Global Economy, online: CGN <http://www.brandt21forum.info/About_BrandtCommission.htm>. See also, for a comprehensive summary of the reports, including the origins and purpose of the Commission, Daniel Sneider, “The Report of the Commission: End”, (1980) 7:9 Executive Intelligence Review at 26 – 31.

651 See, Share the World’s Resources, “The Brandt Report: A Summary” (31 January 2006) online: STWR <http://www.sharing.org/information-centre/reports/brandt-report-summary>. This was so, even though the proposals put forward by the Commission were never adopted by governments due to the Cold War and a collective lack of political will among world leaders. Ibid.

“development” that had emerged over the years; one that was narrowly construed in terms of “what poor nations [needed to] do to become rich”. According to Ms. Brundtland, however:

The “environment” is where we all live; and “development” is what we all do in attempting to improve our lot within that abode. The two are inseparable. Further, development issues must be seen as crucial by the political leaders who feel that their countries have reached a plateau towards which other nations must strive. Many of the development paths of the industrialized nations are clearly unsustainable. And the development decisions of these countries, because of their great economic and political power, will have a profound effect upon the ability of all peoples to sustain human progress for generations to come.

Within this context, the Brundtland Commission articulated and elaborated the concept of sustainable development (SD). Indeed it is this ground-breaking work on the concept of SD that has kept the work of the Commission so relevant within international circles till date. The Commission defined SD as development that meets the needs of the present without compromising the ability of future generations to meet their own needs. There is a temptation to mentally construe to the term ‘future generations’ within the context of ongoing ‘development’ as defined by industrialization. What this sadly does is that it excludes the very needs of sustainable indigenous development from the concept of sustainable development. Therefore, when we discuss benefit sharing, we often view benefit sharing exclusively as a way of supporting sustainable forms of industrialization. Benefit sharing is however also a mechanism to ensure the sustainability of indigenous existence, livelihoods and their development. In essence, in interpreting SD, the ability of future generations of indigenous peoples to enjoy their indigeneity must form a central basis of sustainable benefit sharing practices. The Commission, in support of this point, noted that the articulation of SD must be carried out through a prioritization and understanding of the essential

653 The concept of sustainable development was first coined by Barbara Ward from where it spread to the international environmentalist scene. Though not developed by this Commission, the concept of sustainable development was defined and elaborated by the Brundtland Commission. Borowy, Defining Sustainable Development, supra note 341 at 3 – 4, noting that the Brundtland Commission did not invent either the expression or the concept of sustainable development. As far back as 1987 when its report was submitted to the UN General Assembly, the role of traditional communities and their knowledge in the attainment of the goals of sustainable development were clearly identified. See generally World Commission on Environment and Development (WCED), Our Common Future, 1987, online: <http://www.un-documents.net/ocf-06.htm#1>. [WCED Our Common Future].

654 Ibid. Cap 2. 1. See also Borowy, Defining Sustainable Development, supra note 341 at 3.
needs of the world’s poor. In recognizing these extreme development spectrums, it noted the importance of equity in any real solutions aimed at achieving SD. According to the Commission:

Development involves a progressive transformation of economy and society. A development path that is sustainable in a physical sense could theoretically be pursued even in a rigid social and political setting. But physical sustainability cannot be secured unless development policies pay attention to such considerations as changes in access to resources and in the distribution of costs and benefits. Even the narrow notion of physical sustainability implies a concern for social equity between generations, a concern that must logically be extended to equity within each generation.

The idea of benefit sharing thus emerged as an attempt to ensure that global development is pursued with regard to equity within generations and between generations. In other words, the development drives of a particular region/country within a generation was pursued in full recognition of the impact it had on other regions of the world, such that development in one area did not come at the cost of development in other areas. This is popularly discussed today in the context of inclusive development. Inclusive development involves, inter alia, a pro-poor approach to development which essentially advocates a development which is not to the detriment of a sector of society, but rather one which includes all sectors within the growth process.

In addition to its inclusive development angle, the Commission also focused on the impact of present development strategies on future generations. In this regard, the Commission recognized that the development drives of today could have a negative effect on the future generations and the ability of next generations to attain development objectives. In this regard, the Commission was concerned with the rapid extinction of species and the implications of a depleted biosphere on the future of the world. It is this very concern as identified by the Brundtland Commission that the WSSD reiterated in calling for the negotiation of an international ABS regime. It thus saw the need to recognize and address the effects of declining biodiversity due to human development as central to the conceptualization of SD. An important conclusion to be made here is that benefit sharing is therefore a sustainable development tool or mechanism. In other words, the sustainable development of biodiverse regions and indigenous peoples therein lies at the heart

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655 Cap 2.1 WCED Our Common Future, supra note 653. It also identifies an understanding of the increasing limitations on the ability of the environment to meet its present and future needs due to technological advances and social organization as a core consideration for the articulation of SD.

656 Cap 2.3 WCED Our Common Future, supra note 653.

of the benefit sharing mechanism. This point, which has translated into the three objectives of the CBD, must be held close throughout discussions on the CBD as well as the implementation of the ABS regime.

It was against this backdrop that a valid justification lay for the calls for cooperative action in the area of conservation and management of biodiversity, especially as the Commission considered prophetically that “the earth’s endowment of species and natural ecosystems [would] soon be seen as assets to be conserved and managed for the benefit of all humanity”. Consequently, there was a need to ensure a cooperative action in terms of the management and distribution of resources arising from the use of biodiversity. It is worth recalling that at this time, biodiversity was considered to form a public good which existed as a part of the common heritage of mankind. Consequently, the unsustainable acquisition of resources had continued on the basis of the world’s resources being goods which were freely available for public use and private appropriation irrespective of where they were located. Individual countries could then not claim exclusive rights over resources or benefits associated thereto, located within their borders. The Brundtland Commission’s report was however important as it pointed to the global implications of biodiversity loss arising from unsustainable use, and the global need to cooperate in addressing this phenomenon for the sake of the present and future generations of mankind. Benefit sharing was put forward in this light as a concept which would promote this cooperative action. It was from this point that the need for a Convention on the management of biological diversity was suggested.

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658 Cap 6.50 WCED Our Common Future, supra note 653.
659 Within the temporal period of the Brundtland Commission, for instance, the International Undertaking on Plant Genetic Resources for Food and Agriculture was adopted by the Food and Agriculture Organization of the United Nations (FAO) in 1983. See, International Undertaking on Plant Genetic Resources for Food and Agriculture, Resolution 8/83, adopted 23 November 1983. Article 1 of the International Undertaking places in perspective the global viewing of GRs at the time:

The objective of this Undertaking is to ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes. This Undertaking is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction [emphasis added].

The Undertaking was expected to serve as a legally-binding convention that would counteract the privatization of GRs by establishing their status as the “common heritage of mankind”. Problems arising from this agreement were that the industrialized governments refused to make it binding due to concerns of the International Undertaking challenging the legitimacy of IP rights. As a result, the International Undertaking became a voluntary undertaking instead of a convention. See, GRAIN, “International Undertaking on Plant Genetic Resources: The Final Stretch” (16 October 2001) online: GRAIN <https://www.grain.org/article/entries/90-international-undertaking-on-plant-genetic-resources-the-final-stretch>.
The conservation of biodiversity is however an extremely costly venture. Undertaking this as part of a government priority required some form of real incentive. From the perspective of biodiverse developing countries, benefit sharing was consequently a reward mechanism which was expected to serve as an incentive to encourage the conservation of biodiversity located within their borders. Even where developing countries prioritized the conservation of biodiversity, they faced challenges such as the dearth of scientific skills, a lack of institutional capacity as well as a shortage of necessary funds. In the words of the Commission Report,

[m]any developing nations recognize the need to safeguard threatened species but lack the scientific skills, institutional capacities, and funds necessary for conservation. Industrial nations seeking to reap some of the economic benefits of genetic resources should support the efforts of Third World nations to conserve species; they should also seek ways to help tropical nations and particularly the rural people most directly involved with these species realize some of the economic benefits of these resources.

From the perspective of industrialized countries that sought to use and reap from the benefits of biodiversity, benefit sharing was a means of compensating poorer regions of the world for the negative consequences of unsustainable biodiversity use, as well as participating, partnering and/or assisting developing countries with the future costs associated with biodiversity conservation through a realization of some economic benefits from their resources. Not just some of the benefits but, rather, as the Report stipulates, ‘developing countries must be ensured an equitable share of the economic profit from the use of genes for commercial purposes.’

These lofty recommendations by the Committee lacked a basis for realization on two main fronts. First, the principle of the common heritage of mankind still existed as the governing standard relating to the appropriation and commercial use of biodiversity. This meant that resources were considered to be for the good of humanity. In other words, there were no international restrictions accompanying the access, privatization and use of resources. Second, benefit sharing in the use of biodiversity as a principle or concept did not yet exist as legally binding standard or requirement. There was therefore the need for some form of international law which could serve as a basis for requiring action in this regard. The Commission

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660 Peria, “Benefit Sharing from the Use of Genetic Resources”, supra note 605 at 163.
662 Ibid. Cap 6.51.
thus put forth a recommendation for the negotiation of an international species convention which would redefine the concept of common heritage within the context of cooperative action for conservation as well as promote the sharing of benefits aimed at the conservation of species:

"Governments should investigate the prospect of agreeing to a 'Species Convention', similar in spirit and scope to the Law of the Sea Treaty and other international conventions reflecting principles of 'universal resources'. A Species Convention [...] should articulate the concept of species and genetic variability as a common heritage… Collective responsibility for the common heritage would not mean collective international rights to particular resources within nations…but it would mean that individual nations would no longer be left to rely on their own isolated efforts to protect species within their borders… Any such arrangement...must not only seek to ensure the conservation of genetic resources for all people, but assure that the nations that possess many of these resources obtain an equitable share of the benefits and earnings derived from their development...this would greatly encourage the conservation of species."

5.1.2.2 The Convention on Biological Diversity

In response to this recommendation, the CBD was negotiated. Adopted in 1992, the CBD is the first and most comprehensive international instrument relating to biodiversity and GRs. Drawing from the premise for its negotiation, it was negotiated as a direct response to the alarming rate at which human activities were resulting in the extinction of species and pursues the intertwined objectives of biodiversity conservation, the sustainable use of biodiversity’s components and the fair and equitable sharing of benefits arising from the utilization of genetic resources (GRs). More importantly, drawing from the discussion so far, the CBD achieved two significant results in support of the Brundtland Committee’s recommendations.

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663 Ibid. Cap 6.58 – 6.60.
664 The CBD was adopted by the Fifth session of the Intergovernmental Negotiating Committee for a Convention on Biological Diversity at the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, May 1992. Its text was open for signature at Rio de Janeiro from June 5 1992 until June 4 1992 during which period it received a total of 168 signatures. It entered into force on December 29, 1993 – 90 days after the 30th ratification – in accordance with Article 36 (1) of the Convention.
665 It is the first attempt by the international community to address biological diversity as a whole in a global legal instrument. Unlike most other conservation agreements which adopt a sectoral approach, the CBD is based on a broad ecosystem approach. See Greiber et al, A Nagoya Explanatory Guide, supra note 354 at 3.
666 In November 1988, the Ad Hoc Working Group of Experts on Biological Diversity was convened by the United Nations Environment Program (UNEP) to explore the need for an international convention on biological diversity which would address the rapid decline in human species and ecosystems.
667 See Article 1, CBD.
First, the CBD put an end to the common heritage of mankind principle with respect to the use of biodiversity. By this token, the CBD secured the recognition within an international legal framework of the sovereignty of States over their biodiversity. Article 15.1 of the CBD provides

Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.\(^{668}\)

This is absolutely significant as the common heritage concept which had so far defined the appropriation of biodiversity through history had served to preclude individual state responsibility and authority over resources located within their territories. As noted in the historical discussion of biopiracy in chapter four, this standard meant that a legal basis for biopiracy was non-existent. In essence, biodiverse states were not deemed as legitimate resource owners, with rights of exclusion as well as rights to determine conditions for accessing such resources located within their borders. The irony became even more apparent with the rise of the biotechnology industry, including its boom following the decision of the US Supreme Court in the celebrated case of Diamond \textit{v.} Chakrabarty.\(^ {669}\) The rise of the biotechnology industry corresponded with a rapid rise in biodiversity-based inventions.\(^ {670}\) The intellectual property (IP) system guaranteed that private rights could then be secured over biodiversity-based inventions. The importance of biotechnology products to modern life, in the areas of health, agriculture, cosmetics, to name a few, meant that the rapid rise in the privatization of biodiversity through the IP system in favor of corporations based in industrialized countries continued unabated. In this sense, the CHM principle supported the disproportionate transfer of wealth to user countries from the countries providing the resources, which were left with little or no benefits from the commercialization of biodiversity.

\(^{668}\) The Contracting Parties to the CBD also reaffirm, as part of the preamble to the CBD, that States have sovereign rights over their own biological resources. See para 4, preamble to the CBD.


\(^{670}\) Ibid. According to Chidi Oguamanam, though biotechnology is not a new phenomenon, the discovery of recombinant DNA in the 1970s and the impact of digital technology (especially in the 20th century) provided the fillip for the exponential rise, delivery and induction of biotechnology as a vital driver of the new global knowledge-based economic order. See, Chidi Oguamanam, “Genetic Resources & Access and Benefit Sharing: Politics, Prospects, & Opportunities for Canada after Nagoya” (2011) 22:2 Journal of Environmental law & Practice, 88 – 89.
The establishment of sovereign rights over resources was thus a first step to remedying this. By asserting ownership over resources to the providing state, including the rights to determine access and establish benefit sharing terms, an important incentive for the preservation of such resources was fashioned. This was premised on ideas of wealth redistribution, as well as inclusive and sustainable development which could be secured through the equitable sharing of benefits. It is worthy of mention here that the recognition of sovereign rights with the advent of the CBD has been hugely debated. The vast majority of scholars, such as Srinivas and Robinson, contend that the principle of state sovereignty over the biodiversity occurring within state territories was actualized with the CBD. This is in keeping with the line of thought contained within this dissertation and implies that prior to the adoption of the CBD, biological resources constituted a part of the common heritage of mankind to which no country could claim exclusive rights. Other scholars, such as Nwabueze and Mgbeoji have, however, argued that this principle of state sovereignty over resources was recognized long before the CBD’s adoption. Mgbeoji posits that States had always had the inherent right to control legal access to resources, including plant resources located within their territories.

These discrepancies are particularly helpful in articulating the illegality of biopiracy. For all the justifications for both sides, including the conflicting observation that the CBD’s preamble uses the word ‘reaffirm’ – suggesting a confirmation of a previously established concept, while the actual text (Article 15) of the CBD uses the term ‘recognizing’ – suggesting a novel paradigm shift, the exact determination of when states were granted sovereignty over biological resources remains contested in international discourse. While the point made by Nwabueze and Mgbeoji is therefore arguable, the CBD’s significance in clarifying and restating this principle of sovereign rights over resources in international law must not be understated. For the purpose of this dissertation, therefore, the view that sovereignty over biological

672 See generally, note 558 below.
673 Srinivas, “TK and IPRs”, supra note 248 at 89.
674 Mgbeoji, Global Biopiracy, supra note 19 at 12.
resources was introduced with the CBD is adopted. This suggests that an international paradigm shift took place after the CBD, on the basis of which GRs were no longer considered to form part of the common heritage. A significant implication of this, drawn from Article 15 of the CBD, is that states were then granted the authority to determine access to GRs through national legislation. The development of national legislation regulating access to resources thus forms a key component of countries exercising their sovereignty over the biological resources within their territories. However, as I point out below, the lack of a globalized standard in this regard – one by which the legislation of provider states find support within the legislation of user states – meant that users based in foreign territories were able to violate national provider laws. The inadequacy of national legislation in countering instances of misappropriation thus forms an underlying reason for which the international ABS regime established by the Nagoya Protocol was negotiated.

Second, was the entrenchment of the benefit sharing philosophy as a price for access to resources within the discourse on the utilization of GRs. The third objective of the CBD places the fair and equitable sharing of benefits arising out of the utilization of GRs as one of the core pillars of the CBD’s provisions.\textsuperscript{676} This objective, further developed through the CBD’s provisions,\textsuperscript{677} laid the foundation for the design of an ABS system forming a component part of the utilization of GRs. Simply put, the ABS system requires users of GRs, in return for access to the resources, to share in an equitable manner the benefits arising from such use with source countries from which such resources were obtained. From the perspective of biodiverse countries (most of which were developing countries), this was necessary to address the worrying trend by which the biodiversity located within their territories was accessed and appropriated, with non or insignificant benefits returning to them. Going by the above explanation regarding the history of benefit sharing in international law, the foundations of benefit-sharing, as we know it today, lie in a discourse on sustainable development and must be interpreted within the context of a ‘biodiversity’ regime which principally seeks to conserve and ensure the sustainable use of biodiversity.

\textsuperscript{676} See Article 1, CBD.
\textsuperscript{677} Notably Articles 8 & 15, CBD.
Relating this historical account with the present discourse, benefit sharing may be viewed as a moral and equitable form of compensatory justice. Castle and Gold note that the concept of benefit sharing (with specific reference to TK) has been shaped by two key ideas: the idea that TK is a unique form of knowledge that, in part due to its purported uniqueness, can be owned and protected; and the idea that the exploitation of TK by non-owners is inherently unjust and deserves remedy. They argue that these two key ideas form the basis of benefit sharing’s interpretation as a form of compensatory justice. Beyond compensation for unjust actions, some authors have further contended that benefit sharing is also grounded in the concept of distributive justice relating to the shared decision-making of users with providers about the scientific and technological utilization of resources fundamental to human welfare. Again, benefit sharing may be justified on ethical lines. The global benefits arising from the conservation of biodiversity, such as, food security, ecosystem balance, and global health among others, justify an adequate and equitable benefit sharing framework. The economic implications of benefit sharing in light of the conservation of biodiversity have resulted in it being described as a market-based approach towards the preservation of biodiversity.

5.1.2.3 The Bonn Guidelines

Despite the incorporation of benefit sharing into the CBD in 1992, the first efforts to implement it came about 10 years later with the adoption of the Bonn Guidelines in 2002. It is worthy of mention that the adoption of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits arising out of their Utilization [Bonn Guidelines] came just a few months prior to the WSSD.
For this reason, the inclusion of a call for a negotiation of an international regime (the Nagoya Protocol) within the Plan of Implementation was expectedly met with mixed reactions. The negotiation of the Bonn Guidelines, which was the first step taken to address the weak implementation of the benefit sharing provisions of the CBD, had taken two years of direct negotiation within which period the possibility of a binding protocol had already been considered. At the time, the idea had been jettisoned in favor of a set of guidelines which set forth broad principles within which varying national approaches to the ABS challenge could be pursued. The real issue here, it is worth reiterating, was that even though the principle of benefit sharing had become a part of the international legal framework, Parties to the Convention had struggled to implement it in national law. I discuss some of the reasons below. Article 15 of the CBD cited above significantly renders the rights of governments over their resources subject to national legislation. In other words, the transposition of the internationally accepted system of benefit sharing into national law was a central prerequisite for its implementation.

The Bonn Guidelines were therefore negotiated as an alternative to a binding regime as the majority consensus within the negotiations had been that ABS was an issue more contingent on national regulation than on international regulation. Through the experience gained in national implementation, it was considered that a further evolution of the regime could take place. The Guidelines were thus designed to serve as inputs to national efforts to develop and draft legislative, administrative, or policy measures. The key characteristics of the Guidelines were its voluntary nature, its ease of use, its practicality, its acceptability to users and providers, its complementarity with other international instruments, its evolutionary approach, its flexibility and its transparency. Significantly, the Parties recognized that the

Guidelines’, was derived from the location of the intergovernmental meeting which held in Bonn, Germany in October 2001 and which prepared the first draft of the eventual agreement. It had, for instance been discussed at the COP 4, where it was decided to set up an expert group on ABS which could discuss all the options for ABS arrangements (see CBD Decision IV/8). Further, it was discussed at two meetings of the CBD’s Panel of Experts on ABS in San Jose, Costa Rica (October 1999) and Montreal, Canada (March 2001). The discussion also took place within the CBD’s Scientific Body on Technology and Technological Advice (SBTTA) as well as in the final deliberations at COP-6 where the Bonn Guidelines were formally adopted. Chambers, “WSSD & an International Regime”, supra note 197 at 310.

Ibid.

Ibid.

See COP Dec VI/24, supra note 196 at 262 (para 4). See also, I.A.1, Bonn Guidelines. Again, see Kamau, Fedder & Winter, “The Nagoya Protocol”, supra note 200 at 249.

See I.A.7 of the Bonn Guidelines
Bonn Guidelines merely represented a useful first step of an evolutionary process in implementing the ABS provisions of the CBD.\textsuperscript{690} As such, further developments to the Guidelines, arising from experience gained in the implementation of ABS provisions, were envisaged.\textsuperscript{691} If anything, the Bonn Guidelines were therefore an international experiment in operationalizing the ABS regime, given the limited experience available to negotiators and the international community in developing and implementing ABS provisions.\textsuperscript{692} This feature facilitated the quick negotiation of the Guidelines, with governments being more accommodating to a wider spectrum of views as well as allowing several difficult issues to be glossed over.\textsuperscript{693} The Bonn Guidelines were unsurprisingly ineffective and, as noted by Kamau et al, the Guidelines’ voluntary nature played a major role in its ineffective outcome and weak implementation.\textsuperscript{694} The signs regarding the potential inefficacy of the Bonn Guidelines were spotted early and, according to Zedan, were already noticeable amongst developing countries prior to the adoption of the Bonn Guidelines:

\textit{[d]uring the final negotiations of the Bonn Guidelines, developing countries felt that although the Bonn Guidelines provided useful assistance in the development of national systems of regulation, it did not represent an effective international framework for addressing uses of misappropriation and benefit sharing. Following the adoption of the Guidelines, the Group of Like-Minded Megadiverse Countries (LMMC) declared the need to go a step further toward this end. In September 2002, prompted by the LMMCs, governments at the WSSD called for action “to negotiate within the framework of the Convention on Biological Diversity … an international regime to promote and safeguard the fair and equitable sharing of benefits arising from the utilization of genetic resources.”}\textsuperscript{695}

Therefore, the call for action with respect to the negotiation of an international regime was primarily the result of the lobbying by developing countries, specifically the LMMC. Several of the LMMC countries, for instance, threatened to restrict access to GRs for researchers, business and private investments.

\textsuperscript{690} Para 6, COP Dec VI/24, \textit{supra} note 196 at 262. See also, para 8, preamble \textit{Cusco Declaration on Access to Genetic Resources, Traditional Knowledge and Intellectual Property Rights of Like-Minded Megadiverse Countries}, 2002 [\textit{Cusco Declaration}].

\textsuperscript{691} This evolutionary approach to the Guidelines forms one of its central features. This approach anticipated a review, revision and improvement of the Guidelines based on experience from ABS. See I.A.7(f), Bonn Guidelines.

\textsuperscript{692} Hamdallah Zedan, the Executive Secretary of the CBD at the time the Bonn Guidelines was adopted, for instance remarked that though the CBD had been in force since 1993, the Bonn Guidelines, adopted in 2002, was the first effort to operationalize its provisions. See CBD, \textit{Bonn Guidelines on Access to Genetic Resources & Fair & Equitable Sharing of the Benefits Arising out of their Utilisation} (Montreal, Canada: Secretariat of the Convention on Biological Diversity, 2002) [CBD, Bonn Guidelines] at iii.

\textsuperscript{693} Chambers, \textit{“WSSD & an International Regime”}, \textit{supra} note 197 at 311, He notes that in some ways, ‘the Bonn Guidelines resemble[d] a wish list for every country’s interests…”

\textsuperscript{694} Kamau, Fedder & Winter, \textit{“The Nagoya Protocol”}, \textit{supra} note 200 at 249.

\textsuperscript{695} Zedan, \textit{“Patents & Biopiracy”}, \textit{supra} note 204 at 195 – 196.
if there were no clear international rules on access to GRs. Not only were developing countries concerned, several environmental NGOs at the time of the adoption of the Bonn Guidelines similarly expressed fears that the Bonn Guidelines could mark the end of a needed evolutionary process. For them, the adoption of the Bonn Guidelines was no substitute for a legally binding international instrument. Therefore, while the demandeurs for the international regime were not opposed to the voluntary Bonn Guidelines, and actually considered it an important development, they simply did not want its emergence to interfere with, or substitute for the development of what they perceived to be the real need; a binding international regime on ABS.

In sum, the implementation of this ABS mechanism prior to the adoption of the Nagoya Protocol remained problematic for most Parties to the CBD due to both legal and practical reasons. Two reasons which are particularly relevant to this dissertation are: first, provider countries were limited in monitoring and enforcing domestic ABS obligations and/or agreements once the resources crossed into foreign territories. In this regard, the main weakness of the pre-Nagoya ABS mechanism was its failure to create obligations for user countries to implement legislation for the purpose of ensuring compliance and therefore protection for provider countries. This is the user-failure challenge of ABS implementation. Second, the IP mechanism served as a vehicle for the continued appropriation of resources without regard for ABS regulations. The ABS system had no effective system of checking and/or preventing ABS defaulters from securing IP rights over their inventions based on GRs and/or TKaGRs. These limitations, conceptualized within this dissertation as the trans-border and trans-regime challenges of biopiracy respectively, highlighted the need for a more effective international structure of compliance for the ABS regime as well

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698 Ibid.
699 See, for instance, the Cusco Declaration on Access to Genetic Resources, Traditional Knowledge & Intellectual Property Rights of Like-minded Megadiverse Countries, Bolivia, Brazil, China, Colombia, Costa Rica, Ecuador, the Philippines, India, Indonesia, Kenya, Malaysia, Mexico, Peru, South Africa and Venezuela, 29 November 2002 [Cusco Declaration], where the usefulness of the Bonn Guidelines as a first step in an evolutionary process for the development of ABS regimes is firmly acknowledged. [Para 8 of the Preamble].
700 Paragraph 44 (n) of the Plan of Implementation, for instance, called for action to promote ‘the wide implementation of and continued work by the Parties to the Convention on the Bonn Guidelines...as an input to assist the Parties when developing and drafting legislative, administrative or policy measures on access and benefit-sharing as well as contract and other arrangements under mutually agreed terms for access and benefit-sharing’.
as the need for greater coordination with neighboring regimes, particularly the IP regime. For clarity, as mentioned in chapter four, trans-border limitations relate to the limitations of securing compliance with domestic ABS measures of providing countries where such resources have crossed into the foreign territories in which the accessed resources are being used. Trans-regime limitations, however, relate to the limitations of securing compliance with domestic ABS obligations due to the working of neighboring international regimes which bear direct relevance to the working of the ABS regime.

Against this backdrop, the call for, and negotiation of the Nagoya Protocol was premised on the need to establish a legally binding international ABS regime, with clear obligations for both “provider” States and “user” States. This international ABS regime was expected to build on the Bonn Guidelines’ voluntary provisions in its establishment of an international binding regime to implement the CBD’s third objective. It was expected that this framework would address the limitations which provider countries had hitherto faced in the enforcement of their domestic regulations especially with regard to cases of trans-border misappropriation of GRs and TKaGRs. The framework was also expected to ensure greater legal certainty for users and providers of GRs and TKaGRs by clarifying the applicable terms regulating access to GRs and the sharing of benefits. As a binding international regime, it was expected to ensure that the responsibility of monitoring compliance with ABS obligations would be borne by all Parties and not just the providing countries.

So far, in discussing the emergence of the international ABS regime, I have focused on the underlying rationale for the benefit sharing system through a discussion of historical evolution of benefit sharing in international law. This evolution of benefit sharing was significantly as part of regulations to address the loss of biodiversity, summed up in the CBD. By the time the CBD was therefore adopted in 1992, the international community had come to a unanimous understanding of the implications of the continued decline in biodiversity and had taken steps to mitigate these through the entrenchment of a principle, described by the Brundtland Commission as the only remedy to addressing the rapid loss of biodiversity – the benefit sharing principle. This was incorporated as the third objective of the CBD. It was

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Tvedt & Young, Beyond Access, supra note 426 at 3 (the authors note that one impetus behind the international regime negotiations was the perception that users were not bound by ABS when they were outside the source country’s jurisdiction).
an innovative strategy which received wide recognition and acceptance for several reasons, not least that it offered developing countries an incentive to conserve biodiversity on behalf of all present and future generations of humanity. With the benefit sharing principle now entrenched in international law, it is worth considering, why a regime was then deemed necessary? Why did the insistence on an international regime occupy the negotiations within WSSD? The simple reason: the ABS system was not working!

5.1.2.4 The Push for an International Regime for Benefit Sharing

Ten years after the adoption of the CBD, there still was no functional international system of ABS in place\(^\text{702}\) and the instances of biopiracy continued. As a matter of fact, by this time (2002) less than 10 per cent of the CBD parties had adopted any kind of legislative, administrative or other ABS measures, and even then virtually none of these were actually functioning effectively.\(^\text{703}\) With those that had adopted legislation, a variety of approaches had been taken with overall uncertainty as to how an ABS system should be designed or function. The complexity of the system was yet another prominent factor. While the ABS mechanism is captured in such simple terms – access and benefit sharing – the simplicity of its conceptualization could easily mask the complexity of its meaning and implementation. Several aspects of benefit sharing such as, the policy arrangements, the monitoring and enforcement, questions of retroactivity, cross-regime interpretation of standards, to name a few, pointed to the complexity of the ABS system. Developing countries bore the responsibility of implementing the system in their national laws, often with limited resources and infrastructure. For many, owing to the complexity, the balancing of interests and the attendant costs – both direct and forgone, associated with the design and implementation of measures – did not justify further investments in implementing the system. The resultant lack of interest by some provider countries in ABS due to skepticism arising from actual benefits in comparison to the lots of effort and policy adjustments required to implement ABS measures is another reason advanced for explaining the non-


\(^{703}\) Morten Tvedt & Tomme Young, Beyond Access, supra note 423 at 1 (especially note 3) & 16.
functional ABS system.\textsuperscript{704} Another popular reason is the user failure theory. This theory suggests a major failure of the system as being the one-sided efforts to pursue implementation.\textsuperscript{705} The user failure theory offers an important basis for explaining the emergence of the international regime within the context of addressing the incidence of biopiracy. While for instance, a limited number of countries had enacted and implemented national legislation on ABS, the problem for most of these countries was actually linked to the inability to enforce and track compliance outside their jurisdictions.\textsuperscript{706} This theory directly connects with the trans-border challenge of biopiracy. The 2004 WSSD therefore represented an opportunity for delegates, especially developing countries, to address this concern and seek political commitment regarding the negotiation of an effective international system of ABS – one that would make the ABS mechanism effective.

5.1.3 The Nagoya Protocol as the International Regime

The United Nations General Assembly, at its 57\textsuperscript{th} session, endorsed this call for action and invited the Conference of the Parties (COP) of the CBD to take appropriate steps towards fulfilling this commitment.\textsuperscript{707} Pursuant to this resolution by the UN General Assembly, as well as the recommendation of the Inter-Sessional Meeting on the Multi-Year Program of the Work of the COP up to 2010,\textsuperscript{708} the seventh meeting of the COP\textsuperscript{709} commenced work on the negotiation of an international regime on ABS. Outlining an elaborate Terms of Reference,\textsuperscript{710} the COP decided at that meeting to mandate the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (WG-ABS) to elaborate and negotiate the international regime on ABS, ‘with the aim of adopting an instrument/instruments to effectively implement the

\textsuperscript{704} Ibid. at 16, noting the complexity theory, the lack of interest theory, the cost theory and the user failure theory as some theories explaining the early failure of the ABS system.

\textsuperscript{705} Ibid. See also, Jorge Cabrera Medaglia & Christian Lopez Silva, \textit{Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty} (Gland, Switzerland: IUCN, 2007).

\textsuperscript{706} Ibid.


\textsuperscript{708} The Open-ended Inter-Sessional Meeting on the Multi-Year Programme of the Work of the Conference of the Parties to the CBD up to 2010, met from 17 – 20 March, 2003. It recommended, \textit{inter alia}, that, based on Para. 44 (o) of the Johannesburg Plan of Implementation, the Open-ended Working Group on ABS ‘consider the process, nature, scope and modalities of an international regime on access to genetic resources and benefit-sharing and provide advice to the COP at its seventh meeting on this issue’.

\textsuperscript{709} This was held in February 2004, in Kuala Lumpur, Malaysia.

\textsuperscript{710} See COP Dec VII/19, \textit{supra} note 158, D. Annex. The Terms of Reference outlined the process, the nature, the scope and the elements for consideration in the elaboration of the international regime.
provisions in Article 15 and Article 8(j) of the Convention, and the three objectives of the Convention. 711

In line with the COP decision, the WG-ABS was to collaborate with the Ad Hoc Open ended Inter-Sessional Working Group on Article 8(j) and Related Provisions 712 in the execution of its mandate, and was expected to ensure the participation of indigenous peoples, non-governmental organizations, intergovernmental organizations, industry and scientific and academic institutions. As part of the early expectations regarding the international regime, two significant requirements were identified. First was the expectation that the regime should be practicable, transparent and efficient and avoid arbitrary treatment, consistent with the provisions of the Convention. Second, the regime should recognize and respect the rights of indigenous peoples and local communities. 713

The negotiation of the international regime thus commenced within the subsequent sessions of the WG-ABS. 714 A total of 7 WG-ABS’s were held to elaborate this international regime prior to its eventual adoption. According to Zedan, two elements lay at the core of these negotiations. First, was the disclosure of country of origin of GRs and the source of relevant TK in applications for IP rights. Second was the concept of an international certificate of origin, source, or legal provenance of GRs as a mechanism for ensuring compliance with the terms and conditions of access to GRs. 715 The difficulty and sensitivity surrounding the negotiation of these issues within the context of a binding legal framework was evident within these meetings and reflected within the heavily bracketed draft provisions submitted to the eighth meeting of the COP. 716 In addressing this latter aspect in particular, the COP decided to commit the task of

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711 See COP Dec VII/19, supra note 158, D.1.
712 By Article 8(j) of the CBD, the Parties commit themselves to respect, preserve and maintain the knowledge, practices and innovations of indigenous peoples relevant for the conservation of biological diversity, promote their wider application and ensure an equitable sharing of the benefits arising from the use of such knowledge. It is towards the further implementation of this provision that a Working Group on Article 8(j) and Related Provisions was established in 1998 by the COP 4 as one of the bodies of the Convention. See COP 4 Decision IV.9 (1) – (9). Significantly, the drive of the Working Group on ABS is to ensure that considerations relating to the TK of indigenous and local communities are incorporated in all programs of work under the CBD. The Parties considered this aspect of TK to be central part of the international regime. See generally CBD ‘Working Group on Article 8(j)’ online: <http://www.cbd.int/convention/wg8j.shtml> (09/07/2015).
713 See COP Dec VII/19, supra note 158, D. paras 15 & 16, preamble.
714 The WG-ABS met twice in this period; WG-ABS 3 met in Bangkok, Thailand from February 14 – 18, 2005, while WG-ABS 4 met in Grenada, Spain from January 30 – February 3, 2006. The full reports of the meetings are available online: CBD <https://www.cbd.int/doc/?meeting=ABSWG-03> and <https://www.cbd.int/doc/?meeting=ABSWG-04> respectively.
715 Zedan, “Patents & Biopiracy”, supra note 204 at 196. See also COP Dec VI/24, supra note 196 at B.
716 The draft provisions are contained in the annex to COP 8 Decision VIII/4 A.
elaborating the possible options relating to the form, intent and purpose of the internationally recognized certificate (IRC) to a group of technical experts designated for that purpose.\textsuperscript{717} The value of this move was to ensure that negotiators were able to consider informed technical input in adopting their negotiation stances on the matter.

Indeed, these issues constituted two of the most difficult elements of the negotiations which I point out, formed an unconcluded aspect of the Protocol’s mechanism. The resistance from industrialized countries within the negotiations was premised on the argument that the CBD did not represent the appropriate forum of choice for such a disclosure discussion. Furthermore, the CBD would exceed its mandate by developing provisions which mandated changes to the IP system. The reference to WIPO’s developments, particularly the work of its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), within the decision adopting the Protocol points to an intention to support the outcomes of these contentious issues within the Protocol with a ‘proper’ IP solution emanating within an appropriate IP forum.\textsuperscript{718}

The COP requested the WG-ABS to complete its work at the earliest possible time before the tenth meeting of the COP in 2010\textsuperscript{719} and also instructed that the finalization of the international regime be carried out without prejudging or precluding any outcome regarding the nature of the instrument being negotiated,\textsuperscript{720} similar to the wording incorporated within the ongoing WIPO negotiations. It was at WG-ABS 8 that, for the first time, agreement was reached on a single negotiating text – the Montreal Annex.\textsuperscript{721}

5.1.3.1 The Adoption of the Nagoya Protocol

The adoption of the Nagoya Protocol at the tenth meeting of the COP thus brought to a close a sustained and intensive six years of negotiation by the Parties to the CBD on an international regime. A


\textsuperscript{718} Significant concerns were maintained throughout the negotiations over the use of IP rights as a protection mechanism for TK by indigenous peoples. See, Bavikatte & Robinson, “Towards a People’s History of the Law”, supra note 329 at 47 – 48.

\textsuperscript{719} See COP 8 Decision VIII/4, para. 6; and COP 9 Decision IX/12, para. 2

\textsuperscript{720} COP 9 Decision IX/12, para. 3

\textsuperscript{721} WG-ABS 8 took place in Montreal, Canada from November 9 – 15, 2010, hence the designation.
subsidiary legal instrument to the CBD, the Nagoya Protocol has a 27-paragraph Preamble, 36 substantive Articles and an Annex. The Preamble which offers a context for interpretation of its Articles and Annex, references key provisions of the CBD which must be understood for a deeper and contextual understanding of the Protocol. It also refers to other international agreements and treaties that relate directly to the issues dealt with in the Protocol. Though a single instrument was adopted, it sat at the center of what was to be known as the international regime on ABS; made up of the CBD, the Nagoya Protocol, as well as complementary instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Bonn Guidelines. The international regime was opened for signature between February 2, 2011, and February 1, 2012, a period within which it amassed a total of 92 signatures. It entered into force on October 12, 2014, which was the ninetieth day after the deposit of the fiftieth instrument of ratification/accession. As at today’s date, a total of 87 ratifications have been received for the Nagoya Protocol.

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722 As a subsidiary legal instrument, the Nagoya Protocol’s existence is tied to the principal instrument – the CBD. In this respect, Parties must first be members of the CBD before seeking membership of the Protocol. Parties to the Convention which, however, have not ratified the Protocol, are permitted as observers in meetings of the Protocol, however, they may not participate in the decision making process. See Article 32, CBD.

723 The singular annex of the protocol relates to a suggestive list of monetary and Non-monetary benefits which could form the basis of negotiations in benefit sharing agreements.

724 The Vienna Convention on the Law of Treaties provides that the preamble to a treaty must be construed as forming a part of the treaty. See Article 31(2), Vienna Convention on the Law of Treaties, 23 May 1969, 1155 UNTS 331 (entered into force 27 January 1980). The Nagoya Protocol, by the general rules of interpretation of the Vienna Convention forms an appendage to the CBD. See Article 31 (2)(a) Vienna Convention. It must therefore be read and interpreted within the context of the CBD. Though it constitutes a separate instrument in its own self, in a wider perspective, it forms a part of the CBD – its framework agreement. See Article 31 (3)(a) Vienna Convention.

725 See direct references for instance made in Par. 2 (which refers to Article 3 of the Convention), Par. 4 (which refers to Article 15 of the Convention), Par. 5 (which refers to Articles 16 and 19 of the Convention), and Par. 21 (which refers to Article 8(j) of the Convention).

726 Examples of these include, para 17, WHO, International Health Regulations (Switzerland: WHO, 2005), para 19, ITPGRFA, paras 18 & 26, UNDRIP, which in blanket fashion, acknowledges ‘...ongoing work in other international forums relating to access and benefit sharing’.

727 See para 6, preamble to COP 10 Dec X/1, supra note 192.

728 Ibid. at I.2. See also, Article 32, Nagoya Protocol.

729 For a full listing, see CBD, Parties to the Nagoya Protocol, online: CBD <https://www.cbd.int/abs/nagoya-protocol/signatories/>.

730 See Article 33, Nagoya Protocol.

731 For the full listing, see CBD, Parties to the Nagoya Protocol, online: CBD <https://www.cbd.int/abs/nagoya-protocol/signatories/>.
5.1.3.2 A Substantive Overview

As argued in chapter two above, the status of the Nagoya Protocol could be viewed in two ways. On the one hand, it could be viewed as the actual international regime on ABS. Given that it reflects the outcome of the direct negotiation for an international ABS regime, a formal conceptualization of regimes, it could be viewed as the international regime. This is, however, to the extent that it contains the principles, norms, rules and decision making procedures which the ABS regime ascribes to. By this, the various instruments indicated as forming a part of the regime, draw their relevance to the ABS regime, based on their complementarity with the central substantive prescriptions of the ABS regime. For this reason, also, the Nagoya Protocol could be viewed as the core international ABS law upon which the ABS regime is anchored. In outlining a substantive regime strategy for benefit sharing for addressing the problem of biopiracy, the Protocol advances clear obligations on TKaGRs relating to access, benefit sharing, compliance and even capacity building. My discussion of these obligations below are based on their relevance to addressing the benefit-sharing prong of the problem of biopiracy discussed in the previous chapter.

A precondition for sharing of benefits is the grant of access, hence the catch phrase, ABS. The clarification of access requirements thus forms one of the core intents of the Protocol. This is to the end of ensuring legal certainty for intending users of TKaGRs. Prior to the Nagoya Protocol, a major complaint from industry representatives had been depth of legal uncertainty which surrounded the transactions within provider countries. Uncertainty arising from lack of clarity in terms of the appropriate institutions from which access could be sought, unclear legislative frameworks governing the access requirements in several provider countries, informal nature of several transactions which meant that records demonstrating proof were not always readily available, scope of applicable subject matter, amongst others. Indeed, for most of the corporate interests which had been accused of biopiracy, a functional system of benefit sharing required

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732 As noted earlier, the substantive elements of international regimes are located within the regime’s principles, norms, and rules. See, Helfer, “Regime Shifting”, supra note 65 at 10 – 11.
733 Para 8 preamble to COP 10 Dec X/1, supra note 192.
734 Ibid. para 9 Preamble.
legal certainty and clarity. The Nagoya Protocol thus provides a range of provisions which seek to address this problem.

5.1.3.2.1 Two Underlying Principles: Prior Informed Consent and Mutually Agreed Terms

Two core principles underlie the ABS system and the subsequent examination of the provisions of the Protocol must be carried out with these principles in mind. These are the principles of prior informed consent (PIC) and mutually agreed terms (MATs). Recall that an international regime, as discussed in chapter two, is comprised, amongst others, of principles around which actors converge with regard to a given issue area of international relations. Importantly they remind of the contractual nature of ABS, and seek to ensure parity in the articulation, understanding, negotiation, and execution of terms by which consenting indigenous peoples are set to be bound.

5.1.3.2.1.1 Prior Informed Consent

The concept of informed consent, traces its origins to medical practice and is based upon the common law principle that any party entering into an agreement with legal consequences, must be capable of understanding the implications of the transaction. It has remained an issue of extreme practical implementation difficulty most especially arising from the nature of TKaGRs, including the several ways in which it is accessed. The CBD, building on this concept of informed consent, introduced the ‘prior informed consent’ (PIC) principle. Elaborated on by the Bonn Guidelines PIC is defined as

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735 See, 2.2.3. above.
736 See Dutfield, “Can Prior Informed Consent Help?”, supra note 565 at 57. This view is further supported by Rosenthal, noting that “Historically, PIC has been used to ensure that medical research subjects understand the risks of potential harm they may be exposed to in participating in a clinical research project...” See Joshua Rosenthal, “Politics, Culture & Governance in the Development of Prior Informed Consent & Negotiated Agreements with Indigenous Communities” in Charles McManis, ed. Biodiversity & the Law: Intellectual Property, Biotechnology & Traditional Knowledge (UK: Earthscan, 2007) at 375.
738 The ‘informed consent’ principle had however earlier found its way into international environmental law through the Basel Convention on the Control of Trans-Boundary Movements of Hazardous Wastes and Their Disposal: see Dutfield, “Can Prior Informed Consent Help?”, supra note 565 at 57. Article 15(5) of the CBD, states that ‘access to genetic resources shall be subject to prior informed consent of the contracting party providing such resources, unless otherwise determined by that party.’
739 The overall PIC strategy of the CBD is set out in IV.24 – IV.40 of the Bonn Guidelines. The overall strategy sets out the basic principles. They were adopted by Decision VI/24 of the Conference of the Parties in Hague 2002. See generally COP Dec VI/24, supra note 196. The Guidelines are intended to assist parties in developing
consent to an activity that is given after receiving full disclosure regarding the reasons for the activity, the specific procedures the activity would entail, the potential risks involved, and the full implications that can realistically be foreseen. Prior informed consent implies the right to stop the activity from proceeding and for it to be halted if it is already underway.  

Three main implications of this principle to the protection of TK, therefore, are; TK providers must have been given all the information (in their native language) relevant to the activity for which the consent is being sought; the TK holders must understand and agree in writing to the carrying out of the activity for which the consent is sought; the TK holders must understand that they have a continuing right to revoke their consent. As a golden thread running through the Protocol’s attempts to address biopiracy, the centering of PIC in the access and benefit sharing relating to TKaGRs, seeks to place holders of TKaGRs in full control right from the outset of third-party efforts to exploit their knowledge. In fact, this principle serves the effect of redefining the power relations which accompany negotiations for access and benefit sharing in indigenous resources. For, it implies that a full consultation and complete exchange of information, leading to a full and explicit consent prior to any appropriation of information must precede access. This important principle, it must be said, accords with foundational principles of the indigenous rights regime rooted within the UNDRIP as discussed earlier in this chapter. This is important as the

an access and benefit sharing strategy, and action plan, and in identifying the steps involved in the process of obtaining access to GRs and sharing of benefits. See Ullrich, “TK, Biodiversity, Benefit-Sharing” supra note 248 at 16. The Bonn Guidelines set out that the basic principles of a PIC system include; Legal certainty and clarity: minimal access costs; transparency in withholding access, which should be based on legal grounds and not run counter to the objectives of the CBD; Consent of the relevant competent national authority (ies) as well as indigenous and local communities, as appropriate. (see IV.C.26 of the Bonn Guidelines). It also sets out the following elements of the system, which according to IV.27 of the Bonn Guidelines, may include: competent authority (ies) granting or providing for evidence of PIC; timing and deadlines; specification of use; procedures for obtaining PIC; mechanism for consultation of relevant stakeholders; and process.

