



**Background Note for the International Conference on TRIPS-CBD Linkage: Issues and way forward<sup>1</sup>**

**IMPLEMENTATION OF THE NAGOYA PROTOCOL  
SCENARIOS FOR ACCESS AND BENEFIT SHARING**

INTRODUCTION

*Brazzein* is a protein from a West African fruit of the climbing plant ‘Oubli’ (*Pentadiplandra brazzeana Baillon*). People of Gabon originally discovered and nurtured the plant, which was used to help nursing infants “forget” their mother’s milk.<sup>2</sup> A researcher from the University of Wisconsin (UW) observed people and animals eating the berries in West Africa and brought them to the attention of the University. UW-researchers isolated the protein through purification and identified it as naturally occurring amino acid sequence.<sup>3</sup> The protein derived from the berry is 500 to 2,000 times sweeter than sugar and is used as a substitute or natural, low-calorie sweetener. It is thermostable, which makes it suitable for heat processes utilized in food manufacturing.

UW was granted three US patents<sup>4</sup> and one European patent<sup>5</sup> for isolating and reproducing the protein in a laboratory. One claim for the berry in patent<sup>6</sup> is to “provide Brazzein in large quantities, at low cost, by artificial means.” The researchers have since concentrated on the reproduction of the protein in a laboratory, obviating the need to collect and cultivate the plant in Gabon. Despite the well-established documentation of the traditional communities in Gabon of the use of brazzein, UW maintains that Brazzein is “an invention of

<sup>1</sup> The paper has been prepared by Dr. BurcuKilic from public citizen and was commissioned by the Centre for WTO Studies for the International Conference on TRIPS CBD linkages. Geneva, 7<sup>th</sup> – 8<sup>th</sup> June, 2018.

<sup>2</sup> Claudio Chiarolla and BurcuKilic, Developing Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge – Key Questions (Geneva: World Intellectual Property Organization, 2017), <https://ssrn.com/abstract=2987820>. P.17

<sup>3</sup> Upon watching natives of the region eat the j’oublie berries, UW researcher Hellekant allegedly decided, “there was something of value there”. Julie Micalizzi, Misappropriation of Genetic Resources in Africa, A Study of: *Pentadiplandra Brazzeana*, *Impatiens Usambarensis*, and *Combretum Micranthum*, *Journal of Law, Technology & the Internet* · Vol. 8 · 2017, p.11-15

<sup>4</sup> US patents 5,326,580; 5,346,998; 5,527,555

<sup>5</sup> EPO (684995)

<sup>6</sup> US 5,527,555

a UW-Madison researcher” and offers no recognition or benefit-sharing to the people of Gabon.<sup>7</sup> Even worse, the synthetic substitution has caused a significant fall in the price of Brazzein, and many Gabonese women who used to harvest the fruit have lost their source of income.<sup>8</sup>

Brazzein berry of Gabon was not the first case of misappropriation of genetic resources (GRs) and/or traditional knowledge which have been discovered and passed down by indigenous groups for generations and it would not be the last. In fact, GRs have historically been treated as a common heritage of mankind, resulting in the free flow of GRs across boundaries. No international mechanism existed to share the benefits of new products developed or inventions patented which utilized GRs or traditional knowledge of indigenous and local communities. Lack of international governance facilitated extraterritorial free riding of the world's most extensive collections of plant GRs and traditional knowledge. After years of deliberations and building political will, countries rich in biodiversity—whose biodiversity are taken for granted and have been taken advantage of for so long—initiated discussions on the fair and equitable sharing of benefits.

#### THE CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity (CBD) is the first comprehensive international agreement dedicated to biological diversity. It was adopted in Nairobi in May 1992 by the countries convened by the United Nations (UN) Environment Programme. The CBD was opened for signature at the UN Conference on Environment and Development held in Rio de Janeiro in June 1992. The convention entered into force a year after, in 1993,<sup>9</sup> when it gained broad international support for its fundamental principles.

The CBD represents a strong commitment to the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of GRs. It contains core obligations for its contracting parties to take related to access to GRs, benefit sharing, and compliance.

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<sup>7</sup> The global market for artificial and high-intensity sweeteners is estimated to be worth around USD 3 billion. Natur Research Ingredients, a US company, acquired a license to produce Brazzein from food-grade bacteria using the UW patented process. The company had indicated that it wished to commercialize Brazzein under the brand name Cweet as a cost-effective alternative to stevia or monk fruit. At present, it is not known whether this product has been commercialized successfully, Elaine Watson, “Brazzein entrepreneur seeks partner to take next-generation natural sweetener to market”, *Food Navigator*, February 2014, [www.foodnavigator-usa.com/Suppliers2/Brazzein-entrepreneur-seeks-partner-to-take-next-generation-natural-sweetener-to-market](http://www.foodnavigator-usa.com/Suppliers2/Brazzein-entrepreneur-seeks-partner-to-take-next-generation-natural-sweetener-to-market)

<sup>8</sup> Chiarolla&Kilic, supra note 1, p.17-18

<sup>9</sup> See “History of the Convention,” About, Convention on Biological Diversity, <https://www.cbd.int/history/>.

Despite nations having a common interest in addressing global biodiversity as a whole, the CBD was achieved through a complex bargaining process between the Global South (providers of biodiversity) and the Global North (consumers and beneficiaries).<sup>10</sup> The convention exists at the crossroads of environmental protection and development.<sup>11</sup> The CBD affirms the sovereign rights of the states over their natural resources.

#### **Article 15. Access to Genetic Resources**

1. 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.

2. 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.

3. 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.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. 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.

7. 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.

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<sup>10</sup> The terms Global North and Global South clearly divide the world into two halves geographically. The Global South and the Global North represent an updated perspective on the post- 1991 world, which distinguishes not between political systems or degrees of poverty, but between the victims and the benefactors of global capitalism. *See*, Thomas Hylland Eriksen, "What's wrong with the Global South and Global North?", Concepts of the Global South – Voices from around the world Global South Studies Center, University of Cologne, Germany – <http://gssc.uni-koeln.de/node/452>

<sup>11</sup> Elisa Morgera and Elsa Tsioumani, "Yesterday, Today and Tomorrow: Looking Afresh at the Convention on Biological Diversity," *Yearbook of International Environmental Law* 21 (2011):3.

Recognizing the national sovereign rights over biological resources, the CBD introduced the concepts of benefit sharing—access and benefit sharing (ABS) for GRs and traditional knowledge in international environmental law—and provided a set of basic principles on ABS (Articles 15, 16, and 19).

The CBD represented ABS as a tool for equity and as a prospect for sustainable development. It aimed to establish a balance between biodiversity-rich countries, which are predominantly developing countries and developed countries (which hugely benefit from commercial products developed with these GRs). The objective was to share these benefits with the countries of origin of GRs.

The CBD recognizes the close and traditional dependence of many indigenous and local communities on biological resources. According to the CBD, access to GRs shall be on “mutually agreed terms” (MAT) and with “prior informed consent” (PIC), and shall lead to fair and equitable sharing of “the results of research and development and the benefits arising from the commercial and other utilization of GRs.”<sup>12</sup>

The ABS provisions under Articles 15, 16, and 19 have provided very little guidance on how access to and use of GR would be consistent with benefit-sharing requirements.

While a few countries have implemented the CBD principles and have adopted measures supporting effective benefit sharing, the lack of ABS policies and instruments in other countries, particularly developed ones, has created legal ambiguity and uncertainty.

