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SOUTH CENTRE

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MISAPPROPRIATION OF GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE: CHALLENGES POSED BY INTELLECTUAL PROPERTY AND GENETIC SEQUENCE INFORMATION

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ABSTRACT

Improper acquisition of genetic resources (GRs) and associated traditional knowledge (TK) without prior informed consent and on mutually agreed terms, in accordance with national laws of the country providing the GR and associated TK, as well as without any fair and equitable sharing of the benefits derived from their utilization, has been a significant concern for developing countries. Intellectual property (IP) rights can serve as one of the means of such misappropriation. One of the mechanisms sought by developing countries to prevent it consists in the establishment of an effective multilateral legal mechanism for defensive protection against misappropriation, primarily through the introduction of a mandatory disclosure requirement about the source and country of origin of such resources in intellectual property right (IPR) applications. These negotiations have been taking place in different fora. However, there is an increased sense of frustration due to the lack of progress in achieving consensus during the last twenty years. Meanwhile, new modes of misappropriation of GRs are evolving through the use of genetic sequence information and data of GRs, and by applying technological developments in synthetic biology. This paper discusses the use of IP and genetic sequence information and data as modes of misappropriation of GRs and associated TK and the deficits of the current international legal framework in preventing such misappropriation. This paper also maps the state of play of the ongoing negotiations in the context of these issues in different fora, and, in conclusion, proposes possible alternative approaches for addressing these pressing issues at the multilateral level.

La adquisición indebida de recursos genéticos (RG) y conocimientos tradicionales (CT) asociados sin el consentimiento informado previo y en condiciones mutuamente acordadas, de acuerdo con las leyes nacionales del país que proporciona los RG y los CT asociados, así como sin una distribución justa y equitativa de los beneficios derivados de su utilización, ha sido una preocupación importante para los países en desarrollo. Los derechos de propiedad intelectual (PI) pueden ser uno de los medios de esta apropiación indebida. Uno de los mecanismos que buscan los países en desarrollo para evitarla consiste en el establecimiento de un mecanismo jurídico multilateral eficaz para la protección defensiva contra la apropiación indebida, principalmente mediante la introducción de un requisito de divulgación obligatoria sobre la fuente y el país de origen de dichos recursos en las solicitudes de derechos de propiedad intelectual (DPI). Estas negociaciones han tenido lugar en diferentes foros. Sin embargo, existe una creciente sensación de frustración debido a la falta de avances en la consecución de un consenso durante los últimos veinte años. Mientras tanto, están surgiendo nuevos modos de apropiación indebida de los RG mediante el uso de la información y los datos de las secuencias genéticas de los RG, y mediante la aplicación de los avances tecnológicos de la biología sintética. En este documento se analiza el uso de la propiedad intelectual y de la información y los datos de la secuencia genética como modos de apropiación indebida de los RR.GG. y de los conocimientos tradicionales asociados, así como las deficiencias del actual marco jurídico internacional para evitar dicha apropiación indebida. Este documento también traza el estado de las negociaciones en curso en el contexto de estas cuestiones en diferentes foros y, en conclusión, propone posibles enfoques alternativos para abordar estas cuestiones apremiantes a nivel multilateral.

L'acquisition inappropriée de ressources génétiques (RG) et de savoirs traditionnels (ST) associés sans consentement préalable en connaissance de cause et selon des conditions

convenues d'un commun accord, conformément aux lois nationales du pays fournissant les RG et les ST associés, ainsi que le non-partage juste et équitable des avantages découlant de leur utilisation, constituent une préoccupation importante pour les pays en développement. Les droits de propriété intellectuelle (PI) peuvent constituer l'un des moyens de ce genre d'appropriation illicite. L'un des mécanismes recherchés par les pays en développement pour l'empêcher consiste à mettre en place un mécanisme juridique multilatéral efficace de protection défensive contre l'appropriation illicite, principalement par l'introduction d'une obligation de divulgation de la source et du pays d'origine de ces ressources dans les demandes de droits de propriété intellectuelle (DPI). Ces négociations se sont déroulées dans différents forums. Toutefois, le manque de progrès dans la recherche d'un consensus au cours des vingt dernières années suscite un sentiment croissant de frustration. Entre-temps, de nouveaux modes d'appropriation illicite des ressources génétiques se développent grâce à l'utilisation des informations et des données sur les séquences génétiques des ressources génétiques et à l'application des développements technologiques en biologie synthétique. Ce document examine l'utilisation de la propriété intellectuelle et des informations et données sur les séquences génétiques comme modes d'appropriation illicite des ressources génétiques et des savoirs traditionnels associés, ainsi que les lacunes du cadre juridique international actuel dans la prévention de cette appropriation illicite. Il fait aussi le point sur l'état d'avancement des négociations en cours dans le contexte de ces questions dans différents forums et, en conclusion, il propose des approches alternatives éventuelles pour traiter ces questions urgentes au niveau multilatéral.