Dutfield, “Can Prior Informed Consent Help?”, supra note 565 at 60 argues that both the extraction of biogenetic material from lands occupied by traditional communities as well as the acquisition of knowledge from a person or people must be preceded by PIC and that requests for consent of the following should be accompanied by full disclosure in writing in the local language.

This is as provided for in the explanatory note to the National Innovation Foundation, Ahmedabad. Gupta, “The Conundrum of Creativity”, supra note 49 at 346. See also, Moody, The Nagoya Protocol, supra note 280 at 32. Lewis & Ramani, “Ethics & Practice in Ethnobiology”, supra note 737 at 419. The Protocol recognizes that this principle is not absolute, as some instances may arise in which the PIC principle is not attainable, though it fails to explicitly detail such situations envisaged. See, Article 10, Nagoya Protocol, which provides for parties to consider a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits associated with the use of TKaGRs in situations such as trans-boundary situations, or in those situations in which it is not possible to grant or obtain PIC.
implementation of this principle significantly places indigenous peoples at a point of equal advantage within efforts to exploit their TKaGRS.

5.1.3.2.1.2 Mutually Agreed Terms

Closely related to the principle of PIC is the requirement that MATs must be established. While PIC implies ‘full awareness’, MATs implies ‘full participation’. Again, this principle is elaborated by the Bonn Guidelines, and covers a broad scope of terms as well as requirements which should be considered in granting access as well as sharing benefits. MATs are written agreements reached between the providers of TKaGRs, which provide full legal certainty and clarity on the scope of the use for which PIC has been granted. It specifically outlines the obligations for providers and users. In essence, these may be seen as the binding contractual arrangements confirming the terms agreed by both parties. MATs are important as they also play a major role in benefit sharing by outlining the conditions, obligations, procedures, types, timing, distribution, and mechanisms of benefits to be shared. MATs are based on contract principles and increasing efforts have been made to promote capacity building activities to empower indigenous peoples to negotiate favorable contractual ABS terms effectively. In fact, Article 12.3 of the Protocol requires Parties to support indigenous peoples in the development minimum requirements for MATs as well as model contractual clauses, which would help secure the fair and equitable sharing of benefits arising from the use of TKaGRs.

Having outlined these two foundational principles of the ABS regime, I now turn to discuss the rules which govern access and benefit sharing.

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743 See IV.41 – IV.43 of the Bonn Guidelines for the basic requirements for MATs. Significantly, IV.42(f) of the Bonn Guidelines, while establishing the basic principles and requirements for the development of MATs simply provides with respect to the timing that ‘mutually agreed terms should be negotiated efficiently and within a reasonable period of time’.
744 42 a, Bonn Guidelines.
745 42 c, Bonn Guidelines.
746 See, 45 – 50, Bonn Guidelines.
747 See IV.41 – IV.43 of the Bonn Guidelines for the basic requirements for MATs. Significantly, IV.42(f) of the Bonn Guidelines, while establishing the basic principles and requirements for the development of MATs simply provides with respect to the timing that ‘mutually agreed terms should be negotiated efficiently and within a reasonable period of time’.
748 See Article 12.3(b).
5.1.3.2.2 Access

A first clarification that need be made from the outset is that the Protocol requires implementation in national law or domestic regulation for applicability. Consequently, the need for domestic legislation addressing access and benefit sharing is consistently alluded to through the text of the Protocol. Articles 7 and 12.1, for instance, adopt the phrase ‘in accordance with domestic law’ to imply that the stipulations of the Protocol can only be made applicable to a particular party where such a party has undertaken the important task of implementing domestic regulation. Article 7 thus provides:

In accordance with domestic law, each party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Consequently, the onus is placed on providing parties to implement measures which ensure that TKaGRs of indigenous peoples are protected. From the perspective therefore of developing countries, the development of national legislation must be made a central priority. Pursuant to Article 7, the promulgation of domestic legislation must be hinged, *inter alia*, on operationalizing the two core principles of PIC and MATs, in other words, ensuring that these rights of indigenous peoples are guaranteed.

Recognizing the need to balance legal certainty for users with the rights of indigenous providers, the Protocol mandates institutional measures which will support legal certainty in the grant of PIC. To this end, it directs each Party to designate a single National Focal Point (NFP) on ABS. This NFP is expected to provide information to applicants who seek access to TKaGR with respect to the procedures for obtaining

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749 Indigenous representatives viewed this point with disaffection and would have preferred such measures to be ‘in accordance with customary laws’ on the argument that not all national laws take into consideration the unique customs, practices and livelihoods of TK holders. See Reji, “International Regime on ABS”, *supra* note 605 at 80. See also Saez C ‘Final Lap for Talks on Global Biodiversity Benefit-Sharing Protocol’, October 2010, Intellectual Property Watch Vol.7 No.10. 1., online: Intellectual Property Watch, <http://www.ipwatch.org/user/newsletter>. The final text of the Protocol is sensitive to such a concern and mandates Parties to take the ILCs’ customary laws, community protocols and procedures with regard to TK, into consideration while implementing obligations under the Protocol. See Article 12.1, Nagoya Protocol. Such community protocols where developed, will, on the understanding of Article 12.1 of the Protocol, contribute to developing the national laws and thereby promote TK holders’ interests at the national level.

750 Article 7, Nagoya Protocol.

751 See Article 13, Nagoya Protocol. A listing of all current National Focal Points, including their contact information is available on the ABSCH.
PIC of indigenous groups and the establishment of MATs. This NFP is responsible for liaising with the Secretariat of the CBD. In other words, the CBD sets out a structure whereby it (the CBD) sits at the epicenter of an information network comprised of NFPs from all over the world, thus ensuring that clarity and certainty remain a central feature of the ABS regime. Closely related to the NFPs, another significant creation of the Protocol is its provision for the designation of one or more competent national authorities (CNA) within Parties. The CNA is responsible for advising prospective users of TK on applicable procedures and requirements for obtaining PIC. The CNA is also responsible for granting access, or in the alternative issuing written evidence that access requirements have been met. The CNA is central with respect to the proper implementation of the Protocol’s access requirements. The Protocol thus lays down strict procedures to ensure that both users and providers of such TK are fully informed of all the obligations with respect to access required or expected of them. Parties are expected to notify the Secretariat of such CNA’s and NFP’s as well as any maintain an updated record of changes to the contact information or responsibilities of these designated authorities. Such information is then made accessible to all Parties to the Protocol through the ABS Clearing House (ABSCH).

The NFP and CNA are significant for several reasons. First, they exist as entities which seek to promote legal certainty for bioprospectors and users of TK. As I discussed in chapter three above, some of the major concerns with the protection of TK relates to the uncertainty and the resulting disincentive which it provides to potential users of TK. Through these designated bodies, the Protocol ensures that users are

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752 See Article 13.1(b), Nagoya Protocol. This Article provides that the National Focal Point shall make available to ‘applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit sharing’.

753 See Article 13.1, Nagoya Protocol.


756 Importantly, Parties may decide to combine the functions of the CNA and the NFP in one single entity (See Article 13.3, Nagoya Protocol).


758 See Article 13.4, Nagoya Protocol.

759 This initiative is established by Article 14 of the Protocol as part of the Clearing House Mechanism provided for under Article 18 par. 3 of the CBD. This Clearing House Mechanism as provided for under Art. 18 par. 3 is specifically geared at promoting and facilitating technical and scientific cooperation. Such information to be made accessible by the Access and Benefit Sharing House includes information on legislative, administrative and policy measures on access and benefit sharing, information on the NFP and CNA, permits or their equivalents issued at the time of access as evidence of the decision to grant PIC and of the establishment of MATs.

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able to secure the needed information from the reliable sources within the provider country. This is also important in addressing instances where the actual holders of TK are unknown; the NFP and CNA are expected to fill the role of clarifying authoritatively the line of action to be taken by a potential user. Again, from the perspective of the indigenous group, it is widely accepted that several groups lack the capacity to negotiate specialized terms which will be most favorable for them within such transactions. For this reason, NFPs, and particularly the CNAs play an important role of safeguarding the interests of the indigenous groups within their territory by ensuring that the terms are fair, and in some instances, actually negotiating the terms on behalf of the indigenous groups. It is worth noting that as part of efforts to support indigenous peoples in developing terms, the Protocol requires all parties to encourage the development of model contractual clauses, as well as codes of conduct, guidelines and best practices.760

Again, it is important that the Protocol makes the participation of the TK holders (communities) in developing access obligations a priority. For instance, Article 12 provides that in developing national laws on ABS, Parties must take local communities’ customary laws into consideration.761 It also mandates Parties to establish mechanisms, through which the effective participation of concerned ILCs can be secured, and for informing potential TK users of their obligations for access to such knowledge.762 The Protocol, with regard to obtaining PIC and establishing MATs, mandates the NFP to provide information where possible to applicants seeking access to TKaGRs on the procedure for obtaining the involvement of ILCs.763 Trans-boundary cooperation, with the participation of the indigenous groups involved, in instances where the same TKaGRs is shared by one or more ILCs in several Parties’ jurisdictions is also provided for in the Protocol.764 This is a very significant point as a result of the manner in which TK evolves; communities which possess similar GRs may have developed similar knowledge as to their (GRs) use. This provision prevents users circumventing the requirements imposed by one provider Party with regard to the

760 See Articles 19 and 20, Nagoya Protocol.
761 Article 12.1, Nagoya Protocol.
762 Article 12.2, Nagoya Protocol. This mechanism shall also include the dissemination of information regarding such measures as made available through the Access and Benefit Sharing clearing house, provided for under Article 14 of the Protocol.
763 Article 13.1(b), Nagoya Protocol.
764 Article 11, Nagoya Protocol.
exploitation of such TK, by resorting to another territory sharing similar TK practices, having less stringent conditions.765

Finally, on access, it is worth noting that the Protocol mandates Parties, especially providers, to support research which contributes to the conservation and sustainable use of biodiversity through their ABS legislation.766 This includes, though not limited to, simplified measures on access to TK and GRs for non-commercial research purposes. Such measures are expected to take into account the possibility of a change of intent of such research.767

5.1.3.2.3 Benefit Sharing

The objective of benefit sharing in the use of TKaGRs is laid out within the preamble768 and developed in the text of the Nagoya Protocol. Articles 5 and 12 provide, respectively

   [e]ach Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be on mutually agreed terms769

   [i]n implementing their obligations under this Protocol, Parties shall, in accordance with domestic law, take into consideration indigenous and local communities’ customary laws, community protocols and procedures, as applicable with respect to traditional knowledge associated with genetic resources770

A combined reading of these provisions indicates the benefit sharing regime envisaged. Article 5 places the obligation on every Party to establish regulatory frameworks for the sharing of benefits. Thinly

765 According to Reji, “International Regime on ABS”, supra note 605 at 88, Genetic resources may spread across a geographical area which consists of many countries. An example cited is that of the similar diverse GRs contained within the Mesoamerican region from Mexico to Columbia. The region consists of more than 15 countries. The poor regulation as well as cooperation among countries within the region enables buyers to substitute one country with fewer restrictions on access with another. In this light for instance, when Brazil began to strictly regulate its access policies, American Bio Industry Alliance (ABIA) commented that, ‘this has all but shut down both academic and commercial research in Brazil in favor of better operating environments in neighboring states: Scientists say the rules are so stringent and overzealously enforced...reducing research to a crawl and driving many scientists to move their research to Ecuador, Bolivia and Peru.’.

766 See Article 8(a), Nagoya Protocol.

767 This change in intent would necessarily include circumstances in which the research is sought to be commercialised. The ABS laws should create avenues/provisions for such a transition in intent to be actualised.

768 Par. 21 of the Preamble to the Protocol provides that the Parties to the Protocol ‘...recall the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilisation of such knowledge...’.

769 Article 5.5, Nagoya Protocol.

770 Article 12.1, Nagoya Protocol.
veiled within this article is an important blended reading of inter-state (User-to-State) benefit sharing as well as intra-state (State-to-community) benefit sharing. By this, regulatory frameworks are expected to ultimately ensure that benefits are shared ‘with indigenous and local communities holding such knowledge’. This again reinforces the need to ensure that indigenous peoples, and not just provider countries, actually benefit from the exploitation of their knowledge. To this end, the Protocol makes it obligatory for Parties to take legal measures to ensure that benefits are shared equitably and places the onus on the providing party to establish measures which not only protect the local communities from exploitation by other Parties, but also from the domestic government, institutions and users too. The measures must also take into account the sharing of benefits between local users and the providing communities. Benefit-sharing measures may be laws, regulations, administrative directives, or mere policy statements.

The measures must take full account of the customary laws and protocols of indigenous communities. The Protocol also directs parties to endeavor to support indigenous peoples in developing community protocols for the fair and equitable sharing of benefits arising from the utilization of their TK, minimum requirements for MATs to secure the fair and equitable sharing of benefits arising from the use of TK, as well as model contractual clauses for benefit sharing arising from the utilization of TKaGR. These provisions reflect the emphasis placed by the Parties on capacity building for local communities who hold TK for the purpose of ensuring that they are adequately equipped to reap the full benefits of implementation. Furthermore, these provisions seem to point to the need to again place the interests and existing practices of indigenous communities at the center of benefit sharing strategies. To this end, the need to respect and abide with existing community protocols and customary laws which indigenous peoples have utilized to govern their affairs is an important aspect of the ABS mechanism. Again, legal certainty

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771 The overall obligations of the Protocol suggest that the introductory phrase of Article 5 will necessarily encompass measures regulating inter-State benefit sharing, as well as State to community benefit sharing. Morgera & Tsioumani “The Evolution of Benefit Sharing” supra note 403.
772 See Article 5.5, Nagoya Protocol.
773 See Article 12.1, Nagoya Protocol.
774 See Article 12.3 (a), Nagoya Protocol.
775 See Article 12.3 (b), Nagoya Protocol.
776 See Article 12.3 (c), Nagoya Protocol.
and clarity is promoted by requiring Parties to submit legislative, administrative and or policy regulations on benefit sharing to the ABSCH.777

Another key element relates to the development of MATs within benefit sharing arrangements. A distinction can be drawn here between the concept as used in relation to access and its use in relation to benefit sharing, even though the same underlying principle may be said to apply in both situations. Article 7 (on access) presupposes that such terms are established prior to access, at the point of PIC while Article 5 places the obligation at the point of sharing of benefits, which could be after physical access. The importance of this distinction is to establish that the negotiation of MATs may arise both at the point of access and at the point of benefit sharing within a singular application for the use of TKaGRs. Even where the both sets of MATs are negotiated prior to access, the terms must be negotiated to cover all separate aspects of the transaction. The NFP, as discussed earlier, is mandated to provide information on procedures available for establishing MATs including benefit sharing.778 The Protocol encourages the development and use of model contractual clauses for developing and establishing MATs.779

To address the fair and equitable sharing of benefits derived from the utilization of TKaGRs for which it is impossible to grant or obtain PIC, or for such TK which occurs in trans-boundary situations,780

777 See Article 14.2 (a), Nagoya Protocol. The ABS-CH provides a platform for exchanging information on ABS, and is established pursuant to Article 14 of the Protocol, as part of the Clearing House of the CBD established under Article 18 of the CBD. See, CBD, “The ABS Clearing-House”, online: CBD <https://www.cbd.int/abs/theabsch.shtml>. The ABSCH offers three main functions. First, it enables the registration of ABS information in a publicly accessible forum. Second, it provides stakeholders with free access for searching ABS-related information, and third, it enables the browsing of country profiles. Two categories of information are published within the ABSCH: national records (referring to national information published by Parties and non-Parties which are relevant for the implementation of the Protocol, including information Parties are obliged to provide in accordance with the Protocol), and reference records. For the former, only countries are able to publish national records in the ABSCH, while anyone with a CBD account is able to publish reference records. Such reference records may include meeting documents, communications, literature about ABS, as well as training and capacity building materials. These are however verified by the CBD Secretariat before publishing. The ABSCH is a significant element in the fight against biopiracy, particularly in its role in information dissemination, including the clarity and certainty with respect to national regulations as well as competent authorities for utilizing TK. Presently, 26 countries have published 74 legislative, administrative, or policy measures, 170 countries have published 178 ABS National Focal Points, 36 countries have published 48 Competent National Authorities, 12 countries have published information on 29 checkpoints, and four countries have published 38 International Recognized Certificates of Compliance. Ibid.

778 See Article 13.1 (b), Nagoya Protocol.

779 See Article 19.1, Nagoya Protocol. Parties are enjoined to promote as appropriate the development of both sectoral and cross-sectoral model contractual clauses for MATs.

780 In explaining ‘trans-boundary situations’, Article 11 of the Protocol which provides for cooperation in trans-boundary situations, offers an insight into trans-boundary situations where it describes such situations as being ‘where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several parties...’. See Article 11.2, Nagoya Protocol.
the Protocol calls Parties to consider the need and modalities for a Global Multilateral Benefit-Sharing Mechanism.\footnote{See Article 10, Nagoya Protocol.} Such benefits accruing from this mechanism are specifically to be directed at the conservation of biodiversity and the sustainable use of its components globally. Overall, the Protocol envisages both monetary and non-monetary benefits,\footnote{See 1(a)-(j) and 2(a)-(q) of the Annexe to the Protocol.} which could be immediate or long term, and repeats practically verbatim the understanding of benefits found within the Bonn guidelines.\footnote{See 1(a)-(j) and 2(a)-(q) Appendix II to the Bonn Guidelines.}

5.1.3.2.4 Capacity Building

In addition to clarifying access and benefit sharing obligations, the Nagoya Protocol recognizes that effective protection of TK requires capacity development of indigenous peoples (as well as developing countries) who hold TK, and provides for it. Capacity development under the Protocol is thus directed primarily at developing country Parties.\footnote{Article 22.1, 22.2 & 22.3, Nagoya Protocol. Least developed countries (especially the small island developing states among them), and the Parties with economies in transition are given priority in this consideration.} Parties are enjoined to cooperate in capacity building, capacity development, and strengthening of human resources and institutional capacities for the purpose of effectively implementing the Protocol.\footnote{Article 22.1, Nagoya Protocol. See also The Protocol in this context further provides for Parties in this context to facilitate inter alia the involvement of indigenous communities.}

Four key areas are identified for capacity building and development activities, including, building the capacity of Parties to implement and comply with the obligations of the Protocol; building the capacity of Parties to actually negotiate MATs effectively; building the capacity of Parties to develop, implement, and enforce domestic legislative, administrative or policy measures on ABS; and building the capacity of Parties to develop their endogenous research capabilities.\footnote{See Article 22.4, Nagoya Protocol.}

To achieve the above capacity building priorities, the Protocol outlines a list of possible measures which could form part of the strategies used for capacity building activities.\footnote{See, Article 22.5, Nagoya Protocol.} These measures range from trainings on the negotiations of MATs, technology transfer, legal and institutional development etc.\footnote{Ibid.} The Protocol also emphasizes developing measures to increase the capacity of relevant ABS stakeholders.\footnote{Article 22.5(i), Nagoya Protocol.}
Such measures are extended to include indigenous peoples and local communities with an emphasis on women in such communities.\textsuperscript{790} Developing countries and LDCs are expected to identify their capacity needs and priorities through national capacity self-assessments that give priority preference to the capacity needs of indigenous peoples.\textsuperscript{791} Technology transfer, as well as infrastructure and technical capacity to make such technology transfer sustainable, is also identified as a measure which may be included in actualizing the aims of capacity development.\textsuperscript{792} Article 23 calls on Parties to specifically cooperate and collaborate in technical and scientific research with respect to Articles 16 and 18 of the Protocol which, deal with compliance with regulatory requirements for TKaGRs, and compliance with MATs.\textsuperscript{793} The capacity building goals are expected to be actualized through cooperation among the Parties with a major emphasis on the involvement of indigenous peoples.\textsuperscript{794} Finally, the Protocol recognizes the need to provide financial resources which will support the capacity building of developing countries with regard to the implementation of the Nagoya Protocol.\textsuperscript{795}

\textbf{5.1.3.2.5 Compliance}

Probably the most important and significant aspect of the entire call for an international regime on ABS was the need to address the question of compliance. While there were already ABS rules within the CBD, as well as the Bonn Guidelines, the fact that they remained ineffective in ensuring compliance with their stipulations was a huge factor prompting the developing country-led efforts to negotiate an international regime. In comparison to the CBD and the Bonn Guidelines, the Protocol provides a more stringent set of compliance rules aimed at ensuring that its measures are binding and enforceable.

\textsuperscript{790} Article 22.5(j), of the Protocol.
\textsuperscript{791} Article 22.1, Nagoya Protocol.
\textsuperscript{792} Article 22.5 (g), Nagoya Protocol.
\textsuperscript{793} See 1.3.3.3.
\textsuperscript{794} Article 22.1 Nagoya Protocol. It is particularly significant that, as part of the terms of reference for the negotiation of the international ABS regime, it was stipulated that this international regime could consist of one or more instruments within a set of principles, norms, rules and decision making procedures. Bearing in mind that regimes are social institutions which unite actors and/or participants towards common objective(s) with respect to specific international issue-area(s), the significance of the open-ended terms of reference draws from the diversity of the instruments which are mentioned as forming part of the regime. It also offers a basis for determining further instruments which could possibly be a part of the regime.
\textsuperscript{795} Article 22.2, Nagoya Protocol.
Its most significant feature is that it provides for Parties to adopt compliance measures to ensure that TKaGRs used in their jurisdiction have been accessed in accordance with the domestic laws or regulatory requirements of the other Party in whose jurisdiction the TK owners are situated. Such measures are further to be complemented by appropriate, effective and proportionate measures to address non-compliance. It is noteworthy that there is a cooperative ‘burden shift’ here to the ‘user’ countries which are required to establish measures to protect holders of TKaGRs. It must, however, be observed that all of such measures by the ‘user’ countries are still based on the domestic regulations as laid down by the provider country. This is significant as it clearly reiterates the importance of comprehensive, clear and informed legislation by the providing Party. In cases of alleged violations of regulatory or legal benefit sharing requirements of the ‘providing state’, the Parties – both providers and users – cooperate ‘as far as possible and as appropriate’ to remedy the situation.

The significance of this feature within the context of the biopiracy discourse must be firmly stated here. As I pointed out in the previous chapter, biopiracy is hinged on two core aspects: a trans-border and a trans-regime aspect. The cooperative strategy outlined above demonstrates the important incorporation of a trans-border strategy for addressing the incidence of biopiracy. This is important as it ensures that the domestic regulations within provider countries are given the force of law even within user countries. Pursuant to this strategy, a wide range of developed countries, particularly in Europe, have developed legislation ensuring that users within their territories are in compliance with the domestic regulations of provider countries. By this, the implementation of the Protocol can be said to hold great promise for addressing the user failure challenge that has hitherto remained a central concern of developing countries in the implementation of ABS laws.

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796 See Article 16.1, Nagoya Protocol. This provision significantly calls on detailed measures by the Party in whose jurisdiction the knowledge is to be utilised in ensuring that such knowledge has been accessed in accordance with PIC, indigenous participation, and firmly established MAT, all in accordance with the domestic regulations of the other Party in whose jurisdiction the indigenous communities are located.

797 See Article 16.2, Nagoya Protocol.

798 In further buttressing this point, the heading of Article 16 reads, ‘Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit Sharing for Traditional Knowledge Associated with Genetic Resources’. This implies that the compliance mechanism of the Protocol is geared at ensuring compliance with the domestic regulation of the providing Party.


800 Examples of such countries include, Switzerland, Denmark, Norway, Australia, to name a few.
Article 18 of the Protocol provides remedies in the case of breach of MATs.\(^{801}\) It directs Parties to encourage users and holders of TKaGRs to include dispute resolution provisions in the MATs.\(^{802}\) Parties are, however, directed to ensure that their legal systems provide opportunities for the Parties to seek justice in cases of disputes arising from MATs.\(^{803}\) The Protocol mandates the Parties to adopt measures to promote accessibility to justice as well as to facilitate the cross-jurisdictional enforceability of judgments and awards.\(^{804}\) It should, however, be observed that the CBDs dispute settlement procedure\(^{805}\) extends to any Protocol negotiated within the purview of the Convention, except where the Protocol concerned provides otherwise.\(^{806}\) The Nagoya Protocol recognizes the Convention’s mechanism but stipulates that its procedures and mechanisms shall be ‘separate from and without prejudice to the dispute settlement procedures and mechanisms under Article 27 of the Convention’.\(^{807}\) The Parties to the Protocol continue to examine cooperative procedures and institutional mechanisms to promote compliance with the provisions of the Protocol and to address cases of non-compliance.\(^{808}\)

Indeed, this trans-border cooperation, though important, remains insufficient to address the problem of biopiracy as it remains unable to deal with the trans-regime concerns which also play a central role in biopiracy cases. In this instance, the trans-border cooperation can be seen as strategy located within a regime and, as such, it can only address a part of the problem of biopiracy. As argued in chapter four, the trans-regime aspect of biopiracy requires a cooperation strategy, similar to what the protocol proposes across national borders, but across international regimes. Specifically, the Protocol requires its obligations

\(^{801}\) See Article 18, Nagoya Protocol.

\(^{802}\) Such provisions on dispute resolution should include the jurisdiction to which they plan to subject such dispute resolution process; the applicable laws; and/or options for alternative dispute resolution such as mediation or arbitration. See Article 18.1(a)-(c).

\(^{803}\) See Article 18.2, Nagoya Protocol.

\(^{804}\) See Article 18.3, Nagoya Protocol.

\(^{805}\) See Article 27, of the CBD.

\(^{806}\) See Article 27.5, of the CBD.

\(^{807}\) See Article 30, Nagoya Protocol.

\(^{808}\) See Article 30, Nagoya Protocol. Importantly, at COP-MOP 1, the COP-MOP developed and adopted a document entitled “Cooperative Procedures and Institutional Mechanisms to Promote Compliance with the Provisions of the Nagoya Protocol and to Address Cases of Non-Compliance” [“Cooperative Procedures and Institutional Mechanisms”] pursuant to Article 30, Nagoya Protocol. These “Cooperative Procedures and Institutional Mechanisms”, established a Compliance Committee to carry out the functions contained within the Committee. See, Report of the First Meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2014) UNEP/CBD/NP/COP-MOP/1/10.
to find the force of law within the neighboring intellectual property (IP) regime. Picturing symbolically the ABS and IP regimes, therefore, in a manner similar to independent states discussed above, the ability of the IP system to ensure that users of TKaGRs are in compliance with their obligations under the ABS regime is a critical trans-regime solution for which the Nagoya Protocol requires further reinforcement. Such a reinforcement must necessarily come from within the IP system. As I argue in the next chapter, the ongoing work within the World Intellectual Property Organization’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), is central and critical to the realization of this need.

Before proceeding to the next chapter, I will discuss what I consider to be an important and relevant segue between the Protocol and the IP regime. Specifically, as I have argued in chapter two, the Protocol was negotiated as the core ABS law upon which the ABS regime is built. The ABS regime, I further explained, is an open-ended one. In other words, the mentioned instruments which form a part of the ABS regime – the CBD, the Nagoya Protocol, the Bonn Guidelines, the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) – are not an exhaustive list of instruments which are recognized as being central to the ABS regime. Other instruments may be added on the basis of complementarity. By looking at what I term the evolutionary context of the Protocol, however, it becomes clearer that the WIPO IGC is an important forum holding promise of a complementary instrument(s) which will form a part of the ABS regime, and importantly serving as an important next step in the design of the needed trans-regime solution to biopiracy.

5.2 An Evolutionary Context for the Nagoya Protocol

As part of the decision adopting the Nagoya Protocol, the COP 10 decided to establish an Open-Ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol [ICNP]. The ICNP served as an interim Committee for the administration of relevant preparatory modalities to assist with the early

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809 Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of their Utilization to the Convention on Biological Diversity [ICNP]
ratification and implementation of the Protocol.810 With the entry into force of the Protocol, and the first meeting of the Conference of the Parties serving as the Meeting of the Parties to the Protocol (COP-MOP),811 the ICNP has ceased to exist. Its recommendations, covering a range of implementation issues for the Protocol, however, formed the basis for the first COP-MOP meeting.812 The present effort of the COP-MOP, which meets biennially, continues to be focused on the issue of effective regime implementation. This lends credibility to the relevance of the present research as its analyses will be useful for the COP-MOP in navigating the Protocol’s complex framework of implementation. Specifically, it is worth noting of the COP-MOP’s role in the implementation of the Protocol:

In understanding the Protocol’s implementation, it is worth noting that the decision adopting the Protocol hints at an evolutionary approach to the international ABS regime. For this reason, a strong review mechanism is built into the Protocol. The COP/MOP, for instance, which meets biennially, is expected to keep under regular review the Protocol’s implementation.813 Centrally, in ensuring the implementation of the Protocol, the COP-MOP is tasked, inter alia, with making necessary recommendations, establishing subsidiary bodies, as well as considering and adopting possible amendments to the Protocol which are deemed necessary for the implementation of the Protocol.814 Importantly, however, the COP-MOP is also expected to

[s]eek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies815

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810 See COP 10 Dec X/1, supra note 192 at II.7 & II.8. In laying the foundations for the successful implementation of the Nagoya Protocol, the ICNP was guided by an approved workplan (Decision X/1 II.12) as contained in Annex II to the COP 10 Dec X/1, supra note 192.

811 See Article 26, Nagoya Protocol. COP-MOP 1 took place in Pyeongchang, Republic of Korea, from October 13 – 17, 2014. Documents, as well as decisions arising from the meeting are available online: CBD <https://www.cbd.int/npmop1>.

812 The ICNP met three times in preparation for the COP-MOP 1. Its deliberations, contained in documents UNEP/CBD/NP/COP-MOP/1/INF/1, UNEP/CBD/NP/COP-MOP/1/INF/2, and UNEP/CBD/NP/COP-MOP/1/INF/3, formed the basis for the COP-MOP 1.

813 See, Article 26.4, noting: the [COP-MOP] shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation.

814 Ibid. paras (a), (b), and (e).

815 Article 26.4(c).
Pursuant to the above, therefore, the COP-MOP is expected, and mandated, to reach out to utilize the services and cooperation of other competent international organizations for the effective implementation of the Protocol. Given the need to address IP elements of biopiracy which significantly lie at the heart of the Protocol’s effective implementation, and which draw principally from the IP regime, the COP-MOP will therefore be expected to coordinate, amongst others, with WIPO as the specialized agency of the United Nations charged with the promotion and protection of IP. The inbuilt review mechanism of the Protocol alludes to this fact.

An inbuilt review of the Protocol’s mechanism to ensure compliance with domestic regulatory requirements regarding TKaGRs is provided for.\(^\text{816}\) It notes that this review of Article 16 will be carried out in light of developments in other relevant international organizations, including the World Intellectual Property Organization (WIPO), provided that such developments do not run counter to the objectives of the CBD and the Protocol.\(^\text{817}\) It is particularly telling that though an insinuation is made to the related developments in several other relevant international organizations, WIPO is the only intergovernmental organization specifically mentioned. It is worth mentioning here that the specific reference to WIPO is an indication of the central relevance of WIPO in the design and the projected evolution of the international regime on ABS. This relevance of WIPO is specifically with regard to the implementation of the ABS regime. Consequently, the ABS regime’s effectiveness in addressing the incidence of biopiracy points to a needed evolution of the ABS regime which relies on WIPO developments.

In the year 2010 when the Protocol was adopted and the decision of the COP adopting the Protocol was drafted, the ongoing work was within the WIPO IGC. This continues to be so. A policy forum established within WIPO for the purpose of discussing IP issues arising within the context of the protection of GRs and TK, the IGC remains engaged in negotiations towards an international instrument for the effective protection of GRs, TK and traditional cultural expressions (TCEs). As I argue therefore, the IGC is an important part of the ongoing evolution of the international ABS regime. To justify this assertion, it is worth taking a closer look at two key implications of the evolving context within the Protocol is situated.

\(^{816}\) See Article 16 and 31, Nagoya Protocol.

\(^{817}\) COP 10 Dec X/1, supra note 192 at I.6.
First, the implementation of the ABS system is largely untested. Similar to the challenges witnessed within the negotiation of the Bonn Guidelines as well as the framing of paragraph 44(o) of the Johannesburg Plan of Implementation, the negotiation and adoption of the Nagoya Protocol was colored with a strong aversion by several countries to the emergence of a binding regime within an area of governance in which limited experience is available. As some commentators have explained, the eventual adoption of the Nagoya Protocol was more the victory of the host nation, than the victory of negotiators.\textsuperscript{818} For, in the final analysis, amidst unresolved controversial issues within the negotiations, desperate diplomatic measures were resorted to for the purpose of ensuring a compromise outcome could be salvaged from the intensive negotiations that characterized the entire COP 10.\textsuperscript{819} The evolutionary nature of the deal therefore implies a required reworking and/or fine tuning of the regime in line with practical realities derived from the implementation experience.

Another significant implication of the evolutionary context of the Protocol, also drawing from the fact that the issue of ABS implementation is largely untested, is the uncertainty surrounding the required support structure within which the regime would operate. This is in addition to the reworking and/or fine tuning of the regime through implementation noted above. In this context, the open-ended nature of the components of the international regime on ABS is noteworthy. The decision adopting the international regime on ABS indicates that the regime is made up of the CBD, the Nagoya Protocol and other complementary instruments, including the Bonn Guidelines and the ITPGRFA. This suggests that the four mentioned instruments do not constitute an exhaustive list. Rather, they merely indicate the minimal components of the regime. As discussed in chapter two, additional components of the regime may thus emerge and be included on the basis of complementarity. It is striking in this regard that the projected developments at WIPO are specifically referred to as being relevant for the Protocol’s implementation,

\textsuperscript{818} See, for instance, Gurdial Nijar, commenting that the Nagoya Protocol may best be considered to be a partially negotiated text, given that it was a text crafted by a small unelected group that was presented by the Japanese presidency to delegates in the closing hours of the deadline given for the adoption of the Protocol. See Gurdial Singh Nijar, “The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries” (2011) 36 South Centre Research Papers at 1.

‘provided they do not run counter to the objectives of the Convention and the Protocol’. Drawing interpretive guidance from the *Vienna Convention on the Law of Treaties* (VCLT), the relevance of WIPO may be gleaned from Article 4 of the Protocol which, in similar wording to the decision adopting the Protocol, states:

> [t]his Protocol shall be implemented in a *mutually supportive manner* with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

From a WIPO perspective, as part of efforts to negotiate an international instrument which will ensure the effective protection of TK and GRs, its latest text on GRs, has similarly identified, as one of its core objectives, the promotion of complementarity/mutual supportiveness with other international agreements relating to the protection of GRs. The Nagoya Protocol, as an instrument primarily negotiated to address the protection of GRs and TKaGRs, clearly fits into this bracket. In essence, therefore, a discussion on the implementation and future evolution of the international ABS regime must be viewed within the context of the relevant ongoing work within WIPO’s IGC which is geared at ultimately ensuring that the international IP system is complementary and mutually supportive to the ABS regime.

Laying further credence to this view, Simon West has argued that a textured interpretation of the Nagoya Protocol requires its interpretation within the context of the broader political economy of IP. This, he argues, is because the Protocol is imbued with obligations which are subservient to the IP system, thus leaving its beneficiaries in a state of dependence on the IP system for the actuation of their rights. In the light of the above, the next chapter will examine the ongoing work within the IP system, with a particular focus on the efforts of developing countries to secure a support system for the Nagoya Protocol. It explains the development of this support system as an ongoing result of regime shifting (a concept introduced in

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820 COP 10 Dec X/1, *supra* note 192 at I.6 [The Conference of the Parties...[d]ecides that the first review under Article 31 of the Protocol shall assess the implementation of Article 16 in light of developments in other relevant international organizations, including, inter alia, the World Intellectual Property Organization, provided that they do not run counter to the objectives of the Convention and the Protocol].

821 Vienna Convention on the Law of Treaties, 23 May 1969, 1155 UNTS 331 (entered into force 27 January 1980 in accordance with Article 84(1)) [VCLT].

822 See Article 4.3, Nagoya Protocol.


chapter two), by third world participants, a positive outcome of which is central to the effective implementation of the Protocol. In articulating the development of an IP support system, however, as explained above, the related developments within WIPO’s IGC must be given prominence.

With specific reference to the Nagoya Protocol’s implementation, vis-à-vis a complementary IP system, four key factors prompt a further look into its potential to achieve, in an effective manner, its stated objectives. First, there exists an antecedent of weak implementation for instruments agreed on the platform of the CBD, especially those within the issue area of the Nagoya Protocol. Prior to the Protocol, the CBD and the Bonn Guidelines were negotiated to address, inter alia the fair and equitable sharing of benefits arising from the utilization of TK and GRs. Recognizing this, the Protocol specifically mentions, amongst others, the CBD as well as the Bonn Guidelines as forming component parts of the international regime it establishes. Both of these instruments have, however, not enjoyed a successful implementation till date for differing reasons. While the CBD has often been cited as hard law characterized by a soft nature, evidenced by its lack of an effective enforcement mechanism, the weak implementation of the Bonn Guidelines has generally been attributed to the voluntary nature of its undertakings. Addressing the weaknesses of these prior instruments, the Nagoya Protocol is drafted in conformity with the Bonn Guidelines, albeit with binding obligations, and is expected to further aid the implementation of the CBD, with a specific emphasis on its third objective – the fair and equitable sharing of benefits arising from the utilization of GRs.

Second, is the nature of the issue area to which the Nagoya Protocol is addressed. While the stated objective of the Nagoya Protocol is the fair and equitable sharing of benefits arising from the utilization of GRs, the underlying subtext to the Protocol relates to the protection of GRs and TK from the increasingly rampant incidence of biopiracy. Indeed, based on chapter four’s analysis, the contested and trans-regime nature of biopiracy makes it virtually impossible to sufficiently address biopiracy through a single regime. Benefit sharing is aimed at addressing biopiracy and thus constitutes, from a Third World Perspective, the

825 This has been attributed to its strict natured provisions which use mandatory language to describe obligations of Parties, yet fail to accompany such mandatory obligations with requisite enforcement measures in case of breaches. See Harrop, “Harmony with Nature”, supra note 203 at 117 – 128.
827 See Article 1, Nagoya Protocol.
raison d’être for the Protocol. Indeed, this was the key issue that prompted the call by demandeurs, most of which were megadiverse developing countries, for an international regime on ABS. The negotiation of this regime resulted in the adoption of the Nagoya Protocol. Biopiracy, by its nature, involves the misappropriation and/or misuse of GRs and TK. It has, however, thrived due to the incentives and overall normative dominance of the global IP system specifically in the governance of the use of TK and GRs. The issues, problems and solutions relating to biopiracy, therefore, cannot be fully understood without an understanding of the IP system.828 This brings into focus the contrasting norms inherent within the IP system and the ABS system, and the effect of these on efforts to develop solutions to biopiracy. Within the context of the Nagoya Protocol’s implementation, the effect that counter-regime IP norms have on the implementation of the Nagoya Protocol, then forms an important consideration while assessing the potential efficacy of the instrument.

Third is the diversity of the stakeholders and power relations that have prompted the emergence of the Protocol, and upon/through which the implementation drive of the Nagoya Protocol will be sustained. Scholars of international relations have debated extensively the formulation and efficacy of international regimes from the perspectives of power, interest, and knowledge.829 The proliferation of international regimes addressing specific issue areas has led to questions relating to the role of non-state actors in the global governance of specific issue areas. The central non-state beneficiaries of the protection of TK and GRs are indigenous peoples as distinguished from the major non-state beneficiaries of IP protection – multinational corporations. The respective roles and/or influence that these non-state actors have had and continue to exert on the formulation of public policy and/or state agency has a direct bearing on the implementation of the Protocol.

Finally, an underlying mischief regarding the potential implementation of the Protocol is discernible through an analysis of the ongoing related work in the IP regime. Within the World Trade Organization (WTO) and WIPO, negotiations are progressing which address elements that directly impact,

828 Amanda J Landon, “Bioprospecting & Biopiracy in Latin America: The Case of Maca in Peru” (2007) Nebraska Anthropologist at 64, noting that an understanding of IP rights and patents as they apply to indigenous cultures is important for understanding the issues surrounding biopiracy.

829 Hasenclever, Mayer & Rittberger, International Regimes, supra note 64 at 9.
or inform the implementation of the Nagoya Protocol’s main provisions. In contrast to the WTOs characteristic state-centric negotiations,830 WIPO offers an accessible forum, similar to the CBD, which openly draws participation from all major stakeholders.831 WIPO’s negotiations are aimed at developing a *sui generis* IP system which will ensure the effective protection of TK (including traditional cultural expressions) and GRs. Despite the fact that most of the same state actors within the IP negotiations, WIPOs in particular, are those that agreed to the adoption of the Nagoya Protocol on the platform of the CBD, the WIPO negotiations have been beset with difficulties all through its years of existence. The differing postures from the actors within the sphere of the IP discussions *vis-à-vis* the Nagoya Protocol’s provisions, raises a genuine concern about the political will backing the Protocol’s core provisions, its implementation and its ultimate potential to achieve its desired objective. Furthermore, the fact that the United States, which is not a party to the CBD, is a present and engaged negotiator within the WIPO IGC is an important factor when considering the legitimacy and practicality of any WIPO outcome. This is because the United States harbors a major pool of users of GRs and, as such, must form an important part of any effort to design an effective international regime for ABS.

It is this fourth reason that probably provides the most tangible expression of the international realities facing the successful implementation of the Nagoya Protocol and offers relevant context for the other three identified reasons. The discussions within the IP fora, which are considered in the next section, shed light into the power dynamics relating to the biopiracy issue area that the Protocol purports to address; significantly, it highlights the Protocol’s central need for a reinforcement structure within the prevailing system of global politics, largely influenced by the international economic system, of which IP forms a component part. This fourth reason similarly reveals the extent to which developing countries, indigenous groups and NGOs are pressing, albeit cautiously due to historical reservations about the Eurocentric IP system, for IP reinforcements for the Protocol.

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830 Negotiations within the WTO are undertaken strictly by Members and observer states that intend to, or are in the process of negotiating membership to the WTO. Decisions on outcomes are, however, only taken by Member States. See, WTO, “How the Negotiations Are Organized” online: WTO <https://www.wto.org/english/tratop_e/dda_e/work_organi_e.htm>.

831 WIPO’s negotiations, as discussed later in chapter 6, is open to participation from states, indigenous peoples, relevant intergovernmental organizations (IGOs), non-governmental organizations (NGOs), corporate actors (including multinationals and research institutes) etc.
5.3 Conclusion

In conclusion, the Nagoya Protocol presents a trans-border solution to the problem of biopiracy through its cooperative strategy which addresses the user failure challenge that has defined the problem of biopiracy through the years. However, the Protocol remains an insufficient solution to the problem of biopiracy due to its inability to address the central trans-regime concerns of biopiracy. By establishing an international regime on ABS, the Nagoya Protocol lays the foundation for a future evolution of the ABS regime to incorporate relevant treaties which will reinforce its effort to address the problem of biopiracy. WIPO’s ongoing efforts to negotiate a complementary *sui generis* system of protection for TK must be viewed as an important development defining the evolving ABS regime. Indeed, the outcome of the WIPO negotiations would necessarily form a part of the evolving ABS regime-complex, should the negotiations succeed in arriving at an instrument which complements and reinforces the Protocol.

The WIPO negotiation therefore offers a useful basis for analyzing the potential of the Nagoya Protocol to address the problem of biopiracy. This is in line with this dissertation’s central contention that the effective implementation of the Nagoya Protocol in addressing biopiracy requires an outcome within the WIPO negotiations which reinforces and/or sits in coherence with the Nagoya Protocol. Such an outcome, though immediately relevant to WIPO, will ultimately impact the broad regime of IP by significantly establishing a pathway for the actualization of changes to the TRIPS. It will also sit as ‘complementary instrument’ within the ABS regime as established by the COP. In the next chapter, I will turn to address the WIPO negotiations and its significance within the broader context of the IP regime as well as the ABS regime. The analysis draws inspiration from Laurence Helfer’s elaboration of regime shifting, introduced in chapter two. As I mentioned, Helfer’s discussion of regime shifting in IP law making describes regime shifting as an interest-based shifting of negotiations by States and NGOs from one venue to another within a single regime (intra-regime shift) or across regimes (inter-regime shift).\(^{832}\) In a slight departure from Helfer’s approach which is essentially focused on the process of international IP law making, the next chapter reflects on the effort of regime actors, particularly weaker actors, to utilize the WIPO IGC to secure normative *reinforcements* for the normative victories gained within the Nagoya

\(^{832}\) Helfer, “Regime Shifting”, *supra* note 65 at 16 – 17.
Protocol. This is significantly a view of the ongoing negotiations within the IP space (particularly the WIPO IGC) as an attempted expansion of the ABS regime through the capture of an instrument within the frame of the global IP system.
Chapter 6

WIPO: Reinforcing the Nagoya Protocol in the Fight against Biopiracy

The nexus of creativity and commerce that has prevailed in modern times is nowadays in a predicament. Its implications begin with intellectual property, but extend far beyond intellectual property alone…It is hard to see how the situation can be resolved satisfactorily without changing the very terms in which society understands intellectual property and its policing. That is, history suggests that a radical reconfiguration of what we now call intellectual property may be approaching, driven on by antipiracy measures as much as by piracy itself. Such an outcome is not inconceivable.833

In the previous chapter, the normative prescriptions (substantive component) of the Nagoya Protocol were examined. As part of the analysis, some of the limitations of the Protocol in addressing the incidence of biopiracy were highlighted. Significantly, the Protocol lacks the capacity to address the wrongful appropriation of the knowledge and resources of indigenous peoples occurring through the intellectual property (IP) system. The previous chapter also considered the evolutionary context within which the Nagoya Protocol exists – one that significantly envisages a link between the Protocol and relevant developments within the World Intellectual Property Organization (WIPO). Building from the preceding chapter, this chapter emphasizes the importance of WIPO, particularly through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), in addressing the unresolved issues relating to biopiracy. The IGC must be viewed and understood as a complementary process to the Nagoya Protocol which is absolutely essential in the Protocol’s efforts to address biopiracy. Furthermore, its successful resolution must be viewed as the required ‘next’ step in the needed evolution of the access and benefit sharing (ABS) regime-complex. By situating itself within the ongoing work of the IGC, this chapter demonstrates that a positive treaty outcome – one that defensively reinforces the Protocol’s mechanism, is a core element of the current ABS regime’s effort to effectively address biopiracy.

The idea of reinforcement bears within it a reference to a process or action of strengthening an existing thing. It presupposes the use of a separate mechanism or entity, usually a stronger one, to further

833 Johns, Piracy, supra note 581 at 15.
assure or solidify what is already in existence. In this chapter, I utilize this concept of reinforcement to discuss the central thrust of developing country efforts within the ongoing WIPO negotiations vis-à-vis the implementation of the Nagoya Protocol. In this context, the WIPO IGC offers a distinct forum, situated within the global IP regime, within which the articulation of supportive norms to the Protocol are being pursued, particularly by developing countries. This chapter, therefore, focuses on the IP reinforcement of the Nagoya Protocol through the emerging discussions on the platform of the WIPO IGC. By referencing the defensive reinforcement, this chapter suggests a preventive mechanism; in other words, it suggests a strengthening of the ABS regime in its efforts to address biopiracy through a defensive IP strategy.