## I. BONN GUIDELINES

In 2002, the contracting parties to the CBD adopted non-binding, voluntary guidelines called the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. These guidelines aimed to support the implementation of ABS measures at the legislative, administrative, and policy levels. The Bonn Guidelines illustrated possible approaches to support compliance with ABS requirements, such as ABS contracts and PIC.

The document provided some guidance on the possible interactions between the intellectual property (IP) system and the CBD. It also introduced a few measures to encourage disclosure of the country of origin of GRs and of the origin of traditional knowledge, prevent use of GRs obtained without PIC, and discourage unfair trade practices.

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<sup>12</sup> Convention on Biological Diversity, *Article 8 (j): Traditional Knowledge, Innovations & Practices*, <https://www.cbd.int/doc/meetings/cop/cop-09/media/cop9-press-kit-tk-en.pdf>.

While the Bonn Guidelines provided some clarity on ABS-related IP issues, specific guidance on the implementation of the ABS provisions remained limited. However, the guidelines served as a platform for further advancement of a global ABS framework.

## II. THE NAGOYA PROTOCOL

The Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, known as the Nagoya Protocol, was adopted in 2010 and signed by 92 countries. The Nagoya Protocol implements and further specifies the ABS obligations of the CBD by establishing a framework for users' compliance at the national level. The Protocol established a global framework on the rules and mechanisms for access to GRs and associated traditional knowledge.

Following the adoption of the Bonn Guidelines, the biodiversity-rich countries had called for negotiation of “an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.”<sup>13</sup> The negotiations kicked off in 2004 with the establishment of an ad hoc working group on ABS. The Conference of the Parties (COP 10) scheduled to be held in October 2010 was initially set as the deadline for the negotiations on an international regime within the existing framework of the CBD.<sup>14</sup> Intense negotiations between developed and developing countries brought confrontation on issues such as benefit sharing, access to GRs, compliance, and disclosure of source/origin.

The negotiations between developed and developing countries, and consultation between the COP 10 chair and representatives of each region, continued until the last day of the Conference. The Draft President's text, which included compromise language acceptable to both sides, was adopted under the agreed upon title of the Nagoya Protocol on Access and Benefit-Sharing.<sup>15</sup>

The Protocol which entered into force on 12 October 2014 comprises four interrelated pillars: access to GRs, benefit sharing, traditional knowledge, and compliance. The Protocol defines how the ABS system operates and establishes predictable and legal conditions for access to GRs. At the outset, it reaffirms that parties have national sovereignty over their GRs.<sup>16</sup> It creates a legal framework for users of GRs to share the

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<sup>13</sup> COP 7 Decision VII/19, available at <https://www.cbd.int/decision/cop/?id=7756>

<sup>14</sup> *Plan of Implementation of the World Summit on Sustainable Development*, 2002, para. 44(o), available at [http://www.un.org/esa/sustdev/documents/WSSD\\_POI\\_PD/English/WSSD\\_PlanImpl.pdf](http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf)

<sup>15</sup> Ryo Kohsaka, “The Negotiating History of the Nagoya Protocol on ABS: Perspective from Japan,” 2012, [www.ipaj.org/english\\_journal/pdf/9-1\\_Kohsaka.pdf](http://www.ipaj.org/english_journal/pdf/9-1_Kohsaka.pdf).

<sup>16</sup> Preamble, the Nagoya Protocol: “*Reaffirming* the sovereign rights of States over their natural resources and according to the provisions of the Convention.”, <https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-00>

benefits of use with the providers of those resources. It also establishes additional new obligations related to users' compliance with domestic legislation or regulatory requirements on ABS in countries other than the provider country. The Protocol does so by creating, among other things, a globally harmonized certification mechanism for users' compliance through an ABS Clearing-House, and by institutionalizing the so-called internationally recognized certificate of compliance.<sup>17</sup>

The text of the Protocol is ambitious, with ambiguities nestled in compromises. The adoption of the Protocol was enabled by bringing in ambiguity on several controversial issues resulting from accommodating competing proposals from developed and developing countries. Even when the Protocol was ratified and came into force, the text still included procedures that needed to be clarified and negotiated.<sup>18</sup>

Many of these ambiguities relate to the scope of the Protocol, including whether it applies to traditional knowledge associated with GRs held by indigenous and local communities and whether it includes certain derivatives developed through the utilization of GRs. There is also ambiguity about the temporal and geographical scope of the Protocol, including whether its application is triggered by a user country's initial access to the genetic resource or its actual utilization of that resource.

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<sup>17</sup>Chiarolla and Kilic, *supra* note 1, p.46

<sup>18</sup>Kohsaka, *supra* note 15, p.17

## Background on definitions in the context of the Nagoya Protocol

The definition of “utilization of genetic resources” is crucial in terms of determining the scope and effectiveness of the Protocol to ensure benefit sharing.

### 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:

(...)

(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;

The Article 2 focuses on the utilization of genetic resources for research and development purposes. It makes references to:

- research and development,
- biochemical composition of genetic resources, and
- application of biotechnology.

The Protocol does not define “research and development”. Based on Article 31(1) of the Vienna Convention on the Law of Treaties, the ordinary meaning of these terms in the context of the Nagoya Protocol is applicable. The *Oxford Dictionaries* definition of “research” is “the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions.” In particular, for the Nagoya Protocol, “research” means “the investigation and study of the genetic and/or biochemical composition of genetic resources in order to establish facts and reach conclusions. “Development” includes the creation of innovations and practical applications (e.g., applied research), including through the application of biotechnology.

The expression “[...] utilization of [GRs] as well as subsequent applications and commercialization” is used to trigger fair and equitable benefit-sharing obligations under Article 5 of the Nagoya Protocol. In addition, patent/intellectual property offices may be designated as possible checkpoints under Nagoya Protocol Article 17. These “[...] checkpoints would collect or receive, as appropriate, relevant information related to [...] the utilization of genetic resources, as appropriate.”

*Source: Chiarolla&Kilic, supra note 1, p.66*

## ABS AND INTELLECTUAL PROPERTY

### I. THE SCOPE OF ABS

The CBD obliges user countries to take legal, administrative, and policy steps to make ABS functional for conservation and sustainable use of biological diversity.<sup>19</sup> The Nagoya Protocol contributes to enhanced multilateralism for ABS. It is an international mechanism, targeting situations in which a genetic resource from one country is used within the jurisdiction of another country. Under the Protocol, the ABS requirements are triggered when GRs are used in research and development (R&D), which could include working on the genetic or biochemical composition of the material or development of products and processes used for biotechnology.<sup>20</sup>

Effective implementation of ABS depends on both provider and user countries. Provider countries are required to introduce or further elaborate detailed domestic ABS legislation to facilitate user countries' compliance with access rules. While implementing ABS regulations, they are also required to take indigenous people's customary laws and rules, community protocols and procedures into consideration.

The ABS rules may include a PIC obligating users to seek consent from GRs/TK providers before accessing the resources and the mutual agreed terms (MAT), a tool of private contract law made between the user and the country of origin or representatives of the indigenous people.

PIC ensures 'fair access' to GRs and traditional knowledge and confirms the primary legal capacity and indispensable role of national authorities in governing a PIC system. However, the authority to grant PIC can be attributed to non-state entities, such as research institutes. In such instances, PIC is embodied in a private law act and can be confirmed with MAT.<sup>21</sup>

In fact the Protocol specifies that where PIC is provided, the access rules should be clear and transparent, and provide fair and non-arbitrary procedures for granting access.<sup>22</sup>

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<sup>19</sup> CBD, Article 15.7.