In chapter four, I established the real need for the development of an internal check within the IP regime which prevents the IP system from being used as a tool of unjust appropriation over traditional knowledge associated with genetic resources (TKaGRs). WIPO’s IGC offers a unique platform for the fulfilment of this. As noted, the situation of the IGC within the IP regime means that any outcome from the negotiations will be an IP instrument, which sits, functions, and is administered by WIPO within the context of the broader IP regime. This understanding critically defines the importance of the IGC’s outcomes to the future evolution of the international IP regime; WIPO’s normative role in advancing the responsiveness of the IP system to modern realities through the creation of new rights, as well as the renegotiation of existing rights, places its ongoing normative endeavor with respect to TK at a significant point within the future direction of the global IP system. Yet, drawing from my arguments in chapter five, such an instrument will also form a significant part of the ABS regime, based on its complementarity to the Nagoya Protocol. As I argue in this chapter, developing countries have made the realization of such a ‘complementary’ outcome to the Protocol a primary goal within the WIPO negotiations.

As part of this research, I spent a considerable period participating in the WIPO IGC. My privileged position within the negotiations offered a unique insight into the Committee’s negotiations. It should be

834 Within the CBD, the principle of complementarity is largely utilized as a funding principle according to which funded activities must be coherent with national programs and policies to maximize global environmental benefits. See UNEP, *Glossary of Terms for Negotiators of Multilateral Environmental Agreements* (Nairobi: UNEP, 2007) at 25. Deducing an interpretation of complementarity in this context, it is by no means indicative of a similitude of approach, of overriding policy objectives, or even of content. Rather, as my analysis in chapter five shows, complementarity could be understood as mutually supportiveness, coherence, as well as a common commitment to the addressing of a central issue area.
noted that several aspects of the ongoing discussions remain sensitive and confidential. For this reason, my analysis here will not focus on the substantive negotiations within the Committee, which are far from concluded. Rather, in making the case in this chapter, I look at the less discussed institutional aspects informing the negotiations. As part of this institutional analysis, the appropriateness or otherwise of the WIPO IGC as a forum providing a reasonable option for the Nagoya Protocol’s reinforcement is examined. This is an extremely important discussion as WIPO as an institution has continued to face intense scrutiny with questions being asked regarding its relevance, especially in the wake of the TRIPS’ incursion into the global IP arena. As I point out here, the IGC is a symbol of WIPO’s continuing relevance in global discourse. While yet pointing out the need for a complementary outcome within the WIPO IGC, this chapter serves the important purpose of demonstrating the institutional complexity surrounding the efforts of developing countries to arrive at an outcome which reinforces the Protocol within the WIPO IGC.

In furthering the arguments contained within this chapter, its analysis is broken down into three major parts. In part one, I contextualize the WIPO IGC by examining the concept of IP and its historical development. As part of this historical analysis, I explain and rationalize the dominance and resilience of the global IP regime and draw attention to the exclusion of TK from its original design. A significant watershed in the strengthening of the IP system was the adoption of the TRIPS, which I refer to. Though an analysis of the TRIPS falls outside the scope of this research, I justify the need to utilize the IP regime as a reinforcement for the ABS regime through a reflection on the IP regime’s strength – an important aspect of which was the reinforcement of the IP system with the international trade system through the TRIPS. Part two then traces the development of the WIPO IGC, pointing to the developing country led efforts, right from its inception, to seek an IP solution to biopiracy through coherence with ABS systems. It analyses the IGC from its historical, substantive, methodological and participatory angles, highlighting through these, the divergent political undertones which continue to define the discussions. I specifically focus on the disclosure mechanism which, as mentioned in the introduction, forms the central normative issue holding up the negotiations till date. In furthering the thesis, this chapter significantly argues that the IGC, as an IP-forum driven by developing countries, plays a central role in the definition and elaboration of the ABS regime. The successful resolution of its negotiations (from the perspective of its demandeurs –
the developing countries) will significantly result in an expansion of the ABS regime-complex to incorporate the evolving treaty(s) which would have been concluded on the platform of WIPO. The diagram below offers a pictorial representation of this proposition.

![Diagram of International ABS Regime Complex]

While this proposition is not presented as a hierarchical structure, its tri-level structure seeks to highlight the elements of the regime complex being described in this work, with a specific focus on where WIPO fits within the picture. Within the first level, the Nagoya Protocol and the CBD provide the basis for the ABS regime complex. In effect, the ABS regime complex as discussed in chapter five is situated within biodiversity regime as outlined in the CBD. The Nagoya Protocol, premised on the third objective of the CBD, defines the main components of this ABS regime. Within the second layer, the Bonn Guidelines and the ITPGRFA are the explicitly mentioned examples of other ‘complementary instruments’ which form a part of the ABS regime. I place the relevant WIPO emerging instrument(s) within a third level, of ‘unspecified’ instruments which may be added to the ABS regime complex on the basis of complementarity. This third layer, it must be noted, offers an open-ended category, and as such is not limited to WIPO’s instrument(s). It is this broadening of the ABS regime, to include instruments which go beyond the CBD-negotiated texts, that creates a basis for defining it as an ABS regime complex. An important implication of this, which I intend to draw on in the subsequent discussion of the IP regime, is that this thesis actually suggests the emerging work on the platform of the WIPO IGC as forming an extension of ABS negotiations on the IP platform. Contrary, for instance, to the views used by Laurence Helfer to describe new approaches
to IP law making which derive, amongst others, from norms created within the CBD,\textsuperscript{835} in this thesis, I switch the primary focus and rather seek to discuss the important expansion of the ABS regime complex through the WIPO IGC.

Before turning to a foundational discussion of the IP system, I wish to restate here the importance of the WIPO IGC within this analysis, which derives from several reasons. The first and most prominent reason is that the evolutionary context of the Nagoya Protocol which I discussed in the previous chapter, demonstrates that compromises which defined the adoption of the Protocol were actually agreed to with the WIPO IGC in mind. It is important to note that the ongoing IGC negotiations were considered an important development in the negotiation and the implementation of the Protocol even at the time of the Protocol’s adoption. As discussed in the previous chapter, several legal and policy loopholes within the Protocol were therefore deliberate, and left intended gaps which require further solutions, the merits of which are being considered within the WIPO negotiations. In particular, I again reference the discussion of the disclosure requirement within the WIPO IGC. The Delegation of Namibia during the Twenty-Third session of the IGC, for example, captured this point succinctly by noting

> When the Nagoya Protocol was being negotiated, [we were] informed that the IGC was the place to deal with disclosure requirements. It is [therefore] not acceptable that some Member States [are] not prepared even to discuss mandatory disclosure requirements.\textsuperscript{836}

This complaint from the Namibian delegate was made in direct response to the perceived unwillingness of several developed countries to engage in good faith with developing countries in the negotiation of the disclosure requirement seeking to implement core provisions of the Nagoya Protocol. This complaint from the Namibian Delegation supports the view that several Delegations, particularly of developing countries, have approached the WIPO negotiations within the context of an ‘unfinished business’ with regard to the Nagoya Protocol’s ABS mechanism. By directly seeking a reinforcement of norms which are contained in the Nagoya Protocol, the characterization of the WIPO IGC as a central and component part of the evolving ABS regime draws some immediate justification.

\textsuperscript{835} Helfer, “Regime Shifting”, \textit{supra} note 65. See also, note 122 above.

Second, the importance of WIPO’s negotiations to this analysis is based on the difficult negotiating climate within which substantive principles and norms are being negotiated in the IGC. The central normative issue being considered within the WIPO IGC, as relating to this research, is the disclosure requirement. As mentioned in the preceding paragraph, this disclosure requirement (including several other issues within the negotiation) is centrally linked to the realization of a defensive reinforcement of the Nagoya Protocol’s normative framework. While this substantive aspect of WIPO’s negotiation is important in supporting the ABS regime, the attitudes and positions of delegations to this issue tells a complicated story. Indeed, these attitudes offer a reasonable basis to question whether the implementation of the Protocol can fulfil the hopes of several developing countries that consider it a solution to biopiracy.

Drawing from the significant difficulties in reaching agreement within the IGC, including the underlying rationales for same, suggestions of a deeper unresolved political resistance by major industrialized countries, including the United States and Canada, to the normative prescriptions of the Nagoya Protocol may be distilled. This is further put into appropriate context when the role of powerful non-state actors, such as pharmaceutical industries in driving the red lines of industrialized countries within the WIPO negotiations is considered. Industries have had a major grip on the IP system and indeed rely on its mechanism to thrive. As I discuss in this chapter, their role in the strengthening of IPRs and even securing its globalization places them as powerful forces even within the WIPO negotiations. One of the most powerful global pharmaceutical coalitions, in a letter to the Director of the U.S. Patent and Trademark Office (USPTO), clearly defined its expectations of the US government within the IGC as follows:

> Our organizations support the overall goals of the CBD, and we recognize that the use of genetic resources and traditional knowledge has the potential to unlock benefits for all people including the holders of these resources and knowledge, through the development of new agricultural, industrial and medical applications. However, we are opposed to linking compliance with the Nagoya Protocol to the patent system as is being proposed by some countries taking part in the [WIPO] negotiations…we strongly urge that the U.S. continue to oppose patent disclosure requirements and work with other like-minded countries to oppose a diplomatic conference at this time.837

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837 See, A joint letter “Re: WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore” by Biotechnology Industry Organization (BIO), Intellectual Property Owners Association (IPO) and PhRMA to the Honourable Teresa Stanek Rea, submitted in preparation for IGC 25, July 2013.
It is therefore unsurprising that several interventions by the USA as well as other developed countries within the IGC negotiations, in aligning with industry views, highlight palpable concerns over the possible implications of the ABS regime’s implementation within the context of IP. Consequently, the ability of the Protocol to meet its objectives without the political support of such major players and actors to which its mechanisms are addressed remains uncertain.

Third, seventy percent of the entire focus of the WIPO negotiations concerns the specific scope of the Nagoya Protocol. Article 3 of the Nagoya Protocol defines the scope of the Protocol as including genetic resources (GRs) and traditional knowledge (TK) associated with GRs (TKaGRs). As discussed in chapter two, the IGC, for its part, has grouped its discussion into three main thematic areas: GRs, TK and traditional cultural expressions (TCEs). Only the discussion on TCEs can be properly delinked from the Nagoya Protocol’s implementation. The two other thematic areas, however, bear direct relevance to the contents and application of the Nagoya Protocol. The point being made here is that over two thirds of IGCs negotiations engage directly with the issues addressed within the Nagoya Protocol. The inability to make a headway on these issues within WIPO, severely questions the seemingly settled regulatory framework within the Nagoya Protocol. It suggests, especially within the context of the issue area of biopiracy which this dissertation addresses, that a closer look is required at the ongoing negotiations within WIPO and the underlying reasons for which delegations are unable to arrive at solutions.

Finally, utilizing the work of the IGC as a basis for reviewing the Nagoya Protocol’s potential effectiveness draws from WIPO’s institutional commitment to the IGC and the very issues of TK protection which are being negotiated therein. For example, WIPO’s budgetary allocations for the development of programs within this area of TK protection continues to demonstrate an established commitment of the organization to realizing a positive resolution. Over the past five biennia, the allocations to TK (reflected as program 4) as drawn from the respective program and budgets is reflected in the table below.

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838 Data drawn up from WIPO’s program and budget as approved by the WIPO Member States over the past five biennia. Official copies of the respective program and budget are available online. See, WIPO, Results, Budget & Performance, online: WIPO < http://www.wipo.int/about-wipo/en/budget/>.  

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<table>
<thead>
<tr>
<th>Biennium</th>
<th>WIPO Approved Budgetary Total for Program 4 (Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016/2017</td>
<td>6,115,000CHF</td>
</tr>
<tr>
<td>2014/2015</td>
<td>7,864,000CHF</td>
</tr>
<tr>
<td>2012/2013</td>
<td>7,980,000CHF</td>
</tr>
<tr>
<td>2010/2011</td>
<td>7,159,000CHF</td>
</tr>
<tr>
<td>2008/2009</td>
<td>7,118,000CHF</td>
</tr>
</tbody>
</table>

While the table seems to show a sharp decline in the budgeted amount for the 2016/2017 biennium, the explanatory note within the budget points to the fact that, amongst other personnel considerations, the significant amount normally included within the budgetary allocation in anticipation of a diplomatic conference (marking the conclusion of the process through the adoption of a treaty) has been placed within another segment of the organization’s budget. What is important, however, is that right from the period in which the Nagoya Protocol was adopted (2010), WIPO as an organization has continued to invest heavily within this program 4 with the aim of enabling the more effective use of existing and emerging IP principles, systems and tools for the protection of traditional knowledge (TK) and traditional cultural expressions (TCEs) against misappropriation and misuse, and for addressing the IP issues related to genetic resources (GRs), including those that arise in the course of access to and equitable benefit-sharing in GRs.

The successful resolution of the IGC negotiations therefore forms a component part of WIPO’s current institutional objective. To this end, a well-established team of secretariat staff within an efficiently organized TK Division continues to provide Secretarial support to the Committee, pointing to a long term commitment of the Secretariat to Committee, and the issues being negotiated therein. WIPO is therefore

840 Ibid. at 40.
841 The Traditional Knowledge Division is well reputed within the Organization for its efficiency and extreme professionalism. This view is also widely held by the delegates of Member States who consistently express their satisfaction at the professional running of the Committee, including its innovative strategies to facilitate agreement among Member States. In a recent evaluation of its services, the Traditional Knowledge Division was given an overall 96% rating by Member States in terms of its delivery of services and efficiency within the IGC. The Internal Audit and Oversight Division of WIPO reported to the WIPO assemblies as follows.
not treating the issues as subsets of other programs (as has been the case in time past), but is rather intent on making a bold statement on the Organization’s relevance and responsiveness to this emerging area of IP – specifically within the context of the much needed reconfiguration of the IP system which is required to address the needs of a hitherto excluded set of beneficiaries and knowledge systems.

As a first step, I now turn to offer a historical and conceptual introduction to the IP system. This is to provide a relevant context for the discussion of the WIPO IGC in the second part of this chapter.

6.1 The Intellectual Property Regime: An Embodiment of Regime Strength and Resilience

In chapter one, I explained that a regime’s resilience and robustness draws from its staying power. It is important to start out with a brief explanation of the intellectual property (IP) system – the very system which justifies the existence of WIPO. While an elaboration of the IP system is not the main focus of this chapter, an understanding of its underlying rationale as well as relevant principles affords a useful foundation and context for the ensuing analysis of the discussions within the WIPO IGC. This is because the WIPO IGC is primarily an IP forum, and as such exists within the context of the values, justifications, and administrative structure of the global IP system. Its limitations as a negotiating body, in terms of its subjects for negotiation, as well as possible solutions being pursued, ordinarily derive from the IP mandate within which WIPO operates. The introductory discussion of the IP system also helps to support a visualization of the IP regime’s strength within the field of global governance. This lends credibility to the suggestions that an emerging instrument(s) from the WIPO IGC can serve as a potential reinforcement for the Nagoya Protocol.

The main objective of this evaluation was to assess the effectiveness and efficiency of support services provided by the WIPO Secretariat to the IGC. This assessment looked at the extent to which support services have met the needs of the IGC, and identified lessons for this and other multilateral processes. In conclusion, the overall needs of the IGC were being met by WIPO with a 96 per cent positive rating from participants. In providing the necessary expertise, the Secretariat was found to be playing its role effectively. Practical recommendations were made on communication and publications, registration process and the selection process for the WIPO Voluntary Fund. Also, given the current juncture reached in the negotiations, some participants suggested that the Secretariat could be even more pro-active.


See, Section 1.1.3. above, specifically note 71.
6.1.1 Intellectual Property

Over the development of human society, the concept of property has taken a central position in human interactions. In fact, property is considered to be one of the oldest institutions of human civilization.\textsuperscript{843} For the greater part of human history, the conceptualization of property was generally limited to tangibles. However, in more recent times, this concept of property has been extended to intangibles.\textsuperscript{844} The legal framework of intellectual property has arisen to describe and regulate a form of property in intangibles. As a field of law, ‘intellectual’ describes the character of the material regulated within this area of law, while ‘property’ is used to describe the form of regulation that is modelled.\textsuperscript{845} Thus, IP regulates the products of the human mind through the grant of individual exclusive rights that operate in a manner similar to private property rights over tangibles.\textsuperscript{846} Dutfield and Suthersanen explain IP in this context as,

[a] type of property regime whereby creators are granted a right, the nature of which is entirely dependent on the nature of the creation on the one hand, and the legal classification of the creation on the other. To be placed within one or other of the different classifications of ‘intellectual property’ one has to fulfil the relevant criteria (for example, novelty, originality or distinctiveness) and comply with certain formalities. Depending on these legal (and often artificial) classifications, the creation is accorded a bundle of rights, which vary considerably across the intellectual property spectrum in terms of scope and duration.\textsuperscript{847}

In simple terms, therefore, IP is a term which broadly encapsulates proprietary rights arising from creations of the mind. It includes inventions, literary and artistic works, designs, symbols, names and images which are used in the fields of commerce.\textsuperscript{848} The bundle of legal rights which derive from such intellectual creations are often referred to as IP rights (IPRs).\textsuperscript{849} According to the Convention Establishing WIPO [CEWIPO],

\textsuperscript{844} Lionel Bently & Brad Sherman Intellectual Property Law 4 ed (UK: Oxford University Press, 2014) 3 [Bently & Sherman, IP Law], noting that while the law has long granted property rights in intangibles, IP was only accepted as a distinct form of property under the law in the 18th century.
\textsuperscript{845} Ibid. at 1.
\textsuperscript{846} Ibid.
\textsuperscript{849} According to Spence, ‘an intellectual property right is a right: (i) that can be treated as property; (ii) to control particular uses; (iii) of a specified type of intangible asset. In addition, intellectual property rights normally share
IP includes all rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields, including the rights relating to: literary, artistic and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavor; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; and protection against unfair competition.\textsuperscript{850}

IPRs provide the legal basis through which creators of works are able to benefit from their investments in creation. Through these rights, which are generally time-limited, creators are entitled to control the use made of their works and to collect rents within the stipulated period to which their rights apply. The grant of these rights also serve to encourage inventors to create new technologies and share the results of new knowledge with the larger society for the benefit of all. The IP system is thus a system of rights and corresponding obligations,\textsuperscript{851} aimed at safeguarding the interests of creators and thereby incentivizing further creation for the benefit of society.

There is still, however, an opportunity for inclusion of TK protection within the IP frame. The broad expanse of varied IPRs arising in different, yet related, contexts means that there are various types of rights grouped under the term IP. These rights are quite distinct, even though they sometimes overlap.\textsuperscript{852} Bently and Sherman note in this context that IP is not a single homogenous body of law but is rather used to describe a number of areas of law, including for instance, copyright law, patent law, trade mark law, each with its peculiar characteristics.\textsuperscript{853} While differences exist between these forms of IP, they share the common feature of establishing property protection over intangible things, such as ideas, inventions, signs, and information that would otherwise be non-rivalrous and non-excludable.\textsuperscript{854}

the characteristics that they are (i) only granted when the particular intangible asset can be attributed to an individual creator or identifiable group of creators, the creator(s) being presumptively entitled to the right; and (ii) enforced by both the civil and criminal law’. See, Michael Spence, \textit{Intellectual Property} (Oxford: Oxford University Press, 2007) at 12 – 13.


By corresponding obligations, reference is made to the duties imposed on rights holders in some of the areas of IP law, such as, duty to disclose of inventions under patent law etc.

\textsuperscript{852} Dutfield & Suthersanen. \textit{Global Intellectual Property Law, supra} note 278 at 13. [noting that the various forms of IP reflect an ‘increasingly complex array [of] sometimes overlapping rights for the benefit of creators, owners and traders’].

\textsuperscript{853} Bently & Sherman, \textit{IP Law, supra} note 844 at 1.

\textsuperscript{854} Bently & Sherman, \textit{IP Law, supra} note 844 at 3. Ideas, ordinarily, are non-rivalrous as the sharing of ideas does not serve to diminish or deprive the owner of the idea. Furthermore, ideas are not exclusive, in that my possession of the idea does not preclude others from having the same idea. Tangible property however can occupy only one place at a time, meaning that my possession of property, necessarily excludes others from having it. Merges, Menell & Lemley, \textit{The New Technological Age, supra} note 843 at 3. See also, Amani, “What’s Wrong with IPRs?”, \textit{supra} note 12, where she explains about knowledge,
Recalling the discussion of TKaGRs in chapter three, it is worth pointing out here that TK is locatable within the definition of IP. As a lived experience of indigenous peoples relating to their biodiversity, TK is a body of ideas, inventions, information derived from the cultural association of indigenous peoples with their environments. In other words, TK is a body of knowledge created by indigenous peoples. Yet, for reasons which shall later be examined in this chapter, the protection of TK and the safeguarding of its creators (indigenous peoples) has faced exclusion from the IP system. The conflict between the contexts in which TK is created, and the underlying justifications for the IP system, puts this exclusion in perspective.

6.1.1.1 Justifying the Need for Intellectual Property Rights

Several justifications for IP exist. Bently and Sherman note that such justifications may be placed within one of two main categories: the ethical/moral justifications and the instrumental justifications.\(^{855}\)

From an ethical/moral perspective, IP draws justification from the natural rights that a creator has in his/her creation. Authors, for instance, in most jurisdictions have natural moral rights over their works in the field of copyright law. Also, trade mark law is justified in that it prevents third parties from reaping benefits and goodwill which they have not earned. Through the use of distinctive signs, consumers are able to safely make market choices as well as assign value to products on the basis of brand reputation and quality. IP in this ethical context serves to preserve the integrity of the market place both from the perspectives of the consumers and the producers.

On the other hand, the instrumental justification for IP is premised on the position that without IP protection, there would be an insufficient production of intellectual products.\(^{856}\) In this sense, IP is seen as a stimulant for innovation and creativity. According to Keith Maskus,

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\text{[t]he need for IP [rights] arises from the fact that, without them, a piece of potentially valuable information would suffer from overuse, to the extent that access to it is not }
\]

\[^{855}\text{Bently \\& Sherman, IP Law, supra note 844 at 5.}\n\[^{856}\text{Ibid.}\]
costly, from the standpoint of its development and improvement. This use would rapidly deplete the economic value of the information, limiting incentives to create it. This congestion problem, arising from free-riding behavior, imposes the dynamic costs of limited cultural and product development, and reduced growth, on economies that fail to recognize it adequately.857

The patent system, for instance, draws justification on the basis of its role in providing incentives for investments in research and development (R&D) for new products, as well as encouraging the disclosure of valuable inventions to the public for the benefit of society. As the justification goes, this disclosed information, absent a system of IP, would otherwise have been kept secret or not even be in existence at all.858 As part of providing incentives, the patent system offers time-limited protection for inventors, facilitating an opportunity for them to recoup their investment as well as profit from their creativity. Speaking more to the economic justification for patents, Robert Hahn identifies four key overlapping arguments that support strong IP protection:

[p]atents and copyright provide incentives to innovate because they enable innovators to exclude competition, thereby increasing the expected returns on inventions; patents provide incentives to turn innovations into commercial products by making it possible to prevent imitation and to sell rights to developers; patents enhance social welfare by facilitating contracts among inventors and others; [and] patents enhance social welfare by reducing innovators’ incentives to hide information.859

Summarily, IP rights are generally viewed as pursuing the central objectives of promoting innovation and creativity, while yet ensuring the integrity of the market place.860 Indeed, these two objectives fit within the widely regarded utilitarian theory (and the economic framework built on it) which serve to justify IP.861

As I have noted in 3.3.2.4. above, these incentive and innovation based justifications for the IP system do not necessarily support or explain the manner in which TK emerges. It is, therefore, interesting to question, ‘whose innovation and creativity anyways’? As the analysis undertaken in chapter three has

858 Bently & Sherman, IP Law, supra note 844 at 5.
861 Ibid. at 10.
shown, indigenous communities are innovative. Innovation and creativity within such communities do not, however, necessarily represent incentive-driven outputs of human intellectual activity. Rather, they emanate from an adaptive, cultural experience of indigenous peoples connected to the lands, traditions, and resources that define them. What this quickly shows is that the innovation being driven by the IP system refers to a ‘type’ of innovation, while the beneficiaries intended also refers to a ‘category’ of beneficiaries who can be (or are) incentivized to innovate within the context of these prescriptions. TK is evidently excluded from this ‘type’ of innovation, while its holders do not constitute a ‘category’ of innovators to which these IP justifications apply.

The history of the IP system is useful in explaining this exclusion. Moreover, it offers a helpful basis for understanding the present difficulties being encountered in efforts to address this exclusion through modern processes of the IP system, including the WIPO IGC.

6.1.2 The Early Development of the Intellectual Property System

Three main phases are generally referenced when the history of IP is discussed: the national phase, the international phase, and the global phase. National IP systems date as far back to the 15th century, while the foundations of the international IP system is traceable to the 1880s with the conclusion of Paris Convention for the Protection of Industrial Property [Paris Convention] and the Berne Convention for the Protection of Literary and Artistic Works [Berne Convention]. The Paris and Berne Conventions yet represent the core pillars or bastions of the system of IP as we know it today, though the use of the collective

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862 See, Sell, Private Power, Public Law, supra note 85 at 10.
864 Paris Convention for the Protection of Industrial Property, March 20, 1883, as last revised at Stockholm, July 14 1967, 828 UNTS 305 [Paris Convention].
term ‘intellectual property’ in reference to a body of law only gained prominence with the establishment of WIPO in 1967.

For our purposes, the history of the IP system reveals that the foundational ideas about knowledge, creativity, and innovation which permeate the present global IP system were linked to European ideas of knowledge. As Mgbeoji has asserted, the notion that IPRs are universal truths ‘distanced from the cultural and genetic fingerprints of its European origins and unmediated by economic impulses is simply false.’ Similarly, the mechanisms incorporated within the IP system to facilitate the development of such knowledge bears roots in the early experience of Medieval Europe and the development of the patent system there, which was primarily aimed at incentivizing and attracting holders of foreign technologies. For its failure to meet the regulatory criteria for protection, TK practices and innovations, as we know it, are thus excluded from the formal IP system. Drawing from the early history, some of the underlying assumptions around innovation and creativity, including the justifications for extending property rights thereto, do not align with the underlying realities within which TK is generated, held, maintained and transmitted. Consequently, a level of incompatibility is clearly seen within efforts to utilize the IP system to protect TK.

From a third world perspective, the idea of a reconfiguration and a broadening of the IP system continues to be pursued within the context of this understanding. Indeed, as Okediji argues, there is a need to question and directly challenge this regulatory capture of IP which has served to exclude third world innovation. This continued exclusion of TK challenges the legitimacy of the IP system as a representative system of global innovation. In this research, I have not sought to address the important questions

866 See generally, David, “IP Institutions”, supra note 863. See also, Okediji, “The International Relations of IP”, supra note 18. Again, see, Ikechi Mgbeoji, “TRIPS and TRIPS-Plus Impacts in Africa” in Daniel J Gervais, ed. Intellectual Property, Trade & Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era (New York: Oxford University Press, 2007) [Mgbeoji, “TRIPS & TRIPS-Plus” at 263, noting that though IP rights are often promoted as universal verities, there is no doubt that the specific forms of IPRs within the formal system have their origins in the cultural, legal, and economic traditions of continental Europe and of Western jurisprudence and economic tradition.

867 Ibid. at 263.


870 See, for instance, Bita Amani, who contends that the IP system’s claim to legitimacy alienates the contributions of indigenous communities and renders their stories, traditional (medicinal and ecological) knowledge and even biological contributions of (economic) value free for the taking as ‘public’ inputs for the ‘private’ outputs of those culturally conditioned for compliance.

Amani, State Agency, supra note 431 at 40.
surrounding the needed reconfiguration of the IP system to in line with its claims to universality. Indeed, my ultimate emphasis will touch on this need. However, my primary intention is to address the central need of a defensive IP solution to biopiracy; one which ensures that the IP system reinforces the Nagoya Protocol by plugging the possible holes through which its mechanism facilitates the misappropriation of TK. A discussion of the early development of the IP system advances the argument that the IP system is incompatible with the protection of TK, and further points to the important need to develop an internal system within the IP frame which serves to prevent instances of biopiracy.

Against this backdrop, I turn now to briefly describe the foundational pillars of the IP system.

### 6.1.2.1 The Paris Convention

The Paris Convention was adopted in 1883 and is the first major international agreement in the field of IP. Though the Paris Convention is most well-known for its provisions dealing with patents, it extends to the broad scope of industrial property. The Paris Convention covers a range of industrial IP forms such as patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition.\(^{871}\) Within all these categories, protectable IP applies, beyond industry and commerce alone, to the ‘agriculture and extractive industries and to all manufactured or natural products’.\(^{872}\) While the intellectual creation is more defined within some industrial property categories, for others, it is less defined (though still existent) with the focus rather being on the signs transmitting information to consumers with respect to products and services in the market place.\(^{873}\) In such instances, the protection is targeted at the unauthorized use of such signs which are likely to mislead consumers.\(^{874}\)

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\(^{871}\) See Article 1(2), Paris Convention. The scope of the Paris Convention was, however, limited initially to ‘patents, utility models, industrial designs or models, trade-marks and trade names’. See, Dutfield & Suthersanen. *Global Intellectual Property Law*, supra note 278 at 24.

\(^{872}\) In articulating the scope of industrial property, the Paris Convention defines industrial property in the broadest sense and with application not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour. See Article 1(3) Paris Convention.

\(^{873}\) Such other examples include trademarks and geographical indications, for instance.

The patent system, covered under the Paris Convention, bears direct relevance to the subject of biopiracy and is given special attention in this dissertation’s discussion of the IP system. Recalling chapter four’s discussion of biopiracy, the instances of acquisition of rights over GRs and TKaGRs of indigenous peoples were largely facilitated through the patent system. In the hoodia case, for example, the emphasis on the P57 secured with respect to the slimming properties of the hoodia drew wide criticism as a symbol of the wrongful appropriation of the knowledge of the San peoples. Similarly, in the Neem example, WR Grace’s process patent on the making of neem-based bio pesticides was the subject of controversy and an eventual revocation by the European Patent Office on the grounds that it was wrongly awarded given the existence of documented prior art within the indigenous communities of India. This places in relevant perspective the importance and centrality of the patent system within the conversation of biopiracy. While it is not the only IP form implicated within biopiracy cases, its significant role in assigning private rights to inventors based on the IP justifications outlined above, makes it the most visible IP form within the discussion on biopiracy.

The adoption of the Paris Convention did not establish patents as a tool of innovation. Rather, it significantly ushered in an era of internationalization in the evolution of patent law; one which still exists today. Dutfield and Suthersanen note that at the time of the adoption of the Paris Convention, five main areas of variation existed among national patent systems. These were, the existing interpretations of novelty, the length of protection terms, the treatment of foreign applicants, the issue of whether or not patents needed to be worked domestically, and also, the possible exceptions to patentability. Some of these areas have not drawn a consensus and are rather left to the national laws. The Paris Convention, therefore, did not harmonize patent laws of its signatories but rather provided *substantive minima* which formed a minimum and reciprocal level of IP protection requirement for state signatories.

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875 Robinson, *Confronting Biopiracy*, supra note 29 at 77 – 78., noting that trademarks as well as plant varieties protection systems have also played a major role in several biopiracy cases.

876 WIPO outlines three periods as being important in the history and evolution of patents. These are the period of Privileges (15th to 18th Centuries), the period of National Patents (1790 – 1883) and the period of internationalization (1883 – date). See WIPO, *Introduction to IP*, supra note 863 at 17 – 20.


878 Dinwoodie, “The International IP system”, *supra* note 579 at 66.
Despite the divergent national standards of patents (within the frame of minimal standards of the Paris Convention), the principle of national treatment was adopted as a core principle of the Convention.\textsuperscript{879} Described as being ‘fundamentally a rule of non-discrimination’\textsuperscript{880}, the national treatment principle requires member states of the Paris Union to extend the same levels of protection to the nationals of other member states as the member state gives to its own nationals.\textsuperscript{881} In other words, country A cannot discriminate between the levels of protection it affords its own nationals and the levels it affords nationals of country B. These two propositions – the substantive minima and the national treatment underlie the Paris Convention, and formed the foundation for what is commonly referred to as the second pillar of the IP system – the Berne Convention.

### 6.1.2.2 The Berne Convention

The Berne Convention was adopted in 1886, three years after the adoption of the Paris Convention and sought to recognize and establish an international system of protection for literary and artistic works and rights of authors.\textsuperscript{882} The Convention notes that literary and artistic works include ‘every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression…’\textsuperscript{883} By ascribing certain minimum rights to authors over their works,\textsuperscript{884} the Berne Convention outlines the

\textsuperscript{879} Dutfield & Suthersanen. *Global Intellectual Property Law*, supra note 278 at 25, noting that national treatment was and continues to be one of the pillars of international intellectual property law. See also, Dinwoodie, “The International IP system”, supra note 579 at 66. Again, see Lionel Bently & Brad Sherman, *Intellectual Property Law* 3d ed (UK: Oxford University Press, 2009) [Bently & Sherman, IP Law3] at 5, noting that the central criterion within both the Paris and Berne Conventions was the principle of national treatment – a rule of non-discrimination.

\textsuperscript{880} Bently & Sherman IP Law3, supra note 879 at 5.

\textsuperscript{881} Ibid.

\textsuperscript{882} Three main principles underlie the Berne Convention; \textit{viz}, the principles of national treatment (by this principle, works originating in one of the Contracting States, must be given the same protection in each of the other Contracting States as the latter grants to the works of its own nationals. See Articles 5 (1) and 5 (3), Berne Convention), automatic protection (This principle indicates that protection must not be conditional upon compliance with any formality. See Article 5(2) Berne Convention), and independence of protection (Protection is independent of the existence in the country of origin of the work. See Article 5 (2) Berne Convention).

\textsuperscript{883} See Article 2(1) Berne Convention. Examples include books, pamphlets and other writings; lectures, addresses, sermons and other works of the same nature; dramatic or \textit{dramaticomusical} works; choreographic works and entertainments in dumb show; musical compositions with or without words; cinematographic works to which are assimilated works expressed by a process analogous to cinematography; works of drawing, painting, architecture, sculpture, engraving and lithography; photographic works to which are assimilated works expressed by a process analogous to photography; works of applied art; illustrations, maps, plans, sketches and three-dimensional works relative to geography, topography, architecture or science. Ibid.

\textsuperscript{884} The minimum standards of protection relate to the scope of covered works, on the one hand, and to the nature of rights on the other. As to works, protection, as noted above, includes ‘every production in the literary, scientific
international framework for what we know as copyright law today. The modern copyright system is traceable to the development of the printing press\(^885\) and has evolved through varied national epochs into an international phase with the adoption of the Berne Convention. The Berne Convention guarantees nationals of Member States reciprocal national protection over their right to control and receive payment for the use of their creative works. Given that the scope of the Berne Convention falls outside the ambit of this dissertation, limited attention and discussion is accorded to the Berne Convention. This is because this research does not address the concept of traditional cultural expressions (TCEs) – the aspect of TK which generally aligns with the literary and artistic work of indigenous peoples. I should however mention that the issue of TWIP, in the form of TCEs, or expressions of folklore, was an attempted inclusion into the Berne Convention as far back as the 1967 Stockholm Diplomatic Conference for the Revision of the Berne Convention.\(^886\) Though an article aimed at offering a possibility for the protection of TCEs under the Berne Convention was adopted,\(^887\) it quickly became clear that the Eurocentric copyright basis of the Berne Convention was not an adequate fit for protecting folklore. A key reason for this was that, unlike the author-centric nature of copyright, which requires a mark of individual originality, TCEs is an experience of and artistic domain. Rights over such works extend to the right to translate, the right to make adaptations and arrangements of the work, the right to perform in public, the right to recite, the right to communicate to the public, the right to broadcast, the right to make reproductions, the right to use the work as a basis for an audiovisual work, and a whole range of moral rights. See WIPO, “Summary of the Berne Convention for the Protection of Literary and Artistic Works (1886)”, online: WIPO <http://www.wipo.int/treaties/en/ip/berne/summary_berne.html>. See also Dinwoodie, “The International IP system”, supra note 579 at 66, noting that a minimum substantive base also formed a core proposition of the Berne Convention.

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\(^885\) See WIPO, Introduction to IP, supra note 863 at 23, noting that the idea of copyright protection only began to emerge with the invention of printing which made it possible for literary works to be duplicated through mechanical processes. For a detailed historical account of the copyright system, however, see generally, Johns, Piracy, supra note 581. Dutfield & Suthersanen. Global Intellectual Property Law, supra note 278 at 63 – 74.


\(^887\) Article 15(4) of the Stockholm (1967) and Paris (1971) Acts of the Berne Convention provides:

"(a) In the case of unpublished works where the identity of the author is unknown, but where there is every ground to presume that he is a national of a country of the Union, it shall be a matter for legislation in that country to designate the competent authority which shall represent the author and shall be entitled to protect and enforce his rights in the countries of the Union (b) Countries of the Union which make such designation under the terms of this provision shall notify the Director General [of WIPO] by means of a written declaration giving full information concerning the authority thus designated. The Director General shall at once communicate this declaration to all other countries of the Union."
indigenous peoples, like TKaGRs, which derives from an ‘impersonal, continuous and slow process of creative activity exercised in a given community by consecutive imitation’. Though, as noted, this discussion falls outside the scope of this thesis, it is useful in highlighting the difficulty in reconciling the foundations of the IP system with TWIP. Indeed, the rest of this analysis is focused on the ongoing difficult effort to reconcile TKaGRs with this international IP system.

Though these twin instruments (the Paris and Berne Conventions) represent the foundations of the international IP system, it is worth noting that the ‘international’ nature of the instruments was by no means indicative of a global outlook. They were international because they offered a system of protection amongst more than one country, and not necessarily because they represented a global view on IP. In fact, as Ruth Okediji explains, these agreements emerged within an imperial era, and in several ways, were imperialist projects by which European superpowers regulated their IP affairs amongst themselves within their colonies. Susan Sell points out that these conventions actually did not even serve to create new substantive IP law, neither did they impose new laws on Member States. Rather, they simply reflected a consensus among Member States that was legitimated by the domestic IP laws already in place within these European countries. It is worth pointing out here that IP rights are territorial by legal tradition, with each country or region establishing the terms under which it will define and protect such property. Furthermore, the territoriality of IP rights means that an IP right is limited to the territory of the state granting it, and as such, the exclusive rights can only cover activities occurring within the respective

888 WIPO, “International Protection for Folklore”, supra note 886 at 5. As a result of this, sui generis systems of protection for TCEs have taken the fore. Indeed, WIPO traces its early engagement with the protection of TCEs to 1978 in cooperation with UNESCO. A concrete output of this early work was the adoption of the Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and other Prejudicial Actions in 1982. See, WIPO Document 26/6, supra note 90 at para 12.

889 Through a narrative series of ‘multiple multilateralisms’, Ruth Okediji offers an important third world viewing of the historical participation of developing countries in the IP system. Her compelling discussion of the evolution of the IP system, with a focus on the participation of developing countries, is extremely helpful here in outlining the national, international and global phases of IP’s development within the context of developing countries and their participation. It also sheds light on the power imbalances that have accompanied the development of the global IP system till date – power dynamics that remain a part of the ongoing WIPO negotiations. Okediji identifies three multilateral eras defining the development of IP till date – imperialism/colonialism, formalism and consolidation. Okediji, “The International Relations of IP”, supra note 18 at 315 – 385.

890 Sell, Private Power, Public Law, supra note 85 at 11.

891 Maskus, “The International Regulation of IP”, supra note 857 at 1.
Though these Conventions extended an international system of protection, the territorial basis of IP rights was preserved, though merely extended beyond jurisdictional confines. The Paris and Berne Conventions emerged within an era of imperialism/colonialism. Indeed, this ties in with the history of biopiracy alluded to in chapter four, one which Mgbeoji notes is traceable to the early expeditions of Columbus in the late 1400s. This early contact by Columbus initiated interaction between Europeans and discovered territories. Against this backdrop of early contact between the Europeans and non-Europeans, dating as far back as 1500s, the colonial era emerged as the first of three major phases which provide relevant historical context for the evolution of the IP system. This colonial era was characterized by three main components. First, the extension of IP laws to the colonies for purposes associated with the colonial strategies of assimilation, incorporation, and control. Second, by efforts to secure national economic interests against other European countries in colonial territories. Third, by the

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892 See, Alexander Peukert, “Territoriality & Extraterritoriality in Intellectual Property Law”, in Gunther Handl, Joachim Zekoll & Peer Zumbansen, eds. Beyond Territoriality: Transnational Legal Authority in an Age of Globalization (Boston: Brill Academic Publishing, 2012) at 189 – 190, further noting that no intangible subject matter is protected by one uniform right applying world-wide. Instead, technical inventions could be subject to a bundle of possibly more than 150 territorial rights of national or regional provenance. Ibid.

893 Sell, Private Power, Public Law, supra note 85 at 11.

894 From the early 1500s, trade relations between local African citizens and Europeans necessitated the negotiation of legal arrangements to govern the relations between local citizens and European merchants. These arrangements including the power dynamics were significantly altered overtime as trade evolved from early trade in gold and spices, to trade in slaves (and subsequent abolition thereof) and trade in cash crops based on the needs of the industrial revolution in Europe – a period which stretched from the late 1700s to the early 1800s. Given the industrial revolution and the attitudes of superiority that accompanied same, a resistance to African terms of trade began to increase as Europeans targeted the civilization of their African counterparts through religion, education etc. This attitudinal change resulted in formal administrative structures replacing informal terms of trade with non-Europeans, thus imposing their ‘civilized’ standards in the regions outside Europe. Okediji, “The International Relations of IP”, supra note 18 at 321 – 322.

895 Okediji argues that even prior to the conclusion of the Paris and Berne Conventions in the 19th Century, many territories in Africa, Asia and the Pacific were already affected by IP regulations implemented through the various forms of formal and informal European administration in these regions. This was significantly achieved through the terms of trade imposed by Europeans in dealing with their non-European counterparts. Okediji, “The International Relations of IP”, supra note 18 at 323. See also, Richard Roberts & Kristin Mann, “Law in Colonial Africa”, in Richard Roberts & Kristin Mann, eds, Law in Colonial Africa (Heinemann: James Curry, 1991) at 13. Examples in this regard, include the use of reception acts to impose the whole body of common law, equity and statutes of general application in force in England at the time, on colonies. Thus, for instance, countries like Nigeria had its first contact with copyright law through the British Copyright Act introduced into Nigeria by means of an Ordinance that introduced English law into Lagos as early as 1862. See note 29. Furthermore, with the conclusion of the Berne and Paris Conventions, IP law was firmly entrenched in colonies of European superpowers.

896 Okediji notes that IP was not merely an incidental part of the colonial legal apparatus, but a central technique in the commercial superiority sought by European powers in their interactions with each other in regions beyond Europe. Okediji, “The International Relations of IP”, supra note 18 at 324. Through the international system of IP, with particular reference to the conclusion of the Paris and Berne Conventions, a network of relationships among European member countries – one which consolidated colonial power by ‘expanding the geographic
exclusion of local citizens from the application of these laws on the premise that non-Europeans were subjects, rather than citizens of the European powers.\textsuperscript{897}

It is extremely important to note that the European superpowers failed to recognize or appreciate the existing knowledge systems within their conquered territories and rather viewed these as barbaric and uncivilized. The early connotations of TK being barbaric and uncivilized draws from this history. The Paris and Berne conventions succeeded in extending the scope of influence of IP rights acquired within governing countries into the colonies.\textsuperscript{898} IP was in fact a civilized tool, guiding the interactions of European powers in uncivilized regions beyond Europe. Take the emergence of the Paris Convention, for instance.

\textbf{6.1.2.3 The Emergence of the Paris Convention}

Patents were historically developed as a means of incentivizing the importation of technologies into laggard countries in Europe.\textsuperscript{899} According to Dutfield and Suthersanen, IP, as known today, was generally treated in extremely protectionist fashion within western societies.\textsuperscript{900} Countries were extremely protective of their expertise and technologies – both in the sense of shielding from competition, as well as in preventing others from benefiting or learning from such expertise. Consequently, for instance, Venetian glass-makers in the Middle Ages, whose techniques were acquired partly from Germany and Syria, were forbidden from plying their trade outside the city state and/or giving away their secrets.\textsuperscript{901} To beat these national restrictions, a system of privileges, through the grant of open letters (or patents), emerged to encourage foreign technicians to immigrate to new countries, thereby sharing their knowledge with local craftsmen. The aim of incentivizing persons skilled in foreign technologies, was to build domestic capacity in such

\begin{itemize}
\item scope of rights acquired in the governing country to the colonies, and in some cases, the protectorates, was established. Ibid. at 323 – 324.
\item Okediji, “The International Relations of IP”, \textit{supra} note 18 at 325. The late 19th century witnessed a transformation in intra-European commercial relations. A proliferation of treaties including reciprocal commitments on IP were also witnessed. These commitments were made generally by European countries amongst themselves and were not directed at the inhabitants of the governed territories at all, but ‘instead to facilitate commercial relations among colonial powers as trade between European powers occurred on and among the various colonized territories on behalf of foreign sovereigns’.
\item Okediji, “The International Relations of IP”, \textit{supra} note 18 at 323 – 324
\item David, “IP Institutions”, \textit{supra} note 863 at 45.
\item Ibid.
\end{itemize}
new technologies. England, for instance, was technologically weak in comparison to several regions in Europe in the fourteenth century, and sought to use the grant of patents to acquire more advanced industrial practices from its neighbours. National protection through patents was usually granted for 14 years and was designed to permit the training of two sets of apprentices (a standard apprenticeship ran for seven years) while yet ensuring that foreign technology holders were not stifled in their specialized know-how by competition from their students. At this stage of development, patents were rewards for the holders of new technology and not necessarily the creators of such technologies. Patents thus developed in this context as a bundle of rights and privileges aimed at attracting foreign technologists for the purpose of building local content in foreign craft. Patents have, however, evolved today with slight departure from their original design, currently rewards innovation which is new, capable of industrial application and the outcome of an inventive activity. This reflects the reworking of the patent system through its years of implementation.

Paul David thus notes,

> [t]he criteria of "originality, novelty, and non-obviousness" that have emerged as definitions of what does and doesn't qualify as an invention at the U.S. Patent Office, and elsewhere, might well be seen as the make-shift results of a two hundred year long struggle to utilize the grant of patent privileges to accomplish a restricted purpose for which, originally, it had not been designed

The earliest uses of patents were thus developed, not for innovation purposes, but rather for the purpose encouraging technology transfer.

The first effort to place these independent national patent practices within an international system for the recognition and protection of IP is often traced to the international exhibition of inventions in Vienna in 1851.

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902 The conditions attached to the grant of patents was therefore usually the conduct of the trade or craft, and the consequent training of apprentices and journeymen. Paul A David, “The Evolution of Intellectual Property Institutions & the Panda’s Thumb”, online: Compiler Press <http://www.compilerpress.ca/Competitiveness/Anno/Anno%20David%20Evolution%20of%20IP%20Institutions%201992.htm>. [David, “The Evolution of IP Institutions” at 10.

903 Examples of this include the grant by Edward III to John Kempe, a Flemish weaver, in 1331, as well as protection granted to three clock makers from Delft in 1368. Ibid at 9.

904 See also, Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? (UK: Earthscan Publications Ltd, 2002) 35, who note that when states granted patents to foreigners, they generally insisted on the foreign patent holder ‘locally working’ the patent within the state.


organized by the Government of the Empire of Austria-Hungary in 1873.\textsuperscript{907} Several foreign exhibitors (mainly Europeans) refused to attend the event due to the inadequate legal protection on offer to exhibited inventions.\textsuperscript{908} They balked at the opportunity to showcase their inventions, as they feared that their ideas would be stolen.\textsuperscript{909} In response to this setback, two main developments emerged: first, was the development of a special Austrian law which secured temporary protection to all foreigners participating in the exhibition; second, the Congress of Vienna for Patent Reform (described by Gervais as the first international conference on industrial property)\textsuperscript{910} was convened in 1873 to elaborate, \textit{inter alia}, principles which should underlie an effective and useful patent system.\textsuperscript{911} At this Congress, governments were urged to treat with urgency the need for an international understanding on patent protection.\textsuperscript{912} As several European countries at the time already had domestic patent standards, a basis already existed for discussions on the possibility of developing a \textit{civilized international system} which would ensure the protection of inventions even outside the inventor’s jurisdiction. The quest for commercial superiority amongst countries


\textsuperscript{909} Sell, \textit{Private Power, Public Law}, supra note 85 at 11. See also, Daniel J. Gervais, ed, \textit{International Intellectual Property: A Handbook of Contemporary Research} (Cheltenham, UK: Edward Elgar Publishing Limited, 2015) at 41 – 42 [Gervais, International IP] who explains the limitations under the existing Austrian law as being twofold: first, under Austrian law, patents were invalidated where they had not been manufactured in Austrian territory within 12 months from the date of patent grant, and second, was the absolute novelty requirement based on the filing date, which constituted one of the patentability criteria in many European countries. This prevented applicants from obtaining patents where any prior foreign patent or publication had disclosed the same invention. Applicants therefore sought to file their applications in various countries at roughly the same time in order to avoid destroying the novelty of the invention.

\textsuperscript{910} Gervais, International IP, \textit{supra} note 909 at 42.

\textsuperscript{911} WIPO IP Handbook, \textit{supra} note 907 at 241. See also, Gervais, International IP, \textit{supra} note 909 at 42.

\textsuperscript{912} WIPO IP Handbook, \textit{supra} note 907 at 241. Stephen Pericles Ladas explains that the Congress voted four resolutions; the first affirmed the natural right of the inventor, which ‘should be protected by the laws of all civilized nations’; the second laid down an equal number of principles on which an effective and useful patent law should be based; the third noted that ‘the necessity of reform is evident, and it is of pressing moment that Governments should endeavor to bring about an international understanding upon patent protection as soon as possible’, and the fourth converted the preparatory committee of the Congress into a permanent executive committee and empowered them to continue the work commenced, publish widely the principles discussed and convene meetings and conferences from time to time. These four resolutions were aimed at securing/clarifying the rights of inventors and laying down the rules which would offer them complete protection. See Ladas, Patents, Trademarks & Related Rights, \textit{supra} note 908 at 60. See also, David Castle, ed, \textit{The Role of Intellectual Property Rights in Biotechnological Innovation} (Cheltenham, UK: Edward Elgar Publishing Limited, 2009) at 107 [Castle, IPRs in Biotechnology].
in Europe meant that IP served as a central tool, guiding the interactions of European powers even in regions beyond Europe.\textsuperscript{913}

The principles underlying the Paris Convention represented a series of rules which governed innovation within the \textit{civilized} world at a time in which colonialism was still rife. Going by the prevailing attitudes of superiority at the time in Europe,\textsuperscript{914} the \textit{uncivilized} world included the colonies, as well as undiscovered territories – a large proportion of which is today considered to form a part of the Third World. It is not surprising in this connection that most of the African traditions, including the knowledge systems and customary rules governing their use, for instance, were considered non-existent and/or barbaric and uncivilized.\textsuperscript{915} Furthermore, this superior attitudes meant that ‘\textit{uncivilized}’ knowledge and innovation was generally considered no knowledge and represented fertile unprotected domain which ‘\textit{civilized}’ actors could access for the purpose of securing rights from the civilized knowledge system. It is this foundation that lends writers like Mgbeoji to suggest the patent system as inherently racist.\textsuperscript{916}

Within the context of this attitudinal sphere, a follow up congress – the International Congress on Industrial Property was organized by the French Government and held in Paris in 1878.\textsuperscript{917} As a main outcome, the Congress recommended that an international diplomatic conference be convened ‘with the task of determining the basis for uniform legislation’ in the field of industrial property.\textsuperscript{918} A final draft

\textsuperscript{913} Okediji, “The International Relations of IP”, supra note 18 at 324.
\textsuperscript{914} Okediji describes the political and social attitudes in Europe during this period of the emergence of the Paris Convention as being characterized by ‘a sense of superiority in all spheres, and culminated in the desire to spread this enlightenment to non-Europeans’. Ibid at 322. This is also discernible from the Congress of Vienna for Patent Reform’s first resolution referred to above, which emphasizes the thinking among the participants of the discussions as being one of superiority; one that conceived of themselves as representing the civilized standard to which lesser countries, including their colonies, should aspire to.
\textsuperscript{915} Mgbeoji, \textit{Global Biopiracy}, supra note 19 at 90 – 91, noting that most of the colonizers of traditional and indigenous non-Caucasian societies and peoples held racist views of the natives, whom they dismissed as “a barbarous race, possessing inferior rational capacities”. In such intensely racist conceptions of other peoples and the outright dismissal of indigenous and native knowledge frameworks, it was the opinion of some that “the Indians had an inalienable right to be slaves”. Ibid.
\textsuperscript{916} Mgbeoji, \textit{Global Biopiracy}, supra note 19 at 56, noting that the early western scientific world was an elitist structure which emerged within a narrow construct on knowledge, thus alienating all that did not conform to such standards. This led to the assumption that there was no science or knowledge amongst the races and peoples of the South. See also Pat Mooney, noting that the argument that IP is only recognizable when performed in laboratories with white lab coats is fundamentally a racist view of scientific development. Ibid at 140.
\textsuperscript{917} Castle, IPRs in Biotechnology, supra note 912 at 107. Ladas provides further details of this meeting and notes that it met September 5 – 17, 1878 and was attended by about 500 persons, with official representation from the following countries: Germany, Hungary, Italy, Luxembourg, Russia, Spain, Sweden, Norway, Switzerland and the United States of America. Senator Bozérian of France was elected as the Chair of the Congress. Ladas, Patents, Trademarks & Related Rights, supra note 908 at 60.
\textsuperscript{918} Castle, IPRs in Biotechnology, supra note 912 at 107. See also WIPO IP Handbook, supra note 907 at 241.
proposing an international ‘union’ for the protection of industrial property was subsequently prepared and circulated by the French Government to several other countries with an invitation to attend the 1880 International Conference in Paris. At this International Conference, a draft convention, which contained the substantive provisions which, in essence, are the main features of the Paris Convention, was adopted.\textsuperscript{919} On this basis, the Paris Convention was adopted and signed at a Diplomatic Conference convened in Paris in 1883.\textsuperscript{920} It entered into force in July 1884, signed by a total of 11 states, the majority of which were European.\textsuperscript{921}

For the non-European States, there yet remained a strong European influence informing their decisions to sign. Tunisia, for instance, was notably at the time of the conclusion of the Paris Convention under the French colonial rule. In fact, it had become a French protectorate in 1881 with the conclusion of the Treaty of Bardo.\textsuperscript{922} The Treaty of Bardo significantly gave the French, \textit{inter alia}, the right to direct the diplomatic and external affairs of Tunisia, while leaving domestic affairs to the Bey.\textsuperscript{923} While it may, therefore, seem that there was a certain representativeness about the initial signatories to the Paris Convention, the European influence remained prevalent even over the non-European signatories. The Berne Convention entrenched a similar pattern.\textsuperscript{924} The Convention’s influence has over the years spread

\textsuperscript{919} Ibid.
\textsuperscript{920} The International Conference of 1883 was called on March 6, 1883, for the final approval of the text of the Convention and for its signature. The Convention was signed on March 20, 1883 in Paris, France. Ladas, Patents, Trademarks & Related Rights, \textit{supra} note 908 at 67 – 68.
\textsuperscript{921} The Convention entered into force on July 7, 1884, which was a month after the exchange of ratifications to the Convention. Ladas, Patents, Trademarks & Related Rights, \textit{supra} note 908 at 67 – 68. The 11 signatories to the Paris Convention were Belgium, Brazil, El Salvador, France, Guatemala, Italy, the Netherlands, Portugal, Serbia, Spain and Switzerland. Great Britain, Tunisia and Ecuador had adhered to the Paris Convention when it entered into force in July 1884, thus bringing the total number of countries upon its entry into force to 14. Interestingly, countries like El Salvador, Guatemala and Ecuador, later denounced their membership of the Paris Convention, only to join again later in the 1990s, pointing again to the fundamental differences which existed in conceptions of innovation, knowledge and beneficiaries to protection between developed countries and developing countries. Ibid. at 68. See also, WIPO IP Handbook, \textit{supra} note 907 at 241, again see, Gervais, \textit{International IP}, \textit{supra} note 909 at 42.
\textsuperscript{922} Treaty of Bardo between France and the Bey of Tunis (signed, May 12, 1881).
\textsuperscript{923} This was short-lived as the Convention of Marsa, concluded on 8 June 1883, gave France a right to also intervene in Tunisia’s domestic affairs. See, Ryo Ikeda, \textit{The Imperialism of French Decolonization: French Policy & the Anglo-American Response in Tunisia & Morocco} (UK: Palgrave Macmillan, 2015) at 13. See also, Vladimir Borisovich Lutsky Modern History of the Arab Countries 1969; Chapter XXI “The Seizure of Tunisia by French Imperialism” online; <https://www.marxists.org/subject/arab-world/lutsky/ch21.htm>.
\textsuperscript{924} See for instance, Article 19, Berne Convention, which originally gave colonial powers the right to accede to the convention at any time for their colonies or foreign possessions.
with the expansion of the IP ideology, and presently, as at April 1, 2016, it has a total of 176 Contracting Parties\textsuperscript{925} drawn widely from countries all around the world.

Several scholars have argued that though the Third World did not have a say in the emergence of the foundational IP agreements, most ‘new’ states voluntarily acceded to these Conventions upon independence. While this is true, Okediji notes that this was, however, the result of a reverse form of compulsion, as there really was no other option for new States to survive in the real world than to join the existing international system. Though some revisions have been made to the respective agreements, it remains heavily skewed in favor of European conceptions of knowledge, protection and ideas of development. The dominance of the economic and political systems of Europe and the United States have continued to have a major impact on the global development of the IP system. In particular, as I will later show in this chapter, these respective foundational agreements (Paris and Berne Conventions), despite the Eurocentric underpinnings, have been consolidated and transposed into the national laws of even developing countries through the mechanism of international trade and multilateral trade agreements. Through what Dutfield discusses as globalized localism, the standards of innovation and creativity which defined a ‘type’ of the world’s innovation, now occupies the center of global standards, definitions, and interpretations of human creativity. This was achieved through the adoption of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the most significant modern landmark within the field of IP.

In sum, the background to the early IP conventions, as well as the actual negotiation of the treaties reveal a Eurocentric nature of the applicability, prescriptions, and understandings contained within these early instruments. Furthermore, the changing nature of rights within the IP system’s evolution, particularly as evidenced, amongst others, through the functional shift of patents as tools for technology transfer, to their present role as incentives for innovation, offers an important reflection point for this thesis: IP rights are not static. The evolution of IP has seen a continued expansion of its tenets across sectors and subjects, as well as a creation of new categories of protection in response to modern needs and realities. The IP

\textsuperscript{925} A full listing of the 176 Contracting Parties, including dates of accession and /or ratification is available online at WIPO, “WIPO-Administered Treaties”, online: WIPO <www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2>.  

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system’s claims to legitimacy thus hinges on its ability to further evolve into a system which *equally represents* the various types of innovation and creativity, as well as various categories of beneficiaries. In this context, the ability of the IP system to address critical questions relating to the innovation of indigenous peoples, lies at the heart of its legitimacy as a representative system of global innovation.

### 6.1.2.4 Indigenous Innovation, Legitimacy, and the Intellectual Property System

A major difficulty for the continued justification of the IP system, as we know it today, is that it is not sufficiently representative of knowledge holders and creators all around the world. This is because it significantly excludes the category of knowledge, popularly referred to as traditional knowledge (TK), as well as its holders – indigenous peoples – from its protective ambit. Furthermore, it fails to recognize the innovative tendencies of such indigenous and local communities which are undoubtedly a significant driver of ‘modern’ innovation. This exclusion, which draws from fundamental suggestions of incompatibility, is due to the peculiarities of TK which do not align with the general frame of knowledge recognized and catered for within the classical IP system.

Within the context of the patent system, for instance, an invention must be new, must involve an inventive step (be non-obvious), and must be capable of industrial application (be useful) to be considered eligible for patent protection. Further to these patentability requirements, inventors are required, as part of the patent application process, to clearly disclose their inventions in a manner which would enable a skilled person in the art to replicate it. Notably, these requirements highlight the intent of the patent system which, beyond merely stimulating innovation, is aimed also at early disclosure of such inventions to society for the purpose of affording persons skilled in the art, a platform for further innovation. As a reward for the invention, the patent owner is conferred with monopoly rights over the commercialization of the product for a stipulated period of time, usually twenty years. This is to afford the right holder an

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926 See, Frankel, Ka Mate & the Protection of TK, supra note 14 at 193 – 194.
927 Bavikatte, "Towards a Rights Based Approach to Protection of IK", supra note 15 at 4 – 5.
928 See Article 27.1 TRIPS Agreement.
929 See Article 29, TRIPS, requiring that the patent applicant disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.
930 See Article 28, TRIPS.
opportunity to recoup its investment while yet guaranteeing legal certainty and predictability for investors – key business ingredients which serve to encourage further investment in innovation.

It is in the underlying principles and the very working of this very system that Sanjay Bavikatte identifies the following four main anti-TK assumptions which underlie the IP system. First, the IP system assumes that the owners or progenitors of knowledge are clearly identifiable. As discussed in chapter three, however, TK is largely an unwritten body of knowledge which evolves within a community, and as such, is not necessarily traceable to an individual or specified group of individuals. Within some communities, some particular TK may be held by specific sections or families within the community, such as shamans, or traditional healers who hold specific traditional medical knowledge. Even in such instances, community protocols do not generally ascribe ownership of such knowledge for the purposes of commercialization to such individuals. Rather, TK holders are considered stewards of such knowledge.

Second, according to Bavikatte, the IP system assumes that new knowledge is clearly distinguishable from old knowledge. In this sense, the conception of a public domain, representing a free field of ‘old’, ‘unattached’ knowledge for the public good exists. To increase the scope of publicly available knowledge for the further development of society, the IP system seeks to distinguish, through its reward mechanism, new knowledge from old knowledge. Through this, new knowledge is rewarded and ultimately made freely available to the public for further innovation. New knowledge is thus seen as the result of a deliberate creative process, often stimulated by IP incentives to engage in such creative acts. Comparing this to TK and the manner in which it is generated, TK is an integrated holistic body of knowledge which evolves naturally in response to community needs. The stereotypes of TK being old, antique knowledge has repeatedly been discredited by evidence of TK as a living body of knowledge which is constantly evolving in the face of the realities of its holders. Dutfield thus describes TK as progressive, highly innovative, and involving a continuous reformation of knowledge handed down to meet up with the adaptive requirements of the present environmental realities by indigenous communities.

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932 Ibid. at 5, noting that TK holders are generally considered to be stewards over the knowledge and not owners of the knowledge.
933 For a more fulsome discussion of TK, including its characteristics and definition, see chapter three.
In short, knowledge held and generated within “traditional societies” can be new as well as old...TK has been adaptive because adaptation is the key to survival in precarious environments...while TK is handed down from one generation to another, this does not mean that what each generation inherits is what it passes on...TK develops incrementally with each generation adding to the stock of knowledge. Financial gains are not in issue and, as such, do not necessarily provide incentives for the creation of TK. Rather, a lot of TK is closely linked to the adaptation and survival of indigenous groups as against being motivated by economic rewards.

This segues nicely into Bavikatte’s third observation of the IP system’s underlying assumption that knowledge creation and development is primarily motivated by the potential of future economic rewards. Consequently, according to him, creators would be willing to share their knowledge with society in exchange for such rewards. In essence, the IP system builds into its fabric a system of reward for inventors based on the premise that without such incentives and/or rewards, individuals and corporations would not be encouraged to invest in innovation. This is an effort to correct the market failure for IP which, as Bently and Sherman note, arises where a market is unable to guarantee that an investor in research would recoup its investment. As mentioned earlier, however, financial rewards do not necessarily stimulate the creation of TK or tradition based inventions. This ties into an important consideration about TK: why is TK generated? Does it, for instance, emerge for personal gain? Generally, no. As I have shown in chapter three above, TK arises within a cultural and communal context. Isolating individual TK practices and assigning private rights over such practices to individual members of the community thus tends to go against the very communal context within which TK is ordinarily generated and held.

Fourth, is the assumption that IP rights adequately reward developers of new knowledge by guaranteeing their exclusive and time-bound use of such knowledge in exchange for sharing the knowledge with society. This is an assumption that the economic package which inventors enjoy offers an adequate system of protection and reward for new knowledge being created. Several indigenous groups have reiterated that they would want no financial returns on their TK, but rather contend that the significance of

935 Bently & Sherman IP Law3, supra note 879 at 5.
936 Gupta, “The Conundrum of Creativity”, supra note 49 at 332. See 3.3.2.4. above.
the knowledge goes beyond economic considerations, bearing deep roots in their traditions, culture and spirituality. To this end, the idea of moral rights, such as respect, acknowledgment, attribution, etc. in the use of TK, as against economic rights is emphasized. Furthermore, the significance of this assumption lies in the fact that TK holders have continued to challenge systems which suggest that their knowledge is alienable. Any reward mechanism for TK must therefore bear in mind the perpetual ownership by indigenous groups over TK.

Bavikatte’s assertions explain why the classical IP system remains insufficient to address the protection of TK. It should be said that some TK may fit within the protection scope of the above requirements of the patent system (or other IP forms). However, just as in the case of the TCEs referenced earlier, a novel tailor-made system of protection for TK is required for effectively addressing its unique nature. It is against this backdrop that the idea for a sui generis system for the protection of TK is being pursued within the WIPO IGC. The term sui generis is a Latin expression which means ‘of its own kind’. While philosophers have used the term to indicate a concept of an idea that has a unique foundation that prevents it from being included as a part of the larger whole, it is used in law as a ‘term of art’ to indicate an independent category within legal classification that stands alone due to its peculiarity or the specific rights or entitlements it creates. The WIPO IGC’s efforts to design a sui generis system of protection thus offers an interesting platform to view the attempted design of an independent category of novel IP rights addressed at the effective protection of TK for the purpose of addressing the core issue of biopiracy.

It is my contention at this point, flowing from the above, that unless a complete reconfiguration of the IP system is achieved, including a redefinition of the core justifications underlying the system of IP as we have it today, TK cannot be protected through the IP system. Even where a sui generis system, as is being pursued within the WIPO IGC, continues to make progress on IP-like rights for indigenous peoples, the overarching justifications through which such sui generis rights will ultimately be viewed and interpreted, remain the underlying rationales which support the IP system. Indeed, this explains why the

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938 Ibid. According to Professor Mark Walters, the law of aboriginal rights in Canada has similarly long employed the expression sui generis to convey the idea that aboriginal approaches to lands and other rights cannot be fit into juridical boxes derived from European law. The term was first used in the modern case law in Guerin v. The Queen, [1984] 2 S.C.R. 335.
WIPO IGC’s negotiations still need to be construed within the context of the IP system. As shown above, these do not represent justifications that could support the effective protection of TK.

TK represents a knowledge base that draws from values, conditions and communal systems of indigenous peoples which are deliberately removed from western ideas and ideals. In fact, as noted in the discussion of indigenous peoples in chapter three, their very definition incorporates a reference to those who have deliberately pursued a retention of their traditional lifestyles and communities in the face of dominant exogenous colonial influences. Developing and assigning rights which draw justification from western ideas as outlined above, will only have the ultimate effect of weakening the very indigenous substrate upon which indigenous innovation has continued to evolve. To be clear, therefore, my point is that TK cannot be protected as it is by the IP system. However, the IP system must play a central role in the protection of TK particularly from biopiracy. In this regard, the need for an IP system influence in the protection of TK from biopiracy draws from the need to restrain the IP system from being used as a mechanism towards the further misappropriation of TK.

In a significant way, therefore, the efforts to incorporate a check within the IP system which ensures that inventors who utilize GRs and TK in their inventions, have complied with the various international and local regulations (in particular ABS) governing their (GRs and TK) use, presents the most cogent IP need for addressing biopiracy. In other words, as this thesis has maintained, the need for the Nagoya Protocol’s regulations to be effectively supported by a corresponding mechanism within the IP system is critical to realizing the Protocol’s mechanism for addressing biopiracy. Significantly, the suggestion here is not for an ascription of new IP rights to indigenous peoples, but rather seeks to ensure that the IP system assumes full responsibility for addressing its role in the facilitation of biopiracy. The proposed mandatory disclosure mechanism presents an important strategy for addressing this. It, however, remains a contentious issue which lies at the heart of the very establishment of, and continued negotiations within the WIPO IGC. It also sits at the core of demands from developing countries concerning revisions to the TRIPS. As part of this section’s attempt to provide a reflection on the IP context within which the WIPO IGC exists, the TRIPS embodies the global strength of the IP system and must be understood in discussing the WIPO IGC
as well as the efforts therein to design IP solutions to biopiracy. The TRIPS emerged as part of the evolution of the IP system, targeted towards the reinforcement of these early foundational instruments.

6.1.2.5 An Evolving System of Property Rights

The expansion of IP’s tenets into virtually every facet of human society has continued on the premise that human progress and wellbeing are dependent on technological innovation through human creativity, which is said to be facilitated through a strong and efficient IP system. The continued strengthening of the IP system is linked to the highly politicized nature of IP which reflects wide divergences in the views of existing rights holders and non-rights holders on the adequacy of IPRs. On the one hand, holders of IPRs, tend to argue that the existing laws provide inadequate protection, while developing countries, consumers and users of IP are generally opposed to the further strengthening of IP protection. The economic and political dominance of the former group, however, means that despite the seeming resistance from the latter group, the influence of IPRs has continued to grow. It is in fact difficult to fully comprehend and estimate, in precise terms, the vast scope of influence wielded by the global IP system on modern life today. Even more so, is the role of the IP system in reordering global relations with a focus on the prioritization of certain forms of knowledge and its protection as the principal drivers of development. Indeed, the growth of the IP system is associated with the understanding that the strengthening of IP offers increased pathways and greater opportunities for development. According to WIPO,

\[\text{[t]he promotion and protection of intellectual property spurs economic growth, creates new jobs and industries, and enhances the quality and enjoyment of life. An efficient and equitable intellectual property system can help all countries to realize intellectual}\]

940 Bently & Sherman, IP Law3, supra note 879 at 3. See also, Dutfield & Suthersanen. Global Intellectual Property Law, supra note 278 at 6, also noting that IP is an ‘inherently political activity’ and that stronger IPRs do not necessarily correlate with a better economy.
property’s potential as a catalyst for economic development and social and cultural well-being.942

This oft glorified causal link between IP and economic development is one which aligns with a ‘generalized’ – or rather, a ‘globalized local’943 – thinking that successful nations are those that have placed knowledge at the heart of their economic development drives.944 This is not entirely accurate, especially when the fortunes of oil-rich countries like Saudi Arabia are considered.945 This causal link between IP and development also accords with the earlier mentioned view that knowledge and creativity are increasingly being viewed as the key transformational resources today. According to Adrian Johns,

[i]nformation has indeed become a principal foundation of modern social, economic, and cultural order. As it has become the key commodity in the globalized economy, so control and management of information have vastly increased in overt importance. In the nineteenth century, manufacturing held the key to economic power; for much of the twentieth, energy occupied that position. Now knowledge and imaginative creativity seem to be challenging for primacy.946

Despite proof from several scholars that this view lacks sufficient empirical justification,947 this line of thought continues to exist as a global standard, driven principally by the United States and countries in

943 Contrary to localised globalism, which refers to situations when local conditions change and adapt to international and transnational influences, globalised localism occurs when a local phenomenon is successfully globalised. See, Dutfield & Suthersanen. Global Intellectual Property Law, supra note 278 at 3. Noting the globalized local nature of IPRs, Bently and Sherman note that the globalization of IP standards has largely been a process whereby the wish-lists of various developed-world lobby groups are inscribed into public international law. Bently & Sherman IP Law3, supra note 879 at 9. Further, identifying the central role of the United States in exporting this ideology, Drahos and Braithwaite note, “The US...has a deeply held belief about the proper ordering of global commerce. Key individuals within US policy circles routinely proclaim the arrival of the global information economy, the information society. They believe, with an almost messianic intensity, that new property rights based on the ownership of ideas and information have to be created, globalized and enforced.” Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? (UK: Earthscan Publications Ltd, 2002) at 25.  
946 Johns, Piracy, supra note 581 at 4.  
Europe – main beneficiaries of the IP system. It is this thinking that has served to justify the globalization of IPRs and the continuous expansion of its scope of protection across sectors and subjects, including its controversial extension to life forms.\textsuperscript{948}

6.1.2.6 International Trade and the Globalization of Intellectual Property Rights

The most significant leap in the IP system’s scope and force of influence occurred with the globalization of IP – a feat achieved through the emergence of the World Trade Organization (WTO) and its Agreement on Trade-Related Intellectual Property Rights (TRIPS). Soederberg et al discuss the concept of globalization as a highly contested concept with a multitude of definitions.\textsuperscript{949} Not only are its definitions varied, its perceptions, effects and prospects differ across actors within the developing and developed world.

According to Dutfield and Suthersanen,

\begin{quote}
[g]lobalization is a process, or a series of processes, which create and consolidate a unified world economy, a single ecological system and a complex and dynamic network of communications that covers the world\textsuperscript{950}
\end{quote}

\begin{flushright}
2005 at 31, noting that empirical analyses on the relationship between strong IPRs and economic growth has failed to yield clear cut results.
\end{flushright}

\textsuperscript{948}Most notable in this regard is the US Supreme Court’s 1980 decision in Diamond v Chakrabarty, 447 U.S. 303 (1980), in which the court held that a live, man-made microorganism is patentable subject matter under Section 101 of the US Patent Act. See Douglas Robinson & Nina Medlock, “Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents” (2005) 17:10 Intellectual Property & Technology Law Journal, at 12. Within the context of this dissertation, the extension of IP into life forms offered a huge impetus for the growth and rapid development of the biotechnology industry. As Robinson & Medlock note, no one could have foreseen in 1980 the phenomenal pace at which new biotechnology advances would develop. Neither could anyone have predicted the exponential growth in the number of patent applications and issued patents on biotechnology-related inventions that would occur over the next 25 years.

\textsuperscript{949}Ibid, at 13. By 2003, the US biotech industry revenues had increased from $8 billion in 1992 to $39.2 billion. Furthermore, a total of $17.9 billion on research and development had been spent while the total value of the US biotech industries had risen from $45 billion in 1994 to $311 billion in 2004. Some scholars have argued for restraint with judicial and administrative standards that are lacking doctrinal support yet have enabled biopatenting. See, for example, Amani, \textit{State Agency, supra} note 431. See also, Bita Amani, “Biopatenting & Industrial Policy Discourse: Decoding the Message of Biomedia on the Limits of Agents & Audiences” in Courtney Doagoo, Mistrate Goudreau, Teresa Scassa & Madelaine Saginur, eds. \textit{Intellectual Property for the 21st Century: Interdisciplinary Approaches} (Toronto: Irwin Law, 2014) at 137.

\textsuperscript{950}See Susan Soederberg, Georg Menz & Philip G Cerny, eds., \textit{Internalizing Globalization: The Rise of Neoliberalism & the Decline of National Varieties of Capitalism} (New York: Palgrave Macmillan, 2005), 1 – 22, noting the highly contested nature of globalization and outlining three main categories for conceptualizing the existing definitions of globalization: the essentialist or teleological definitions, narrow economic definitions and the additive or interactive definitions. 5 – 6.

\textsuperscript{950}Dutfield & Suthersanen. \textit{Global Intellectual Property Law, supra} note 278 at 3.
The concept of economic globalization describes the gradual integration of national economies into one borderless global economy.\textsuperscript{951} It involves the most fundamental redesign of the planet’s political and economic arrangements since the Industrial Revolution\textsuperscript{952} and forms an underlying rationale for the international trade regime.\textsuperscript{953} The international trade regime, anchored on the multilateral institution of the WTO, has roots in the General Agreement on Tariffs and Trade (GATT) 1947.

With the theme of globalization becoming increasingly pronounced in the period after World War II, international trade was looked upon as a viable solution to forestall the possibility of further international conflict. This rationale was based on the premise that economic customers don’t fight\textsuperscript{954} Rather, by increasing the scope of competition on a global scale, innovation would be spurred, which would in turn raise productivity and lower prices of goods. The resulting division of labor would also allow for specialization, increasing the dependence of individual states on each other, and also achieve the objective of increased productivity and lowered prices. With a larger production unit, proponents of globalization pointed out that greater benefits would be on the horizon.\textsuperscript{955} Furthermore, through the ideals of free trade, the benefits of globalization were to be seen in economic growth, increased opportunities, full employment, and ultimately a prosperous world. The preamble to the Marrakesh Agreement establishing the WTO puts it this way:

> [p]arties to this Agreement [recognize] that their relations in the field of trade and economic endeavor should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world’s resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the

\textsuperscript{951} Bossche, \textit{Law & Policy of the WTO, supra} note 69 at 4. In itself, the word globalization, a highly contested subject, has been subjected to a variety of meanings. It has been defined as the closer integration of the countries and peoples of the world which has been brought about the enormous reduction of costs of transportation and communication, and the breaking down of artificial barriers to the flow of goods, services, capital, knowledge, and (to a lesser extent) people across borders. See, Joseph Stiglitz, Globalization and Its Discontents (New York: WW Norton & Company, 2002) 9.


\textsuperscript{953} See Bossche, \textit{Law & Policy of the WTO, supra} note 69 at 2, noting that the process of economic globalization is characterised by high levels of international trade and foreign direct investment.


means for doing so in a manner consistent with their respective needs and concerns at
different levels of economic development.\textsuperscript{956}

The system has not yielded the promised dividends to a wide range of participants, particularly developing
countries. In fact, the negative impacts of globalization, including insecurity, importation of hazardous
technologies and products, unemployment, closure of local industries and increased poverty, amongst
others, have largely reflected the experience of developing countries.\textsuperscript{957} The late Nelson Mandela succinctly
described the realities of globalization to developing countries as far back as 1998 while speaking at the
50\textsuperscript{th} Anniversary of the General Agreement on Tariffs and Trade (GATT):

\begin{quote}
[f]ifty years ago, when the founders of the GATT evoked the link between trade, growth
and a better life, few could have foreseen such poverty, homelessness and unemployment
as the world now knows… [f]ew would have imagined that the exploitation of the world's
abundant resources and a prodigious growth in world trade would have seen the gap
between rich and poor widening. And few could have anticipated the burden of debt on
many poor nations\textsuperscript{958}
\end{quote}

The disparities between the expectations and the realities to the developing world explain why so many
developing countries have continued to oppose so called globalization. Of importance, however, to this
dissertation is the incorporation of IP within the central stream of globalization through its introduction into
the international trading system; a move which bears central significance for the role of IP in the facilitation
of biopiracy today. Importantly, it also demonstrates the need for solutions which are internal to the IP
system in addressing IP-related concerns in biopiracy.

\textbf{6.1.2.6.1 A Multilateral System of Trade and the Reinforcement of Intellectual Property}

In pursuit of a reconstruction of the international economic order after World War II, three main
institutions were proposed; the International Bank for Reconstruction and Development (the IBRD/World
Bank), the International Monetary Fund (IMF) and the International Trade Organization (ITO). The Bretton
Woods Conference of 1944 significantly resulted in the establishment of the IMF and the IBRD.\textsuperscript{959} The

\begin{footnotesize}
\textsuperscript{956} Para 1, preamble, Marrakesh Agreement Establishing the World Trade Organization.
\textsuperscript{959} Bossche, Law & Policy of the WTO, supra note 69 at 77 – 78.
\end{footnotesize}
IMF was designed to defend the international monetary system as well as assist governments overcome balance of payment problems. The IBRD was established to assist countries with reconstruction after the War. Despite this success, a significant gap was left in the Bretton Woods structure given the failure of the intended third organization – the International Trade Organization (ITO), to subsequently materialize.\footnote{960}

The process for establishing the ITO had been launched in 1946 when the United Nations Council for Economic and Social Affairs (ECOSOC) mandated the draft of the ITO Charter for the purpose of promoting the expansion of trade and production, exchange and consumption of goods.\footnote{961} The aim was to create the ITO at a United Nations Conference on Trade and Employment in Havana, Cuba, in 1947.\footnote{962} The ITO Charter was successfully negotiated and adopted in Geneva, 1947.\footnote{963} Its broad scope contained rules on employment, commodity agreements, restrictive business practices, international investment, and services.\footnote{964} It, however, never entered into force. Though the direct reason is that no acceptances were received by the UN Secretary General,\footnote{965} the failure of the US Congress to approve the Charter was instrumental to this failed outcome.\footnote{966} Following the US Congress’ rejection of the Charter, the United States Department of State issued a policy statement in 1950, officially stating that the Havana Charter would not be resubmitted to Congress.\footnote{967} In effect, the US officially backed out of the agreed ITO Charter, and as such, would not have been a member even if it eventually entered into force.\footnote{968} Peter Van Den Bossche explains that, in the circumstances, no country was interested in establishing an international

\begin{footnotes}
\item[960] Ibid. at 80.
\item[961] See Gervais, The TRIPS Agreement, supra note 72 at 4.
\item[963] Two separate ITO drafts were produced, and discussed at separate conferences in Westminster (1946) and New York (1947), respectively. The results of the second draft was successfully signed along with the text of the GATT in October 1947 by the representatives of 25 countries in Geneva. See Gervais, The TRIPS Agreement, supra note 72 at 4.
\item[964] See, Love & Lattimore, ‘Trade Rounds’, supra note 962 at 79.
\item[965] Gervais, The TRIPS Agreement, supra note 72 at 4.
\item[966] Bossche, Law & Policy of the WTO, supra note 69 at 80.
\item[967] Gervais, The TRIPS Agreement, supra note 72 at 4.
\item[968] See Barton, Goldstein, Josling & Steinberg, The Evolution of the Trade Regime, supra note 142 at 35 – 38, noting that the US’ preference for the GATT over the ITO was rooted in domestic politics; both the concerns about the potential loss of sovereignty arising from the ‘excessive’ powers placed within the ITO (especially with respect to decision making), as well as the political preference of letting the Executive and not the Congress set the trade agenda. As the authors note, “…From the US perspective, the GATT was part of a project of recasting US institutions so as to allow the executive branch, and not the Congress, to set the trade agenda”. Ibid. at 38.
\end{footnotes}
organization for trade of which the United States, the leading economic and trading nation, would not be a member. The ITO Charter was thus stillborn.\footnote{See Bossche, Law & Policy of the WTO, supra note 69 at 78 – 80.}

A substantial part of the ITO Charter which dealt with international trade in goods; the GATT, however came into force in 1948.\footnote{For a detailed discussion on the history of the GATT, see, Amani, State Agency, supra note 431 at 146 – 150.} The GATT represented a less controversial aspect of the broad ITO agreement and served as a provisional agreement to lock in the fruitful aspects of the ITO negotiations. The implementation of the GATT led to the establishment of a GATT Secretariat for administrative purposes. Beyond a mere international Agreement, GATT thus began to take on the form of a more permanent international organization with a physical presence, staff and council meetings. As part of its work, successive trade rounds seeking to further advance the mandate of globalization through the further liberalization of international trade were convened.\footnote{Love & Lattimore, ‘Trade Rounds’ supra note 962 at 81, noting a total of nine rounds convened from the adoption of the GATT 1947 till date.}

Between 1986 and 1994, the largest ever trade round of negotiations, which resulted in the biggest single reform of the world’s trading system since the inception of the GATT in 1947 was convened.\footnote{For a concise summary of the key issues undertaken during the Uruguay Round, including the agenda for the negotiations, see WTO, ‘The Uruguay Round’, online: WTO <http://www.wto.org/english/tratop_e/urun_e/urun_e.htm>. See also, Amani, State Agency, supra note 431 at 150.} Popularly referred to as the Uruguay Round, its effect on the multilateral trading system remains unmatched by any other Round. Launched in Punta Del Este, the Uruguay Round lasted for a total of seven and a half years.\footnote{According to the Secretariat of the WTO, this was almost twice the original schedule for the Round. It was planned that the Round would cover virtually every outstanding trade policy issue and as such represented the largest negotiating mandate on trade ever agreed. Four years were proposed for its completion. Ibid. See WTO, ‘The Uruguay Round’, online: WTO <http://www.wto.org/english/tratop_e/urun_e/urun_e.htm>.} It was aimed at improving access to the world’s markets, reforming the rules and institutions of the international trading system and establishing an international organization for international trade.\footnote{See Amani, State Agency, supra note 431 at 150.} It significantly ushered in a new era of multilateral trade policy by expanding the scope of disciplines covered and strengthening the dispute resolution mechanisms.\footnote{These new issues included investment, trade in services, and the protection of IP rights. See Sell, Private Power, Public Law, supra note 85 at 7.} Furthermore, substantive IP rules were introduced
within the multilateral trading system through the mechanism of the TRIPS.\textsuperscript{976} The emergence of the TRIPS as an annex to the WTO Agreement was in itself a victory of the developed countries led by the USA, who, as Nicolas Lamp convincingly argues, coerced developing countries into agreeing to the deal.\textsuperscript{977} Despite strong resistance from countries like India,\textsuperscript{978} the TRIPS emerged, incorporating universal minimum global standards for IP protection\textsuperscript{979} as well as minimum obligations for remedies, administrative and judicial processes and border controls. Furthermore, it was brought within the effective enforcement mechanism of the WTO judicial settlement system.\textsuperscript{980}

Given the manner in which the TRIPS came about, it retains an acrimonious undertone in the North-South debates.\textsuperscript{981} The TRIPS is often viewed as representing an era of consolidation within the field of IP\textsuperscript{982} as it brought together, into one binding document, the major principles which underlie the global IP system.\textsuperscript{983} Furthermore, the TRIPS is largely discussed within the contexts of the globalization of IP rights,\textsuperscript{984} given that it defined a uniform minimum standard of IP protection for all members of the multilateral trading system.

How does WIPO, or the IGC, fit within this story of consolidation through the TRIPS? Prior to the Uruguay Round, the global governance of IP was solely within the mandate of WIPO.\textsuperscript{985} WIPO as an organization was established in 1967 pursuant to the adoption of the CEWIPO.\textsuperscript{986} Its roots, however, reach

\begin{footnotesize}
\footnote{976}{For a detailed historical account of the TRIPS Agreement, see Gervais, \textit{The TRIPS Agreement}, supra note 72. See also, Duncan Matthews, \textit{Globalizing Intellectual Property Rights: The TRIPS Agreement} (USA: Routledge, 2002) [Matthews, \textit{Globalizing IPRs}], and Sell, \textit{Private Power, Public Law}, supra note 85.}
\footnote{978}{Ibid.}
\footnote{979}{Amani, \textit{State Agency}, supra note 431 at 163 – 164.}
\footnote{980}{Okediji, “The International Relations of IP”, supra note 18 at 337.}
\footnote{981}{See for instance, Barton, Goldstein, Josling & Steinberg, \textit{The Evolution of the Trade Regime}, supra note 142 at 140 – 141, suggesting that the TRIPS agreement has been responsible (since its adoption), above any other issue area or agreement, for exacerbating North-South acrimony.}
\footnote{982}{Okediji, “The International Relations of IP”, supra note 18 at 320 – 341.}
\footnote{983}{Particularly, it is worth noting that the TRIPS Agreement did not necessarily serve to alter the foundational principles underlying the IP system – as contained in the Paris and Berne Conventions. Rather, it gave these Conventions a further critical edge in terms of scope and strength. Article 9, TRIPS for instance, requires Members to ‘comply with Articles 1 through to 21 of the Berne Convention’. It thus served to incorporate key provisions of the Berne and Paris Conventions within the context of an international trade treaty.}
\footnote{984}{Matthews, \textit{Globalizing IPRs}, supra note 976.}
\footnote{985}{To a lesser extent, the United Nations Conference on Trade and Development also addressed some IP issues before the emergence of the WTO. See, Mgbeoji, “TRIPS & TRIPS-Plus”, supra note 866 at 260.}
\footnote{986}{See Article 1, CEWIPO.}
\end{footnotesize}
much further to the earlier discussed Paris and Berne Conventions. The Paris and Berne Conventions established respective Unions which consisted of all member states to the respective treaties.987 These Unions – the Paris Union and the Berne Union, had the form of international organizations as we know them today and established International Bureaus for carrying out the administrative tasks required under the respective Unions.988 From their inception, the respective Secretariats of the Paris and Berne Conventions were placed under the supervision of the Swiss Federal Government.989 These secretariats continued to provide independent administrative support for the respective Conventions until 1893 when both united to form an international organization called the United International Bureaux for the Protection of Intellectual Property (BIRPI)990; the predecessor to WIPO. In 1970, following the adoption and the entry into force of CEWIPO, BIRPI became WIPO. It underwent structural and administrative reforms and acquired an independent Secretariat which was answerable to all the Member States, including former colonies, as against the Swiss Federal Government. In 1974, WIPO became a specialized agency991 of the United Nations system of organizations, with a mandate to administer IP matters recognized by the member States of the UN.

As a specialized agency of the United Nations system of organizations, WIPO was mandated to administer IP matters recognized by the member States of the UN. It is worth noting that, as a specialized agency of the United Nations, WIPO retains its independence as an international organization but draws its connection to the United Nations system through a special agreement.992 Pursuant to this agreement,

987 See, Article 1, Berne Convention, providing that ‘The countries to which this Convention applies constitute a Union for the protection of the rights of authors in their literary and artistic works’. See also Article 1(1), Paris Convention, noting in similar wording that the countries to which this Convention applies constitute a Union for the protection of industrial property.
988 See Article 15, Paris Convention, see also Article 24, Berne Convention.
989 WIPO, Introduction to IP, supra note 863 at 27.
990 This was best known by its French acronym BIRPI – Bureaux Internationaux Reunis de la Protection de la Propriete Intellectuelle.
991 WIPO represents one of 16 specialized agencies of the UN. These are autonomous organizations that are connected to the United Nations through special agreements. Specialized agencies of the United Nations system are so called because each of them has specialized knowledge and expertise, and has accumulated vast international experience in a particular subject or field of activity of importance to the international community. Thus, for instance, the ILO is a specialized agency in labour, UNESCO in education, WHO in health, FAO in food and agriculture, WIPO in IP etc. See WIPO, Introduction to IP, supra note 863 at 28.
WIPOs status as a specialized agency is based on the recognition that it has specialized knowledge in the field of IP – one which is of importance to the international community – and that it has accumulated vast international experience in administering this area of specialization.\textsuperscript{993} It is, in effect, an endorsement of WIPO as the relevant organization for matters which fall within the purview of IP. WIPO has continued in this capacity since 1974, and today administers a total of 26 IP treaties dealing with standards of IP protection, global IP protection systems, and IP classification systems.\textsuperscript{994} It therefore represents an important forum which must be considered in discussing normative changes within the IP system.

With WIPO’s establishment to promote the global protection of IP through cooperation among States,\textsuperscript{995} and its further endorsement as the specialized agency of the United Nations for matters within the purview of IP, the introduction of IP within the multilateral trade negotiations of the Uruguay Round raised questions. Reasons, however, existed for this. According to Daniel Gervais, the introduction of IP into the Uruguay Round was linked to concerns from powerful contracting parties, notably the United States, about the growing international trade in counterfeit and pirated goods.\textsuperscript{996} As Dutfield suggests, the overwhelming context within which the introduction of IPRs into international trade should be viewed, is one which recognizes the rise of the biotechnology and information technology industries, and the important implications arising from the limited/non-protection of their products and rights in foreign jurisdictions.\textsuperscript{997}

The main existing IP treaties administered by WIPO failed to address these concerns for two main reasons:

i. They lacked detailed rules on the enforcement of rights before national, judicial, and administrative authorities;\textsuperscript{998}

\textsuperscript{993} See WIPO, \textit{Introduction to IP}, supra note 863 at 28.
\textsuperscript{994} The full listing of the 26 treaties is available at WIPO, \textit{WIPO-Administered Treaties}, online: WIPO <http://www.wipo.int/treaties/en/>.
\textsuperscript{995} See Article 3 (i), CEWIPO.
\textsuperscript{996} Gervais, \textit{The TRIPS Agreement}, supra note 72 at 10. These powerful parties considered the enactment of binding obligations a necessity.
\textsuperscript{998} Gervais, \textit{The TRIPS Agreement}, supra note 72 at 11. See also Gustavo Bravo, “From Paris Convention to TRIPs: A Brief History” (2001 – 2002) 12 J. Contemp. Legal Issues 448, noting that the lack of progress on substantive and enforcement issues for international IP within WIPO led the US and other industrialized nations to turn to the GATT negotiations for remedying this situation. See also Dutfield, \textit{IPRs, Trade & Biodiversity}, supra note 997 at 11.
They also lacked binding and effective dispute-settlement mechanisms for disputes between States. These powerful contracting parties, prompted by lobbies from the pharmaceutical, software and entertainment industries, considered the elimination of trade in counterfeit and pirated goods through binding obligations, a necessity. Indeed, as Sell notes, these IP negotiations were driven almost entirely by the private sector, particularly within the United States’ business community. The prevailing perception was that the gains by the developing world in the unauthorized use of western IP represented losses for the holders of the rights. Driven to address these concerns, IP protection proposals were introduced within the Tokyo Round – the trade Round immediately prior to the Uruguay Round. These efforts ultimately failed. According to Gervais,

[d]uring [the Tokyo Round] held between 1973 and 1979, trade in counterfeit (trademark) goods had started to emerge as a serious issue. Attempts to agree common rules to stop trade in counterfeit goods failed at the end of that Round but efforts to include a specific discipline within the GATT framework continued.