<sup>20</sup> UNCTAD, *The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications, a Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property* (Geneva: United Nations Conference on Trade and Development, 2014), p.36

<sup>21</sup> Elisa Morgera, Elsa Tsioumani & Matthias Buck: Article 15 "Unraveling The Nagoya Protocol : A Commentary of the Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity", 2014, *Legal Studies on Access and Benefit-sharing*, pp. 252-25

<sup>22</sup> Nagoya Protocol (Access to Genetic Resources), Article 6.3:

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

Standardization of access rules could help enforcement in the user country. If the access side of ABS is streamlined, it would be more difficult for user countries to use legal uncertainty in provider countries to argue against introducing ABS enforcement provisions under their jurisdictions. Even then, there is no guarantee that the provider country would receive benefits. However, without access legislation, the provider country would rely on only the goodwill and philanthropy of the bioprospector to receive any benefits.<sup>23</sup>

The legal functionality of ABS largely depends on national laws introducing user measures and effective enforcement mechanisms. Under the Protocol, user countries have considerable leeway in implementing user measures. The Protocol does not specify concrete measures. It mentions only effective measures and often qualifies obligations by adding the language “as appropriate.”<sup>24</sup> Given the economic and technological interests at stake and institutional challenges, it requires a tremendous effort to identify cases in which users are required to submit a certificate.<sup>25</sup>

It should be noted that the ABS governance is built on the notion of a contract between the provider country and the user. It is regarded as a system for creating incentives for private (or public) entities to share benefits generated by the GRs in a fair and equitable manner. Arguably, the limited success of benefit sharing in practice is mostly due to lack of incentives.

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- (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.

<sup>23</sup> Morten WalløeTvedt, “Beyond Nagoya: Towards a Legally Functional System of Access and Benefit-Sharing,” in *Global Governance of Genetic Resources Access and BenefitSharing after the Nagoya Protocol*, eds. Sebastian Oberthür and G. Kristin Rosendal (Abingdon: Routledge, 2014), 161.

<sup>24</sup> Nagoya Protocol, 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.

<sup>25</sup> Linda Wallbott, Franziska Wolff, and JustynaPozarowska, “The Negotiations of the Nagoya Protocol: Issues, Coalitions, and Process,” in *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol*, eds. Sebastian Oberthür and G. Kristin Rosendal (Abingdon: Routledge, 2014) 53–54.

*“A core question is why a company from one country, which finds a useful GR on the territory of another country, should share a part of its earnings with that country. The GR user has a moral obligation, translated into law in CBD Article 15, to share a fair and equitable part of the benefits arising from such utilization with the providing country. Those benefiting from biodiversity should contribute to its sustainability over the longer term. When a company’s shareholders want the largest return from their investment, however, voluntary benefit sharing is illusion. At the moment there is a lack of both positive incentives and negative sanctions motivating companies to share benefits.”<sup>26</sup>*

The enforcement of MAT and PIC, and even compliance with provider rules across borders under another jurisdiction, proves to be a major challenge for global ABS governance. Historically, access measures have proved to be inadequate to prevent IP rights from being granted in situations in which the genetic material has been illegally accessed or is used without authorization in an inventive process or incorporated into an invention as emanating from another jurisdiction.

The cooperation of user countries and the companies in sharing benefits from use of GRs of other countries is essential for the international ABS system to function and to contribute to the conservation and sustainable use of biodiversity. Getting provider and user countries to adopt compatible national legislation becomes highly crucial to provide legal certainty and predictability for the users.

These challenges can be overcome through patent disclosure requirements related to GRs and traditional knowledge. The requirements can be utilized as a tool for compliance with any national legislative, administrative, or policy measures on ABS as required by the Nagoya Protocol.

## II. ABS AND INTELLECTUAL PROPERTY

ABS discussions started as early as the 1980s in three interlinked political arenas: agriculture, trade and IP, and the environment.

In the trade and IP arena, the revision of the 1991 International Union for the Protection of New Varieties of Plants (UPOV) and the signature of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)—introducing minimum standards for IP, including on biological matter—created perverse incentives for the misappropriation of biodiversity.

Since then, the relationship of GRs, traditional knowledge, and IP has been among the most controversial agenda items in the negotiations of several bilateral and multilateral agreements.

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<sup>26</sup>Tvedt, supra note 21, p. 161

## o Agreement on Trade-Related Aspects of Intellectual Property Rights

IP rights created the conflict preventing parties from reaching a consensus on building an international ABS regime.

TRIPS establishes the minimum standards for IP protection for all WTO members. It covers a wide range of IP issues, including provisions on the domestic enforcement of IP rights. All the WTO member countries are required to ensure compliance with these minimum standards.

Article 27 of TRIPS defines the types of inventions that must be eligible for patent protection and those that can be exempt. These include both products and processes, and they cover all fields of technology.

### *Article 27*

#### *Patentable Subject Matter*

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

(...)

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

TRIPS establishes minimal criteria for patentability but leaves some room for flexibility regarding the way the protected subject matter is defined, owned, managed, and made subject to exceptions.

GRs, as encountered in nature, are not considered an invention (i.e., patent-eligible subject matter) and cannot be directly protected as IP. However, inventions based on or derived from GRs may be patentable (or subject to other forms of IP rights). WTO members have full discretion to determine what should be deemed an invention. They may take advantage of TRIPS-enumerated exclusions on diagnostic, therapeutic, and surgical methods for the treatment of humans or animals; plants and animals other than micro-organisms; and, essentially, biological processes for the production of plants or animals other than nonbiological and microbiological processes.

WTO members may exclude plants, animals, and essentially biological processes from patentability. The developed countries have taken an increasingly narrow view of these exclusions and have argued that a

process is not “essentially biological” if there has been substantial interference by man.<sup>27</sup> Thus, biotechnological inventions should be covered. They also circumvented this exclusion by including provisions in free trade agreements obliging parties to grant patents for plants and animals.<sup>28</sup>

Some countries exclude the mere extraction or isolation of a naturally existing substance from qualifying as patent-eligible subject matter. GRs (and their derivatives) as found in nature or isolated therefrom may not be considered patent-eligible subject matter, and they can be excluded from patent protection.

#### *Indian Patent Act, 1970*

Section 3 (c) states that:

[...] The following are not inventions within the meaning of this Act: [...] the discovery of any living thing or non-living substance occurring in nature.

Thus, the extraction and isolation of biological materials is generally considered as the mere discovery of a naturally occurring substance, and may not be patent eligible subject matter in India.

Furthermore, Section 3(j), which is almost verbatim of TRIPS Article 27.3 excludes “plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals” from patentability. However, other areas involving microorganisms as well as processes which are not essentially biological are patentable, since the Act only prohibits patents on essentially biological processes for production or propagation of plants and animals. The Act neither defines the term ‘microorganism’ at all nor prohibits the patentability of any seeds or plants derived from patented microorganisms.

In fact, biodiversity-rich countries with no or little patent examination capacity to inspect complex biotechnology patents may want to take advantage of this provision to address misappropriation concerns at the national level.<sup>29</sup>

The relationship between TRIPS and the CBD has been described as an “arms race<sup>30</sup>.” Both were negotiated in parallel discussions in the late 1980s and early 1990s, with different motives.<sup>31</sup> While the CBD promotes

<sup>27</sup> World Conservation Monitoring Centre, *Global Biodiversity: Status of the Earth’s Living Resources* (Berlin: Springer, 2012), 498.