However, at the Uruguay Round, the lobbyists secured their desired outcome. Through a negotiating process which is often described within varying narratives of power, the Uruguay Round issues, including IP, were all basically resolved by December 15, 1993. By April 1994, the agreement was signed in Marrakech in a last minute all or nothing package. The TRIPS, along with the other results of the Uruguay Round, entered into force in 1995.

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999 Ibid. at 12. See also, Gervais, The TRIPS Agreement, supra note 72 at 11.
1000 Gervais, The TRIPS Agreement, supra note 72 at 10.
1001 Sell, Private Power, Public Law, supra note 85 at 7. In fact, Daniel Gervais notes that the main push came from the Intellectual Property Committee (IPC), which was a 12-member committee composed of top executives from the above-mentioned industries. Gervais, The TRIPS Agreement, supra note 72 at 12.
1002 Ibid. at 12. Dutfield for instance refers to an estimation by the United States International Trade Commission (USTC) which suggested that US corporations were victims of foreign intellectual piracy amounting to losses of between $40 billion and $60 billion per year. Dutfield, IPRs, Trade & Biodiversity, supra note 997 at 11.
1003 Gervais, The TRIPS Agreement, supra note 72 at 8 – 9.
1006 See, Amani, State Agency, supra note 431 at 145.
Interestingly, though the IP outcome was a new international agreement on the trade-related aspects of IPRs, the proponents’ plan from the beginning had not been that ambitious. As a matter of fact, several commentators have noted that the US never expected to secure such a comprehensive IP agreement within the Uruguay Round. The express resistance of countries like India to the positions of the US was reflective of the concerns that a majority of developing countries had about the insertion of IP disciplines within the multilateral trading system.\(^{1007}\) Securing the deal was thus made possible, not necessarily because developing countries accepted or conceded to all that was in the agreement, but rather due to a combination of factors, including the use of trade-offs in other subject areas of the trade round.\(^{1008}\) This ‘package’ approach – which led to developing countries weighing up the potential losses within the IP deal against the potential benefits which were being offered in other areas of importance to them, was instrumental. The contentious ‘single undertaking’ principle which guided the discussions, was eventually utilized by developed countries to bully developing countries into Agreement,\(^{1009}\) with the tradeoffs later being characterized as not entirely fair, but at which time it was erroneously seen by developing countries as a next best alternative to ward of US unilateralism.\(^{1010}\)

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\(^{1007}\) Lamp, ‘The Club Approach’, supra note 977 at 57 – 66, for a detailed discussion of the politics underlying the negotiation of the TRIPS Agreement.

\(^{1008}\) Amani, State Agency, supra note 431 at 151 – 152, noting the centrality of agricultural concessions to the successful outcome; some of the developing countries including agricultural exporting countries of Latin America refused to deal in any area, including IP, unless there was agreement on the agricultural issues addressing the domestic subsidy of such products, reducing tariffs, and eliminating quantitative restrictions. Ibid. at 151.

\(^{1009}\) Lamp, “The Club Approach”, supra note 977 62 – 65, noting how the ‘single undertaking’ was reinterpreted within the course of the negotiations to the disadvantage of developing countries. As noted by the Indian Ambassador, at a meeting of the United Nations Conference on Trade and Development (UNCTAD) in March 1991, [t]he concept of a ‘single undertaking’ had been introduced at a ‘very late stage’ and was tantamount to ‘breach of good faith’. It was not part of the basis of negotiations and had been introduced to force Third World countries to accept all the results of the Round or opt out of the system. It would be prudent to avoid such an approach. The provision of flexibility for the Third World had not only to be in terms of time derogation but in absolute terms so that they were not forced to accept obligations inconsistent with their development, financial and trade needs (Ibid. at 65).

\(^{1010}\) See Amani, State Agency, supra note 431 at 162, noting that one of the key factors which helped secure the commitment to TRIPS from developing countries was the naïve belief that locating IP within the multilateral trading system would insulate them against unilateral action, such as those available under US law, by making them GATT inconsistent for failure to deploy the multilateral regime’s mechanisms. The US had for instance used the threat of the withdrawal of the generalised system of preferences, and priority watch lists under Special
The adoption of the TRIPS, which covers most parts of modern IP law, is considered the most significant milestone in the development of IP in the twentieth century.\textsuperscript{1011} Watal describes it as the most wide-ranging and far-reaching international treaty on the subject of IP, and the first international IP law instrument that obliges, in a single undertaking, new global standards on as many as eight types of IPRS.\textsuperscript{1012} Dinwoodie, notes the significant transformation of the classical IP system arising from the emergence of the TRIPS, and suggests that beyond trade alone, the particular institutional character of the WTO, has served to further magnify the transformative force of the shift of IP rules within the context of international trade.\textsuperscript{1013} Indeed, in placing IP rules within the context of international trade, the dominance of the international trade regime has served to redefine the strength, scope, and effectiveness of the IP regime.

How has this redefinition taken place? While most scholars have focused on the consolidation\textsuperscript{1014} as well as globalization\textsuperscript{1015} of the IP system through the TRIPS, it is also important to view this redefinition in the context of a reinforcement strategy for the IP system. Distinct from a mere consolidation of IP rules and an imposition of minimum standards globally, the TRIPS was a successful attempt to utilize the regime strength of the international trade regime to secure a reinforced IP regime which would be able to address the concerns developed countries had with the WIPO-based IP regime. Consequently, the TRIPS in itself is not primarily a trade agreement,\textsuperscript{1016} but rather exists as an IP agreement embedded within the trading system. The significance of this, amongst others, is that the TRIPS’ disciplines on IP form a part of the ‘covered agreements’ of the WTO which ultimately make it eligible for compliance and enforcement.

\footnotesize{301 to attack Thailand for inadequate pharmaceutical patent protection it offered American firms in 1991. Anthony D’Amato & Doris Long, eds. \textit{International Intellectual Property law} (Boston: Kluwer Law International, 1997) at 67 – 70. But, according to Amani, the threat of use of unilateralism seems to have increased rather than decreased with TRIPS. Amani, \textit{State Agency, supra} note 431 at 162. Again, see, Gregory Shaffer & Susan K Sell, “Transnational Legal Ordering & Access to Medicines” in Ruth Okediji & Margo Bagley, eds. \textit{Patent Law in Global Perspective} (USA: Oxford University Press, 2014) at 105, in referencing the strategies that led to the creation of the TRIPS Agreement, note that US used, and continues to use its Special 301 Procedure under which countries are placed on watch lists of varying priority regarding their IP protections. From 1985 to 1995, at least 18 countries reformed national laws to strengthen patent protection due to other measures taken by the United States and the European Union.}

\footnotesize{\textsuperscript{1011} Gervais, \textit{The TRIPS Agreement, supra} note 72 at 3. See also, Watal, \textit{Intellectual Property, supra} note 576 at 2. \textsuperscript{1012} This is including Plant Varieties Protection. Watal, \textit{Intellectual Property, supra} note 576 at 2 – 3. \textsuperscript{1013} Dinwoodie, “The International IP system”, \textit{supra} note 579 at 62. \textsuperscript{1014} See, for instance, Okediji, “The International Relations of IP”, \textit{supra} note 18 at 339, noting the emergence of the TRIPS Agreement as signalling an era of consolidation in the international IP system, one characterized, inter alia, by the active pursuit of the progressive integration of developing countries into the international IP system. \textsuperscript{1015} See, for instance, Sell, \textit{Private Power, Public Law, supra} note 85; Matthews, \textit{Globalizing IPRs, supra} note 976. \textsuperscript{1016} Barton, Goldstein, Josling & Steinberg, \textit{The Evolution of the Trade Regime, supra} note 142 at 142.}
procedures through the WTO dispute settlement system.\textsuperscript{1017} Furthermore, it incorporates enforcement procedures which make it mandatory for states to make provision for the domestic enforcement of IPRs. By this token, the very concerns which led the developed countries to place the subject of IP within the trade regime were effectively addressed.

The lobbyists, realizing the benefits and limitations of the existing IP system, sought means to reinforce the system through the international trade regime – a reinforcement which would ensure effectiveness in addressing the incidence of international piracy and ultimately secure their economic monopolies even in foreign territories. The reinforcement of IP through the TRIPS thus suggests three mutually inclusive elements; first, the existence of a distinct substantive standard of IP as contained within the multilateral IP treaties, such as the Berne and Paris Conventions. These principles, rules and norms emerged and existed outside the trade regime. Though these IP treaties afforded IP rights holders foundational IP rights, they were unable to address effectively the problems associated with their unsecured interests abroad, arising from the varying and/or non-existent standards of IP protection within various states, particularly in the third world. Second, the existence of a relevant and/or related dominant mechanism or institution of governance which offers a platform for strengthening the existing obligations. By this, suggestions of a stronger regime – one which possesses functional elements which can effectively address the mischief for which further protection is sought. In this case, the GATT’s framework (and indeed the eventual WTO Dispute Settlement System) was seen as a viable solution to the effective dispute settlement needs which WIPO was unable to provide. Furthermore, the international trade regime, constructed within the context of the international economic order, was seen as an indisputable source of strength and resilience which would address these concerns of the IP system. Third, is the transposition of the substantive IP standards into the related regime for the purpose of seeking the effective protection of existing IP rights through the related regime. In this case, as has been identified, such transposition occurred largely as a form of imposing standards on developing countries. This is particularly due to the fact that

\textsuperscript{1017} See Article 1, DSU, \textit{supra} note 73.
most of these standards were already in effect in developed countries. Developing countries have continued to struggle with the costs and effects of implementing the TRIPS.\footnote{Mgbeoji, “TRIPS and TRIPS-Plus”, supra note 866.}

In sum, the reliance on WIPO as the sole administrator of IP globally has encountered significant challenges in the course of the growth of the global IP regime. By placing IP rules within the international trading system, a twin institutional administrative structure for the global IP regime, comprised of both the WTO and WIPO emerged.\footnote{Ruth L Okediji, “WIPO-WTO Relations and the Future of Global Intellectual Property Norms” (2008) 39 Netherlands Yearbook of International Law [Okediji, “WIPO-WTO Relations”] 69 at 72, noting the shared institutional oversight of IP.} Importantly, to ensure a mutually supportive relationship between the two organizations, as well as establish appropriate arrangements for cooperation between them, an Agreement Between WIPO and the WTO was adopted in 1995.\footnote{See, Preamble, Agreement Between the World Intellectual Property Organization and the World Trade Organization (of December 22, 1995), available online: WIPO <http://www.wipo.int/wipolex/en/other_treaties/text.jsp?file_id=305457>. [WIPO-WTO Agreement]. For a detailed discussion of this agreement, see generally Okediji, “WIPO-WTO Relations”, supra note 1019 at 72.} Furthering the reinforcement explanation above, this Agreement effectively supports a single coordinated administrative structure for the management of the IP regime. On the basis of this Agreement, WIPO serves as the central library (or repository) of IP laws and regulations,\footnote{In addition to the IP treaties which WIPO administers, the WTO is also required to transmit to WIPO for its collection, all laws, regulations, final judicial decisions, and administrative rulings which relate to IP notified by its Member States pursuant to Article 63.2 TRIPS, ‘in the language or languages and in the form or forms in which they were received’. Article 2 (4)(a). WIPO-WTO Agreement.} yet providing non-discriminatory access to the laws, and WIPO databases containing them, to WTO Members and nationals (whether or not they are WIPO Members),\footnote{Articles 2.1. and 2.2. WIPO-WTO Agreement.} as well as the Secretariat and the TRIPS Council.\footnote{Article 2.3. WIPO-WTO Agreement.} In effect, therefore, this Agreement coordinates the ties between the two organizations in terms of access to laws and regulations, access to WIPO databases, information sharing,\footnote{See Article 4(3).} legal-technical assistance, and technical cooperation.\footnote{See Article 4 (1) and 4(2) WIPO-WTO Agreement.} Though the Agreement omits substantial aspects of the working relationship between WIPO and WTO, including the difficult questions of normative jurisdiction, Okediji argues that a hierarchal structure in favor of the WTO can be distilled from the Agreement.\footnote{See, for instance, Okediji, “WIPO-WTO Relations”, supra note 1019 at 73.} For this reason, she contends that the WTO is the appropriate forum for discussions

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\item \footnote{Mgbeoji, “TRIPS and TRIPS-Plus”, supra note 866.}
\item \footnote{In addition to the IP treaties which WIPO administers, the WTO is also required to transmit to WIPO for its collection, all laws, regulations, final judicial decisions, and administrative rulings which relate to IP notified by its Member States pursuant to Article 63.2 TRIPS, ‘in the language or languages and in the form or forms in which they were received’. Article 2 (4)(a). WIPO-WTO Agreement.}
\item \footnote{Articles 2.1. and 2.2. WIPO-WTO Agreement.}
\item \footnote{Article 2.3. WIPO-WTO Agreement.}
\item \footnote{See Article 4(3).}
\item \footnote{See Article 4 (1) and 4(2) WIPO-WTO Agreement.}
\item \footnote{See, for instance, Okediji, “WIPO-WTO Relations”, supra note 1019 at 73.}
\end{itemize}
relating to the further evolution of IP norms. In advancing this argument, she presents an understanding of norm making within the IP context, which is relevant here:

In the context of IP, I view norms to include the goals or objectives the relevant treaty rules and standards are intended to accomplish, as well as the processes by which those expectations are assimilated into international law. Thus, in terms of norm-setting activity, for example, the way in which WIPO or the WTO determine the constitutive elements of ‘technical assistance’ and assesses whether such assistance is, first, necessary and, second, effective, is part of the normative orientation likely to manifest in the expectations that states have with respect to compliance with treaty obligations. Similarly, the manner in which the WTO evaluates state IP laws for compliance with TRIPS also injects normative bias into the global IP framework by altering state behaviour along the lines of such WTO counsel. Accordingly, one of the benefits of WTO primacy over global IP rules is the range of avenues available to it to create and diffuse IP norms through its various offices and tasks [footnotes omitted].

While the above reflection on norm making holds sway within the context of the operational implementation of the TRIPS especially in the light of the strength of the WTO’s compliance regime which I have discussed above, the viewing of norm making in the substantive context of regimes which I highlight in chapter two, however, casts into doubt whether the WTO can actually be considered the relevant forum for the development of IP norms on issues relating to the protection of TK.

It is respectfully submitted that the legitimacy of norm making within the context of TK, fundamentally derives from the legitimacy of the forum from the perspective of the Third World over the TK norms being developed. In discussing the legitimacy of international law systems, Alan Boyle and Christine Chinkin note the role that has traditionally been played by powerful states in the making of international law:

International law rules such as those relating to acquisition of territory, diplomatic protection of aliens, or compensation for alienation of foreign investment were formulated by a small number of powerful states to uphold their interests. Unequal status was discounted in international law. Capitulatory regimes were imposed upon weaker states by European powers; economic coercion was excluded from the body of the Vienna Convention of the Law of Treaties and located in an Annex, and there is no generalized doctrine of unequal treaties within that Convention. Actions of the powerful were legitimated by the concept of the civilizing mission. Resistance was discounted.

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1027 Ibid. at 73, 107 – 108, arguing that the WTO should be considered as the locus of substantive IP regulation with respect to the creation of IP norms affecting the regulation of global public goods for reasons, such as, the ‘linkage’ advantage within the WTO, the WIPO-WTO Agreement’s institution of a hierarchical structure, and the possible economic benefits derivable to developing countries from such a hierarchical structure.

1028 Ibid. at 108.
since the doctrine of protest and lack of acquiescence was not applied to relieve the burden of the rules for those who had been made subject to them [emphasis added].

For this reason, the question of international legitimacy is one which varies across countries, regions, and political traditions. The review of the emergence of the TRIPS above, confirms this power dynamic within the context of the WTO. In particular, from the perspective of the Third World, the TRIPS continues to be viewed as a tool utilized by powerful states to secure their interests to the detriment of third world actors and a major facilitator of biopiracy. For such third world actors, the TRIPS, and indeed the TRIPS Council, may thus hold little legitimacy. This is placed in further perspective where the state-centric nature of the TRIPS negotiations is considered; a factor which serves to exclude indigenous peoples from participating in the negotiations.

As I have discussed earlier in chapter one, a central demand from developing countries yet lies in the revision of the TRIPS, for the purposes of incorporating a disclosure requirement to address the facilitation of biopiracy through the TRIPS. There is no denying that this is an ultimate need for which the norm-making relevance of the WTO must be called upon to actualize. Article 71 of the TRIPS, for instance, provides that the TRIPS Council may undertake reviews in the light of any relevant new development which might warrant modification or amendment of this Agreement. Furthermore, the article provides, that where the proposed amendments serve the purpose of adjusting to higher levels of protection for IP rights achieved, and in force, in other multilateral agreements, and accepted under those agreements by all members of the WTO, such could form the basis of an amendment to the TRIPS on the basis of a consensus proposal from the TRIPS Council.

My argument therefore is that where legitimate IP norms are secured for protecting TK within, for instance, the WIPO IGC, these could form ‘relevant new developments’ within the context of Article 71 of the TRIPS for driving amendments to the TRIPS. As at today’s date, it is worth recalling that though the Nagoya Protocol constitutes a relevant development to efforts to amend the TRIPS in line with Third World

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1030 Ibid. at 28
1031 See 1.1.3. above.
1032 See Article 71.1 TRIPS Agreement.
1033 See, Article 71.2 TRIPS Agreement.
concerns on biopiracy, it does not constitute an IP instrument. As such, its discussions and, indeed, the Secretariat of the CBD, have remained excluded from the WTO and TRIPS Council negotiations at the insistence of powerful actors, in particular the United States.\footnote{1034}

As far back as 2011, the minutes of the TRIPS Council meeting reflected the difficulty of getting the CBD secretariat to provide the TRIPS Council with a briefing on the Nagoya Protocol.\footnote{1035} This standoff continues till date.\footnote{1036} Alternative proposals have been for the informal participation of the CBD within the TRIPS Council (via side events). These have also been resisted on the ground that ‘without a formal link to the Council’s work’, such efforts at participation would not add value.\footnote{1037} Further yet, the formal request from the CBD for observer status within the TRIPS Council negotiations remains pending.\footnote{1038} It is worth noting that this resistance to the CBD’s engagement within the TRIPS Council persists despite the 2001 Doha Ministerial Declaration’s instruction to the TRIPS Council to examine the relationship between the TRIPS and the CBD, as well as its relationship with the protection of TK and folklore.\footnote{1039} This continued

\footnote{1034}{\textit{Council for Trade-Related Aspects of Intellectual Property Rights: Minutes of Meeting, held in the Centre William Rappard on 7 – 8, June 2016}, IP/C/M/82, WTOOR (2016) at para 117, with the United States noting that it was not in a position to support the continued requests by developing countries for a formal briefing from the CBD Secretariat within the Council.}

\footnote{1035}{See, \textit{Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting: Held in the Centre William Rappard on 7 June 2011}, WTOOR, IP/C/M/66 (2 September, 2011). India, and a number of other developing countries had requested to hear from the CBD Secretariat on the outcome of the COP 10 and wished that the Secretariat be invited to provide a briefing on a one-time basis. This was due to the fact that they considered that the Secretariat would be best placed to give further in-depth information on the interpretation and implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol). However, some others had felt that the countries that had negotiated the Nagoya Protocol would themselves be best placed to discuss any specific issues relating to it. Ibid. at paras 9 – 10.}

\footnote{1036}{See, for instance, the report of the \textit{Council for Trade-Related Aspects of Intellectual Property Rights: Minutes of Meeting, held in the Centre William Rappard on 7 – 8, June 2016}, IP/C/M/82, WTOOR (2016), at paras 60 – 120.}

\footnote{1037}{Ibid. at para 11.}

\footnote{1038}{See, CBD, \textit{Cooperation with WTO}, online: CBD <https://www.cbd.int/incentives/coop-wto.shtml>. Of the several observer requests submitted by the CBD Executive Secretary to WTO Committees, including the Committee on Agriculture, Committees on Sanitary and Phytosanitary Measures and on Technical Barriers to Trade, only the Committee on Trade and Environment in Regular Session has been granted.}

\footnote{1039}{This was the official resolution by members of the WTO at the end of the Fourth Ministerial Conference in Doha, Qatar November 2001. This Declaration was adopted on 14 November 2001. See \textit{Ministerial Declaration}, WT/MIN(01)/DEC/1, WTOOR, 4\textsuperscript{th} Sess (2001) at para 19, which provides in relevant part, We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore.}
tension between the Secretariat of the CBD and the TRIPS Council highlights why the WIPO negotiations play a critical role in advancing the biopiracy-related interests of developing countries within the IP regime.

The TRIPS Council has been more accommodating, for instance, to updates from the WIPO IGC.\textsuperscript{1040} Indeed, WIPO participates as an observer within the TRIPS Council meetings.\textsuperscript{1041} Interestingly, all members of the WTO are members of WIPO\textsuperscript{1042} and as such, the barriers faced by the CBD in accessing the TRIPS Council does not arise. In fact, the major developed countries, including Canada, Japan, and the United States have continued to advocate for a prioritization of WIPO’s discussions in the context of TK and GRs.\textsuperscript{1043} The ongoing work within the WIPO IGC, therefore, which is primarily driven towards the actualization of an international \textit{sui generis} system for the protection of TK occupies the center of the existing chasm between the WTO and the CBD. My contention is that a positive outcome within the WIPO IGC which sits in complementarity with the ABS regime (while yet representing an IP instrument), will offer an important opportunity for channeling a pathway for developing countries in advancing needed amendments to the TRIPS for the purpose of addressing the IP regime concerns with respect to biopiracy.

In sum, the WIPO IGC presents an opportunity to bridge the gap between the ABS regime and the formal IP regime. Its outcomes will definitely form the basis for a concerted push to achieve the proposed amendments to the TRIPS. It is for this reason that the development of a disclosure requirement within the WIPO negotiations, which continues to divide the negotiators, must be viewed as an imperative need. For reasons suggested in my earlier discussion in chapter one, the State-centric nature of the TRIPS Council

\textsuperscript{1040} In response, for instance, to El Salvador’s 2011 request for an update from the WIPO Secretariat on the work of the IGC, for the purpose of helping smaller delegations that lacked the resources to cover WIPO to be briefed of the developments within the Council meeting, the concerns raised were rather about the timing and not so much the propriety of the request. Council for Trade-Related Aspects of Intellectual Property Rights, \textit{Minutes of Meeting: Held in the Centre William Rappard on 7 June 2011}, WTOOR, IP/C/M/66 (2 September, 2011) at para 12.


\textsuperscript{1042} The WTO has a total of 164 Member States, while WIPO currently has 188 Member States. Save for entities such as the European Union, Hong Kong – China, Macao – China, and Taiwan Province of China, all members of the WTO double as members of WIPO. A full comparative table reflecting the membership across treaties and institutions is available on WIPO’s Website. See, WIPO, “Summary Table of Membership of the World Intellectual Property Organization (WIPO) and the Treaties Administered by WIPO, Plus UPOV, WTO and UN”, online: WIPO <http://www.wipo.int/treaties/en/summary.jsp>.

\textsuperscript{1043} See, for instance, the report of the Council for Trade-Related Aspects of Intellectual Property Rights: Minutes of Meeting, held in the Centre William Rappard on 7 – 8, June 2016, IP/C/M/82, WTOOR (2016).
means that the TRIPs Council remains a difficult terrain for indigenous peoples, and developing states to advance their concerns, especially when we consider norms in the context of Helfer’s substantive categorization of regimes as discussed in chapter two. In concluding this thesis, my discussion in part two of this chapter demonstrates the central importance of WIPO as the relevant ‘next step’ to ongoing efforts to secure ultimate TRIPS reinforcements for the protection of TKaGRs from biopiracy. My focus within the rest of this dissertation is therefore on WIPO, and the next section of this chapter situates itself within the ongoing efforts therein to elaborate an international instrument which will ensure the effective protection of TK.

6.2 The World Intellectual Property Organization, a Sui Generis System and the Defensive Protection of Traditional Knowledge associated with Genetic Resources

[We are] particularly reflective at this time about the importance of this process […] This is a process that is important to the intellectual property system, to the administration of patent law, important for institutional coherence and perhaps for the first time in the history of this Organization and certainly in the history of Intellectual Property, reflecting fundamental principles of law and equity. We believe that the draft with which we have ended covers the core minimal elements necessary to ensure that the demands and the hopes and fears of those whose intellectual commitments and resources are reflected in genetic resources and associated TK will become a formal part of the global innovation system…We believe that this task is doable. And we believe that the end is foreseeable. And at the end of the day, the hope is that the innovation process as well as all of the legal systems we have put in place to respect the investments made by firms, by individuals, by communities, by indigenous groups will be reflected in an instrument that is both binding but, most importantly, in an instrument that reflects the aspirations of all human communities, namely that we are able to live in an environment not marked by division but instead defined by our mutual respect for one another”.

Right across the wide expanse of land that hosts the headquarters of the United Nations in Geneva – the Place des Nations, the buildings that comprise the World Intellectual Property Organization (WIPO) proudly stand. Geneva has been home to WIPO since 1960. Designed as a campus with an interlinked chain of four principal buildings, the sprawling WIPO complex is a majestic sight to behold. It exudes

1044 Professor Ruth Okediji, speaking on behalf of the Delegation of Nigeria at the close of the Twenty-Third Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Geneva, February 8, 2013.
1045 See WIPO, Introduction to IP supra note 863 at 27.
wealth, perfection, and a stunning glimpse of architectural innovation and creativity. Its themed blue-glass structures both blend in, and yet stand out, within the scenic outlay of one of the world’s most multicultural cities. The buildings are reputed for their advanced technologies and sustainable resource use. Importantly, these buildings are symbolic of the Organization. For, even amongst the United Nations and its agencies, WIPO is noted for its affluence. A key reason for the seeming affluence of WIPO is that WIPO generates the majority of its income. This is unlike other agencies of the United Nations, as well as the United Nations itself, which operate primarily on budgetary contributions from Member States. One of WIPO’s main buildings, known as the PCT building, is often described as the Organization’s goose that lays golden eggs. Within it, patent applications from all over the world are received and processed. These patent filings have consistently been on the rise, meaning that the Organization has not been short of funds. A strong business model is therefore built into the running of the Organization. Indeed, while WIPO is responsive to its Member States, it is strategically driven to retain relevance through improved administration and enforcement of IPRs.

Okediji, “When Should We Invent IPRs?”, supra note 366 at 20, noting WIPO to be the richest UN agency. WIPO generates its own income. According to CEWIPO, WIPO’s budget is expected to be financed inter alia, from charges due for services performed by the International Bureau. See Article 11 (2)(ii), CEWIPO. Under its 2016/2017 Program and Budget (P&B), as adopted by the Assemblies of the Member States on October 14, 2015, the main source of income for the Organization remains fee income from its international registration services, accounting for an estimated 94.5 per cent of all WIPO’s income. These international registration services include filings under the PCT, Madrid and The Hague Systems and are expected to further increase. Other sources of income for WIPO include contributions from Member States, as well as income from other revenue streams, such as the services provided by the Arbitration and Mediation Centre, as well as WIPO publications and interest income. These additional sources jointly account for the outstanding 5.5 percent of WIPO’s income. For a detailed summary of WIPO’s income, see WIPO “WIPO Program & Budget for the 2016/17 Biennium” online: WIPO <http://www.wipo.int/export/sites/www/about-wipo/en/budget/pdf/budget_2016_2017.pdf>, at 7 – 9 (paras 3 – 11). Indeed, WIPO relies heavily on the PCT. Despite the fact that 94.5 percent of WIPO’s income is from international registration services, a further breakdown reveals that approximately 76 percent of the entire revenue is generated by the PCT. WIPO “WIPO Program & Budget for the 2016/17 Biennium” online: WIPO <http://www.wipo.int/export/sites/www/about-wipo/en/budget/pdf/budget_2016_2017.pdf>, at 10 (para 12).

While this reference to WIPO as an affluent self-funding specialized agency, traceable to a physical location within the heart of Geneva is accurate, WIPO may also be described as the 188 WIPO Member States which have submitted instruments of ratification or accession to the Convention Establishing the World Intellectual Property Organization (CEWIPO). Indeed, these Member States constitute the Organization, and the study of their collaboration and cooperation in achieving the Organization’s objectives may be seen as the study of WIPO. As part of their collaborative efforts, Member States constantly engage to advance and develop norms in furtherance of their shared objectives. A discussion of WIPO’s engagement in norm-building exercises is therefore a reference to the work of the Member States that constitute WIPO. The history of the IP system, described earlier reflects the emergence of WIPO as traceable to the smaller offices (and their subsequent merger) which were established to administer the Berne and the Paris Conventions. Drawing also from the Eurocentric foundations upon which the early treaties were instituted, Okediji points to the geopolitical undertones that have underlined the expansion of WIPO to accommodate developing countries. Particularly, she notes that the perceived threat developing countries posed to the international framework established by the Paris and Berne Conventions, kept WIPO politically occupied with how to accommodate the concerns of those countries without disrupting the predominantly western European features of the system to which they objected. These tensions between a redefinition of IPRs, and a maintenance (and strengthening) of the status quo has played a major role in the institutional politics which has defined the pooling together of the 188 Member States under the umbrella of WIPO and must be brought to bear when considering WIPO’s efforts to develop a system of protection for TK, folklore, and GRs.

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1050 Pursuant to Article 5, CEWIPO, WIPOs membership is open to States which are members of the Unions or to any State which is a member of the United Nations, any of the specialized agencies of the UN, the International Atomic Energy Agency or is a party to the Statute of the International Court of Justice. The General Assembly could also invite a State to become a party to the Convention.

1051 WIPO upon creation was saddled with a range of normative as well as administrative functions within the area of IP governance. Normatively, it was for instance expected to encourage the conclusion of international agreements designed to promote the protection of IP, See Article 4(iv), CEWIPO, as well as promote the development of measures aimed at facilitating the efficient protection of IP through the world (Article 4(i) CEWIPO).

1052 Okediji, “When Should We Invent IPRs?”, supra note 366 at 17.
Third, located in the physical WIPO buildings is a professional support team of over 1000 international staff who, led by the Director-General, advance the core areas of the Organization’s work. These staff provide professional advice and execute the programs as directed by the Member States. As career professionals and support staff, these international civil servants are accountable to the Member States. They may, however, in some contexts be understood also as WIPO. The invitation of WIPO, for instance, to provide technical assistance, participate in a seminar, deliver a presentation, or yet offer professional comments on a piece of legislation, is an invitation of the professionals employed by WIPO to carry out the said task. My field study in the course of this research, significantly placed me within this characterization of WIPO. Working within the Traditional Knowledge Division, under the supervision of the Director of the Division, primary reflections reveal the central role which the Secretariat plays in advancing the normative efforts of the Member States. The Secretariat for instance, research and provide background secretariat documents for the negotiations, advise the Chairs of various committees within WIPO (including assisting the Chairs with the framing of the content of the discussions, where requested), support the coordinators of Regional Groups, and contribute significantly to awareness raising, education and promotional activities all around the world, particularly within developing countries. Restating the importance of this group, the administrative scope of WIPO’s functions revolves around program activities, international classification and standardization activities, and registration and filing activities which rely on the expertise of professionals.  

WIPO as an organization administers a total of 26 treaties – treaties which reflect the consensus of signatory Member States to specific normative prescriptions within the field of IP. These principles, norms, and rules embody the substantive expanse of IP law as we know it today. According to WIPO, these treaties can be classified along three main lines. First, those that establish international protection. In other words, treaties which are the source of legal protection agreed between countries at the international level. They define internationally agreed basic standards of IP protection. A total of 15 treaties fall into this category,

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1053 See generally Article 4, CEWIPO. Article 4(vii), CEWIPO, for example notes (with respect to registration and filing activities) that WIPO shall maintain services facilitating the international protection of IP as well as provide for registration where appropriate. See also WIPO, “Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967)”, online: WIPO <http://www.wipo.int/treaties/en/convention/summary_wipo_convention.html>.  

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including the Paris and Berne Conventions. Second, those that facilitate this international protection by ensuring that international registrations and/or filings have effect in all signatory states. They are known as the global protection system treaties and serve to simplify and reduce the cost of making individual applications and or filings in every country within which IP protection is sought. A total of six treaties fall into this category. Finally, the third category involves those treaties which establish classification systems that organize information regarding inventions, trademarks, and industrial designs into manageable structures for easy retrieval. Four treaties are classed within this category. For several of the treaties, Committees within WIPO exist to constantly review and update the laws, as needed and in line with present realities. WIPO has also continued to serve in this context as a platform for the negotiation of new international rules on IP. The negotiation of an international legal instrument for the effective protection of TK is currently being pursued in this context. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) is the forum within which these negotiations are taking place.

6.2.1 An Introduction to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore


The treaties included within this classification are, Locarno Agreement Establishing an International Classification for International Designs (1968), Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks (1957), Strasbourg Agreement Concerning the International Patent Classification (1971), and the Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks (1973). Ibid.
The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources,Traditional Knowledge and Folklore (IGC) is the first and only multilateral policy forum within WIPO (and indeed the international IP framework) established to facilitate the policy-based examination of the relationship between IP, and the protection of GRs, TK, and TCEs. The Committee was established in October 2000 by the WIPO General Assembly (GA).\textsuperscript{1057} The IGC was established as a policy forum within WIPO – a policy forum which would enable Member States to discuss IP issues arising within the context of access to GRs and benefit sharing, as well as to discuss, from an IP perspective, the protection of TK, whether or not associated with GRs, and, finally, the protection of TCEs.\textsuperscript{1058} This was based on an understanding, by Member States, that the emergence of modern biotechnologies had offered increased economic, scientific and commercial value to GRs and TK\textsubscript{a}GRs amongst a wide range of stakeholders.\textsuperscript{1059}

Even though it was recognized, at the inception of the IGC, that the issues of conservation, management, sustainable use, and equitable benefit sharing arising from access to, and use of GRs and TK\textsubscript{a}GRs, had been addressed in several other policy areas,\textsuperscript{1060} WIPO recognized that within all these areas, IP issues had arisen and were assuming increasing importance.\textsuperscript{1061} Due to the complexity of the issues as well as varying national interests within the IGC, amongst others, the work of the IGC has stalled severally over the period of its existence.\textsuperscript{1062}

\begin{footnotesize}
\begin{enumerate}
\item This was at the 26\textsuperscript{th} (12\textsuperscript{th} Extraordinary) Session of the General Assembly, October, 2000. For the full text of the proposal, see WIPO Document 26/6, \textit{supra} note 90. For the GA Decision adopting the proposal, see WIPO Document 26/10, \textit{supra} note 90 at par. 71.
\item See Paras 13 – 15, WIPO Document 26/6, \textit{supra} note 90. The rationales for the establishment of the IGC are varied. Three main justifications have, however, been put forward by WIPO: first, it was established to address the themes of GRs, TK and TCEs which were simultaneously regarded as the ‘common heritage of humanity’ and as intellectual valuables which required an appropriate form of IP protection; second, GRs, TK and TCEs were seen as the intellectual assets of new key players in IP policy-making (developing countries and indigenous and local communities); third, it was conceived as part of a larger and structured endeavour by WIPO to move towards a modern, responsive IP system that could embrace non-Western forms of creativity and innovation, be comprehensive in terms of beneficiaries, and be fully consistent with developmental and environmental goals. See WIPO Background Brief 2, \textit{supra} note 91 at 2.
\item See WIPO Document 26/6, \textit{supra} note 90, par. 1
\item Some of these areas include food and agriculture, biological diversity, biotechnology innovation and regulation, human rights, cultural policies and trade and economic development. See WIPO Document 26/6, \textit{supra} note 90, par. 2.
\item Ibid. For a detailed history of the emergence of the IGC, including the historical development of discussions relating to GRs, TK and TCEs within WIPO, see generally WIPO Document 26/6, \textit{supra} note 90 paras. 27 – 71. See also WIPO Background Brief 2, \textit{supra} note 91.
\item Dutfield & Suthersanen. \textit{Global Intellectual Property Law, supra} note 278 at 342 – 43.
\end{enumerate}
\end{footnotesize}
Usually, and rightly so, the work of the IGC, like most of WIPO’s work, is situated within the ongoing expansionist drive of the IP regime. In this context, though several forms of classifications exist for IP forms, the creation of new IP categories aligns with an evolutionary approach to IP classification which offers a useful basis for understanding the work of the IGC. Through this approach, patents, copyright and trademarks are generally considered to represent the bastions of IP, with other forms constituting derivatives and/or mere reflections of the modern evolution of the IP system.1063 This underscores the non-static nature of the IP system and the fact that it exists in a constant state of reconsideration and development. WIPO, in the discharge of its role, has served as the platform for the development of new rights and/or revision of old ones in keeping with novel challenges. Cornish describes the mechanism for the evolution of the IP system. As he explains,

[i]ntellectual property may be extended to new subject matter either by accretion or by emulation. Accretion involves re-defining an existing right so as to encompass the novel material; emulation requires the creation of a new and distinct right by analogy drawn more or less eclectically from the types already known.1064

A lot of the recent normative work within the field of IP has been based on accretion. For example, the recent adoptions of the Beijing Treaty on Audiovisual Performances,1065 as well as the Marrakech Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled,1066 offer interesting examples of accretion. Through these treaties, new rights which accord with

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1063 Ibid. at 14, noting that IP is hardly a static conception, but is in a state of constant evolution and reconsideration.
1065 Adopted by the Diplomatic Conference on the Protection of Audiovisual Performances, which took place in Beijing from June 20 – 26, 2012, the Beijing Treaty on Audiovisual Performances significantly addressed a long standing lacuna with respect to performers in audiovisual performances by granting them economic rights (right of reproduction, right of distribution, right of rental and right of making available) and moral rights (the right to claim to be identified as the performer, and the right to object to any distortion, mutilation or other medication that would be prejudicial to the performer’s reputation) over their performances both in fixed and unfixed performances (performers are granted rights of broadcasting, right of communication to the public, and the right of fixation on unfixed works).
1066 Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled, 2013 online: WIPO <http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=301019>. Adopted on June 27, 2013, by the Diplomatic Conference to Conclude a Treaty to Facilitate Access to Published Works by Visually Impaired Persons and Persons with Print Disabilities which took place in Marrakesh, Morocco from June 17 to 28, 2013. The Treaty has the main goal of creating a set of mandatory limitations and exceptions for the benefit of the blind, visually impaired and otherwise print disabled by requiring Parties to introduce a standard set of limitations and exceptions to copyright rules in order to permit reproduction, distribution and making available of published works in formats designed to be accessible to the above described beneficiaries and to permit the exchange of these works across borders by organizations that serve these beneficiaries. See WIPO, Summary of the Marrakesh Treaty to Facilitate Access to Published Works for Persons
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expansions as well as exceptions have been made to the existing field of copyright law; in other words, aspects of the existing rights in the field of copyright law have been redefined on the basis of these new treaties. Through emulation, however, new rights are created. An example was the negotiation of the Treaty on Intellectual Property in Respect of Integrated Circuits, which establishes a new form of IP protection for layout-designs (topographies). This Treaty significantly provides that protection for this new IP right could be effected through a sui generis law on layout designs, or through an adaptation of existing IP laws, such as copyright, patents, utility models, industrial designs, unfair competition or any other law or through a combination of any of these laws. This aspect of norm creation – emulation – is thus also important for understanding the creation of sui generis forms of protection. Given that the WIPO IGC is focused on the development of a sui generis system of protection for TK – one which addresses the protection of TK and the needs of its holders – new beneficiaries (indigenous peoples), the IGC may be seen as an international IP project focused on expanding the frontiers of the IP regime through a process of emulation.

My intention in this analysis of the IGC below, however, in keeping with my central argument, is to consider the work of the IGC within the context of the expansionist drive of the access and benefit sharing (ABS) system. In other words, rather than considering the IGC through the lens purely of an IP-driven enterprise, the IGC may be considered as a process being driven by third-world actors for the purpose of complementing an evolving ABS regime-complex being designed for the effective protection of TKaGRs from the incidence of biopiracy. The evolution of the IGC, including the discussion of TK and GRs within WIPO below supports this thinking and seeks to advance this thesis.

6.2.2 How Did the WIPO Intergovernmental Committee Come About?
Tracing the history of the IGC is important in appreciating its current work, including the present challenges facing its operations today. I will provide a brief history of the discussion of TK and GRs within WIPO as these provide the direct basis establishing the need for the IGC.

6.2.2.1 Early Associations and an initial Learning Curve

WIPO’s initial foray into the area of TK discourse, is traceable to a series of Roundtables organized within the 1998 – 1999 biennium under the leadership of the then Director General of WIPO, Mr. Kamil Idris.\footnote{1070} The first of these Roundtables, held in July 1998,\footnote{1071} significantly initiated a dialogue between WIPO Member States and indigenous peoples regarding the protection of human creativity and ingenuity.\footnote{1072} The Roundtable was organized for the purpose of sharing information and experiences on the protection of the TK of indigenous peoples. It importantly afforded Member States an opportunity to learn from the experiences of indigenous peoples and understand their aspirations with respect to the protection of TK through IP. It is worth noting that, from an internal WIPO Secretariat perspective, the Roundtable was organized by the Global Intellectual Property Issues Division – a new Division within WIPO at the time, set up, amongst other reasons, to explore and investigate the needs and expectations of potential new beneficiaries of IP.\footnote{1073} The July Roundtable was an indication of the recognition of the primacy of indigenous peoples as a first group of potential new beneficiaries of IP protection.

\footnote{1070} In making this temporal assertion, I am aware of the earlier references to TK within the context of the 1967 debates over the Stockholm Act to the Berne Convention where Member States of WIPO failed to achieve consensus on protection of folklore, particularly expressed as works of unknown authorship under the international copyright law. See Okediji, “When Should We Invent IPRs?”, supra note 366 at 15. However, this consideration of TK (to include traditional cultural expressions (or folklore) has been excluded from the scope of this thesis. Consequently, in focusing on the aspects of WIPO’s work which directly relate with the problem of biopiracy being articulated in the thesis, the 1998/199 biennium provides the first instances of WIPO’s foray into the field of TK. For a full description of the objectives of WIPOs work within the 1998/199 biennium as well as the expected results defined by the Organization, see “Main Program 11: Global Intellectual Property Issues”, in WIPO Program & Budget 1998/1999, February 9, 1998, A/32/2; WO/BC/18/2, [Program 11: Global IP Issues] at 105 – 113. Also available online: WIPO <http://www.wipo.int/edocs/mdocs/govbody/en/a_32/a_32_2_wo_bc_18_2-programme11.pdf>.


\footnote{1072} Ibid. at 2.

A second Roundtable was organized in November 1999. This second Roundtable broadened the discussion with a focus on the diversities in TK and in the diversities amongst the holders of TK. At this second Roundtable, the then Deputy Director General, Mr. Shozo Uemura, clearly reiterated the learning objective of WIPO’s initial efforts in the area of TK:

From the beginning of WIPO’s work in this field […] our approach to the subject of traditional knowledge has been to learn. We have sought to learn about the needs and expectations of holders of traditional knowledge in regard to the intellectual property system. We have attempted to learn about how traditional knowledge is conserved, used, and transmitted according to customary law. We have sought to learn the views and approaches of our Member States, particularly officials from the intellectual property administrations, concerning the protection of traditional knowledge. We have also learned from the work of our sister UN organizations who are active in this field within their respective areas of competence. In seeking to learn about traditional knowledge, we have had a single, clear objective: to identify ways that WIPO, in furtherance of its mandate as the UN specialized agency for intellectual property, may promote the protection of tradition based creativity and innovation throughout the world.

These Roundtables were organized, pursuant to the 1998/1999 Program and Budget, at a time in which WIPO considered the universality of IP a challenge worth looking into. This was with the aim of making the IP system more inclusive to hitherto excluded groups – a primary focus of which was indigenous peoples.
The interest of WIPO in the subject of TK aligned with the impending entry into force of the provision of the TRIPS for developing countries\textsuperscript{1079} as well as the proposal for the introduction of a discussion on TK within the controversial Seattle WTO Ministerial Conference.\textsuperscript{1080} It emerged in an era which followed from the CBD’s formal codification of an action plan regarding the protection of TK in 1992,\textsuperscript{1081} and the WTO’s assertion of itself as a competing organization through the codification of WIPO’s core treaties within the international trading system in 1994.\textsuperscript{1082} Following on from these major developments, as well as the involvement of several other agencies in IP discussions, the relevance of WIPO had come under huge scrutiny. WIPO’s incursion into the field of TK, must be understood in the context of WIPO’s efforts to extend its role and relevance within the field of IP.\textsuperscript{1083}

A perusal of the initial approach undertaken by WIPO in this quest, reveals the learning curve taken to understand the expanse of issues to be covered within this new area of endeavor. In addition to the Roundtables, resources were also channeled at extensive fact-finding missions as well as a feasibility study on the establishment of TK databases.\textsuperscript{1084} A total of nine fact finding missions were conducted to regions

\textsuperscript{1079} See, Article 65 (1) & (2), TRIPS Agreement, which granted developing countries a 5 year transition time from the date the WTO Agreement became effective. It was therefore expected to enter into force on January 1, 2000 for developing countries, given that the WTO Agreement entered into force on January 1, 1995.


\textsuperscript{1081} Okediji, “When Should We Invent IPRs?”, \textit{supra} note 366 at 13, noting of the emergence of the CBD that, “the CBD translated a historical fascination with the cultural objects of societies that were largely invisible in the discourse on global innovation, into a concrete action plan”.

\textsuperscript{1082} See, generally 6.1.2.6 above.


\textsuperscript{1084} Mr. Roberto Castelo, the Deputy Director General of WIPO, speaking at the opening of the first Roundtable on July 23, 1998, contextualized the Roundtable within the frame of the broad foundational work envisaged when he noted:

\begin{quote}
The Roundtable is only one of the activities related to new beneficiaries which will be undertaken in the 1998-99 biennium. Other activities include a series of fact-finding
\end{quote}
around the world with the purpose of documenting and assessing firsthand the IP needs and expectations of TK holders. The summaries and results were contained in a monograph which continues to retain central significance within discussions on TK today. This empirical research by WIPO, in the form of a fact finding mission, significantly filled an important subject matter, leadership, structural, and IP gap which had existed within the international discourse relating to the protection of TK, and provided a critical justification for WIPO’s assumption of prime responsibility in addressing this issue.

The subject of Genetic Resources (GRs) was also formally introduced to WIPO’s discussions in the 1998/1999 biennium and was pursued pursuant to its program and budget (P&B) for the period. This is important as, unlike TK, GRs as they exist in nature cannot be considered to be IP. While a valid justification may therefore be made for TK being IP, GRs do not fit within that spectrum and the justification for WIPO’s interest needed to be well defined, especially where the relevant forum for addressing the regulation of GRs (CBD) had only been in existence for about five years. Indeed, WIPO has been very clear about its lack of jurisdiction in questions relating to the protection of GRs, noting instead the CBD as the appropriate forum for questions on the protection of GRs. What then is the rationale underlying the introduction of GRs into WIPO?

See Roundtable Program, supra note 1012 at 2.

For a full report of the fact finding missions, see WIPO, Fact Finding Missions, supra note 216.

Okediji, “When Should We Invent IPRs?”, supra note 366 at 19 – 20, noting that with no internal analysis of its own to rely on, WIPO required a carefully-defined and well-defined basis for taking on the issue of TK and then for determining whether and how to incorporate it within WIPO’s official mandate. Ibid. at 20.

See Program 11: Global IP Issues, supra note 1009 at 109.

GRs are, for instance, not the product of the human intellect and as such cannot be considered to be creations of the mind in accordance with the traditional definition of IP.

In the lead to the Twenty-Third and the Twenty-Sixth sessions of the IGC, for instance, which dealt with the theme of GRs, the Chair of the IGC for the 2012/2013 and 2014/2015 biennia, Ambassador Wayne McCook of Jamaica issued an informal issues paper on GRs which, though not a working paper for the session, offered a summary of the key issues that members needed to focus on for the purpose of solution-seeking negotiations within the IGC. The Chair notes that:

The relevant international frameworks for regulating access to and benefit-sharing in GRs are the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol), as well as the International Treaty on Genetic Resources for Food and Agriculture (ITPGRFA) of the United Nations Food and Agriculture Organization […]. GRs can be differentiated from the two other subjects being dealt with by the IGC: traditional knowledge (TK) and
The core objective underlying its initial discussion of GRs was twofold. First, WIPO sought to examine the role of IP in the preservation, conservation, and dissemination of global biodiversity. Second, WIPO’s interest was directed at examining the potential of new technologies in the management of IP for the documentation, conservation, and dissemination of biodiversity. In other words, WIPO’s early interest in biodiversity was limited to biotechnology, the transfer of technology arising from such technologies, and the role of the IP system in preserving, conserving, and spreading biodiversity. WIPO was therefore backing the objectives of the CBD by focusing on the role of IP in the attainment of its objectives. Importantly, this points to the beginning of an attempted policy cooperation between WIPO and the CBD in matters relating to the protection of biodiversity and innovation; one that continues to define even the present discussion of the Nagoya Protocol.

Again here, it must be flagged, the issue of WIPO’s attempt to expand its institutional relevance is clearly seen. WIPO’s concerns over GRs were based on its interest in asserting its relevance within the field of biodiversity management, without actually taking over the responsibility of biodiversity protection. This is important, as it highlights that WIPO, in engaging with the discussion of GRs, was merging its stakes with the CBD and as such, a textured understanding of WIPO’s work in this area must be considered against the backdrop of existing and emerging developments in the field of biodiversity management. This calls into sharp focus the discussions I have made, both in chapters three and five, relating to biodiversity and the emergence of regulatory frameworks for its management, including the Nagoya Protocol. These regulatory frameworks significantly define and lead WIPO’s work in this area. Moreover, it further supports an argument that has been made so far in this work; the WIPO discussions are being advanced to address core IP concerns which the Nagoya Protocol is unable to address. In perspective therefore, while the Nagoya Protocol has taken the lead in defining a protection strategy for TKaGRs that is based on ABS, and is located within the context of the conservation and sustainable use of biodiversity, the examination by the

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traditional cultural expressions (TCEs). TK and TCEs, which are developed by the human mind, can be considered “intellectual property” suitable for direct protection by an intellectual property (IP) instrument. By contrast, GRs as such are not produced by the human mind and the IP issues that they raise are distinct.


See Program 11: Global IP Issues, supra note 1009 at 109.
WIPO IGC of the role of IP in achieving these broader objectives, places its discussions within a complementary frame to the Protocol; one which justifies a consideration of the IGC as a fundamental part of the ABS regime. It is concerned with the IP implications, however.

Ever since the entry into force of the CBD in 1993, the role of IP in the conservation, use, and sharing of benefits arising from the use of GRs, has taken on an even greater importance. Reciprocating this interest, as well as signifying an acknowledgement of the importance of WIPO and its programs relating to biodiversity and IP, the Conference of the Parties (COP) to the CBD welcomed the developments. The COP requested the Executive Secretary of the CBD to apply for observer status in WIPO to ensure the representation of the CBD at all of such biodiversity related meetings within WIPO.1091 A direct consequence of this decision of the COP was WIPO’s first major project with respect to GRs. This was contained in a study, commissioned jointly with the United Nations Environment Program (UNEP), on the role of IPRs in the sharing of benefits arising from the use of biological resources and associated TK.1092 The study was commissioned in 1998 and published later in 2004. Within this timeframe, however, a series of events had already led to the formation of the WIPO IGC.

6.2.2.2 The Developing Country Request

In 1999, at the Third Session of the Standing Committee on the Law of Patents (SCP),1093 discussions continued among member states on a proposed Patent Law Treaty (PLT). The SCP had actually only been established in 1998 as a forum created to discuss issues, facilitate coordination and provide guidance concerning the progressive international development of patent law.1094 Its first major project, the

1092 See, Gupta, WIPO-UNEP Study, supra note 550. The study, prepared by Professor Anil Gupta of the Indian Institute of Management, utilized some case studies to explore and identify the role of IPRs in the sharing of benefits arising from the utilization of biological resources and associated TK. He specifically concluded on the need for a stronger IP regime which would support the rights of indigenous peoples and local communities in the preservation of their knowledge. Interestingly, he viewed the possibility of a strengthened IP regime as one which could offer incentives to augment and nurture the innovation inherent within local communities. Ibid. at 163.
1093 This Third Session took place in Geneva, from September 6 – 14, 1999. All the documents of the session, including proposals and the session’s report, are available online, WIPO: <http://www.wipo.int/meetings/en/details.jsp?meeting_id=3824>.
PLT being negotiated, was aimed at streamlining administrative requirements for patent applicants, thus facilitating the cross-border acquisition of patents. It was intended to harmonize certain patent procedures while steering clear of matters relating to substantive patent law. This third session was significantly the final meeting planned before the proposed Diplomatic Conference for the adoption of the Patent Law Treaty (PLT). Generally, at this stage within WIPO treaty negotiations, the fine lines on most of the issues are more or less settled. Though differences in positions may still remain, proceeding to the diplomatic conference is generally construed as an indication that there is sufficient political will to see through the finalization of the treaty. Also, within WIPO, diplomatic conferences are generally associated with the adoption of a binding treaty. It therefore represents a sensitive period within the negotiations, especially where hints of opposition to the conclusion of the proposed treaty are observed.

Enter the Delegation of Colombia. Representing Latin American countries, and based on an initiative of the Andean Community, the Delegation had sought the consideration of procedural and formal aspects of the protection of biological and genetic heritage which would ensure that elements of heritage, including GRS, were acquired legally whenever utilized in the acquisition of patents. According to the proposal,

> [a]ll industrial property protection shall guarantee the protection of the country’s biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired legally.

Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products

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1095 Okediji, “When Should We Invent IPRs?”, supra note 366 at 23.
1098 Several countries hold on to differing positions up till the diplomatic conferences for various reasons. One key reason is that it affords them leverage at the late state of the negotiations to secure deals within other areas of interest, or secure more favourable terms within the negotiation.
1099 See, for instance, the intervention by the Delegation of Sweden, noting “WIPO diplomatic conferences [were] used to adopt binding instruments”. 305
thereof, of which one of the member countries is the country of origin [numbering omitted].

In effect, this proposal was seeking a form of disclosure mechanism within the patent system which ensured that IP rights were granted over inventions which made use of GRs, only where such GRs had been acquired legally. While this proposal would not prevent the misappropriation of GRs, it could prevent the IP system from being used a vehicle for misappropriation. In fact, it sought to redefine a role for the IP system – one which would ensure compliance of inventors who make use of GRs, with domestic and international laws governing access. Based on the biopiracy analysis in chapter four, this was a clear effort by the Delegation of Colombia to address the IP problem of biopiracy.

This proposal, coming at a time of advanced negotiations on the draft text of the PLT, was met with significant resistance from major developed countries, even though it received broad support from developing countries. This significantly delayed the negotiations, as developing countries were insistent on their positions and concerns being addressed within the PLT. The WIPO Secretariat was interested in the success of the PLT, as were developed countries. To ensure the success of the PLT, a two-pronged political compromise, which would lay the foundation of the future IGC, was thereafter agreed. According to this compromise, the International Bureau would

[… include on the agenda of the Working Group on Biotechnological Inventions, to be convened at WIPO in November, 1999, the issue of protection of biological and genetic resources. The SCP further invites the International Bureau to take steps to convene a separate meeting involving a larger number of Member States early in 2000, to consider that issue.

1101 The proposal received support from the Delegations of Bolivia, Paraguay, China, Namibia, Cameroon, Mexico, South Africa, Chile, Cuba, India, Kenya, Costa Rica and Barbados, while the Delegations of Germany, United States of America, Republic of Korea, Japan, Finland (speaking on behalf of the European Community and its Member States), Romania and France stood firmly against the proposal on the grounds that it related to issues of substantive law which were inappropriate for inclusion in the draft Treaty. See, Standing Committee on the Law of Patents, Draft Report: Prepared by the International Bureau, WIPO SCPOR, 3d Sess, SCP/3/11 Prov (1999) [SCP 3, Report of the Session] (para 205) at 30.
1102 Okeji, “When Should We Invent IPRs?”, supra note 366 at 23, notes that this delay was significant for several reasons. First, developed countries had a direct vested interest in facilitating the cross-border acquisition of patents. Second, the WIPO Secretariat had an interest the PLT for two key reasons: to secure the Standing Committee on Patent’s future vitality (given its tenderness of years), and to ease the administration of patents which could create opportunities for more revenue for patent filings.
Despite what may be characterized as a negative outcome for developing countries,\textsuperscript{1104} the Colombian proposal remains significant for several reasons. Three are highlighted here. First, it initiated the first known formal discussion in WIPO on the interrelationship between GRs and the working of the patent system. Second, it shows that right from the inception of these discussions within WIPO, developed countries have not been so comfortable with the idea of new rights for TK and GRs being discussed on the IP platform of WIPO. In fact, they have sought to keep the issues of the protection of GRs separate from the patent system on the ground that this constitutes a substantive issue which is best served/addressed in a separate and designated forum. This also lays a basis for the view from several commentators who identify the initial move of the discussions from the SCP to a new venue as an effort to isolate the discussion and locate same within a futile ‘talk shop’ in WIPO – one that would serve the political need for a consideration of TK and GRs, yet would be of no, or at least, minimal consequential effect.\textsuperscript{1105} Third, it highlights the fact that the central concern of addressing the problem of biopiracy (as facilitated through the patent system), provided the very basis underlying the existence of the IGC. In effect, the prevention of the IP system from being used as a vehicle of misappropriation for the GRs and TKaGRs, as well as the use of the IP system as a mechanism for ensuring compliance with ABS laws, defined the initial tensions, and continues to define the difficult discussions within WIPO’s IGC to date.

\textbf{6.2.2.3 The Secretariat Response}

\textsuperscript{1104} Dutfield considers that despite the seemingly negative outcome, the proposal did not fail, as it remains the unintended source of the eventual WIPO IGC. See Graham Dutfield, \textit{Intellectual Property, Biogenetic Resources and Traditional knowledge} (UK: Earthscan, 2004).

\textsuperscript{1105} See, Graham Dutfield, \textit{Intellectual Property, Biogenetic Resources & Traditional Knowledge} (UK: Earthscan, 2004), noting that “American support for the new mandate [establishing the Global Intellectual Property Issues Division] was secured in return for the concession that [it] was not ‘on a norm setting track’; that is to say that its work is not intended to feed into a process which would end with the creation of a treaty or recommendations”. See also, Stefan Groth, \textit{Negotiating Tradition: The Pragmatics of International Deliberations on Cultural Property} (Gottingen: Universitatsverlag Gottingen, 2012) at 41.
Pursuant to the first element of the SCPs decision, the Working Group on Biotechnology took up the discussion as requested, and included a minor reference on its agenda to the proposed discussion on GRs within one of its five core categories viz

...the nature of the relationship between patent systems and certain issues, including the moral or ethical dimensions of commercialization of inventions involving genetic alteration of plants or animals, the conservation and preservation of the environment (including the protection of biological diversity) and the protection of animal and human health (including such issues as biosafety, food security and sustainable development).

For the Group, the best approach to the consideration of GRs was through an initial study which would address a summary of characteristics of existing IPRs relevant to the protection of TK, a survey of issues related to the use of IPRs and contractual terms within collaborative agreements related to R&D of naturally occurring biological resources and, a survey of legal systems and regulatory or other practices that exist in WIPO Member States which govern the collection and use of biological resources.

With respect to the second element of the SCP decision, a framework for the formalization of a forum for the discussion of GRs and TK related issues was laid. A meeting on IP and GRs was held in April 2000 with a clear consensus to the effect that WIPO should facilitate the continuation of consultations of Member States in coordination with the other concerned international organizations, through the conduct of appropriate legal and technical studies and through the setting up of an appropriate forum within WIPO for future work.

Arising from this consensus recommendation, a series of consultations were held by Dr. Kamil Idris, the Director General, with Member States regarding possible formalities on addressing GRs within...
the context of WIPO. These consultations affirmed the need for a discussion on GRs to continue within WIPO and left the working out of formalities to the discretion of the Director General, in consultation with WIPO Member States.\textsuperscript{1110} It is worth noting that these consultations took place during the Diplomatic Conference for the Adoption of the Patent Law Treaty (PLT)\textsuperscript{1111} and the outcome bears every semblance to another political compromise which guaranteed to developed countries the successful adoption of the PLT, while yet securing a commitment in favor of developing countries, for the establishment of the IGC. Reference to this political commitment has been made in several preparatory documents for the IGC.\textsuperscript{1112} The consultations by Member States continued after the Diplomatic Conference for the purpose of clarifying the possible format and content of such discussions to be undertaken in the proposed forum. It was in the context of these discussions that the idea of a Committee, as an appropriate forum, beyond a workshop or a Roundtable, was floated – one that would provide an avenue for the discussion of issues related to GRs, TK and folklore [hereinafter traditional cultural expressions (TCEs)]. From the forgoing, therefore, the prevention of the continued facilitation of biopiracy through the patent system informed the very need and underlying rationale for the IGC.

A final point regarding the emergence of the IGC to be made here relates to the role of the Director-General in brokering this compromise. As noted above, the political compromise which was foundational to the IGC’s formation left wide discretion to the Director-General to fashion out the mode in which the conversations within WIPO would continue. At the time of these early exchanges, a new Director-General had recently been appointed in 1997. Mr. Kamil Idris, a Sudanese national, was the first (and remains the only) African to hold the office of the WIPO Director-General. His tenure was marked with political and

\textsuperscript{1110} “Member State discussions concerning genetic resources will continue at WIPO. The format of such discussions will be left to the Director General’s discretion, in consultation with WIPO Member States.” WIPO Document 26/6, \textit{supra} note 90, at para 9.

\textsuperscript{1111} This Diplomatic Conference for the Adoption of the Patent Law Treaty took place from May 11 to June 2, 2000.

\textsuperscript{1112} See, in support of this, the statement of the Delegation of the Dominican Republic, speaking on behalf of the Group of Latin American and Caribbean States (GRULAC), noting that the successful establishment of the IGC stemmed from a major political commitment made at the Diplomatic Conference which adopted the Patent Law Treaty, WIPO Document 26/10, \textit{supra} note 90 at para 30. See also, para 13, WIPO Document 26/6, \textit{supra} note 90, noting the commitment reached in the context of the Diplomatic Conference for the Adoption of the Patent Law Treaty as a major reason underlying the justification for the establishment of the Committee. Furthermore, see \textit{Proposals by the Delegations of the Dominican Republic & Brazil Concerning Articles 2, 13 & 14 of the Draft Substantive Patent Law Treaty: Document Prepared by the International Bureau}, WIPO SCPOR, 8\textsuperscript{th} Sess, SCP/8/5, 2002, at para 8, suggesting that the removal of the issue of GRs from the PLT was a package deal which involved the establishment of a forum for discussing issues related to GRs.
administrative controversies, some of which stemmed from his vision of a democratic IP system which was more representative to all.\textsuperscript{1113} In fact, it is worth reiterating that the roundtables referenced above, in which WIPO for the first time engaged in formal discussions with indigenous peoples regarding the protection of TK, were conceived by him.\textsuperscript{1114} While his approach to IP governance made him widely regarded among developing countries,\textsuperscript{1115} several of his initiatives were generally perceived by developed countries as a threat to their established interests in the \textit{status quo}, if not hegemony, of the IP system. The IGC was one of such threats. While the Director General cannot singlehandedly establish a Committee of this magnitude, he is afforded significant discretion in driving the direction of the Organization. It is fair to say, that without a Director General sympathetic to indigenous peoples and developing country interests within the IP system, the IGC may never have materialized at the time it did.

\subsection*{6.2.3 Surviving through the Odds}

Since its inception, the IGC’s existence has been marked with a constant battle for survival. To appreciate the difficulties in the continued existence of the Committee, it is worth noting first that the IGC does not constitute a Standing Committee within WIPO. Consequently, unlike the various other Standing Committees within WIPO which exist in perpetuity to monitor and review established areas of global IP policy, the IGC, as a specialized Committee within WIPO, has its continued existence tied to the successful renegotiation of specific biannual mandates. While this approach has its benefits, including a consistent

\begin{itemize}
\item \textsuperscript{1113}According to Mr. Roberto Castelo, the Deputy Director General, speaking at the first Roundtable on Intellectual Property and Indigenous Peoples, “[i]t is the view of Dr. Idris, the Director General, that the international intellectual property system must be democratic if it is to survive, that the system’s benefits must be available to all.” See, \textit{WIPO Roundtable on Intellectual Property & Indigenous Peoples: Geneva, July 23 & 24, 1998, Opening Address by Mr. Roberto Castelo Deputy Director General, WIPO [Roundtable 1 Opening DDG Remarks]} at 2,
\item \textsuperscript{1114}Ibid. at 2, noting, of the first Roundtable, “[t]he Roundtable is part of a new program at WIPO, which will be carried out primarily by the \textit{Global Intellectual Property Issues Division}. Conceived by Dr. Idris and approved by the Member States of WIPO only in March of this year, the Division has as part of its duties the exploration and investigation of the needs and expectations of potential \textit{new beneficiaries} of intellectual property
\item \textsuperscript{1115}See, for instance, William New, “Developed Countries Seek Clarification of Idris’ Alleged Age Discrepancy” (15 June, 2007) \textit{Intellectual Property Watch}. Online: IP Watch < http://www.ip-watch.org/2007/05/15/developed-countries-seek-clarification-of-idris-alleged-age-discrepancy/> noting the support of the African Group to the Director General even at the height of controversies regarding his age which eventually led to his resignation. The Group, in a letter sent to the DG, noted that it considered the allegations to be ‘a smear campaign […] aimed at impeding the effective performance of the duties’ for which he had been elected, and rather encouraged him to pursue his ‘excellent work without being distracted by it in any way’.
\end{itemize}
periodic stock taking and review of the agenda for its negotiations, the negotiation of the IGC mandate highlights the controversial and divisive nature of the Committee’s negotiations. Furthermore, it reveals a lack of shared understandings and clarity amongst major stakeholders regarding the objectives of the negotiations, deep mistrust in some instances, and generally a wide gap between the expectations and interests of developed and developing countries within the Committee. Importantly, it has had a major impact on the substantive negotiations within the Committee. These concerns, including concerns about whether a non-standing committee is able to develop norms, has led, *inter alia*, to a developing country-led call for the conversion of the IGC into a Standing Committee. From a process perspective, the consistent renegotiation of the mandate and work programs for the Committee has tended to have a disruptive effect on the smooth progress of the Committee’s negotiations, especially around the times in which the mandate renewals arise. The negotiation of the 2014 – 2015 mandate offers an excellent example of the negative impact of the mandate renewals on the progress of the Committee.

The 25th session of the IGC took place from July 15 – 24, 2013. It was the final session marking the end of the mandate for the 2012 – 2013 biennium. Member States had agreed to an eight-day session which would incorporate five days for a thematic discussion on traditional cultural expressions (TCEs) and the remaining three days for the Committee to ‘review and take stock of the text(s) of the international legal instrument(s) ensuring the effective protection of TCEs, TK, and GRs, and to make a recommendation to the General Assembly’. It was however unclear how this stock taking was to be structured; what did it mean? Was it to take an approach of reviewing the various texts individually? Was it to involve the

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1116 See, for instance, the African Group proposal to the 2015 WIPO General Assembly. Noting the weight of distraction which the constant renewal of mandates has posed to the substantive discussions within the Committee, the Group submitted a proposal requesting the General Assembly to convert the IGC into a Standing Committee – Standing Committee on Intellectual Property and Genetic Resources, Traditional knowledge and Traditional Cultural Expressions (SCTK). The full proposal, including the rationale for the proposal, is contained in WIPO General Assembly, *Conversion of WIPO Intergovernmental Committee on Intellectual Property & Genetic Resources, Traditional Knowledge & Folklore (IGC) into a Standing Committee: Proposal by the African Group to the 2015 General Assembly: Document Prepared by the Secretariat*, WIPOGAOR, 47th (22nd Ordinary) Sess, WO/GA/47/16 (2015). See also the present mandate of the Committee, in WIPO General Assembly, *Report: Adopted by the General Assembly*, 47th (22nd Ordinary) Sess, WO/GA/47/19 (2015), at para 289 (g). Also, see Okediji, “When Should We Invent IPRs?”, supra note 366 at 25, noting that WIPO’s norm-setting processes take place only through permanent standing committees.
renegotiation of the texts of the GRs and TK negotiations which had already been concluded in February and April respectively? Was it to assess and declare how much progress had been made?

Despite the seeming progress that had characterized the earlier thematic sessions in the year, the lack of clarity regarding the stock taking element of the session, led to the 25th session being characterized by a general sense of non-cooperation. Developing countries sought to highlight the ‘amazing’ progress over the biennium in advancing the texts. For these deman-deurs, the negotiating texts were mature and the negotiations were ripe for a Diplomatic Conference for the adoption of a binding normative outcome. Their expectations were however met with frustration stemming from a seeming lack of shared interest by several developed countries. Developed countries were eager to demonstrate that the texts were nowhere near a stage for adoption. This affected the entire course of the negotiations, leading to tempers, threats of walk outs, and feelings of angst within sectors of the WIPO Secretariat. It seemed as though the hard work over the biennium was crumbling. In truth, many developed countries voiced their preferences for soft outcomes, such as Declarations, or Recommendations on the protection of TK and constantly referenced the need for more time, through proposals such as studies, clarification from capitals etc. A major root cause for this frustration was the wording of the 2012-2013 mandate (and, indeed, most of the IGC’s mandates), which had deliberately been couched in sufficient ambiguity to allow for the continuation of the negotiations, with varying interests holding on and building expectations around their respective interpretations of a mandate worded in such a way as to be subject to a variety of interpretations. The Chair concluded the night session, which was required to finalize the IGC 25, describing the Committee session as an ‘unusual session’,\(^{1117}\) with the African Group noting that the session ‘had been a difficult week for everyone’.\(^{1118}\) Not only were the substantive negotiations affected, the mood and cooperative spirit that had defined the negotiations earlier in the year had been replaced with a sense of distrust and frustration by the close of the 25th Session.


\(^{1118}\) Ibid. at Para 430.
The negotiation of the mandate thus constitutes a central component of the IGC and its evolution through time. The IGC relies on the decision of the General Assembly every two years for the redefinition of its continued existence and its work program. Over the 16 years of the IGC’s existence, a total of thirty-one sessions have been held as well as three Intersessional Working Groups. Within this period, the IGC has evolved from a mere fact finding and investigative policy forum seeking to understand the interrelationship between IP and the protection frameworks for TK, TCEs, and GRs. Today, its wealth of experience gathered over the 16 years of its existence lends credibility to its present efforts to negotiate, design, and set a normative agenda for the IP based protection of TK. The accumulated wealth of experience has also served to increase the pressure on the Organization to secure an outcome which justifies the years, resources, and expectations placed on the intergovernmental body right from its inception.

To date, a total of eight mandates have been concluded since the inception of the IGC. While on the face of it, the mandate is negotiated by the General Assembly, as distinct from the IGC, upon a review of the work of the Committee including progress made, in practice the delegates to the Committee represent the very same delegates to the General Assembly who are tasked with the renegotiation of the mandate. This poses significant challenges to the Committee work as, for political ends, the work of the Committee is remarkably affected in and around the period when the mandate comes up for renewal. The mandates also provide a sense to the evolution of the Committee, including its current focus.

Though the IGC is currently engaged in text-based negotiations for agreement on an international instrument for the protection of TKaGRs, the negotiation of an international instrument has not always been the central focus of the Committee. A review of the mandates offers insight into its evolution. For this dissertation, a mandate-based review of the Committee’s evolution offers four main benefits. First, it helps to provide a basis with which to understand and explain the evolution of the Committee’s work as it reveals the changing nature of the periodic short term visions for the Committee at each given point in time. Second, it sheds light on the political sensitivities relating to the continued existence of the Committee, including periodic clarification of its objectives and the setting of its agenda – a delicate task which has continued to rein on delegates alongside the substantive work of the Committee. It importantly reveals that the IGC has continued through the years through a blind progression of competing objectives couched with sufficient
ambiguity to enable a compromise, while yet obscuring hope of reconciliation in the mandate span. Third, it reveals the present context within which the negotiations within the Committee are being driven. Fourth, and most importantly, it demonstrates the core vision of developing countries in addressing biopiracy through the WIPO IGC. Based on biennial mandates, the work of the Committee has evolved over a period of three main phases;

6.2.3.1 Proposal/fact finding phase (1998 – 2003)\textsuperscript{1119}

The first period of the IGC, which runs generally from 1998 – 2003, was aimed principally at setting the agenda of the Committee’s work through the identification of the key issues that merit consideration within the Committee. Significantly, this phase is identified as having begun even before the formal commencement of the Committee, as a lot of work had been concluded prior to the establishment of the Committee, aimed at clarifying the definitions of concepts, the feasibility of a Committee and the modalities with which such a Committee would be run.\textsuperscript{1120} Major achievements during this period include the fact finding mission undertaken in the 1998/1999 biennium which sought to identify the major needs of stakeholders. The Roundtables organized within this biennium are also significant parts of this era. When the proposal for the Committee was then approved by the General Assembly in 2000, no express mandate was agreed upon.\textsuperscript{1121} However, the decision establishing the Committee\textsuperscript{1122} adopted a proposed work program for the Committee,\textsuperscript{1123} and significantly noted that the Committee was expected to determine, at its first session, the agenda of items on which its work should proceed, including the priority to be accorded to each item.\textsuperscript{1124} A basis for the deliberations was provided in document WO/GA/26/6 which listed three

\begin{itemize}
\item[Aimed principally at setting the agenda of the Committee’s work, this phase involved the identification and prioritization of issues for discussion within the Committee. It was characterized by a flurry of proposals seeking to define the scope and work of the Committee, including studies, sharing of Member experiences. The main success of this phase was the formalization and concretization of discussions on GRs and TK within WIPO. See, for instance, the fact finding missions, the Round Tables identified above as well as the streamlining of issues for consideration as contained within WIPO Document 26/6, supra note 90.\textsuperscript{1120}
\item[The key components of the mandate are the workprogram for the year (or biennium) – which includes the proposed number of meetings and, more recently, the length and specific focus of the meetings, and the overarching direction which the work within the respective meetings are expected to follow. See WIPO Document 26/10, supra note 90 at para 71.\textsuperscript{1122}
\item[A work program which involved a single session of the Committee in the spring 2001, and for two meetings of the Committee to be held each year in the 2002 – 2003 biennium. See para 16, WIPO Document 26/6, supra note 90.\textsuperscript{1123}
\item[See para 17, WIPO Document 26/6, supra note 90.\textsuperscript{1124}
\end{itemize}
main areas of work of the Committee.\textsuperscript{1125} This mandate, therefore covered the work of the Committee for 2001, and for the 2002 – 2003 biennium. Within this phase, a series of studies were concluded, most significant of which was the technical study on the disclosure requirement at the behest of the Convention of Biological Diversity (CBD).\textsuperscript{1126} At the end of this period, the Committee, in its report to the General Assembly, provided the summary of its work, \textit{viz}:

\begin{quote}
[t]he discussions of the Intergovernmental Committee generally covered three, interlocking aspects of the intellectual property (IP) issues assigned to it: (i) policy discussion about the forms of protection required for and applicable to the intellectual property protection of traditional knowledge (TK), expressions of folklore (traditional cultural expressions (TCEs)) and genetic resources; (ii) pooling, analysis and synthesis of practical experience at the national and regional levels with the legal protection of this subject matter; and (iii) development of capacity building and information resources to support both policy development and practical implementation of protection of TK, TCEs and IP aspects of genetic resources.\textsuperscript{1127}
\end{quote}

\textbf{6.2.3.2 International dimension phase (2004 – 2009)}\textsuperscript{1128}

While this initial phase was largely limited to the discussion of basic concepts, sharing of experiences, as well as the identification of policy options, a push continued from several developing countries to have the discussion proceed to the next level – one which incorporated an international dimension. Within this context, the aim was to set the stage for a discussion of international frameworks

\textsuperscript{1125} See section III of WIPO Document 26/6, \textit{supra} note 90, paras 20 to 24, which outlines three main areas of work for the Committee: access to genetic resources and benefit sharing, the protection of traditional knowledge, and the protection of traditional cultural expressions.

\textsuperscript{1126} The study addresses regulations concerning access to GRs, and the grant of patent rights at the national and international levels. It examines the application of these distinct regime principles through national laws. It also examines the possibility that the national legal system of one country should take account of the operation of a different area of law in another country i.e. the grant/validity of a patent in one jurisdiction may be dependent on compliance with the laws of another country that establish the conditions for access to GRs and TK. See, WIPO, \textit{WIPO Technical Study on Patent Disclosure Requirements Related to Genetic Resources & Traditional Knowledge} (Geneva: WIPO, 2004), online: WIPO <http://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_786.pdf>. The study was based on a request issued by the COP to the CBD at its sixth meeting in The Hague from April 7 – 19, 2002. The study was presented to the seventh meeting of the COP held in Malaysia, in 2004.

\textsuperscript{1127} See WIPO General Assembly, \textit{Matters Concerning the Intergovernmental Committee on Intellectual Property & Genetic Resources, Traditional Knowledge & Folklore: Document Prepared by the Secretariat}, WIPO GAOR, 30\textsuperscript{th} (16\textsuperscript{th} Ordinary) Sess, WO/GA/30/5 (2003) at para 3.

\textsuperscript{1128} At the inception of the international dimension phase, the delegation of Philippines speaking on behalf of the Asian Group remarked, ‘the Asian group is pushing for a move beyond academic work to a discussion on the international dimension of the issues with a view to establishing norms and a legally binding instrument’. See WIPO General Assembly, \textit{Report: Adopted by the Assembly}, WIPO GAOR, 30\textsuperscript{th} (16\textsuperscript{th} Ordinary) Sess, WO/GA/30/8 (2003) [WIPO GA 30, \textit{Report}] at para 59. This neatly summarizes the drive of developing countries within the 2004 – 2009 period. It involved an expansion of the discussion from mere concepts and academic understandings to a reflection on the possibility of international normative work and possible outcomes from the Committee.
and options for the protection of TK, based on all the discussions which had so far been undertaken within the Committee. Several developed countries were generally against this. The period from 2004 to 2009, however, witnessed a redefinition of the IGC’s mandate to incorporate this international dimension, in line with the demands of several developing countries. To this end, the mandate provided that:

> [t]he WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) will continue its work for the next budgetary biennium on questions included in its previous mandate…its new work will focus, in particular, on a consideration of the international dimension of those questions, without prejudice to the work pursued in other fora, and…no outcome of its work is excluded, including the possible development of an international instrument or instruments.\(^{1129}\)

This mandate was essentially recycled for the entire period of this phase.\(^{1130}\) Due to the complexity of the issues as well as varying national interests within the IGC, amongst others, the work of the IGC has stalled severally over the period of its existence,\(^{1131}\) including this phase. Notably, the development of an international instrument was considered up till this phase, a mere possibility as against a defining element of the Committee.

**6.2.3.3 Text negotiation phase (2010 – date)\(^{1132}\)**

In 2009, however, with the adoption of the mandate for the 2010-2011 biennium, a new wave of urgency and direction within the WIPO IGC was witnessed.\(^{1133}\) By this mandate, Member States agreed that the IGC should begin formal text-based negotiations with the objective of reaching agreement on an international legal instrument(s) that would ensure the effective protection of GRs, TK and TCEs.\(^{1134}\) It is significant that this phase and the intensification of work in this era, coincided with the adoption of the Nagoya Protocol. As noted earlier, the ongoing developments within WIPO were specifically cited as being

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\(^{1129}\) IGC mandate for the 2004/2005 biennium. See WIPO GA 30, *Report, supra* note 1095 at paras 93 – 95. Noting, *inter alia*, that the IGC was requested to accelerate its work on these issues.


\(^{1131}\) See Dutfield & Suthersanen. *Global Intellectual Property Law, supra* note 278 at 342 – 43.

\(^{1132}\) Engaging in text based negotiations for the development of agreement on an international instrument(s) for the effective protection of TK. Seeking to clarify the import of this phase, the Director General confirmed, in response to the Delegation of Pakistan, that the phase is principally aimed at arriving at an international legal instrument. See, WO/GA/38/20, paras 233 – 234.

\(^{1133}\) See document WO/GA/38/20, at para 217.

\(^{1134}\) It is for this reason that several authors note the commencement of WIPO’s treaty negotiations as commencing from this date.
relevant for the implementation of the Protocol and that it cannot merely be a coincidence that this reference was made shortly after WIPO commenced a text-based negotiation. It again reinforces the point that the outcome within the WIPO negotiations was viewed as an important complement to the Protocol, necessary for its implementation.

A total of five sessions of the IGC, including three intersessional working groups were planned for the 2010 – 2011 biennium. For the first time, significantly, the idea of a Diplomatic Conference being convened to conclude the work of the Committee was touted. This was significant for several reasons. First, within the WIPO framework, Diplomatic Conferences are convened for the adoption of binding international treaties. The inclusion of the reference was therefore, for several developing countries, a beacon of hope in the direction of an international legal instrument arising from the negotiations. Second, its significance is linked to the idea that its inclusion in the mandate was a precondition by several countries for the continuation of the IGC. To, however, balance the interests, the commitment to a diplomatic conference was couched in sufficient ambiguity – a problem that has permitted the continuation of the Committee, while yet creating divergent expectations amongst member states. On the one hand, some countries were of the view that the General Assembly was required to “decide on convening a Diplomatic Conference” in the sense that it was bound to convene a diplomatic conference. Other delegates, mainly developed countries, argued that the included phrase simply meant that the GA would decide whether to or not convene a diplomatic conference based on the maturity of the texts submitted for its review. While financial preparations were therefore made from a Secretariat perspective to convene a diplomatic conference within the biennium, no such decision was reached at the close of the biennium. Instead, in 2011, the GA further agreed, that during the 2012-2013 biennium, the IGC should, without prejudice to the work in other fora, expedite its text-based negotiations with the objective of reaching agreement on the said text(s) of an international legal instrument(s) which would ensure the effective protection of GRs, TK and, TCEs. Again, the reference to a diplomatic conference was included, albeit with some clarification. It

1136  For the full text of the IGC’s mandate for the 2012 – 2013 biennium, see WO/GA/40/7 par. 16. The IGC’s current mandate, which was agreed on, based on the WIPO Development Agenda recommendations, requires the IGC, in its efforts to develop an international legal instrument(s) for the effective protection, inter alia, of
This rendition insinuated that a decision on convening a diplomatic conference would be linked to the proposed “stock-taking” and the determination within the GA of the progress made over the biennium. This biennium witnessed significant progress in the textual negotiations across the theme areas, save for the TCE negotiations within the 25th Session which I referenced earlier. At the expiration of the mandate, the GA took note of the texts submitted, and in the light of further work required, agreed, albeit with much difficulty, to renew the mandate of the IGC for the 2014 – 2015 biennium as well as to a new work program for the Committee in 2014. By this stage, the patience of the demandeurs was at its tipping point, with threats of boycotts and accusations of bad faith characterizing the negotiations. Not only were delegates affected, the credibility of the organization in its normative activities was also being questioned. Several commentators had begun to write off the IGC as a time-waster and a failed project given the cyclical nature of its developments. This animosity escalated and continued to characterize the negotiations during the 2014 work program. In an unprecedented development, the GA failed to agree on a 2015 work program for the IGC, even though the IGC’s mandate still had a year to run. This was primarily on the insistence of developing countries who insisted on the convening of a diplomatic conference in a take it or

GRs and TK, to expedite its work without prejudice to the work pursued in other forums. Work plan for 2013. The 2012 GA, in consideration of the texts submitted in WO/GA/41/15, and pursuant to para. d of the 2012-2013 mandate, agreed to continue intensive negotiations and engagement in good faith, with appropriate representation, towards concluding the text(s) of an international legal instrument(s) which will ensure effective protection of GRs, TK and TCEs. It decided that the IGC should, in 2013, further hold three thematic sessions, building on the submitted texts, and submit to the 2013 GA, in September, the text(s) of an international legal instrument(s) for the effective protection of GRs, TK and TCEs. The schedule for the IGC in 2013 is: IGC 23; February 4 – 8 (GRs), IGC 24; April 22 – 26 (TK) and IGC 25; July 15 – 14 (TCEs).

See para (d).

In accordance with the Work Plan contained in the mandate, the IGC met thematically three times in 2012: IGC 20; February 14 – 22 (GRs), IGC 21; April 16 – 20 (TK) and IGC 22; July 9 – 13 (TCEs). The resultant texts produced at each session were submitted to the 2012 GA as annexes A, B and C (respectively) to document WO/GA/41/15.


For instance, within the 2014 – 2015 mandate, at the insistence of developed countries, whose efforts to introduce new texts and request new studies had been rebuffed in the previous meetings of the IGC, a new paragraph guaranteed the rights of Member States to request additional studies, provided that such would not delay or serve as preconditions to the negotiation.

leave it deal. It fell through. No formal meetings nor formal consultations were thus held over the course of 2015,\(^{1142}\) in a period that can rightly be described as the darkest period in the history of the IGC.\(^{1143}\)

Though it was a dark period for the IGC, it was probably a needed period. Given the wide disparities in the expectations of the various participants, the IGC was always doomed, or at least appeared so.\(^{1144}\) The majority acceptance of the developing country views was no indication that the industrialized countries would be ‘shamed’ or ‘arm-twisted’ into accepting outcomes that did not register with their political interests. It came as a rude shock to several delegations, and forced a pragmatic clarification of core objectives and underlying principles within which the negotiations would proceed.

The 2015 GA fortunately agreed to renew the mandate of the IGC for the 2016 – 2017 biennium.\(^{1145}\)

The significance of this new mandate manifests in the compromises that have defined it. Given that it came

\(^{1142}\) The Secretariat, in a subtle bid to encourage consultations during the phase, however organized two major seminars on GRs, TK and TCEs. These were an important success as they kept the conversations alive even during the break in negotiations. The first of the two seminars, “Seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: Regional, National and Local Experiences”, was held from March 30 – April 1, 2015. The presentations made, and documents for the Seminar are available online: WIPO <http://www.wipo.int/meetings/en/details.jsp?meeting_id=35602>. The second seminar was entitled “Seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: The Regional and International Dimensions”, and took place from June 23 to June 25, 2015. Presentations made, and full information on the seminar is available online: WIPO <http://www.wipo.int/meetings/en/details.jsp?meeting_id=36502>.

\(^{1143}\) The failure to agree on a new work program was the result of hard bargaining and a refusal to compromise across the developing-developed country divide within the mandate negotiations. While developing countries expressed their disappointment with the outcome, they pointed to the lack of political will. See South Africa para 163. WIPO General Assembly, Report: Adopted by the Assembly, WIPO GAOR, 46\(^{th}\) (25\(^{th}\) Extraordinary) Sess, WO/GA/46/12 (2015) [WIPO GA 46, Report] at para 163. This was significantly linked to the reference to a diplomatic conference. While Nigeria, for instance, stressed that it was no longer enough to keep having meetings and extending mandates without foreseeing a call for a diplomatic conference [Ibid. at para 168], the United States noted that it could not agree to convene a diplomatic conference, or agree on the nature of an instrument before knowing its contents [Ibid. at para 170].

\(^{1144}\) The Delegation of the United States pointed out that it was “disappointed but not really surprised” with the failed bid to agree on a work program, and suggested that the possible need for discussions ahead of holding meetings to identify when political will is absent – pointing out subtly that there was no political will backing the IGC negotiations. Catherine Saez & William New, “Inauspicious Start to Gurry’s Second Term as IP Policymaking Hits Wall at WIPO” Intellectual Property Watch (01 October, 2014) online: IP Watch http://www.ip-watch.org/2014/10/01/inauspicious-start-to-gurrys-second-term-as-ip-policymaking-hits-wall-at-wipo/.


Bearing in mind the Development Agenda recommendations and acknowledging the progress made, the WIPO General Assembly agrees that the mandate of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (Committee) be renewed, without prejudice to the work pursued in other fora, as follows:

(a) The Committee will, during the next budgetary biennium 2016/2017, continue to expedite its work, with a focus on narrowing existing gaps, with open and full engagement, including text-based negotiations, with the objective of reaching an
agreement on an international legal instrument(s), without prejudging the nature of outcome(s), relating to intellectual property which will ensure the balanced and effective protection of genetic resources (GRs), traditional knowledge (TK) and traditional cultural expressions (TCEs).

(b) The Committee’s work in the 2016/2017 biennium will build on the existing work carried out by the Committee with a primary focus on reaching a common understanding on core issues, including definition of misappropriation, beneficiaries, subject matter, objectives, and what TK/TCEs subject matter is entitled to protection at an international level, including consideration of exceptions and limitations and the relationship with the public domain.

(c) The Committee will follow, as set out in the table below, a clearly defined work program, based on sound working methods, for the 2016/2017 biennium. This work program will make provision for 6 sessions of the Committee in 2016/2017, including thematic, cross-cutting and stocktaking sessions. The Committee may decide to establish an expert panel(s) and hold further Ambassadorial/Senior Capital-Based Officials meetings during future Committee sessions.

(d) The Committee will use all WIPO working documents, including WIPO/GRTKF/IC/28/4, WIPO/GRTKF/IC/28/5 and WIPO/GRTKF/IC/28/6, as well as any other contributions of member states, using an evidence-based approach, including studies and examples of national experiences, including domestic legislation and examples of protectable subject matter and subject matter that is not intended to be protected; and outputs of any expert panel(s) established by the Committee and IGC-related seminars and workshops conducted under Program 4. However, examples, studies, seminars or workshops are not to delay progress or establish any preconditions for the negotiations.

(e) Taking note of the utility served by the 2015 WIPO seminars on IGC-related subjects, provision shall be made for the Secretariat, under Program 4, to organize intersessional seminars and workshops to build regional and cross-regional knowledge and consensus on issues related to IP and GRs, TK and TCEs with a focus on unresolved issues.

(f) In 2016, the Committee is requested to provide, for information only, a factual report to the General Assembly on its work up to that time, and in 2017, submit to the General Assembly the results of its work on an international legal instrument(s) relating to intellectual property which will ensure the balanced and effective protection of GRs, TK and TCEs. The General Assembly in 2017 will take stock of progress made, and decide on whether to convene a diplomatic conference or continue negotiations. It will also consider the need for additional meetings, taking account of the budgetary process.

(g) The Committee may also consider the conversion of the Committee into a Standing Committee and, if so agreed, make a recommendation in this regard to the General Assembly in 2016 or 2017.

(h) The General Assembly requests the International Bureau to continue to assist the Committee by providing Member States with necessary expertise and funding, in the most efficient manner, of the participation of experts from developing countries and LDCs, taking into account the usual formula for the IGC.
after the break in negotiations, it contains arguably a sober and pragmatic reflection on the actual state of the IGC and offers a useful basis for projecting the future evolution of the Committee. Several important points may be highlighted here.

First, though the objective remains to agree on the text(s) of an international legal instrument(s), the primary focus of the negotiations has slightly changed. The new mandate seems to reduce the centrality of ‘text-based negotiations’ within the overall pursuit of this objective by suggesting that the text based negotiations form one of the many channels through which the narrowing of gaps in the committee will take place. The previous mandate (as with earlier mandates since the 2010-2011 biennium), had suggested that the work of the IGC was to focus primarily on ‘text-based’ negotiations in pursuit of this objective. There is therefore the likelihood of an increased number of non-text-based initiatives which have often been looked on by developing countries as time wasters within the negotiations. A good example of this is the formalization of WIPO seminars within the mandate, as part of IGC efforts to build regional and cross-regional knowledge and consensus.

Second, the new mandate seems to acknowledge the lack of a shared understanding and objectives by delegates within the negotiations. It therefore seems to return the IGC back to its starting point by noting the primary focus of the negotiations to be the reaching of a common understanding on core issues including definitions, criteria for protection, and exceptions and limitations. The significance of this new focus, lies in addressing the unrealistic expectation that parties who do not share the same objectives or expectations can possibly reach agreement on an instrument. In essence, a clarification of the difficult conceptual issues which were discussed in chapter three around the subject matter of TK, for instance, will form the basis of the IGCs deliberations within the 2016-2017 biennium.

Third, the mandate moves to forestall a repeat of the unfortunate incidents that led to a failed agreement on a work program in 2014. It does this by setting out a two-year program of work (which aligns with the mandate span). As a way of reporting progress, it provides that the annual reporting made to the GA at the end of the first year, will be a mere informational/factual reporting and, as such, not one that will be expected to generate any decisions or controversy as has been the case under previous mandates where
the GA was called on to make decisions, including a stock-taking, assessment of progress, and decisions on the convening of a diplomatic conference.