<sup>28</sup> See US-Morocco Free Trade Agreement, Article 15.9.2. [https://tcc.export.gov/static/final\\_text\\_Morocco\\_FTA.pdf](https://tcc.export.gov/static/final_text_Morocco_FTA.pdf)

<sup>29</sup> See also WIPO, *Indicative List of Outstanding/Pending Issues to be Tackled/Solved*, issue n. 5, [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_30/wipo\\_grtkf\\_ic\\_30\\_5.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_30/wipo_grtkf_ic_30_5.pdf).

<sup>30</sup> Sebastian Oberthür and Justyna Pozarowska, “The Impact of the Nagoya Protocol on the Evolving Institutional Complex of ABS Governance,” in *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol*, eds. Sebastian Oberthür and G. Kristin Rosendal (Abingdon: Routledge, 2014) 184.

<sup>31</sup> *Id.*

fair and equitable benefit sharing between providers and users of GRs, TRIPS introduced a global patent protection for inventions based on GRs and traditional knowledge. IP protection introduced by TRIPS is usually used to circumvent obligations derived from the CBD, resulting in legal conflicts between the agreements.

The WTO's Doha Ministerial Declaration<sup>32</sup> instructed the TRIPS Council to review the relevant provisions of TRIPS that contain several environment-related provisions and further discuss the relationship between the TRIPS and the CBD. They were to be guided by the objectives and principles of Articles 7<sup>33</sup> and 8<sup>34</sup> of the TRIPS development dimension.<sup>35</sup>

Highlighting the inherent conflict between the two instruments, developing countries requested amendment of TRIPS to ensure both agreements are implemented in a mutually supportive manner.

On the other hand, developed countries, led by the United States (US), took the view that there was no conflict between TRIPS and the CBD, and that governments can implement the two in a mutually supportive way through national measures. They considered the amendment of TRIPS neither necessary nor appropriate in achieving the shared objectives, which they insisted could be most effectively realized in other ways without involving the patent system.<sup>36</sup>

Since then, a satisfactory outcome on the interface between TRIPS and the CBD has become critical for the development dimension of the Doha Work Programme for developing countries. The discussions on the amendment of the TRIPS agreement have primarily focused on Article 29.<sup>37</sup> Developing countries proposed

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<sup>32</sup> World Trade Organization, *Wt/Min(01)/Dec/1. 20 November 2001 (01-5859)*, Ministerial Conference, Fourth Session, Doha, 9-14 November 2001. [https://docs.wto.org/dol2fe/Pages/FE\\_Search/FE\\_S\\_S009-DP.aspx?language=E&CatalogueIdList=37246&CurrentCatalogueIdIndex=0&FullTextSearch=](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=37246&CurrentCatalogueIdIndex=0&FullTextSearch=)

<sup>33</sup> TRIPS, Article 7: "[...] the protection and promotion 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."

<sup>34</sup> TRIPS, Article 8, para. 1, allows members to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with" the TRIPS Agreement.

Para. 2 of this provision authorizes members to adopt measures "to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

<sup>35</sup> Doha WTO Ministerial 2001, para. 19, Ministerial Declaration *Wt/Min(01)/Dec/1. 20 November 2001*:

"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, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

<sup>36</sup> WTO Doc, *IP/C/W/368/Rev. 1*, 8 February 2006. [https://www.wto.org/english/tratop\\_e/trips\\_e/ipcw368\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf)

<sup>37</sup> TRIPS, Article 29: "Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the

amendment of the provision to oblige members to require that an applicant for a patent relating to biological materials or to traditional knowledge provide information about the source and country of origin of the biological resource. They would also be required to provide information on the country of the traditional knowledge used in the invention, evidence of PIC from the authorities under the relevant national regime, and evidence of fair and equitable benefit sharing under the relevant national regime.<sup>38</sup>

The discussions have shifted from the WTO to the World Intellectual Property Organization (WIPO). Negotiations have been taking place since 2010 at the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore for an international legal instrument introducing an internationally harmonized patent disclosure requirement related to GRs and traditional knowledge.<sup>39</sup>

Most recently, in 2011, after the signing of the Nagoya Protocol, a group of developing countries—including the African, Caribbean, and Pacific Group of States; the African Group; Brazil; China; Colombia; Ecuador; India; Indonesia; Peru; and Thailand—reiterated their call for the amendment of TRIPS and to table a proposal introducing mandatory disclosure requirement by inserting a new article as follows:<sup>40</sup>

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best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

“Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.”

<sup>38</sup> The proposals called for an additional paragraph to Article 29: “Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin” (African Group, IP/C/W/404). “Where appropriate, Members shall require the disclosure of origin and legal provenance in the patent applications to be submitted” (Peru, IP/C/W/447, IP/C/M/48, para. 21). The introduction of a new article in the TRIPS Agreement (Brazil et al., IP/C/W/403). “The Relationship between the TRIPS Agreement and the Convention on Biological Diversity,” WTO Doc, IP/C/W/368/Rev. 1, 8 February 2006. [https://www.wto.org/english/tratop\\_e/trips\\_e/ipcw368\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf)

<sup>39</sup> The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore is, in accordance with its mandate, undertaking text-based negotiations with the objective of reaching agreement on a text(s) of an international legal instrument(s) that will ensure the effective protection of traditional knowledge, traditional cultural expressions, and genetic resources. For more information, visit <http://www.wipo.int/tk/en/igc/>.

<sup>40</sup> 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, WTO Doc TN/C/W/59, 19 April 2011.

#### **Article 29bis**

##### **Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge**

1. 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.
2. 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.

#### **o The International Union for the Protection of New Varieties of Plants**

The UPOV Convention was adopted in 1961 to provide legal protection for plant varieties in Western European countries. It seeks to protect new varieties of plants and acknowledge the achievements of breeders of new plant varieties. UPOV considerably reduces the flexibility in the TRIPS agreement. It provides exclusive property rights for a limited period of time on any plant variety that is novel, distinct, homogenous, and stable. It creates a high degree of harmonization among the parties.

The convention entered into force in 1968 and has been subject to a couple of revisions. It has two principal versions: the 1978 version and the 1991 version. Advances in biotechnology have made it possible to engineer new plant varieties (and other biologically based "inventions"), which can satisfy the novel and non-obvious criterion. Once this technology was firmly established, the relatively tempered scope of the 1978 UPOV gave way to more stringent requirements in 1991. The 1991 UPOV provides breeders with more exclusive rights at the expense of farmers and indigenous and local communities.

For owners of GRs and traditional knowledge who wish to have fair and equitable sharing of the benefits arising from such exploitation, there is no mechanism in UPOV that can prevent the misappropriation of indigenous variety by commercial forms. Indeed, there is no recognition of indigenous peoples and local communities (IPLC) and the sustainability of GRs in UPOV. This is due to the fact that UPOV provides a model of protection of breeders' commercial interests. It was never intended to provide rights to indigenous and local communities who have used those resources for centuries, resources over which they exercise

authority. Consequently, it does not have any mechanism to facilitate ABS arising from the utilization of plant GRs developed by local and indigenous communities.