Fourth, the new mandate draws a strong emphasis on an evidence-based approach to the negotiations. This has centered on requests by industrialized countries for more empirical studies and examples of national experiences, which would support their fuller consideration of the implications of the proposals within the negotiations. While these are not expected to delay unduly the negotiations, the irony of this insertion lies in the fact that the entire first phase of the IGC’s existence as described above, was devoted to fact-finding and extensive studies relating to the committee’s work. There are, however, still industrialized country concerns with respect to the impact assessment of the proposals within the Committee. Canada has expressed these as concerns regarding the integrity of the IP system as a whole, and the integrity of the public domain.\footnote{See, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Report of the Twenty-Sixth Session, WIPOOR, 26th Sess, WIPO/GRTKF/IC/26/8 (2014) [IGC 26, Report of the Session] at para 50. See also, the intervention by the United States of America, noting that “it was yet to see any concrete evidence which established that new disclosure requirements would be a viable way forward. It informed the Committee that some of its stakeholders were currently experiencing serious problems in countries that had imposed disclosure requirements, such as patent processing delays and uncertainty in obtaining and exercising patent rights”. Ibid. at para 47.}

Finally, the mandate bears an important reference to the possible conversion of the Committee to a standing committee, which may prove a strategic move by developing countries to ensure that the IGC is well positioned to develop and perpetually review and revise an international binding treaty on TK. While the actuation of the Committee’s conversion to a standing committee within WIPO remains to be seen, the inclusion of this proposal within the mandate represents a significant coup by the developing countries in laying the basis for the actual consideration (or negotiation) of this possible conversion within the actual negotiations of the Committee. This is a really important point as it serves to increase the number of stakes which developing countries may leverage in the pursuit of eventual treaty outcomes which favor them.

Take for instance, the discussion of studies and examples within the IGC negotiations which was made possible through its introduction within the mandate. The formal request for a study was presented by the United States within the 23rd Session of the IGC, which took place in 2013 within the period of the
2012/2013 mandate. Under the 2012/2013 mandate, there was no provision made for studies. This proposal by the United States was therefore immediately met with concerns from developing countries as well as indigenous peoples. These third world actors had continually insisted these requests were negative tactics borne out of bad faith, being employed by industrialized countries to frustrate the progress of the Committee’s work. In arguing against the requests, some developing countries relied on the argument that the consideration of examples and studies were not included within the mandate and, as such, had no legal basis for consideration within the Committee. Though a sound argument, it probably ended up having a negative effect, as developed countries have continually ensured that the reference to examples and studies is included within the subsequent mandates to date. This has provided industrialized countries with freedom to request examples and studies within the context of a vague and undeterminable caveat – “delay progress or establish any preconditions to the text-based negotiations”. It was, therefore, a big move by the developing countries to secure the inclusion of this point within the mandate, as it provides a

1147 See Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Draft Report of the Twenty-Third Session, WIPOOR, 23rd Sess, WIPO/GRTKF/IC/23/8 Prov. 2 (2013) [IGC 23, Report of the Session] at para 255, the United States introducing document WIPO/GRTKF/IC/23/6 being the Proposal for the Terms of Reference for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents & Compliance with Existing Access & Benefit Sharing Systems. See, for instance, the intervention of India, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Draft Report of the Twenty-Fifth Session, WIPOOR, 25th Sess, WIPO/GRTKF/IC/25/8 Prov. 2 (2013) [IGC 25, Report of the Session] at para 286, rejecting the need for further studies and pointing to the plethora of existing studies that had been made in support of the Committee’s work. See also, interventions from the indigenous peoples, for instance, arguing that there was no need for further studies as the IGC already had sufficient mechanisms from which such information could be drawn, such as the various side events organized within the margins of the sessions, as well as the indigenous panel. Ibid. at paras 289, 375. Yet, see the intervention from Nigeria, which seemed to acknowledge the importance for studies within the negotiations as these could support the deliberations, but should not be made substitutes for progress within the negotiations. Ibid. at para 291. The concerns reflected by Nigeria as well as several other developing countries as to the implications of the studies on the negotiations is probably most understandable in the context of Japan’s early intervention in support of the proposal when it was first presented at the 23rd session of the Committee. At the time, Japan had requested that this proposal for a study (particularly the proposed study) should be a condition-precedent for the conclusion of negotiations on a disclosure requirement. See IGC 23, Report of the Session, supra note 1087 at para 259. Though it later withdrew this position in writing, the underlying intent of the proposal was distilled as one which required developing countries to act with every suspicion and caution. The compromise reflected in the new 2014/2015 mandate was thus that though delegations were permitted to request studies, such were explicitly required not to ‘delay progress or establish any preconditions to the text-based negotiations’. This language has been retained with a more central prescriptive force in the current 2016/2017 mandate. In other words, the inclusion of studies, examples, and national experiences have been placed as a part of the negotiations.

1148 See, for instance, Chile, noting that the proposed studies and examples, could have the effect of taking away the IGC from its mandate. See Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Draft Report of the Twenty-Fifth Session, WIPOOR, 25th Sess, WIPO/GRTKF/IC/25/8 Prov. 2 (2013) [IGC 25, Report of the Session] at para 296.

1149 See, supra note 1088.
basis for discussions on the conversion of the Committee to a standing committee to be placed within the center of actual committee negotiations, and not just left as a matter for the General Assembly.

The mandate negotiations significantly highlight two main areas of importance for developing countries and which are important for reinforcing the Nagoya Protocol towards addressing biopiracy. First, developing countries within their respective regional formations, are insistent on a binding international treaty. By a binding treaty, developing countries are seeking an outcome within the negotiations which offers a genuine basis for legal action. In other words, an international legally binding instrument which contains more than persuasive obligations but, rather, obligations that are enforceable. To this end, the insistence on a diplomatic conference within the mandate by developing countries contains this implication. Developed countries are generally opposed to a binding outcome and have submitted proposals for soft outcomes to counter this. Even where agreement was made to keep the reference to the diplomatic conference within the previous mandates, the ambiguity of the language led to opportunities for both groups to justifiably interpret the implications from either side. Within the current mandate, the reference to the diplomatic conference is made, though this is to be undertaken in 2017, at which time it will constitute a review of two-years of the Committee’s work.

Second, is the timing of the instrument(s) being negotiated. Developing countries seek an urgent outcome. For most, the countries within the opposed group are using the IGC as a delay tactic to keep reinforcing obligations stalled and thereby afford industry and users of GRs the continued privilege of free riding on the TKaGRs of indigenous peoples. Suggestions to this effect were raised when the opposed group submitted a proposal for a comprehensive study to be undertaken by the Secretariat. Developing countries rejected it and insisted that it could not be made a part of the negotiation. During the negotiation of the mandate, the developed countries thereon insisted on the enabling clause in the mandate which guaranteed their right to request further studies, the compromise being that such studies were not to serve as impediments or delays to the negotiations. An interesting outcome of the break in negotiations is the

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1151 See, for instance, the Joint Recommendation on Genetic Resources and Associated Traditional Knowledge: Document Submitted by the Delegations of Canada, Japan, Norway, the Republic of Korea, and the United States of America, WIPO IGCOR, 31st Sess, WIPO/GRTKF/IC/31/5 (2016) (being the latest resubmission of this proposal, first circulated in 2013).
willingness of developing countries to accept that deals can only be made at the table. In other words, industrialized partners must remain at the table for any useful reinforcement to the Protocol to be made. This has led to an increased flexibility, given that several developed countries were absolutely insistent on a diplomatic conference being held at the close of the 2014/2015 biennium. The pragmatic approach witnessed, which defers a decision on the diplomatic conference to the 2017 General Assembly, indicates a willingness to ensure that diplomacy and engagement are maintained while yet seeking to forge treaty solutions.

The foregoing demonstrates that beyond the substantive discussions within the IGC, a terse political sub-text has shadowed the discussions of the Committee. These political undertones reflect the contested issue of a binding v non-binding character of the emerging instrument; a factor which bears significant implications for the effective implementation of the Nagoya Protocol. A non-binding outcome within the IGC will significantly weaken the intended reinforcements being sought through the IP system. It will leave the question of adherence to the option of the signatories to the agreement and will significantly reduce the political force of the outcome in advancing normative changes across other fora. Voicing this concern, several demandeurs are wary of agreeing to an outcome which offers a mere aspirational ideal as against one which represents a binding commitment from all parties.

The Joint Recommendation on Genetic Resources and Associated Traditional Knowledge submitted by industrialized countries is testament to this. The three-page document is divided into six sections: definitions, objectives and principles, prevention of the erroneous grant of patents, opposition measures, supporting measures, and application. The preamble to this document reaffirms the importance of GRs and TKaGRs to wide range of stakeholders, stresses the need to prevent the erroneous grant of patents while noting the inherent capacity of the patent system to achieve this, stresses the need for improved information for patent offices to assist with their patent examinations, as well as promote

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1152 See, the Joint Recommendation on Genetic Resources and Associated Traditional Knowledge: Document Submitted by the Delegations of Canada, Japan, Norway, the Republic of Korea, and the United States of America, WIPO IGCOR, 31st Sess, WIPO/GRTKF/IC/31/5 (2016) (being the latest resubmission of this proposal, first circulated in 2013).
1153 Ibid. Preamble, at para 1.
1154 Ibid. Preamble, at para 3.
transparency. The preamble concludes on the purpose of the instrument by “recommending that each Member State may consider the use of this Recommendation adopted by the [IGC] as guidelines for the protection of GRs and associated TK”.

In outlining its recommendations, the Joint Recommendation significantly gives primacy to administrative measures which support the prevention of erroneous granting of patents without affecting the incentives for innovation provided by the patent system. To this end, its supporting measures include reference to voluntary codes of conduct and guidelines as well as the development of databases, while avoiding any reference to a disclosure mechanism within the patent system.

The difficulty of this recommendation lies in the fact that it remains a recommendation. It is similar to the Bonn Guidelines discussed in chapter five, in that it may offer a range of relevant suggestions, but is insufficient to bind parties to a common approach in addressing the problem of biopiracy. Indeed, this weakness in soft outcomes, has underscored the primacy which developing countries place on a binding outcome within the negotiations. Furthermore, the recommendation seeks to build a range of support measures around the working of the patent system; support measures which feed into an assumption that the patent system as is, remains a sufficient mechanism for addressing the problems associated with the misappropriation of TKaGRs and GRs.

6.2.4 The Big Disclosure Holdup in the Negotiations: Revisiting Colombia’s Proposal

Beyond a binding and timeous outcome, developing countries have pursued normative reinforcements to the Nagoya Protocol within the IP regime. Recall that the primary reason given by developed countries for a refusal to engage with Colombia’s proposal within the SCP, was that it concerned a matter of substantive law and as such was outside the scope of the PLT. As I have shown, this proposal led to the actual formation of the IGC, and interestingly, it remains the core single normative issue holding up the negotiations till date. As seen in the Joint Recommendation above, industrialized countries have

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1156 Ibid. Preamble, at para 5.
1157 Ibid. 5.1
1158 Ibid. 5.2
1159 See, pages 303 – 305, particularly at note 1039 above.
1160 See note 87 above.
sought to address this concern through administrative measures (both opposition and supporting measures) which, while offering guidance to states, ensure that the integrity of the IP system is preserved. This goes to the foundational discussions in this chapter about the difficulties inherent in reconciliation of the IP system’s justifications with efforts to protect TK through the IP system.1161 Also, this draws into focus the central interest of developed countries in maintaining the classical structure of the IP system even in the face of exogenous needs for its alteration/modification. In this case, the insertion of a disclosure requirement within the patent system represents a central North-South tussle which defines in a critical way an intended developing country stake within the mechanism of the patent system. It is significant for several reasons.

For developing countries, addressing the concern of the Colombia delegate continues to remain the basis for the existence of the IGC. In other words, it is inconceivable for developing countries that the Committee will fail to develop a binding treaty which addresses the mandatory disclosure.1162 For most,

1161 See, section 6.1.2.4. above.
1162 Developing countries from the Asian and Pacific Region (ASPAC) for instance noted, at the start of the Twenty-Sixth session, that “many Member States from the Asia-Pacific Group believed that it was necessary for the IGC to explore the possibility of establishing an effective mandatory disclosure requirement, which would protect GRs, their derivatives and associated TK against misappropriation and would prevent the granting of erroneous patents”. See, IGC 26, Report of the Session, supra note 1113 at para 13. The Group of Latin American Countries (GRULAC), similarly noted, that “the absence of an international legal instrument had facilitated the continued misappropriation of GRs, TK, and TCEs which were often used without PIC. It was vital that the IGC achieved an ambitious outcome and adopted an international legal instrument to ensure the effective protection of GRs, TK, and TCEs, and disclosure of their origin”. Ibid. at para 16. The African Group also noted, that “the appropriate protection of GRs from the illicit granting of IPRs should be enhanced. [This] would be achieved by making the disclosure of the source or origin mandatory”. Ibid at para 17. China, remarked similarly, that “the core work of the IGC should be the establishment of a system of disclosure of source of GRs. The establishment of such a system would be conducive to bridging the IP system and the rules for the protection of GRs as laid out by the CBD, as well as to implementing the principles of PIC and ABS for the utilization of GRs, which was also the purpose of the establishment of [this] new international instrument on GRs”. Ibid at para. 19. Furthermore, the indigenous caucus at the negotiations, in lending their support to the disclosure mechanism, noted, “The legal instrument engendered by the work of the IGC must support international standards governing access to GRs and associated TK and a share in the benefits, while also ensuring that IP offices had the necessary information to take the appropriate decisions on the granting of IPRs, to prevent the granting of IPRs in error as well as the illicit use of their GRs and associated TK. In that sense, indigenous peoples strongly supported the inclusion of mandatory disclosure requirements as a precondition for granting IPRs, which should include information on compliance with PIC given by indigenous peoples and the fair and equitable sharing in the benefits arising from the use of GRs and associated TK”. Ibid. at para 23.

These demands of developing countries can be contrasted with the concerns consistently raised by their developed counterparts within the negotiations. The European Union and its Member States, for instance, cautioned that while they were flexible in their approach to the disclosure requirement, “[any] disclosure requirement which would discourage or create legal uncertainty in the use of the patent system would not facilitate the sharing of benefits and would not be in anybody’s best interest”. Ibid. at 20. Its expressed position, contained in, Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in
no outcome below a binding treaty addressing the concerns of patent-based biopiracy will do. Industrialized countries are generally not favored to this approach.\textsuperscript{1163}

The disclosure requirement is a core spot within the negotiations which significantly divides the major users of the IP system from the main proponents of the ABS regime. It is often considered that the resolution of the disclosure proposal is the only major political issue holding up the conclusion of the IGC process.\textsuperscript{1164} In other words, if the delegates are able to agree on the terms of a disclosure agreement, the remaining outstanding issues within the negotiations (which though equally contentious) will more easily be resolved. Simply put, the disclosure proposal is an initiative driven by developing countries (and more recently, joined in by some developed countries),\textsuperscript{1165} which seeks to ensure that patent applicants for inventions which make use of GRs and/or TKaGRs, disclose the source of GRs and/or TKaGRs, as contained in Colombia’s early proposal. The purpose of disclosure within the context of this dissertation’s analysis must be understood from its role as a potential reinforcement of the Nagoya Protocol’s obligations on ABS.

Recall that the Nagoya Protocol places benefit sharing on the basis of mutually agreed terms, as well as the obtaining of prior informed consent, as two cardinal principles governing the access and utilization of TKaGRs. As I argued these principles exist to empower indigenous peoples and their host countries in the fight against biopiracy. The disclosure mechanism is viewed by developing countries as a key mechanism for reinforcing these principles. Through this mechanism within the patent system, evidence of compliance with international and national laws on ABS is ascertained. I should point out that the Nagoya Protocol contains a disclosure mechanism which is premised on the need to monitor the utilization of GRs and is useful to explain the reinforcement drive within the IGC.


The United States has also been consistent with the view that alternative non-binding approaches to a disclosure requirement should be considered by the committee as “it was yet to see any concrete evidence which established that new disclosure requirements would be a viable way forward”. IGC 26, \textit{Report of the Session}, \textit{supra} note 1113 at para 47.

Canada, the United States, Japan, Korea, etc., have reiterated their concerns in this regard, indicating their absolute preference for non-binding outcomes.\textsuperscript{1164}

See, for instance, the Delegation of Poland, pointing out that “with respect to GRs, the critical issue blocking progress was the lack of consensus in relation to a disclosure mechanism”. Ibid at para 24.

Countries like Australia, New Zealand, Switzerland etc. have been increasingly supportive of the disclosure approach given that they have enacted domestic laws giving effect to these standards.\textsuperscript{1165}
Article 17 of the Protocol provides that, as a way of monitoring and enhancing transparency about the utilization of GRs, each party is required to take appropriate measures to support compliance. As a proof of compliance, the Protocol provides that

[a]n internationally recognized certificate of compliance [IRCC] shall serve as evidence that the GRs which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.\textsuperscript{1166}

The Protocol goes on to clarify that this IRCC shall contain the following minimum information when not confidential: the issuing authority; date of issuance; the provider; unique identifier of the certificate; the person or entity to whom prior informed consent was granted; subject-matter or genetic resources covered by the certificate; confirmation that mutually agreed terms were established; confirmation that prior informed consent was obtained; and commercial and/or non-commercial use.\textsuperscript{1167}

The IRCC is therefore expected to serve as an official confirmation that its bearer (who has accessed GRs) has complied with domestic access and benefit sharing obligations relating GRs in the providing country.

To ensure compliance, Parties are expected to designate one or more checkpoints for the purpose of monitoring and tracking the information contained within the IRCC.\textsuperscript{1168} According to the Protocol, three main characteristics should be inherent within such checkpoints. First, such checkpoints should be effective; second, they must have functions relevant for implementing Article 17.1(a) of the Protocol, and; third, should be relevant to the utilization of GRs, or to the collection of relevant information at any stage of research, development, innovation, pre-commercialization or commercialization.\textsuperscript{1169} With respect to its function, the checkpoint is expected to collect or receive relevant information related to; prior informed consent, the source of the GRs, the establishment of mutually agreed terms and/or to the utilization of GRs, as appropriate.\textsuperscript{1170} These checkpoints are expected to play an important role in the furtherance of compliance with obligations of the ABS regime. Against this backdrop, an attempt to reinforce this provision within the context of the IGCs debate on disclosure requirement is discernible.

\textsuperscript{1166} Article 17.3 Nagoya Protocol.
\textsuperscript{1167} Article 17.4, Nagoya Protocol
\textsuperscript{1168} Article 17.1(a), Nagoya Protocol
\textsuperscript{1169} See Article 17.1(a)(iv), Nagoya Protocol.
\textsuperscript{1170} See Article 17.1(a)(i), Nagoya Protocol.
In this regard, developing countries have viewed a link between the Nagoya Protocol’s mechanism for monitoring the utilization of GRs (as described above) and the proposed disclosure requirement. In particular, developing countries have favored an approach by which the patent offices are designated as possible checkpoints for ensuring that disclosure requirements are met. As part of monitoring compliance, it is important that access to GRs and TKaGRs are properly identified and disclosed for the proper monitoring of attribution and benefit sharing. While the Nagoya Protocol requires Parties to designate checkpoints, no specific mention is made of patent offices fulfilling this role. The attempt to link these processes by developing countries has presented an interesting example of the possible role of the IGC’s negotiations in reinforcing the existing ABS regime. The resistance from developed countries in this regard has been focused on the appropriateness (or suitability) of the IP system being used as a ‘reinforcement’ or a system for ensuring compliance given the possible drawbacks that this may have on the overall role of the IP system as a driver of innovation. As discussed in chapter three, some concerns which developed countries have expressed have centered on the training of patent examiners, the role of the patent offices, the distinction between formal and procedural disclosure, and the nature of the obligation, including consequences of non-compliance.

6.2.5 The IGC: An Important Forum for Developing Countries

On the basis of the above demonstration of the political and substantive efforts of developing countries to develop a complementary system of reinforcement for the Nagoya Protocol, including the difficulties associated with this task, it worth reiterating the central assertion of this thesis; that this IGC process remains a central part of the evolving ABS regime complex, offering the important next step in the evolution of the ABS regime complex. It is important to note that I have not tried to address the questions around resolving the difficulties within the IGC, but rather have pointed these out to highlight the difficult political undertone which necessarily will accompany the implementation of the Nagoya Protocol’s ABS regime. The following three important points about the IGC, underscore its centrality as a needed IP forum within which the ABS reinforcements can yet be realized.

1171 See, for instance, the statement by the Delegation of Peru, noting that the patent office was like a checkpoint. IGC 23, Report of the Session, supra note 1087
6.2.5.1 A Developing Country Led Process

First, the IGC is one of the only Committees within WIPO which exists on the insistence of developing countries. It is thus a developing-country led process.\textsuperscript{1172} Historically, as noted above, the entire concept of an IGC stemmed from Colombia’s proposal, one which was directed at the incidence of biopiracy. In effect, the delegation sought to include some form of mechanism within the patent law treaty which would serve as check to the misappropriation and/or misuse of GRs through the patent system. While this proposal received broad support from developing countries, it was met with significant resistance from major developed countries.\textsuperscript{1173} This industrialized country resistance to several proposals from the developing countries has remained a consistent feature in the evolution of the IGC. Importantly, it is worth noting that several developed countries have continued to hold reservations about the entire IGC construct given its potential to alter the existing structure of the IP system.

While the IGC thus exists as a creation of WIPO, developing countries are the key demandeurs within it. Their views and their demands represent the appropriate perspective from which to view the objectives of the Committee as the work of the Committee is primarily geared towards addressing their concerns. The burden consequently rests on developing countries at every point in the negotiations to convince the developed countries of their desired outcome. Furthermore, it means that in the event of a breakdown of the Committee, developing countries are the losers. Of course, this could lead to wider systemic consequences (which would affect developed countries as well as WIPO), however the immediate

\textsuperscript{1172} See, Begona Venero, “Results and State of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore”, presentation made at the 9\textsuperscript{th} Pan-African ABS Workshop, February 23, 2015, online: ABS Initiative <http://www.abs-initiative.info/fileadmin//media/E vents/2015/23-27_February_2015__Addis_Ababa__Ethiopia/1.7-Venero-WIPO-IGC.pdf>, noting that the WIPO IGC represents the ‘first developing country-led normative process of [its] breadth and complexity’. See also, Catherine Saez & William New, “Inauspicious Start to Gurry’s Second Term as IP Policymaking Hits Wall at WIPO” Intellectual Property Watch (01 October, 2014) online: IP Watch http://www.ip-watch.org/2014/10/01/inauspicious-start-to-gurrys-second-term-as-ip-policymaking-hits-wall-at-wipo/>, where the delegation of Iran is quoted to say, \textit{inter alia}, “The IGC is at the heart of developing country interests in WIPO”

\textsuperscript{1173} The proposal received support from the Delegations of Bolivia, Paraguay, China, Namibia, Cameroon, Mexico, South Africa, Chile, Cuba, India, Kenya, Costa Rica and Barbados, while the Delegations of Germany, United States of America, Republic of Korea, Japan, Finland (speaking on behalf of the European Community and its Member States), Romania and France stood firmly against the proposal on the grounds that it related to issues of substantive law which were inappropriate for inclusion in the draft Treaty. See SCP 3, Report of the Session, supra note 941 at para 205.
impact of a failed IGC would be felt primarily by the demandeurs.\textsuperscript{1174} The outcomes of the IGC are therefore primarily of importance to developing countries.

\subsection*{6.2.5.2 A Middle Point Forum}

Second, it is important to note that as a Committee, the IGC occupies a central point within the difficult relationship between IP and the protection of TKaGRs. The IGC is construable as a ‘middle’ ground between extreme points represented by the ABS regime and the IP regime. It therefore sits at the center of the difficult relationship between these two regimes with respect to the prevention of biopiracy. Though this view of WIPO’s neutrality may be contested due to the fact that, in itself, WIPO is the specialized agency of the UN responsible for administering and enforcing IP globally, the nature of WIPOs \textit{sui generis} project within the IGC, including issues of participation, methodology, and even subject matter, point to the opening up of WIPO, in this respect, as a central platform for the negotiation of issues which lie at the intersection of the two principal regimes. Furthermore, the delegates have generally prioritized principles relating to fairness, justice, and equity over a slavish adherence to IP principles in the formulation of solutions. It thus offers a platform, especially for indigenous peoples and developing countries to assert themselves in the formulation of a supportive system to the ABS system. This point is significant as the protection of TK is also being considered within the WTO TRIPS Council. Contrary, however, to the state-centric nature of the WTO negotiations discussed in chapter one,\textsuperscript{1175} which significantly excludes indigenous peoples and other relevant observers (including the CBD) from its negotiations, the WIPO IGC draws legitimacy and credibility from its wide and inclusive participation. Participation in the IGC is open to Member States and accredited observers, most prominent of which are indigenous peoples.

\textsuperscript{1174} See, for instance, Catherine Saez & William New, “Inauspicious Start to Gurry’s Second Term as IP Policymaking Hits Wall at WIPO” \textit{Intellectual Property Watch} (01 October, 2014) online: IP Watch http://www.ip-watch.org/2014/10/01/inauspicious-start-to-gurrys-second-term-as-ip-policymaking-hits-wall-at-wipo/>, who, describing the difficult outcomes of the 2014 General Assembly, including, amongst others, the notable break down in the IGC deliberations, summed up the implications of \textit{viz}. ‘...developing country goals at the World Intellectual Property Organization died this week, as key issues met roadblocks in every direction’.

\textsuperscript{1175} See 1.1.3. above.
6.2.5.3 A Legitimate Forum

Two areas which support the IGC’s claims to legitimacy are its broad participation and its inclusive methodology.

6.2.5.3.1 Participation

With respect to participation, the simplified process of accreditation to the IGC ensures that a wide array of indigenous groups, industry representatives, as well as relevant NGOs are part of the WIPO Member State-led negotiations. This is important as it places the major stakeholders to the biopiracy debate within a common forum that allows them to dialogue directly. This point is made all the more significant as the United States is not a signatory to the CBD, Nagoya Protocol, nor the ITPGRFA. As mentioned earlier, this has serious implications for the implementation of any mechanism addressing biopiracy given the central role of US-based industries and institutions in several instances of biopiracy. The IGC thus affords a unique opportunity for the US to articulate its positions regarding the problem of biopiracy within the context of a dialogue with other key stakeholders.

WIPO has established a Voluntary Fund which supports the participation of indigenous observers. At the sessions, indigenous participants are provided specialized trainings and offered a special set of facilities, including a fully equipped secretariat and interpretation services for their meetings, all of which serves to enhance their participation. In providing an opportunity for indigenous peoples to express their case on the issues under negotiation, every session of the IGC is commenced with an indigenous panel which draws indigenous experts to comment and field questions from Member State representatives on germane issues to the negotiation. Finally, it is worth mentioning that pursuant to an indigenous fellowship program, an indigenous fellow is employed annually by the Secretariat to work within the Traditional Knowledge Division. Not only does this provide further training to indigenous persons, it affords the Secretariat the opportunity to draw consistently from an indigenous perspective in the formulation of initiatives. This has helped maintain a shade of indigenous sensitivity within WIPO initiatives. The result

is that the indigenous presence within the WIPO negotiations is an integral feature of its normative
development and transformative possibilities.

Various categories of participants may be developed with respect to the participation of countries
within the IGC. Such categories which many times overlap may, for example, be linked to country interests
or geographic locations. Interest based groups for instance would include the Like Minded Group, often
coordinated by Indonesia yet incorporating biodiverse countries irrespective of geographic location.
Several other popular groupings reflect geographic associations. Examples are the African Group, the
Group of Asian and Pacific Countries etc. Combining these, WIPO’s formal classification of countries
organizes countries within seven regional groups: the African Group, the Asian and Pacific Group
(ASPAC), the Group of Latin America and Caribbean States (GRULAC), the Central European and Baltic
States (CEBS), the Central Asian and Eastern European States (CACEES), Group B countries, and China,
which due to its sheer size sits as a single group within the negotiations. These are not all necessarily
geographic-based groups. Group B, for instance, is made up of developed countries – not only those based
in Europe or North America, but also Japan, Australia, New Zealand. The basis of these classifications is
not fully clear. Positions of individual countries, while often expressed through the groups, sometimes
differ from the group to which they belong. Japan, for instance, does not usually share a common position
with countries in the ASPAC Group to which it belongs on the basis of geography. To this end, many times
it is possible to group countries informally within perceived groupings based on their positions and
approaches within the negotiations.

In this context, countries may be classed into one of five loose groups in terms of their expectations
and approach to the negotiation’s outcome. The Deep Red relates to those countries that still require to be
brought into the stream of the demanders’ demands. They are generally resistant to efforts to secure a
binding, normative and complementary outcome. USA, Canada, Japan and the Republic of Korea are the
prominent four in this category. The Red category relates to those which reflect a lot of the views of the
‘deep red’ group, but yet are more flexible in their approach and discussions. The Member States of the
European Union and Russia are some of the examples in this category. The Amber – Australia, New
Zealand, Norway, Switzerland, and Thailand, amongst others, are the countries which generally reflect
compromise views and sit in between the extreme points of the negotiations. From an analytical perspective, the eventual success of the negotiations is most likely dependent on this group. The Green category are those countries which are clearly focused on a binding outcome, yet have seeming margins of flexibility in their approach to the desired outcome. China, Mexico, Brazil are some of the countries within this category. Finally, the Deep Green category, which represents the toughest line of demanders within the negotiations, sit on the other extreme to the ‘Deep Red’ category. These countries noted for their role in championing the drive of the negotiations towards complementary, binding outcomes include South Africa, Indonesia, Kenya, Islamic Republic of Iran, India, Egypt, Nigeria and Peru.

Both the formal and the informal classifications mentioned above are important. Developing country positions are generally expressed through the views of groups like the African Group, ASPAC, GRULAC and China and it is these groups that are the main demanders within the negotiations. Yet, within the other formal groups, individual countries, such as Australia and Switzerland have played important roles in bringing in members of such groups within closer reach of the demands of developing countries, as well as facilitating avenues to bring the views of developing countries within compromise territories which could be acceptable to industrialized countries.

6.2.5.3.2 Methodology

The methodology adopted by the IGC is also worth mentioning as it facilitates the involvement of all participants within the discussions under consideration. The IGC has devoted less time to plenary sessions and rather embraced the more effective ‘expert group’ process to advance the negotiations. Through the expert group process, the regional groups (as well as indigenous peoples) are allotted a limited number of seats. The difficult discussions are thrashed out in the expert group with existing rules on non-disclosure as well as confidentiality of proceedings in force. This affords representatives the opportunity to engage as experts in a frank open exchange on the issues being discussed. Where issues are unable to be resolved within the expert group, the parties that express major divergences are constituted into an informal open ended negotiating group, with a mandate to further explore the issue, along with any other interested party, and report a compromise on the issue to the expert group. This has significantly enabled progress on difficult areas of the textual negotiations. The expert group thereafter reports its work to the
plenary. Facilitators are engaged to take note of the discussions and are tasked with the difficult work of identifying compromises and making textual revisions to the negotiating texts based on the expert group and plenary discussions. While this methodology has helped progress the negotiations, it has enabled more importantly an opportunity for developments based on expert exchanges. Within the expert groups, distinctions are not made between indigenous and non-indigenous speakers, for instance. Rather, indigenous peoples are accorded the same rights as member states in intervening and making proposals. I should note here, however, that this expert process remains subject to the plenary. In other words, upon completion of deliberations, revisions are made to the text and submitted to the plenary for comments. The plenary could reject, accept, modify and offer further comments to the textual revisions. Within the plenary, the regular rules of engagement, which require a Member State to support the proposal of an observer for its insertion into the text, are applicable.

What the above points have served to demonstrate is that the WIPO IGC, though located within the IP system, presents an open forum which draws participants relevant to the biopiracy debate within a frank and open exchange on core difficulties relating to the problem. Furthermore, the IGC has made a continuous effort to ensure its legitimacy over the issues it seeks to address by ensuring that indigenous peoples are fully represented and the methods support their direct participation. Within the context of this thesis, then, the WIPO IGC’s considerations of IP-based solutions to biopiracy represents the most legitimate international effort to engage and design a solution. The fact that the IGC is a developing country-led process explains why the core interest of developing countries in the Nagoya Protocol accords with their positions within the IGC negotiations.

6.3 Conclusion

This chapter has shown that developing countries are particularly pursuing an expansive reconfiguration of the IP system through their search for ABS reinforcements within WIPO, a forum more amenable to the discussion of the protection of TKaGRs from biopiracy. This is due to the fact that the WIPO IGC is a developing country led process, which sits at the centre of the ABS and IP regimes. The IGC further draws legitimacy on the matters of TK protection due to its broad participation (including from indigenous peoples) as well as its inclusive methodology. By laying siege on the WIPO negotiations and
driving the agenda for an outcome which is complementary to the Nagoya Protocol, the expansive evolution of the ABS regime complex is also being actualized through the development of a *complementary* instrument within WIPO. From an IP perspective, however, the prophetic nature of John’s statement opening this chapter offers a suitable lens with which to view the present evolutionary phase of the IP system; an evolution characterized by ongoing efforts led by developing countries to create, define, and assign new rights to a new range of beneficiaries for the purpose of fulfilling the IP system’s claims to universality. WIPO sits in the center of this effort. In the context of Cornish’s elaboration of the ‘emulation’ process in IP law making, the ongoing negotiation of a *sui generis* system of protection for TK threatens the very foundations and underlying justifications of the classical IP system. For, in developing these new rights for new beneficiaries (indigenous peoples), the negotiations are largely driven on towards a reconciliation of the IP system with principles and norms of the ABS regime. The outcome of such an effort will importantly sit in complementarity with the ABS regime, thus again supporting the importance of viewing the IGC as a complementary process within the context of the international ABS regime.

In a useful sense, therefore, while the ABS regime’s evolution (and reinforcement) is being driven on by developing countries through the attempted capture of normative gains on the IP platform, the IP system’s corresponding evolution reflects a ‘weakened’ expansive reconfiguration to accommodate the very beneficiaries of the ABS regime. Should the IGC negotiations end in a complementary manner to the ABS regime, therefore, a radical reconfiguration of the IP system will definitely be on the horizon. This reconfiguration is linked to the ongoing efforts to secure a disclosure requirement both in the WTO TRIPS and on the platform of the IP system. A positive outcome within the WIPO IGC will offer increased leverage for developing countries to push for amendments to the TRIPS within the TRIPS Council. Furthermore, within the context of WIPO administered treaties, a complementary outcome to the Nagoya Protocol will necessarily serve to commence a process of amendments to reconcile possible conflicts. The ABS system,

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1177 Cornish, “International Relations of IP”, *supra* note 1064 at 54 – 55, noting emulation as involving the creation of new and distinct rights by analogy, drawn more or less eclectically from the types already known.
I suggest, requires this reconfiguration of the IP system for its core normative prescriptions to be effective particularly in its fight against biopiracy. It is this reconfiguration of the IP system that offers a reinforcement – a coherent shield – which ultimately supports the effective implementation of the ABS system.

Indeed, WIPO’s commitment to this objective cannot be overlooked. WIPO’s investments and push for relevance within the IP space means that the success of the IGC is an important deliverable to the continued relevance of the Organization. While the implications of a complementary IGC outcomes will be vital to future efforts to push for amendments to the TRIPS, the central import which I have sought to establish in this dissertation is that a complementary outcome will necessarily form an elemental part of the international ABS regime as established by the Nagoya Protocol. In characterizing this international ABS regime, I have sought to establish in this dissertation that it may be best construed as an ‘anti-biopiracy regime complex’ which is being driven on to address the problem of biopiracy. It is in this light that this thesis has sought to establish the indispensability of the WIPO IGC to the effective implementation of the Nagoya Protocol in addressing the problem of biopiracy.
Chapter 7

Conclusion

This dissertation has advanced a number of ideas and suggestions relating to the protection of traditional knowledge associated with genetic resources (TKaGRs) from the incidence of biopiracy. Principally, it has sought to establish the key importance of the ongoing work within the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organization (WIPO) to the very regime instituted by the Nagoya Protocol for the purpose of addressing the protection of TKaGRs from biopiracy. At the core of this thesis, therefore, is the argument that the history, design, nature, content, and limitations of the Nagoya Protocol points to a necessary evolution for the access and benefit sharing (ABS) regime in the fight against biopiracy; an evolution which draws significance from the construing of the WIPO IGC process, as well as its outcomes, as forming an actual indispensable elemental component of the Nagoya Protocol’s ABS regime, more appropriately characterized as a regime-complex aimed at the eradication of biopiracy.

The discussion of the Nagoya Protocol as a regime complex is a novel contribution which this thesis makes to the legal scholarship. Indeed, its categorization of biopiracy as an implicit issue area determining the inclusion of and setting the agenda for complementary instruments within the ABS regime complex has not been done before. Furthermore, a rationalization of the WIPO IGC as a forum which is being driven towards the articulation of a complementary instrument to form a part of the ABS regime is also a new approach to interpreting the developments within the WIPO IGC. I should note that the novelty in these approaches draws from the analytical lens adopted – the third world approach to international law (TWAIL). Indeed, this approach prioritizes the experiences and concerns of historically disadvantaged groups, such as developing countries and indigenous peoples, within the analysis of international law. My analysis has sought to redefine the ABS regime by framing biopiracy as the trans-regime issue area which defines the emerging ABS regime complex; one which requires a complementary outcome from the WIPO IGC for the purpose of initiating a needed reinforcement of its obligations through the IP system.
This thesis is located within a theoretical discussion of international regimes and their interdependence, delivered in chapter two. Regimes consist of principles, norms, rules, and decision-making procedures around which actors’ expectations converge in a given area of international relations. The foundational framework within the context of international regime theory discussed in chapter two highlights three main propositions providing the backbone for this thesis. First, international regimes do not exist in isolation. Scholars and commentators have encouraged stronger institutional coordination among international organizations as one way to overcome institutional isolation and to facilitate effective fulfilment of related mandates.  

The issue of protection for TKaGRs, which forms a key element within the Nagoya Protocol’s access and benefit sharing (ABS) regime, is a component feature within several other competing and supporting international institutions. The resulting institutional complexity which emerges in the area of the protection of TKaGRs underscores the importance of analyzing the interaction of separate regimes towards the advancement of the Nagoya Protocol’s regime objectives.

Second, regime issue areas are political constructs and as such could mean different things to different actors even within the same regime. Andrew Lang’s analysis of the international trade regime’s implicit and explicit objectives, highlights the perception-based nature of regime issue areas. Differing actors could, and often do use regimes to achieve implicit regime objectives that go beyond the explicitly stated regime objectives. This observation as applied to the issue area of biopiracy offers an opportunity for this dissertation to place the central concern of biopiracy for developing countries within the context of the discussion of the effective implementation of the Nagoya Protocol. Doing so, for the purposes of this dissertation, is in keeping with the referenced third world approach to international law (TWAIL) – a methodological school which inspires the dissertation’s emphasis on the interests of the third world. Though the Protocol was, therefore, negotiated to implement obligations within the CBD relating to the equitable sharing of benefits arising from the utilization of biodiversity for the purpose of conserving and ensuring the sustainable use of biodiversity, several developing countries have rather emphasized the eradication of biopiracy through the ABS regime as forming their primary policy concern. This is significant as it offers an interesting basis for examining the Nagoya Protocol’s ability to meet this third

1178 Okediji, “WIPO-WTO Relations”, supra note 1019 at 72.
world objective of addressing biopiracy. Placing the importance of this analysis in perspective, even if the ABS regime were to achieve the objective of equitable sharing of benefits without addressing the problem of biopiracy, the expectations of developing countries in negotiating the ABS regime would not have been met.

Third, issue areas – whether explicit (like the equitable sharing of benefits) or implicit (like preventing biopiracy) – lie at the core of the identification, characterization, and definition of regimes. What this means is that a regime derives its definition from the nature of the issue area to which it is targeted. Where issue areas are complex, in that they extend beyond individual policy areas and draw regulatory activity from multiple fora, the aggregation of regulations and laws addressing the issue area results in the possible characterization of a broader regime structure targeted at that issue area. This broadened regime is construed as a regime-complex. A defining characteristic of a regime-complex, therefore, is the existence of multiple regulations driven by different actors, in different fora, which overlap in scope and time, and address the central issue area of concern. For several reasons, biopiracy is a complex issue area: as a phenomenon, it involves the misappropriation of TKaGRs of indigenous peoples through the mechanism of the IP system. Its regulatory complexity derives, inter alia, from the complex nature and diverse regulations governing TKaGRs (the subject of appropriation), IP (the prevailing mechanism formalizing and/or legitimizing appropriation), indigenous peoples (the victims of appropriation), and the management of biodiversity (the underlying context for defining and addressing misappropriation). Biopiracy as an issue area thus extends beyond a single regime and, as such, is characterized as a trans-regime area in this work.

From this perspective, the open-ended nature of the ABS regime begins to take a new meaning. The ABS regime stipulates the inclusion of the CBD, the Nagoya Protocol, and other complementary instruments, including the Bonn Guidelines and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). These stated instruments point to the design of a regime-complex; especially where the multiple forum, actors and regulations test is applied to these instruments. This open-ended nature of the ABS regime-complex implies an unspecified scope of inclusivity for other complementary instruments to the ABS regime complex. While leaving this scope of inclusivity largely undefined, the decision adopting the Nagoya Protocol (which is annexed to this thesis) specifically mentions
the ongoing developments within WIPO as an important element of the regime’s assessment as long as the developments do not run contrary to the objectives of the ABS regime:

The Conference of the Parties [...] [d]ecides that the first review under Article 31 of the Protocol shall assess the implementation of Article 16 in light of developments in other relevant international organizations, including, inter alia, the World Intellectual Property Organization, provided that they do not run counter to the objectives of the Convention and the Protocol1179

This clearly points to a future envisaged direction for the ABS regime-complex, which considers the related developments in WIPO as key to the evolving structure of the ABS regime. By taking on a discussion of the implicit issue area of biopiracy, the dissertation thus demonstrates that beyond a mere possibility, the evolution of the ABS regime-complex to accommodate the results of the WIPO negotiations is a fundamental need for the effective resolution of developing country concerns of biopiracy. The IGC negotiations with respect to TKaGRs, have similarly been driven by developing countries to achieve objectives of ensuring mutual supportiveness between the IP and the ABS regimes as well as ensuring IP offices have appropriate information on GRs and TKaGRs for making appropriate decisions in granting IP rights. As shown in the chapter six, these negotiations remain in a difficult state.

Focusing on the projected evolution of the international ABS regime as noted above, however, at least two important considerations in line with the theoretical discussions are worth mentioning here. First, it suggests that the problem of biopiracy is a challenge which requires a complementary or coherent global approach. In other words, by establishing a network of complementary instruments which are important for addressing biopiracy, the ABS regime takes the lead in directing a coherent strategy for addressing biopiracy. The mentioned instruments – CBD, the Nagoya Protocol, the Bonn Guidelines, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) – all contribute to this end. The diversity of these instruments also paints a picture of a regime which incorporates instruments from within and without the immediate CBD framework. This is a significant point in rationalizing the possible inclusion of the WIPO negotiations (and the IP instrument(s) arising from therefrom) within the ABS regime-complex.

The second consideration is that the international ABS regime constitutes an open-ended regime. It does not represent an exhaustive list of treaties, and over time several other instruments may very well still serve to complement this regime. However, the analysis of chapter five shows that even in concluding this regime, the CBD’s Conference of the Parties (COP) considered the ongoing developments within WIPO worthy of mention. The singling out of this process (the WIPO IGC), and the important role that this process plays in complementing the contents of Nagoya Protocol for the purpose of supporting efforts to eradicate biopiracy places it as an essential element of the ABS regime. Indeed, this is the central thesis of this work.

As noted earlier, this dissertation’s focus on biopiracy (as an implicit issue area) is taken in line with a third world approach to international law (TWAIL) – a methodological and theoretical school which offers a distinct way of examining and looking at international law. A distinctive feature of the TWAIL approach is that it places a primacy on the voices and struggles of third world actors within international law. The overriding theme of historical inequity in the distribution of wealth arising from the exploitation of biodiversity underlies the ABS system, and makes this approach to analyzing international law extremely significant for this dissertation. Also, noting that the major beneficiaries of the protection mechanism for TKaGRs are indigenous peoples and developing biodiverse countries, again justifies a TWAIL to examining their struggles for recognition and reward within the international legal system. Attempting to resolve the historical exclusion of third world participants within the structures, institutions, and principles which underlie the modern international (and intellectual property) law system, especially as it relates to the commercialization of TK and GRs, forms the main thrust of the ABS regime, and so to the IGC process. The resultant power dynamics of the historical element of exclusion of TK and its holders, continues to play a significant role even in the modern evolution of international law, as well as on how international law is perceived and received by these indigenous peoples and developing states.\footnote{Alan Boyle & Christine Chinkin, \textit{The Making of International Law} (New York: Oxford University Press, 2007) at 28 – 29.} The TWAIL-inspired analysis therefore emphasizes the rebalancing of the international legal system with and through a
prioritization of the views, needs, and aspirations of third world actors. This has not necessarily been the case in ongoing efforts to address the protection of TKaGRs.

An important problem with current international efforts to address the protection of TKaGRs from biopiracy is the reification of TK through western lenses and concepts. Indeed, this approach undoubtedly facilitates the development of modern solutions. After all, how else can we who are not indigenous, yet tasked with responsibility for developing solutions to indigenous challenges, understand indigenous experiences without projecting our own? There are two options: first, is to choose to explain them through our experiences and develop solutions on that basis; while second, is to seek to learn, understand, explain, and work to solve them as what they are – indigenous experiences. My analysis in chapter three suggests TKaGRs to be a lived experience of indigenous peoples concerning genetic material located within their territories. Consequently, it is embodied in indigenous peoples that hold it and is not necessarily distinguishable or conceivable in all instances as a separate body of knowledge. In this sense, the misappropriation of TKaGRs is not just the misappropriation of the ‘knowledge’ of indigenous communities, but rather is a misappropriation of the very experiences which define them. Seeking to explain this misappropriation through western lenses and concepts, as suggested in the first approach above, carries on a colonial legacy; one which is criticized by scholars and activists for perpetuating the view that indigenous experiences require a redefinition and categorization through ‘civilized’ systems of innovation governance. It is in addressing this concern that the term biocolonialism is invoked and elaborated on as a concept arising from the continued unabated practice of biopiracy. The second approach, however, must be seen as the right, fair, and just approach in seeking solutions to the protection of TK, even from biopiracy – a prioritization of indigenous tools, concepts, and understandings towards the development of international solutions.

The importance of this latter approach is most significant within the field of intellectual property (IP) where TK is considered, and rightly so, to be a creative product of human minds. The implication of this is that the modern institutions which govern human creativity and innovation play an important role in protecting TK. However, what kind of role, and what kind of protection should this be? Chapter six undertakes a detailed discussion of the IP regime and puts forward several reasons why the existing global
IP system cannot be used as a system of protection for TK. Primarily, this is because the entire system of IP is built on foundations which pursue objectives, are based on justifications, and are linked to experiences which were not designed for, and do not support, the protection of TK.