The UPOV is ostensibly a member-driven organization. However, the UPOV mission receives a great deal of support from the United States and European Union (EU), and its secretariat has historically taken a position aligned with those countries by opposing disclosure requirements.<sup>41</sup>

#### **UPOV on Disclosure**

*“UPOV expressed the view that the Convention of [sic] Biological Diversity and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive in respect of access to genetic resources and benefit sharing.*

*“As for the disclosure of origin of genetic resources, UPOV is not opposed to the disclosure, per se, of countries of origin or geographical origin of genetic resources in any way that will facilitate the examination of whether a variety qualifies for protection. It should be recalled, however, that under the UPOV Convention, protection shall be granted where the variety is new, distinct, uniform and stable. Further or different conditions for protection are excluded. Therefore, disclosure of origin of genetic resources should not be regarded as an additional condition of protection.”*

UPOV accession rules are described as rigid modelling of national law. The secretariat vets domestic laws of would-be-acceding countries, thereby strongly influencing the plant variety protection (PVP) legislation. Countries are not allowed to join if they deviate from the rigid model established by the secretariat.<sup>42</sup>

UPOV’s position on disclosure requirements reduces countries’ ability to effectively implement their obligations (including the obligation for a fair and equitable benefit-sharing) under the CBD and the UN Declaration on the Rights of Indigenous Peoples. The UPOV system creates incoherence for ABS in the international legal system.

Both UPOV 1978 and UPOV 1991 Acts fail to give due recognition to the contribution of local and indigenous communities and farmers, or acknowledge their continuing important role in the development of plant GRs. Without a disclosure requirement, there is no trace of indigenous and local communities’ contribution or their traditional knowledge in management of plant GR. Moreover, the UPOV 1991

<sup>41</sup> Joseph A. McMahon and MelakuGeboye Desta, eds., *Research Handbook on the WTO Agriculture Agreement New and Emerging Issues in International Agricultural Trade Law* (Northampton, MA: Edward Elgar Publishing, 2012), 147.

<sup>42</sup> Carlos Correa, *Plant Variety Protection in Developing Countries. A Tool for Designing a Sui Generis Plant Variety Protection System: An Alternative to UPOV* (Malaysia: Third World Network, 1991).

restrictions on saving, exchanging, and selling protected seeds could also have a corrosive effect on traditional knowledge.

#### PATENT DISCLOSURE REQUIREMENTS

ABS will not be achieved if patent holders do not disclose the origins of the generic resources that they used for their inventions. Lack of disclosure of source and origin has resulted in a series of famous biopiracy cases involving misappropriation of GRs and traditional knowledge.

It has usually been the case that companies and researchers from developed countries accessed GRs from a biodiversity-rich country without consent, utilized those resources in R&D to develop an invention, and patented those inventions utilizing the resource without mentioning where the resource was obtained.

##### **The neem patents**

The neem tree (*Azadirachta indica*) originates from India and grows in more than fifty tropical countries around the world. Since the 1980s, many neem-related process and products have been patented in Japan, United States, and European countries. Companies claim that neem used for inventions is public domain traditional knowledge.

After the European Patent Office (EPO) granted a patent for fungicidal effects of neem oil (Patent No. 436 257 B1) to the U.S. Department of Agriculture and multinational W.R. Grace in 1995, the patent was challenged by the Indian government. The EPO revoked the patent on the grounds of lack of novelty and inventive step.

The neem patent challenge created a global awareness on neem and its properties, bio-piracy, need for documentation of traditional knowledge, equitable sharing of gains from traditional knowledge, and harmonization of patent rules.

The concerns over unauthorized access to and use of GRs and traditional knowledge and their subsequent misappropriation have led to the introduction of additional measures for protection. It was clear that an information problem existed at the patent application stage. Thus, patent disclosure requirements have been presented as a possible and convenient solution, and several countries have already implemented them. More than 30 developed and developing countries have implemented such requirements through national or regional laws.<sup>43</sup>

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<sup>43</sup>WIPO, *Disclosure Requirements Table*, October 2017, [http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic\\_resources\\_disclosure.pdf](http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf).

Patent disclosure is one of the main elements of the IP system. It aims to increase the degree of knowledge and transparency relating to patents in the course of the patent application process. Full disclosure of the invention is widely regarded as a *quid pro quo* the patentee must provide to gain the benefits of patent exclusivity.<sup>44</sup>

Patent disclosure targets two types of audiences: legal and technical, each of which seeks different information.<sup>45</sup> The legal audience determines whether the invention satisfies the patentability requirements and the scope of the right to exclude, while the technical audience assesses whether the disclosure is adequate and the patentee possesses enough information about the invention to demonstrate that he or she actually discovered it.<sup>46</sup>

Where the subject matter of a patent application concerns or utilizes a genetic resource or traditional knowledge, or appears to include one or both of them wholly or partially in its scope, the question arises whether existing patent disclosure requirements should be expanded through specific disclosure requirements to further improve the understanding of legal and technical audiences of patent disclosure.

Several countries have introduced additional measures to strengthen or broaden the scope of patent disclosure to require patent applicants to disclose, among other things:

- the origin and/or the source of GRs and/or traditional knowledge;
- evidence of PIC for their use connected to research of which the claimed invention was an outcome, from the provider country (and, in some cases, from indigenous peoples and local communities, in accordance with national legislation); and
- evidence of having established a contractual arrangement (i.e., MAT) for the fair and equitable sharing of the benefit derived from such use—if so required by the national legislation of the provider country.<sup>47</sup>

Patent disclosure requirements related to GRs and traditional knowledge (hereinafter, patent disclosure requirements) may well be considered a new “layer” of the conventional disclosure requirements. They impose an additional duty to disclose more information at the legal and/or technical levels and build on the basic obligation to disclose “information material to patentability” within the description of the invention

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<sup>44</sup> Robert P. Merges and Richard R. Nelson, “On the Complex Economics of Patent Scope,” *Columbia Law Review* 90 (1990): 839.

<sup>45</sup> Jeanne C. Fromer, “Patent Disclosure,” *Iowa Law Review* 94 (2009): 539.

<sup>46</sup> *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

<sup>47</sup> Chioralla and Kilic, *supra* note 1, p. 18.

and how to work it. A proper scope of disclosure of information related to source and origin may help the patent examiner to cover relevant prior art. This would help in rewarding true innovations and reduce erroneous patent rewards.<sup>48</sup>

More importantly, patent disclosure requirements create an interface between the patent system and ABS for mutual supportiveness, synergies, and complementarity. Information related to the legal status of the GRs and traditional knowledge utilized for the invention, and the conditions of acquisition by the applicant (e.g., PIC or MAT), is not considered requisite to have a sufficient disclosure requirement. Patent disclosure requirements, however, particularly seek that information. This makes them an effective tool for monitoring the utilization of GRs and traditional knowledge, and thereby for complying with ABS obligations.

### o **Legal Nature**

As of 2017, there were more than 30 countries with some kind of disclosure requirements—whether mandatory, voluntary, or mere encouragement. These requirements impose various levels of obligations for patent applicants.

A mandatory disclosure requirement can be created as a formality in the patent procedure or can be considered part of patentability criterion, with implications for patent validity.

*Formality requirements* usually refer to the form and contents of the application (such as the names of inventors), other documents required by the patent office, and procedural requirements (such as payment of maintenance fees). Failure to meet certain formality requirements may lead to refusal of a patent application, if the issue is not rectified in time.

If a disclosure requirement is considered a mere formality or procedural requirement, it would be subject only to a formality check by the patent office. The patent office may collect relevant information or declarations on source and origin of generic resources and pass them to the relevant ABS authorities.

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<sup>48</sup>Ibid., pp. 20–21.

▶▶▶▶ **Vietnam:** *Circular No. 01/2007/TT-BKHCN of February 14, 2007, guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, Detailing and Guiding the Implementation of a Number of Articles of the Law on Intellectual Property Regarding Industrial Property.*

Under “additional provisions applicable to applications for registration of inventions concerning gene source or [TK]”, Article 23.11 provides:

“[A]n application for registration of an invention concerning gene source or [TK] must also contain documents explaining the origin of the gene source and/or [TK] accessed by the inventor or the applicant, if the invention is directly based on that gene source and/or [TK]. If the inventor or the applicant cannot identify the origin of the gene source and/or [TK], he/she shall so declare and bear responsibility for the truthfulness of his/her declaration.”