For instance, under the IP system, we say that you can define and measure the incremental process of innovation by clearly articulating and circumscribing existing protectable knowledge, and distinguishing same from new contributions to such existing knowledge. As part of this doctoral dissertation, I argue, for example, that I am making an original or new contribution to the existing body of knowledge. To this end, my work has gone through a series of reviews, and is based on an extensive research and analysis of the literature which already exists in the field. This is how we define new knowledge. Therefore, where an applicant requests IP rights over an invention, the examination of prior art by examiners plays an important role in a determination of whether or not the invention is new. Not only does the novelty of the invention come into play, but the invention must be the result of an inventive activity, and must be capable of industrial application. These requirements support an underlying justification for the IP system, which is based on the idea that these incentives are necessary to support and stimulate innovative activity. While this is assumed to be true, and to the extent that it is true, it is problematic when considered to be true for all peoples and in all instances; particularly for indigenous peoples. TK does not evolve in ways, and for reasons which accord with the justifications provided for the IP system. I actually consider that it would be a significant tragedy to mankind if TK began to require the incentives of the IP system to develop. In consequence, the use of a system that defines knowledge in this way, and indeed to define and understand TK from this lens, raises serious concerns.

What then is the IP need? Is there, for instance, a need to assign property rights over TK? Is there a need to create incentives for indigenous based innovation? Is there a need to spur competition in TK practices leading to capitalistic visions of development? Is there a need to carve out precise definitions for TKaGR as a subject matter of protection? Respectfully, I submit not. Rather, the real need to protect TKaGRs in the IP sense, draws from the viewing of TK as a ‘subject of appropriation’ – one being appropriated through the very mechanisms of the system seeking to protect it. Essentially, the need for protection within the IP system is the need for the IP system to be able to assume formal responsibility in
preventing the misappropriation of TKaGRs, which its dominating prescriptions currently permit, and incentivize. Effectively, therefore, the extent to which the IP system draws relevance in the protection of TKaGRs, I argue, is in its ability to implement defensive mechanisms for the protection of TK. In other words, in preventing third parties from utilizing the IP system to secure rights over TK and TK-based inventions without the appropriate permissions from the sources of appropriation. Indeed, this is the vision through which this dissertation has centrally sought to demonstrate that the ABS regime, emerging on the platform of the CBD, requires defensive reinforcements from within the IP system.

Instead of focusing, therefore, on the question of how the IP system can redefine and assign rights over TKaGRs for its protection from biopiracy, we need to be looking at the critical question of how the international community (and indeed the IP system) can preserve and protect indigenous experience by preventing its misappropriation through the IP system, and thereby ensuring that TK continues to flourish within its local contexts. In other words, how can we protect the inherent right of indigenous peoples to sustainably experience and grow in their traditions and knowledge? This is what I discussed as the indigenous advantage within the context of benefit sharing in chapter five. Indeed, several justifications for benefit sharing may be pursued. However, where benefit sharing results in the unsustainability of indigenous experiences, it presents a disadvantage to indigenous communities and also the international community at large, which relies on indigenous experiences for, amongst others, the sustenance and sustainable use of our biosphere.

This recommendation does not by any means diminish the relevance of the IP system to the protection of TK. On the contrary, as I have tried to show in chapter six of this dissertation, the IP system offers a strategic opportunity for developing a bulwark system of defense for indigenous peoples in line with the above rationale, and for this reason forms a basis for linking the IP system with the Nagoya Protocol in the fight against biopiracy. As I have mentioned, the IP system cannot be relied on as a system capable of defining an indigenous experience, neither is it appropriate for the IP system to be charged with the responsibility for doing so. The importance of the IP system should, rather, be viewed from the perspective of correcting the wrongful appropriation of TKaGRs that are currently facilitated through its mechanisms. In other words, the relevance of the IP system is based on its ability to address the misuse of its mechanisms
by current beneficiaries of the IP system seeking to misappropriate and/or misuse the outputs of indigenous experiences contained in TKaGRs. It is for this reason that the difficulties within the efforts of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) to agree on a disclosure mechanism within the patent system must be considered as fundamental to the efforts of the Nagoya Protocol to address the incidence of biopiracy.

The IP system is a system of rights and duties. It principally assigns rights over knowledge to private entities who meet the stated criteria for protection. In chapter four, I argue that a key element (one of the sore spots of emphasis) of the modern conception of biopiracy involves the wrongful assigning of private rights over the knowledge of indigenous peoples. Wrongful on two fronts. First, instances where the permission and informed consent of the indigenous peoples have not been sought, in direct violation of the guaranteed rights which indigenous peoples have over their knowledge practices. Second, from the perspective of the IP system, where such rights are actually granted in error, due to the fact that what is being rewarded as new, actually already forms a part of the experience of indigenous communities. These two problems have provoked debates on how the IP system can be made more valid and accurate in its own right but also, as examined in this dissertation, more responsive to the plight of indigenous peoples who are rendered victims through the working of the dominant system. The analyses contained within this dissertation offer one prescription on how this can be done; I argue the solution must necessarily draw from a cooperation between the IP and ABS regimes.

The Nagoya Protocol, discussed in chapter five, provides the needed international framework for addressing the first part of the problem and adds an extra layer to considerations on the second part of the problem. In other words, the Protocol in providing a system of protection for TKaGRs, places the prior informed consent (PIC) principle at the center of all decision making efforts regarding the external use of TKaGRs. Indigenous peoples, in accordance with the UNDRIP have a right to full participation in decision making procedures which affect them. Further they are entitled to maintain and develop their TK practices. By placing the prior informed consent (PIC) principle at the heart of efforts to access TK, the Nagoya Protocol serves to strengthen the local indigenous experiences, and give a needed voice to indigenous peoples in determining the uses of their knowledge. Not only does it place PIC at the heart of the decision
making process, it also ensures that agreements are clearly contained within mutually agreed terms (MATs). These ensure that clarity and certainty govern the grant of access to third parties, while yet supporting efforts to monitor compliance with such agreed terms.

A central driving objective of the Protocol is the equitable sharing of benefits. As I explain, this obligation to share benefits must not be interpreted as a legalization of misappropriation; as though all appropriation of TKaGRs is justified as long as benefits are paid. It is for this reason that I caution against viewing benefit sharing merely as a system of compensation. Rather, benefit sharing is a necessary option for which indigenous peoples are entitled to receive a fair share of benefits for the sustainability of their practices and experiences. Such benefits – whether immediate, or long term, monetary, or non-monetary – are rewards for the benefits which third parties enjoy by exploiting indigenous experiences. Some indigenous peoples may not be interested in monetary benefits, which is absolutely within their prerogative. For those who do wish to participate, however, it is important that regulatory systems – including national and international initiatives – support the Nagoya Protocol to ensure that they receive a fair reward for the exploitation of their knowledge experiences.

The Nagoya Protocol goes about ensuring that this benefit sharing obligation (or proposed biopiracy solution), which is based on the principles of PIC and MATs, is actualized through the cooperation of parties within the context of the international ABS regime. The idea of the international ABS regime stems from numerous failed previous efforts to make effective this system of benefit sharing to address biopiracy. The first international attempt was contained in the Convention on Biological Diversity (CBD), with the Bonn Guidelines emerging to provide practical and legislative guidance shortly after. Though benefit sharing is presented within the CBD as an objective underlying the global management of biodiversity, from hindsight, this is probably a wrong conceptualization. Benefit sharing was not an objective, and till date, cannot be considered an objective of the CBD. This is in the same way that we cannot consider patenting an objective of the IP system. Rather, benefit sharing was an incentive – a market-based incentive which was developed and expected to support the actual objectives of the CBD – conservation and sustainable use of biodiversity. Right from the genesis of global efforts to address the rapid decline of biodiversity, the importance of indigenous peoples benefiting from the exploitation of
biodiversity has been identified as a prerequisite for the attainment of this objective. While these efforts have not been successful for a variety of reasons, including the complexity of benefit sharing arrangements, the lack of political interest, the lack of capacity, the lack of financial resources, amongst others, the Nagoya Protocol’s emergence is expected to address these through a cooperative strategy contained in an international regime on ABS.

Confirming the centrality of benefit sharing to efforts to address the decline of biodiversity, the Nagoya Protocol reorders the arrangement of the objectives. As a protocol directed principally at elaborating benefit sharing within the framework of the CBD, it sets out a singular objective of benefit sharing with the expectation that this will contribute to its other efforts to conserve and sustainably use biodiversity. At the heart of my analysis of the international ABS regime, has been the contention that this regime, while grounded in a biodiversity management discourse, has pursued the actualization of an ancillary objective from the perspective of third world actors – the implicit objective of addressing the problem of biopiracy. What this means is that the international ABS regime can be viewed as a concerted developing country-led effort to design a comprehensive system of protection for TKaGRs from the problem of biopiracy.

Rationalizing why the WIPO IGC represents such an important part of the biopiracy solutions draws from several reasons, one of which is that the IGC is a developing country-led process. Primarily, however, I argue that this is because the protection of TK from biopiracy requires an IP solution which transposes its mechanism into the field of IP, thereby addressing the IP concerns of biopiracy, particularly the second aspect, I mentioned above. Ensuring that the IP system holds inventors who make use of TKaGRs accountable for complying with the Nagoya Protocol’s mechanism of protection is a major thrust of the ongoing negotiations within the WIPO IGC. Indeed, particular emphasis is placed on ensuring that inventors have obtained the PIC of indigenous groups and have developed MATs. Consequently, the need to prevent instances where the wishes of indigenous peoples are bypassed in the grant of IP rights must be addressed and has formed a core objective of the IGC negotiations, towards full compliance with ABS obligations in the grant of patents over inventions that make use of TKaGRs. This defensive approach to protection is the reason for which the IGC was established, and remains the central issue holding up the
negotiations. Securing a complementary IP-based outcome within the WIPO IGC, however, forms the missing piece for which WIPO’s negotiations were identified as being important for the regime’s evolution. The current difficulties within the negotiations should not detract from the importance of the negotiations to the development of solutions. Rather the lengthy and sustained period of negotiation which has defined the IGC could be viewed as signaling the importance of the process to the objective of reaching an effective biopiracy resolution. Some unique features of the WIPO negotiations support the legitimacy and importance of its process to the development of IP-based solutions.

First, WIPO offers a forum for engagement by providing a platform for all stakeholders relevant to the protection of TKaGRs from biopiracy find expression. Indigenous peoples, industry representatives, NGOs, IGOs, and Member States are all represented. Not only are these various groups present within the negotiations, the methodology adopted within the negotiations serves to ensure that all voices are heard and considered within the discussions. It is also worth pointing out that the United States (one of the most important countries within efforts to address biopiracy) has been missing from most of biopiracy-related discussions given that it is not a party to the CBD and, as such, has not necessarily been a part of CBD’s negotiations, including those for the Nagoya Protocol and the Bonn Guidelines. Furthermore, the US Senate only just recently assented to the ratification of the ITPGRFA1181 which means that the IGC is probably the first direct engagement within which all stakeholders, including the US, have sought to directly negotiate terms for the protection of TKaGRs.

Second, despite the fact that it has taken on the project of developing a sui generis system of protection for TK which often renders its discussions a little less IP-centric, the IGC remains fundamentally an IP forum. Its outcomes will therefore necessarily form a part of the IP regime and be administered as such. This will have important implications for the global IP system by providing a basis for advancing reforms which support the protection of TK within the IP system. As far back as 2003, for instance, the delegation of Switzerland put forward proposals for amending the Patent Cooperation Treaty (PCT) in

support of the prevention of biopiracy.\textsuperscript{1182} A positive outcome within the IGC will definitely lead to a renewal of such concerted efforts to drive further changes towards internal consistency within the IP framework. Ultimately, as discussed in chapter six, this will provide a basis for the actuation of necessary amendments to the TRIPS.

Simply put, there may never again be a better opportunity within the IP system to develop norms which address the IP concerns of biopiracy than in the IGC. This is closely linked to the manner in which its discussions have continued to evolve due to the broad participation of stakeholders and consideration of issues which draw from multiple regulatory sources, including the human rights regime, and the ABS regime. Moreover, the fact that the negotiations have been going on for 16 years within WIPO reflects how deeply invested the parties are and, presumably, is a testament of their desire to secure an agreement. Given the centrality of ABS matters to the discussions within the IGC, the IGC is well placed as a forum which sits at the center of the two regimes, and which will necessarily produce an outcome having the potential to bridge the historical gap between the IP system and the ABS regime, through the provision of mutual reinforcements. It is in this context that this dissertation submits that the International ABS regime cannot achieve its objective of addressing the incidence of biopiracy without a complementary outcome within the ongoing process of the WIPO IGC.

\textsuperscript{1182} See, International Patent Cooperation Union (PCT Union), \textit{Working Group on Reform of the Patent Cooperation Treaty (PCT): Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resource and Traditional Knowledge in Patent Applications, 5\textsuperscript{th} Sess, PCT/R/WG/5/11 Rev. (2003)} by which Switzerland proposed to amend the regulations under the PCT to explicitly enable the Contracting Parties of the PCT to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources, and/or traditional knowledge, if an invention is directly based on such resources or knowledge.
CONFEREN_CE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

Tenth meeting
Nagoya, Japan, 18-29 October 2010

Agenda item 3

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY AT ITS TENTH MEETING

X/1. Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization

The Conference of the Parties,

Recalling that the fair and equitable sharing of the benefits arising from the utilization of genetic resources is one of the three objectives of the Convention on Biological Diversity,

Recalling also Article 15 of the Convention on access to genetic resources and the sharing of the benefits arising from their utilization,
Further recalling its decision VI/24 A adopting the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilization,

Further recalling the Plan of Implementation adopted by the World Summit on Sustainable Development held in Johannesburg in September 2002, which called for action to negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources,\footnote{Report of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August-4 September 2002 (United Nations publication, Sales No. E.03.II.A.1 and corrigendum), chap.I, resolution 1, annex, para. 44 (o.).}

Recalling decision VII/19 D, in which the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (the Working Group) was mandated with the collaboration of the Ad Hoc Open-ended Intersessional Working Group on Article 8(j) and Related Provisions, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions of Article 15 and Article 8(j) of the Convention and the three objectives of the Convention,

Recognizing that the International Regime is constituted of the Convention on Biological Diversity, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, as well as complementary instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture and the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization,

Further recalling decision IX/12,

Noting with appreciation the work carried out by the Working Group,

Noting the valuable work carried out by the Co-Chairs of the Working Group, Mr. Fernando Casas (Colombia) and Mr. Timothy Hodges (Canada), in steering the process through both formal and informal ways,

Noting also with appreciation the participation of indigenous and local communities and stakeholders including industry, research, and civil society representatives in the Working Group,

Recognizing that the objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security,

Recognizing further the progress made by many intergovernmental forums in addressing access and benefit-sharing related issues,

Considering the need for interim arrangements pending the entry into force of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity to prepare for its effective implementation once it enters into force,

Noting with appreciation resolution 18/2009 of the Conference of the Food and Agriculture Organization of the United Nations on policies and arrangements for access and benefit-sharing for genetic resources for food and agriculture,
Recognizing the importance of communication, education and public awareness for the successful implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity,

I. ADOPTION OF THE NAGOYA PROTOCOL

1. Decides to adopt the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Protocol) as set out in annex I to the present decision;

2. Requests the Secretary-General of the United Nations to be the Depositary of the Protocol and to open it for signature at the United Nations Headquarters in New York from 2 February 2011 to 1 February 2012;

3. Calls upon the Parties to the Convention on Biological Diversity to sign the Protocol at the earliest opportunity and to deposit instruments of ratification, acceptance or approval or instruments of accession, as appropriate, with a view to ensuring its entry into force as soon as possible;

4. Invites States that are not Parties to the Convention to ratify, accept, approve or accede to it, as appropriate, thereby enabling them also to become Parties to the Protocol;

5. Agrees, bearing in mind decision II/11, paragraph 2, and without prejudice to the further consideration of this issue by the Conference of the Parties serving as the meeting of the Parties to the Protocol, that human genetic resources are not included within the framework of the Protocol;

6. Decides that the first review under Article 31 of the Protocol shall assess the implementation of Article 16 in light of developments in other relevant international organizations, including, inter alia, the World Intellectual Property Organization, provided that they do not run counter to the objectives of the Convention and the Protocol;

II. Intergovernmental Committee for the Nagoya Protocol

7. Decides to establish an Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Intergovernmental Committee);

8. Decides that the Intergovernmental Committee shall undertake, with the support of the Executive Secretary, the preparations necessary for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, at which time it will cease to exist, taking into account the budgetary provisions adopted by the Conference of the Parties;

9. Notes that the rules of procedure for the Conference of the Parties to the Convention shall apply, mutatis mutandis, to meetings of the Intergovernmental Committee;

10. Decides that the Intergovernmental Committee shall hold its first meeting from 6 to 10 June 2011 and the second meeting from 23 to 27 April 2012;
11. Also decides that the Co-Chairs of the Intergovernmental Committee shall be Mr. Fernando Casas (Colombia) and Mr. Timothy Hodges (Canada) and that the first Intergovernmental Committee will be preceded by a one-day meeting to elect its Bureau and agree on other organizational matters. To that effect, the President is mandated to undertake the necessary consultations;

12. Endorses the work plan for the Intergovernmental Committee as contained in annex II to the present decision;

13. Requests the Executive Secretary to provide technical assistance to Parties, subject to the availability of financial resources, with a view to supporting the early ratification and implementation of the Protocol;

14. Invites the Global Environment Facility to provide financial support to Parties to assist with the early ratification of the Protocol and its implementation;

15. Requests the Executive Secretary, in collaboration with relevant organizations, as appropriate, to carry out awareness-raising activities among relevant stakeholder groups, including the business community, the scientific community and others, to support the implementation of the Protocol;

16. Invites Parties and relevant organizations to provide financial and technical assistance, as appropriate, to support the implementation of the Protocol;

17. Invites Parties that are developing countries, in particular the least developed countries and small island developing States, as well as Parties with economies in transition, to make an initial identification of their needs in relation to capacity-building, capacity development and strengthening of human resources and institutional capacities in order to effectively implement the Protocol and to make this information available to the Executive Secretary no later than two months prior to the first meeting of the Intergovernmental Committee;

18. Requests the Executive Secretary to collect and make available on the clearing-house mechanism sectoral and cross-sectoral model contractual clauses for mutually agreed terms;

19. Also requests the Executive Secretary to collect and make available on the clearing-house mechanism existing guidelines and codes of conduct related to access and benefit-sharing;

20. Urges the Parties to the Convention and other States and regional economic integration organizations to designate, as soon as possible and no later than 31 March 2011, a focal point for the Intergovernmental Committee and to inform the Executive Secretary accordingly;

III. ADMINISTRATIVE AND BUDGETARY MATTERS

21. Decides that, pending the entry into force of the Protocol and the convening of the first Conference of the Parties serving as the meeting of the Parties to the Protocol, the financial costs of the interim mechanisms shall be borne by the Trust Fund for the Convention on Biological Diversity (BY);

22. Takes note of the amounts supplementary to the funding estimates for the Special Voluntary Trust Fund (BE) for Additional Voluntary Contributions in Support of Approved Activities for the biennium 2011-2012 specified by the Executive Secretary and invites Parties and other States to make contributions to that Fund.

/*...*/

In order to minimize the environmental impacts of the Secretariat’s processes, and to contribute to the Secretary-General’s initiative for a C-Neutral UN, this document is printed in limited numbers. Delegates are kindly requested to bring their copies to meetings and not to request additional copies.
Annex I

NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention,

Reaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention,

Recalling further Article 15 of the Convention,

Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

Recognizing also the vital role that women play in access and benefit-sharing and affirming the need for the full participation of women at all levels of policymaking and implementation for biodiversity conservation,

Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,

Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,

Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the
International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

Acknowledging ongoing work in other international forums relating to access and benefit-sharing,

Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

Recognizing the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

Noting the United Nations Declaration on the Rights of Indigenous Peoples, and

Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

Have agreed as follows:

**Article 1**

**OBJECTIVE**

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

**Article 2**

**USE OF TERMS**

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) “Conference of the Parties” means the Conference of the Parties to the Convention;

(b) “Convention” means the Convention on Biological Diversity;

(c) “Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

...
(d) “Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use; (e) “Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Article 3

SCOPE

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

ARTICLE 4

RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Article 5

FAIR AND EQUITABLE BENEFIT-SHARING

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.
4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

**Article 6**

**ACCESS TO GENETIC RESOURCES**

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:
   (a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;
   (b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;
   (c) Provide information on how to apply for prior informed consent;
   (d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;
   (e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;
   (f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and
   (g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:
      (i) A dispute settlement clause;
      (ii) Terms on benefit-sharing, including in relation to intellectual property rights;
      (iii) Terms on subsequent third-party use, if any; and
      (iv) Terms on changes of intent, where applicable.

**Article 7**

**ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES**

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

/...
Article 8
SPECIAL CONSIDERATIONS

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

Article 9
CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

ARTICLE 10
GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Article 11
TRANSBOUNDARY COOPERATION

1. In instances where the same genetic resources are found in situ within the territory of more than one Party, those Parties shall endeavor to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavor to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

Article 12
TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities’ customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.

2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their
obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

3. Parties shall endeavor to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:
   (a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;
   (b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and
   (c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

**Article 13**

**NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES**

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:
   (a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;
   (b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and
   (c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

/...
Article 14

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATION-SHARING

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

(a) Legislative, administrative and policy measures on access and benefit-sharing;
(b) Information on the national focal point and competent national authority or authorities; and
(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

3. Additional information, if available and as appropriate, may include:

(a) Relevant competent authorities of indigenous and local communities, and information as so decided;
(b) Model contractual clauses;
(c) Methods and tools developed to monitor genetic resources; and
(d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 15

COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 16

COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING for traditional knowledge associated with genetic resources

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.
2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

**Article 17**

**MONITORING THE UTILIZATION OF GENETIC RESOURCES**

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:
   (a) The designation of one or more checkpoints, as follows:

   (i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;

   (ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

   (iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

   (iv) Check points must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.

   (b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

   (c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

   (a) Issuing authority;

   (b) Date of issuance;

   (c) The provider;

   (d) Unique identifier of the certificate;

   (e) The person or entity to whom prior informed consent was granted;

   /...
(f) Subject-matter or genetic resources covered by the certificate;

(g) Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

Article 18

COMPLIANCE WITH MUTUALLY AGREED TERMS

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

Article 19

MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

Article 20

CODES OF CONDUCT, guidelines AND BEST PRACTICEs AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

Article 21

AWARENESS-RAISING

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, inter alia:

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

/...
(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;
(d) Information dissemination through a national clearing-house;
(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;
(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;
(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;
(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and
(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

Article 22
CAPACITY
1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.
2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.
3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.
4. In support of the implementation of this Protocol, capacity-building and development may address, inter alia,
   the following key areas:
   (a) Capacity to implement, and to comply with the obligations of, this Protocol;
   (b) Capacity to negotiate mutually agreed terms;
   (c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and
   (d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.
5. Measures in accordance with paragraphs 1 to 4 above may include, inter alia:
   (a) Legal and institutional development;
   (b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;
   (c) The monitoring and enforcement of compliance;

/...
(d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

**Article 23**

TECHNOLOGY TRANSFER, collaboration AND COOPERATION

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

**Article 24**

NON-PARTIES

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

**Article 25**

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States...
among them, and of Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 26

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of /…
the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 27

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

Article 28

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 29

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

Article 30

/...
PROCEDURES AND MECHANISMS to promote COMPLIANCE WITH THIS PROTOCOL

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

Article 31
ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

Article 32
SIGNATURE

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

Article 33
ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 34
RESERVATIONS

No reservations may be made to this Protocol.

Article 35
WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal. Article 36

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

/...
DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex

MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:
   (a) Access fees/fee per sample collected or otherwise acquired;
   (b) Up-front payments;
   (c) Milestone payments;
   (d) Payment of royalties;
   (e) Licence fees in case of commercialization;
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   (g) Salaries and preferential terms where mutually agreed;
   (h) Research funding;
   (i) Joint ventures;
   (j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:
   (a) Sharing of research and development results;
   (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
   (c) Participation in product development;
   (d) Collaboration, cooperation and contribution in education and training;
   (e) Admittance to ex situ facilities of genetic resources and to databases;
   (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
   (g) Strengthening capacities for technology transfer;
   (h) Institutional capacity-building;
   (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
   (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
   (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
   (l) Contributions to the local economy;
   (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
   (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
   (o) Food and livelihood security benefits;
   (p) Social recognition;
   (q) Joint ownership of relevant intellectual property rights.

/...
Annex II

WORK PLAN FOR THE INTERGOVERNMENTAL COMMITTEE FOR THE Nagoya PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING OUT OF THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

A. Issues for consideration by the Intergovernmental Committee at its first meeting

1. The modalities of operation of the Access and Benefit-sharing Clearing-House, including reports on its activities (Article 14, paragraph 4).
2. Measures to assist in the capacity-building, capacity development and strengthening of human resources and institutional capacities in developing countries, in particular the least developed countries and small island developing States amongst them, and Parties with economies in transition, taking into account the needs identified by the Parties concerned for the implementation of the Protocol (Article 22).
3. Measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues (Article 21).
4. Cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance, including procedures and mechanisms to offer advice or assistance, where appropriate (Article 30).

B. Issues for consideration by the Intergovernmental Committee at its second meeting

5. Development of a programme budget for the biennium following the entry into force of the Protocol.
6. Elaboration of guidance for the financial mechanism (Article 25).
7. Elaboration of guidance for resource mobilization for the implementation of the Protocol.
8. Consideration of rules of procedure for the Conference of the Parties serving as the meeting of the Parties to the Protocol (Article 26, paragraph 5).
9. Elaboration of a draft provisional agenda for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (Article 26, paragraph 6).
10. The need for and modalities of a global multilateral benefit-sharing mechanism (Article 10).
11. Continued consideration of items taken up at the first meeting of the Intergovernmental Committee, as needed.
Appendix B
Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources (as at the close of IGC 30 on June 3, 2016)
LIST OF TERMS

[Traditional Knowledge Associated with Genetic Resources]

Option 1

“Traditional knowledge associated with genetic resources” means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, [that subsist in] [that are associated with] genetic resources.

Option 2

“Traditional knowledge associated with genetic resources” means substantive knowledge of the properties and uses of genetic resources [and their derivatives] held by [rightful holders, including] indigenous [people[s]] and local communities [and which directly leads to a claimed [invention] [intellectual property]] [and where, but for the traditional knowledge, the invention would not have been made].

[Biotechnology]

“Biotechnology” [as defined in Article 2 of the Convention on Biological Diversity] means any technological application that uses biological systems, living organisms [or derivatives thereof], to make or modify products or processes for specific use.

[Country of Origin]

“Country of origin” is the [first] country which possesses genetic resources in in-situ conditions.

[[Country Providing] [Providing Country]]

“Country providing/Providing country” means, [in accordance with Article 5 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity], a [providing country] [country providing] that is the country of origin [or that has acquired the genetic resources and/or that has accessed the traditional knowledge in accordance with the [Convention on Biological Diversity]].

[Country Providing Genetic Resources]

“Country providing genetic resources” is the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

ALT

[“Country providing genetic resources” is the country that possesses the genetic resource and/or traditional knowledge in in situ or ex situ conditions and that provides the genetic resource and/or traditional knowledge.]

/...
[Derivative]

“Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

[[Invention] Directly Based On]

“[Invention] Directly based on” means that the [invention] [must] make [immediate] use of the genetic resource, and depend on the specific properties of the resource of which the inventor [must] have had [physical] access.

Ex-Situ Conservation

“Ex-situ conservation” means the conservation of components of biological diversity outside their natural habitats.

Genetic Material

“Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity.

Genetic Resources

“Genetic resources” are genetic material of actual or potential value.

In-Situ Conditions

“In-situ conditions” means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties [Article 2, CBD].

[Member State]

“Member State” refers to a Member State of the World Intellectual Property Organization.

[Misappropriation]

Option 1

“Misappropriation” is the [acquisition] [utilization] of genetic resources, [their derivatives] [and] [or] [traditional knowledge associated with genetic resources] without the [free] [prior informed] consent of [those who are authorized to give [such] consent] [competent authority] to such [acquisition] [utilization], [in accordance with national legislation] [of the country of origin or providing country].

/...
Option 2

["Misappropriation" is the use of genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources] of another where the genetic resources or traditional knowledge has been acquired by the user from the holder through improper means or a breach of confidence which results in a violation of national law in a provider country. Use of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] that has been acquired by lawful means, such as reading publications, purchase, independent discovery, reverse engineering and inadvertent disclosure resulting from the holders of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] failure to take reasonable protective measures, is not misappropriation.]

[Intellectual Property Office] [Patent Office]

["Intellectual property office"] ["Patent office"] means the authority of a Member State entrusted with the granting of [intellectual property rights] [patents].

[[Physical] Access]

["Physical]/[Direct] access" to the genetic resource is its possession or at least contact [which is sufficient enough to identify the properties of the genetic resource relevant for the [invention] [intellectual property]].]

[[Protected] Genetic Resources]

["Protected" genetic resources" means, genetic resources that are protected either pursuant to an intellectual property right or other legal right. Once intellectual property rights in a genetic resource expire, the genetic resource should be in the public domain and not treated as a protected genetic resource.]

[Source]

[Option 1]

"Source" refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, [gene bank] [Budapest depository] or botanical garden.

[Option 2]

"Source" should be understood in its broadest sense possible:

(i) Primary sources, including in particular [Contracting Parties] [Countries] providing genetic resources, the Multilateral System of ITPGRFA, [patent owners, universities, farmers, and plant breeders.] indigenous and local communities; and

(ii) Secondary sources, including in particular ex-situ collections and [scientific literature].]]

1184 Several Member States expressed a difficulty in understanding the meaning of this definition. While it is retained in the list of terms, it is requested that the proponents provide greater clarity.

/...
[Source of Traditional Knowledge with Associated Genetic Resources]

“Source of Traditional Knowledge Associated with Genetic Resources” means any source from which the applicant has acquired the traditional knowledge associated with genetic resources, including indigenous and local communities, scientific literature, publicly accessible databases, and patent applications, and patent publications. ¹¹⁸⁵]

[Unauthorized Use]

“Unauthorized use” is the acquisition of genetic resources, [traditional knowledge associated with genetic resources] without the consent of the competent authority in accordance with national legislation of the providing country.]

(Utilization]

“Utilization” of Genetic Resources means to conduct research and development, [conservation, collection, characterization, among others,] [including commercialization] on the genetic and/or biochemical composition of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity].

ALT

[“Utilization” of genetic resources means to conduct research and development [including commercialization] on the genetic and/or biochemical composition of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity] [and to make a new product, or a new method of use or manufacturing of a product.]]

¹¹⁸⁵ This phrase does not appear verbatim in the document, but was introduced contemporaneously with the global deletion of “associated traditional knowledge” from the text. Upon reflection, it was felt that the Member State which introduced the phrase should have the opportunity to clarify its continuing relevance to the text.

/…
[PREAMBLE]

[Ensure [encourage] respect for [sovereign rights] [the rights] of [rightful holders, including] indigenous [people[s]] and local communities [as well as [people[s]] partially or entirely under occupation] over their genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources], including the principle of [prior informed consent and mutually agreed terms] and total and effective participation in accordance with international [agreements and] declarations [, in particular the UN Declaration on the Rights of Indigenous Peoples].]

[Contribute to the prevention of misappropriation of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]

[Minimize the granting of erroneous [IP] [patent] rights.]

[Reaffirming the important economic, scientific, cultural, and commercial value of genetic resources and [traditional knowledge associated with genetic resources].]

[Acknowledging the important contribution of the patent system to scientific research, scientific development, innovation and economic development.]

[Stressing the need for members to ensure the correct grant of patents for novel and non-obvious inventions related to genetic resources and [traditional knowledge associated with genetic resources].]

Encourage respect for indigenous [people[s]] and local communities.

[The [intellectual property] [patent] system shall/should provide certainty of rights for legitimate users and providers of genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources].]

[Recognize the role the [intellectual property] [patent] system plays in promoting innovation, [transfer and dissemination of technology] to the mutual advantage of stakeholders, providers, holders and users of genetic resources, [their derivatives] and[/or] [traditional knowledge associated with genetic resources].]

[Promote [transparency and] dissemination of information.]

[A global and compulsory system creates a level playing field for industry and the commercial exploitation of [intellectual property] [patents], and also facilitates the possibilities [under Article 15(7) of the CBD] for the sharing of the benefits arising from the use of genetic resources.]

[Foster [patent] [industrial property] protection and the development of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] and encourage international research leading to innovation.]

[The disclosure of the source would increase mutual trust among the various stakeholders involved in access and benefit sharing. All of these stakeholders may be]
providers and/or users of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]. Accordingly, disclosing the source would build mutual trust in the North – South – relationship. Moreover, it would strengthen the mutual supportiveness between the access and benefit sharing system and the [intellectual property] [patent] system.

[[Ensure] [recommend] that no [patents] [intellectual property] on life forms, including human beings, are granted.]

[Recognize that those accessing genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] in a country shall/should, where required, comply with that country’s national law providing protection for the genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]

[[IP][Patent] offices shall/should have a mandatory requirement for disclosure, as elaborated in this international legal instrument, when patenting of genetic resources would cause harm to the interests of indigenous [people[s]] and local communities.]

[Reaffirm, in accordance with the Convention on Biological Diversity, the sovereign rights of States over their [natural] [biological] resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]]

ALT

[Reaffirm, in accordance with the Convention on Biological Diversity, the sovereign rights of States over [their] [natural] [biological] [genetic] resources [within their jurisdiction other than those associated with human beings or those associated with intellectual property rights], and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]]
[I. GENERAL PROVISIONS]

[ARTICLE 1
OBJECTIVE[S]]

1 [The objectives of this instrument are to [enhance the [efficacy] and
[transparency] of the [IP] [patent] system; and facilitate mutual supportiveness with
international agreements relating to genetic resources, [their derivatives] and [traditional
knowledge associated with genetic resources].]

ALT 1

1 [The objectives of this instrument are to [enhance the [transparency] of the [IP]
[patent] system to facilitate the possibility of ABS through the disclosure of country of
origin or source of genetic resources in separate systems such as the CBD.]

ALT 2

1 [The objective of this instrument is to [promote][ensure][the effective protection
of] [contribute to the prevention of] [prevent] the [misappropriation of] genetic resources
[their derivatives] and [traditional knowledge associated with genetic resources] [through
the] [in the context of the] [IP] [patents] system by:

(a) Ensuring that [IP] [patent] offices have access to the appropriate information on
genetic resources [their derivatives] and [traditional knowledge associated with genetic
resources] to prevent the granting of [erroneous] [IP] [patent] rights;
(b) [Enhancing transparency in the [IP][patent] [and access and benefit sharing]
system]; and,
(c) [Ensuring] [promoting] [facilitating] [complementarity] [mutual supportiveness] with
international agreements relating to the protection of genetic resources [their derivatives]
and/or [traditional knowledge associated with genetic resources] [and those relating to
IP].

[ARTICLE 2
SUBJECT MATTER OF INSTRUMENT]

2 This instrument applies to genetic resources, [their derivatives] and [traditional
knowledge associated with genetic resources].

ALT

[This instrument shall/should apply to patent applications for inventions directly based on
genetic resources[, and traditional knowledge associated with genetic resources].]

[II. [MANDATORY] DISCLOSURE]
ARTICLE 3
[DISCLOSURE REQUIREMENT]

3.1 Where the [subject matter] [claimed invention] within a [IP Rights] [patent] application [includes utilization of] [is directly based on] [is directly based on the utilization of] genetic resources [their derivatives] and/or [traditional knowledge associated with genetic resources] each Party shall/should require applicants to:

(a) Disclose the [providing country that is the country of origin] [country of origin] [and] [or [if unknown],] source of the genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources.]

(b) [Provide relevant information, as required by national law, regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]

(c) [If the source and/or [providing country that is the country of origin] [country of origin] is not known, a declaration to that effect.]

3.2 The disclosure requirement [shall/should/may] [does] not place an obligation on the [IP] [patent] offices to verify the contents of the disclosure. [But [IP] [patent] offices [shall/should provide] provide guidance to [IP] [patent] applicants on how to meet disclosure requirement [formalities].]

3.3 A simple notification procedure shall/should be introduced by the [patent] [IP] offices that receive a declaration. [It would be adequate to identify in particular the Clearing House Mechanism of the CBD/ITPGRFA as the central body to which the [IP] [patent] offices shall/should send the available information.]

3.4 [Each Party shall/should make the information disclosed[, except for information related to privacy, business secrets, or other lawful confidentiality] publicly available at the time of application publication [or patent grant].]

3.5 [Genetic resources and [their derivatives] as found in nature or isolated therefrom shall/should not be considered as [inventions] [IP] and therefore no [IP] [patent] rights shall/should be granted.]

ARTICLE 4
[EXCEPTIONS AND LIMITATIONS]

4 [In complying with the obligation set forth in Article 3, members may, in special cases, adopt justifiable exceptions and limitations necessary to protect the public interest, provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument.]

1186 Some members noted a need for a definition for this formulation in the list of terms.

1187 An alternative formulation from the Nagoya Protocol Art. 14(2) is “without prejudice to the protection of confidential information”.

/…
4.1 A [IP] [patent] disclosure requirement related to genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] shall/should not apply to the following:

(a) [All [human genetic resources] [genetic resources taken from humans] [including human pathogens];]
(b) [Derivatives];
(c) [Commodities]; [genetic resources when they are used as commodities];
(d) [Traditional knowledge in the public domain];
(e) [Genetic resources from areas beyond national jurisdictions [and economic zones]]; and
(f) [All genetic resources [acquired] [accessed] before [entry into force of the Convention on Biological Diversity] [before December 29th 1993] [entry into force of the Nagoya Protocol on October 12, 2014].

4.2 [Member States shall/should not impose the disclosure requirement in this instrument on [IP] [patent] applications filed [or having a priority date] before entry into force of this instrument[, subject to national laws that existed prior to this instrument].]
[ARTICLE 5]
SANCTIONS AND REMEDIES

5. Each Party shall put in place appropriate, effective and proportionate legal and administrative measures to address non-compliance with paragraph 3.1[. including dispute resolution mechanisms]. Subject to national legislation, sanctions and remedies [shall/should] [may] [include, inter alia] consist of:

(a) Pre-Grant.  
   (i) Suspending further processing of [IP] [patent] applications until the disclosure requirements are met.
   (ii) A [IP] [patent] office considering the application withdrawn [in accordance with national law].
   (iii) Preventing or refusing to grant an [IP right] [patent].

(b) [Post-Grant.  
   (i) Publication of judicial rulings regarding failure to disclose.
   (ii) [Fines or adequate compensation for damages, including payment of royalties.]
   (iii) Other measures [including revocation, restorative justice, and economic compensation for holders of genetic resources, their derivatives, and [traditional knowledge associated with genetic resources] including indigenous peoples and/or local communities] may be considered, in accordance with national law.]

ALT

[5.1 Each Party shall put in place appropriate, effective, dissuasive, and proportionate legal and/or administrative measures to address non-compliance with Article 3, [including preventing further processing of patent applications.]]

[5.2 Material misstatements made with an intent to deceive the patent office regarding compliance with Article 3, shall be deemed perjury, lying to an official, or other similar infraction, and punishable as such in accordance with national law.]

5.3 [(Failure to fulfill the disclosure requirement] [incorrect or incomplete information], [in the absence of fraud], shall/should not affect the validity or enforceability of granted [IP] [patent] rights.]

[ALTERNATIVES TO ARTICLES 1, 2, 3, 4 & 5]
NO NEW DISCLOSURE REQUIREMENT]

ALT
[ARTICLE 1]
[OBJECTIVE]
[The objective of this instrument is to prevent the grant of patent rights on inventions that are not novel, non-obvious, and industrially applicable.]
ALT
[ARTICLE 3]
[NO NEW DISCLOSURE REQUIREMENT]

3.1 [IP] [patent] applicants may only be required to state where the genetic resource can be obtained if that location is necessary for a person skilled in the art to carry out the invention. Therefore no disclosure requirements can be imposed upon patent applicants or patentees for patents related to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources], for reasons other than those related to novelty, inventive step, industrial applicability or enablement.

3.2 [Where the subject matter of an invention is made using genetic resources obtained from an entity having a legal right over the genetic resource [(including a patent owner)], that entity may in the permit agreement or license granting the applicant access to the genetic resource or the right to use the genetic resource, require a patent applicant to:

(a) include within the specification of a patent application and any patent issuing thereon a statement specifying that the invention was made using the genetic resource and other relevant information, and
(b) obtain consent for uses not encompassed within the permit agreement or license.]

3.3 [Patent offices shall/should publish the entire disclosure of the patent on the Internet, on the date of the patent grant and shall/should strive to make the contents of the patent application publicly accessible over the Internet as well.]

3.4 [Where access to a genetic resource or [traditional knowledge associated with genetic resources] is not necessary to make or use the invention, information regarding the source or origin of genetic resource or the [traditional knowledge associated with the genetic resource] can be provided at any time after the filing date of the application.]

3.5 [Failure to examine a patent application in a timely manner shall/should result in an adjustment of the term of the granted patent to compensate the patentee for delays. Applicants shall/should be provided an opportunity to correct any incorrect or erroneous disclosures.]

[III. DEFENSIVE MEASURES/
DEFENSIVE MEASURES COMPLEMENTARY TO MANDATORY DISCLOSURE1188]

1188 Facilitators Note. Members should note that some members consider Defensive Measures as an alternative option to Disclosure while some other members consider them as a complementary option to Disclosure.

/…
[ARTICLE 6]
[DUE DILIGENCE]

6 Member states shall/should encourage or establish a fair and reasonable due diligence system to ascertain that [protected] genetic resources have been accessed in accordance with [applicable] access and benefit sharing legislation or regulatory requirements.

(a) A database shall/should be used as a mechanism to allow monitoring of compliance with these due diligence requirements in accordance with national law. However, member states shall/should not be obliged to establish such databases.

(b) Such databases shall/should be accessible to potential patent licensees [and potential investors] to confirm lawful chain of title of [protected] genetic resources upon which a patent is based.]

[ARTICLE 7]

7.1 Member States shall/should:

a. Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to prevent patents from being granted [erroneously] with regard to claimed inventions that include genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] where, under national law, those genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]:

   (i) anticipate a claimed invention (no novelty); or
   (ii) obviate a claimed invention (obvious or no inventive step).

b. Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to allow third parties to dispute the validity of a patent, by submitting prior art, with regard to inventions that include genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].

c. [Encourage, as appropriate, the development and use of voluntary codes of conduct and guidelines for users regarding the protection of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]

1189 A Member State requested to change this title to “Protection of the Demand of the Patents”. However, the facilitators do not understand the meaning of this proposal and request clarification before such a change is made.
d. Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases [information associated with] of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] for use by patent offices.

[7.2 As a complement to the disclosure obligation provided for in Article 3, and in the implementation of this instrument, the Contracting State may consider the use of databases on traditional knowledge and genetic resources in accordance with its needs, priorities, and safeguards as may be required under national laws and special circumstances.]

Database Search Systems

7.3 Members are encouraged to facilitate the establishment of databases [information associated with] of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] for the purposes of search and examination of patent applications, in consultation with relevant stakeholders and taking into account their national circumstances, as well as the following considerations:

(a) With a view towards interoperability, databases shall/should comply with minimum standards and structure of content.

(b) Appropriate safeguards [such as filters] shall/should be developed in accordance with national law.

(c) These databases will be accessible to patent offices [and other approved users].

WIPO Portal Site

7.4 Member States shall/should establish a database search system (the WIPO Portal) that links databases of WIPO members that contain information on genetic resources, [their derivatives] and non-secret [traditional knowledge associated with genetic resources] within their territory. The WIPO portal site will enable an examiner [and the public] to directly access and retrieve data from national databases. The WIPO Portal will also include appropriate safeguards [such as filters].

[IV. FINAL PROVISIONS]

[ARTICLE 8]
RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

/...
8.1 This instrument shall/should establish a mutually supportive relationship [between [intellectual property] [patent] rights [directly based on] [involving] [the utilization of] genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] and] [with] relevant [existing] international agreements and treaties.

ALT

8.1 [This instrument should be consistent with international IP agreements. Members recognize the coherent relationships between policies that promote the granting of patents involving the utilization of genetic resources and/or [traditional knowledge associated with genetic resources] and policies that promote the conservation of biological diversity, promote access to genetic resources, and the sharing of the benefits of such genetic resources.]

8.2 [This instrument shall/should complement and is not intended to modify other agreements on related subject matter, and shall/should support in particular, [the Universal Declaration on Human Rights, and] Article 31 of the UN Declaration on the Rights of Indigenous Peoples.]

8.3 [No provision in this instrument shall be interpreted as harming, or being to the detriment of the rights of indigenous people enshrined in the United Nations declaration on the rights of indigenous people. In the case of a conflict of laws, the rights of indigenous people enshrined in such declaration shall prevail and any interpretation shall be guided by the provisions of such declaration.]

[8.4 The [PCT] and [PLT] shall/should be amended to [include] [enable Parties to the [PCT] and [PLT] to provide for in their national legislation] a mandatory disclosure requirement of the origin and source of the genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]. [The amendments shall/should also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.]]

[ARTICLE 9]
INTERNATIONAL COOPERATION

9 [[Relevant WIPO bodies shall/should encourage Patent Cooperation Treaty members to] [The PCT Reform Working Group shall/should] develop a set of guidelines for [the search and examination of applications related to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]] [administrative disclosure of origin or source] by the international search and examination authorities under the Patent Cooperation Treaty].

/…
[Patent examination authorities should share information related to sources of information related to genetic resources and/or traditional knowledge, especially periodicals, digital libraries and databases of information related to genetic resources and traditional knowledge. WIPO Members should cooperate in the sharing of information related to genetic resources and knowledge, including traditional knowledge, regarding the use of genetic resources.]

[ARTICLE 10]
TRANSBOUNDARY COOPERATION

[In instances where the same genetic resources [, their derivatives] and [traditional knowledge associated with genetic resources] are found in in-situ conditions within the territory of more than one Party, those Parties shall/should endeavor to cooperate, as appropriate, with the involvement of indigenous [people[s]] and local communities concerned, where applicable, by taking measures that make use of customary laws and protocols, that are supportive of and do not run counter to the objectives of this instrument and national legislation.]

[ARTICLE 11]
TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING

[Relevant WIPO bodies [shall/should]] [WIPO shall/should] develop modalities for the creation, funding and implementation of the provisions under this instrument. WIPO [shall/should] provide technical assistance, cooperation, capacity building and financial support, subject to budgetary resources, for developing countries in particular the least developed countries to implement the obligations under this instrument.]
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