▶▶▶▶ **Switzerland:** Article 49(a) of the *Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012)* states:

“The patent application must contain information on the source: a) of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; b) of [TK] of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this resource.”

Article 81(a) of the Federal Act further states:

“Any person who willfully provides false information under Article 49(a) is liable to a fine of up to 100,000 francs. The court may order the publication of the judgment.”

▶▶▶▶ **Norway:** Section 8(b) of the *Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)* provides:

“If an invention concerns or uses biological material or [TK], the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of [TK] shall be subject to prior consent, the application shall state whether such consent has been obtained. [...] Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”

**Substantive requirements** generally relate to the actual nature of the invention and must be satisfied before any invention can be patented. These requirements include patentable subject matter, novelty, inventive step, industrial applicability, and sufficiency of disclosure. A disclosure requirement that is substantive in nature requires the patent examiner to check whether the claim or evidence of PIC is valid and sufficient.

▶▶▶▶ **Andean Community:** Article 26 of *Decision No. 486 Establishing the Common Industrial Property Regime (2000)* states:

“The application for a patent shall be filed with the competent national office and shall contain the following: [...] (h) where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from [GRs] or products derived therefrom of which any of the member countries is the country of origin; (i) where applicable, a copy of the document accrediting the licensing or the authorization of the use of the [TK] of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force.”

▶▶▶▶ **South Africa:** Section 30 of the *Patents Amendment Act (Act No. 20 of 2005)* provides:

“(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, [GR], or [TK] or use.”

“(3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, [GR], or of the [TK] or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, [GR], or [TK] or use.”

▶▶▶▶ **India:** Article 10(4)(d)(ii) of the *Patents Act, 1970, as amended by the Patents (Amendment) Act, 2005*, provides:

“If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b),<sup>11</sup> and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely: [...] (d) disclose the source and geographical origin of the biological material in the specification, when used in an invention.”

A **voluntary requirement** can be merely an encouragement. It can also be a formal requirement in the patent application process that has no bearing on the processing of the patent application or its validity in case of noncompliance.

▶▶▶▶ **European Union:** *Directive 98/44/EC on the Legal Protection of Biotechnological Inventions of July 6, 1998*. In its Preamble, the Directive encourages applicants to mention the geographical origin of biological material in the patent application:

“(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.

“(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”

▶▶▶▶ **Germany:** Section 34(a) of the *Patent Act as published on December 16, 1980 (as last amended by Article 1 of the Act of October 19, 2013)* provides:

“Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents.”

## o Placement

The vast majority of countries have introduced some sort of disclosure requirements related to GRs and/or traditional knowledge in their patent law or through other measures within their intellectual property system.<sup>49</sup> On the other hand, some countries have introduced disclosure requirements in their biodiversity and ABS legislation, often applying to all relevant intellectual property rights.

### Disclosure requirements in patent laws

▶▶▶▶ **South Africa:** Section 30 of the *Patent Law (as amended in 2005)* provides:

“Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.”

### Disclosure requirements through other measures within IP system

▶▶▶▶ **Philippines:** Rule 12 Section 3 (c) of the *Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010)* provides:

“[...] The subject matter contained in the IPR application must depend on the specific properties of, or must be consciously derived from, such biodiversity and [GR] or materials, [TK], and indigenous knowledge, systems and practice.”

### Disclosure requirements in biodiversity laws

#### Brazilian ABS Law

*Law No. 13.123 of May 20, 2015 on Access and Benefits Sharing of GRs and associated TK* has created an electronic registration system for companies interested in exploiting genetic heritage or associated TK. In particular, Article 12 states that “the access registration must be performed prior to the request of any [IP] rights” (e.g., a patent filing). Article 47 further provides that “the granting of [IP] rights by the competent body, regarding a final product or reproductive material obtained as a result of the access to [GRs] or associated [TK] is subject to registration or authorization in accordance with this Law.”

#### Costa Rican Law on Biodiversity

*Article 80 of the Biodiversity Law of 1998* provides that the Technical Office (TO) of the National Biodiversity Commission (CONAGEBIO) within the Ministry of Environment, Energy and Telecommunications (MEET) will act as a mandatory consultative body for all application procedures involving the protection of IP rights related to biodiversity. Its decisions are binding on the IP office. In particular, Article 80 states that “justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation”.

<sup>49</sup>See WIPO, *Disclosure Requirements Table*, [http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic\\_resources\\_disclosure.pdf](http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf).

The provision of disclosure requirements in ABS legislation instead of patent legislation may reflect different motivations regarding a government's objectives. It can also reflect different implications regarding key operational features (e.g., triggers) and applicable compliance measures.<sup>50</sup>

Provision of disclosure requirements that are formally embedded in national ABS legislation generally build on the national biodiversity framework, with the goal of fostering mutual supportiveness. These requirements may help to build solid bridges between ABS and patent regimes. They usually include measures directly related to monitoring and enforcing compliance with ABS requirements, such as the submission of evidence concerning PIC and the establishment of mutually agreed terms. However, the implementation of this kind of disclosure requirement is not placed exclusively in the hands of biodiversity authorities. The patent and IP offices may support the identification of potential cases of noncompliance by transmitting relevant information to ABS-competent authorities, to the country providing prior informed consent, and/or to the ABS Clearing-House of the Nagoya Protocol, as appropriate.

On the other hand, provisions of disclosure requirements that are incorporated directly into patent law have the potential to generate information that may enable patent examiners to reach a more accurate, informed, and fair decision about patent applications—hence, the frequent use of specific “triggers” that refer to the invention being “based on” or “directly based on” a particular GR or associated traditional knowledge.<sup>51</sup>

### III. PATENT DISCLOSURE REQUIREMENTS AND THE NAGOYA PROTOCOL

Article 16 of the CBD addresses the impact of IP on ABS. The Bonn Guidelines provided some guidance on the possible interactions between the IP system and the CBD. Even though the Bonn Guidelines inspired many of the Nagoya Protocol provisions on ABS, the Nagoya Protocol cautiously avoided any discussion of IP. The Protocol was cautious and ambiguous in terms addressing misalignment between the CBD and TRIPS. It avoided, by all means, any provision that would be interpreted as mandating deviations from the rights purportedly secured by TRIPS.<sup>52</sup>

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<sup>50</sup> For more information, see Chiarolla and Kilic, *supra* note 1, section 13 below on remedies and sanctions to address situations of noncompliance.

<sup>51</sup> *Id.*

<sup>52</sup> Riccardo Pavoni, “The Nagoya Protocol and WTO Law,” in *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective*, eds. by Elisa Morgera, Matthais Buck, and Elsa Tsioumani (Boston, MA: Brill, 2013), 202.

There were a few references to IP (only three) as a means of possibly securing equitable benefit sharing but not imposing IP-related benefit sharing<sup>53</sup>.

Under the Nagoya Protocol, there is no obligation for parties to provide for patent disclosure requirements. The earlier drafts of Article 17 (previously Article 13 or Article 13*bis*) on certificates, checkpoints, and compliance made references to IP and disclosure requirements. They also had language on disclosure requirements at patent offices. Disclosure requirements were regarded as a mandatory measure to ensure compliance with the ABS legislation of provider countries, and IP offices were to serve as mandatory checkpoints for compliance review. The submission of an internationally recognized certificate of compliance was regarded as the evidence of fulfillment of disclosure requirements and proof of PIC and benefits sharing.<sup>54</sup> The references both to disclosure requirements and IP offices were removed in the final text.

However, this kind of provision would have not required substantial changes in IP laws. Parties might have needed only to request that IP applicants submit national ABS permits when applying for IP protection on inventions related to GRs as a means to monitor their utilization. Further details could have been left to national IP legislation. Still, it was rigorously rejected<sup>55</sup> by developed countries on the basis that it was an unjustified interference with the IP system. Led by the EU, these countries insisted on strict separation of the IP and ABS systems. In a closed-door, limited-participation ministerial meeting, they eventually managed to remove any reference to disclosure requirements and IP offices.<sup>56</sup> The text adopted in a green-room<sup>57</sup> manner was imposed on other countries in a take-it-or-leave-it style.<sup>58</sup>

Consequently, the Nagoya Protocol leaves it up to each contracting party to decide whether they wish to use the IP system to monitor the utilization of GRs (and associated traditional knowledge) within their jurisdiction.<sup>59</sup>

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<sup>53</sup>Hartmut Meyer et al., *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization: Background and Analysis* (Zurich: Berne Declaration; Berlin: Bread for the World; Emmendingen: Ecoropa; Philippines: Tebtebba; and Malaysia: Third World Network, 2013).

<sup>54</sup>Pavoni, *supra* note 50, p. 203.

<sup>55</sup> On IP-related issues, Brazil, Norway, and Switzerland stated that their intellectual property laws had been amended with disclosure requirements and that this had not caused serious problems or triggered complaints by the WTO or WIPO. Discussing market approval offices, the EU and New Zealand admitted that they had no experience with such checkpoints in relation to ABS matters and hardly any experts. They said they could not judge the implications of this provision in the draft article and therefore rejected it. Hartmut Meyer et al., *supra* note 51

<sup>56</sup> *Ibid.*

<sup>57</sup> “Green room” is a reference to the precedent started by the WTO of having select small groups of negotiators decide on a deal, which would later be imposed on all parties, and then get other members to agree without having a say.

<sup>58</sup>Pavoni, *supra* note 52, pp. 203–204.

<sup>59</sup> UNCTAD, *supra* note 20, p.12

The Protocol presents a paradigm shift from mandatory to voluntary commitments.<sup>60</sup> The lack of authoritative guidance and intentional ambiguity make it difficult to understand the interface between IP and ABS from the CBD and the Protocol alone.<sup>61</sup> On the other hand, the ambiguity can also be interpreted as wiggle room for the parties regarding the manner in which they domestically implement their obligations under the protocol and the CBD.<sup>62</sup>

### **Designation of IP/Patent Offices as a checkpoint**

Under the Nagoya Protocol (Article 13), each party is required to designate a National Focal Point on ABS and one or more Competent National Authorities (CNAs) on ABS. The CNA is a governmental institution that is responsible for granting access, issuing written evidence that access requirements have been met, and advising on applicable procedures and requirements for obtaining PIC and entering into MATs.<sup>63</sup>

The Protocol also requires the parties to establish one or more checkpoints, which may include, among others, IP and/or patent offices. These “[...] checkpoints would collect or receive, as appropriate, relevant information related to [PIC], to the source of the genetic resource, to the establishment of [MATs], and/or to the utilization of genetic resources. [...] 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 [PIC] and to the [ABS] Clearing-House, as appropriate.”<sup>64</sup>

The publication of a national ABS permit in the ABS Clearing-House constitutes an “internationally recognized certificate of compliance.” The certificate serves “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.” In stark contrast to the other provisions of the Protocol, the certificate system under Article 17 does not apply to associated traditional knowledge. However, this does not mean that it cannot be included in the certification system through national legislation.

National patent and IP offices have historically been considered as a “natural” checkpoint in biodiversity-rich countries. The Protocol neither includes a list of indicative checkpoints nor refers to patent and IP offices. Checkpoints “must be effective and should have functions relevant to the utilization of genetic resources or collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.” An IP or patent office may well be designated as a checkpoint to a CNA in discharging its duties. It can support the identification of potential cases of noncompliance by collecting or receiving, and subsequently transmitting relevant information to the country providing prior informed consent to the ABS Clearing-House of the protocol.<sup>65</sup>

<sup>60</sup>Pavoni, *supra* note 52.

<sup>61</sup> UNCTAD report, *supra* note 20, p.34

<sup>62</sup> Barbara Lassen, *The Two Worlds of Nagoya: ABS Legislation in the EU and Provider Countries: Discrepancies and How to Deal with Them* (Switzerland: Public Eye, and South Africa: Natural Justice, 2016).

<sup>63</sup> Article 13, Nagoya Protocol

<sup>64</sup> Article 17, Nagoya Protocol

<sup>65</sup> Chiarolla & Kilic, *supra* note 2, pp.92-93

Any contracting party to the Protocol has flexibility to introduce mandatory, voluntary, or no patent disclosure requirements at all. Patent disclosure requirements can also be used as a checkpoint to monitor users' compliance in accordance with the Nagoya Protocol—or to establish other relevant checkpoints, as appropriate, to fit national circumstances.

#### o **Scenarios for the Effective Implementation of the Protocol**

Given the divide between developed and developing countries, ABS governance under the Nagoya Protocol remains unclear. The ABS provisions have a very limited on-the-ground impact. This is largely due to lack of international policies establishing policy coherence and alignment between ABS and IP; national guidelines on ABS; limited institutional capacities to implement these policies and guidelines; and limited awareness of how to use ABS for the benefit of supporting conservation, sustainable use, innovation, and benefit sharing.

Among all the policy measures for effective implementation of the Nagoya Protocol and sustainable ABS governance, a mandatory patent disclosure requirement remains the most effective single measure. It has also been a long-standing demand of developing countries.

Efficient and dynamic interactions between the ABS and IP systems may help to serve the public interest in the (defensive) protection of GRs and traditional knowledge, and the prevention of their misappropriation. Mandatory patent disclosure requirements can enhance enablement and clarify the invention for patent examiners to reach a more accurate, informed, and fair decision about patent applications. This could enhance the overall efficiency of the patent system.

More importantly, by reinforcing the effects of an ABS system, the disclosure requirements would reduce the free-riding incentives to freely obtain a benefit from someone else's GRs or traditional knowledge without proper compensation or authorization. Ultimately, this would lead to changes in the attitudes and practices of users and help to prevent misappropriation.<sup>66</sup>

Opponents of such an obligation argue that the patent system is not suited for ABS governance and should not serve to implement exogenous ABS objectives. Traditionally, the basis of their opposition has been that the “cumbersome” mandatory disclosure requirements create legal uncertainty in the patent system<sup>67</sup> and

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<sup>66</sup> Chiarolla & Kilic, *supra* note 1, p.27

<sup>67</sup> See statements from Japan, the Republic of Korea, and the United States of America, *WIPO/GRTKF/IC/29/8*, pp. 11, 54, 94.

that there is a lack of institutional capacity in developing countries to deal with such complex requirements. Throughout the years, opponents expressed a variety of concerns about disclosure requirements in different forums, and they strictly oppose mandatory patent disclosures in patent laws.<sup>68</sup>

Unfortunately, the key for effective implementation of a global ABS system lies with those opponents—namely, the user countries. Thus, ensuring effective operation of the global ABS system remains a challenge. No single patent disclosure scenario can capture all existing concerns about GRs and traditional knowledge utilized by the patented inventions, nor can any one proposed solution easily fit diverse countries.

Disclosure requirements can be implemented in diverse ways, reflecting different policy motivations and political trade-offs, local priorities and needs, and legal and institutional systems. There are a variety of scenarios in which disclosure requirements can be embedded in national ABS legislation, building on the conventional disclosure requirements in the IP system, with the goal of mutual supportiveness. For instance, measures directly related to monitoring and enforcing compliance with ABS requirements, such as the submission of evidence concerning PIC and the establishment of a MAT, may help to build solid bridges between ABS and patent regimes. The patent or IP office can act supportive in terms of identifying potential cases of noncompliance and passing relevant information to ABS-competent authorities, to the country providing prior informed consent, and/or to the ABS Clearing-House of the Nagoya Protocol, as appropriate. In such a scenario, a patent or IP office can be designated as a checkpoint so that the applications including inventions based on biological material can be filtered by the patent office to determine whether they trigger a mandate for disclosure.

If the invention subject to the application meets any of the conditions for mandatory disclosure, the patent office would then be required to check whether there is a disclosure for the origin and source, and verify PIC and MAT. If the applicant failed to disclose the country of origin, or the patent office is unable to verify PIC and MAT, the patent office may deny the application or provide an opportunity for the applicant to revise the application accordingly.<sup>69</sup>

In this scenario, the IP or patent office would contribute only to collecting or receiving information regarding the utilization of GRs and traditional knowledge. This information then would be shared with

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<sup>68</sup> Chiarolla and Kilic, *supra* note 1, p. 24.

<sup>69</sup> Wallace Feng, “Appropriation without Benefit-Sharing: Origin-of-Resource Disclosure Requirements and Enforcement under TRIPS and the Nagoya Protocol,” *Chicago Journal of International Law* 18, no. 1 (2017), <https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1724&context=cjil>.

national ABS focal points and CNAs. They can rely on this information to monitor and flag potential cases of interest and follow up with the applicant. In this scenario, the burden on the patent office would be minimal because the patent examiner's inspection is limited.

Most recently, France has implemented these kinds of measures in its biodiversity and ABS laws.

**Biodiversity Law of France**

Art. L. 412-18. II 2° provides that when a patent application arises from the utilization of GRs and associated TK, the applicant shall, on his or her own initiative, transmit relevant information to the National Industrial Property Institute (INPI). INPI then makes the information available to the competent administrative authorities (i.e., those responsible for the application of the Regulation of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union of April 14, 2014) without examining it.

*Source: Chiorolla&Kilic, supra note 1, p.79*

The following would help alleviate the burden on the IP offices to confirm legal provenance in an easily recognizable fashion: a requirement for the submission of evidence that the applicant has complied with basic PIC and MAT obligations (i.e., certificate or underlying contract, particularly if the contract is pre-dated to CNA) in the provider country.<sup>70</sup>

More importantly, such a requirement will facilitate complementary relationships between the IP office and CNAs while they retain their relatively independent roles.<sup>71</sup> This requirement would provide for a transparent interface between the IP and ABS systems by clearly defining the respective implementing functions of patent or IP offices and national ABS-competent authorities with regard to an applicable disclosure requirement. It would help to establish effective communication between the two offices, while respecting their distinct instructional mandates and competencies. Thus, it becomes crucial to establish a consultative framework for structured dialogue between ABS agencies, including CNAs and the ABS Clearing-House. Such a framework would facilitate effective compliance-tracking mechanisms for this kind of procedure, generate positive synergies, and foster mutual supportiveness between these systems.

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<sup>70</sup> UNCTAD, supra note 24, p. 63.

<sup>71</sup> *Ibid*, p. 56.

## CONCLUSION

The concerns over extent and level of unauthorized access and use of GRs and TK and their subsequent misappropriation have led to the introduction of additional measures for protection in provider countries. The lack of compliance measures in the user countries have long been one of the major problems in the international ABS regime. The Nagoya Protocol aimed to tackle this issue by regulating the access to GRs and associated TK and ensuring the fair and equitable sharing of benefits arising from their utilization. It introduced a new balance to the ABS system by creating a virtuous circle between provider and user countries by turning legal access to GRs and associated TK into the rule rather than the exception and eventually making a fair and equitable sharing of benefits derived from the use of such resources a common practice.

The Nagoya Protocol introduces three obligations for the Parties in terms of compliance measures:

- Provider countries are required to introduce or further elaborate detailed domestic ABS legislation to facilitate user countries' compliance with the access rules.<sup>72</sup>
- Parties are obliged to take "appropriate, effective and proportionate legislative, administrative and policy measures" to ensure that GRs and TK utilized within their jurisdiction have been accessed in accordance with the PIC and MAT as required by provider country laws.<sup>73</sup>
- Parties are required to designate at least one checkpoint where the legal procurement of the genetic resource must be disclosed. The purpose of this requirement is to "monitor and enhance transparency about the utilization of genetic resources" in order to "support compliance".<sup>74</sup>

The Nagoya Protocol does not determine a mandatory checkpoint common for all Parties or provides a list of indicative checkpoints. The Protocol, however, does stipulate that checkpoints "should be effective" and

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<sup>72</sup> Article 15.1 requires Parties to adopt "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."

<sup>73</sup> Article 17.1: "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"

<sup>74</sup> *Id.*

"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"<sup>75</sup>.

The domestic patent/IP office appears to be the most practical checkpoint to compile information on the source/origin of the invention and verify the validity of PIC and MAT. Building on the conventional disclosure requirements in patent system, patent disclosure requirements related to GRs and traditional knowledge can be embedded in national ABS and/or IP legislation in order to create an interface between patent system and ABS for mutual supportiveness, synergies and complementarity.

The debate surrounding the relationship between IP and ABS—and the manner in which this relationship may be reconciled in a coherent, legal policy framework—is multifaceted. The effective implementation of the Nagoya Protocol is one issue. Implementing the Protocol in a manner that is coherent, or at least not detrimental to innovation, is another.

While there is clearly no one-size-fits-all approach, a growing number of countries have demanded some degree of harmonization through new, legally binding language on patent disclosure requirements supported by mechanisms and institutions to enforce them, including noncompliance measures.

Countries vary in terms of their biodiversity endowment, research capability including in biotechnology, level of public and private R&D spending, biocultural sensitivities, and their national IP examination capacities. While the particular paths that countries take may be distinct, there are some common traits, and following general recommendations can be drawn.

These recommendations may offer a practical pathway to implement the Nagoya Protocol and provide a careful balance of the various interests at stake:

- development of an effective and efficient ABS regime by creating a clear ABS frameworks in scope, coverage and definitions;
- designation of IP/patent offices as a checkpoint to filter applications related to GRs and traditional knowledge;

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<sup>75</sup> Article 17.1.(iv): Checkpoints must be effective and should have functions relevant to implementation of this sub-paragraph (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.

- introduction of a mandatory patents disclosure requirement in relevant IP/patent or biodiversity legislation;
- a pre-grant and post-grant opposition opportunities for any interested party (primarily for indigenous communities but not limited to ABS authorities, and other relevant stakeholders) under an inquisitorial administrative process to submit information and analyses to patent examiners;
- non-compliance measures leading to significant sanctions such as invalidation, civil or criminal sanctions ranging from penalties to refusal, invalidation or transfer of the ownership;
- development of significant tracking and verification mechanisms, and a consultative framework between IPLC and competent agencies;
- information tools and databases compiling and referencing a wide range of information and reference materials, on GRs and traditional knowledge, derivatives, and relevant scientific articles on GRs and traditional knowledge; and
- capacity-building and training to raise awareness among IPLC and other stakeholders.