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I. INTRODUCTION

Developing countries have been the reservoir of a great portion of the world's biodiversity, which has made an immeasurable contribution to the progress of human civilization.[1] However, developing countries are at a disadvantage when it comes to benefiting similarly from harnessing their biological and genetic resources (GRs), over which they have sovereign rights, due to the constraints in scientific and technological knowledge and research capacities in these countries.

Different economic interests are at play in the international debate concerning the use of GRs. For some megadiverse countries,[2] the majority of which are developing countries, control over GRs in their territories as sovereign States, building research and development (R&D) capacity for their utilization and deriving economic benefits from them are of major importance. On the other hand, developed countries seek to secure sustainable access to these resources for further R&D of new products by entities in their territories.[3] For all countries, the conservation and sustainable use of these resources is critical in order to advance science and their economic interests. Beyond a State centric approach, indigenous and local communities in various countries consider the need for a recognition of their legal rights over their traditional knowledge associated with GRs as fundamental for their expression of self-determination.[4]

A major paradox is that GRs were considered under international law in the past to be the "common heritage of mankind" or "global public goods", while the products derived from their

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[1] The quest for biological resources in developing countries was a major motivating factor behind the rise of colonialism. Products derived from biological and genetic resources "explored" from the colonies contributed to the wealth generation of the colonial powers. Even post-decolonization, bioprospecting of GRs for developing new innovative products have been a major source of wealth generation for developed countries. See Chetan Gulati, "The 'Tragedy of the Commons' in Plant Genetic Resources: The Need for a New International Regime Centered Around an International Biotechnology Patent Office", *Yale Human Rights & Development Law Journal,* vol. 4, No,1 (2001), p. 63. Available from https://digitalcommons.law.yale.edu/yhrdlj/vol4/iss1/3.

[2] The term "megadiverse country" is commonly used to refer to the most biodiversity-rich countries in the world. According to the United Nations Environment Programme's (UNEP) World Conservation Monitoring Centre (WCMC) there are only 17 such countries - the United States of America, Mexico, Colombia, Ecuador, Peru, Venezuela, Brazil, Democratic Republic of Congo, South Africa, Madagascar, India, Malaysia, Indonesia, Philippines, Papua New Guinea, China, and Australia. *See* Biodiversity A-Z, Megadiverse Countries, (accessed 30 November 2020). Available from https://www.biodiversitya-z.org/content/megadiverse-countries. However, in 2012 a group of 12 developing countries that harbour 60-70 per cent of the world's biodiversity and associated traditional knowledge came together to form a group of Like-Minded Megadiverse Countries (LMMC) as a body of consultation and cooperation to promote interests related to the conservation and sustainable use of biological diversity, and fair and equal participation in the benefits derived from the use of genetic resources. The LMMC was a major group that pursued the negotiations of the Nagoya Protocol to the CBD and is comprised currently of 16 developing countries - Brazil, China, Costa Rica, Colombia, Ecuador, India, Indonesia, Iran, Guatemala, Kenya, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela. *See* generally, Republic of South Africa, Department of Environment, Forestry and Fisheries, "Group of Like-Minded Megadiverse Countries". Available from https://www.environment.gov.za/likeminded_megadiversecountries_lmmc.

[3] Some developed countries are also rich in genetic resources and are increasingly seeing value in the international regime on access and benefit sharing (ABS) for GRs. For instance, France has an important bio-economy, substantially based on its natural and cultural heritage and has developed specific legislation oriented to comply with international rules on access to genetic resources and associated traditional knowledge within its territory. In 2016, France became a party to the Nagoya Protocol on ABS. See Union for Ethical BioTrade, "ABS in France", 29 May 2018. Available from https://static1.squarespace.com/static/58bfcaf22994ca36885f063e/t/5b3239078a922db513b9307f/1530018056500/UEBT-France-Factsheetfinal.pdf.

[4] Rebecca M. Bratspies, "The New Discovery Doctrine: Some Thoughts on Property Rights and Traditional Knowledge", *American Indian Law Review,* vol. 31, No. 2 (2006/2007), p. 317. Available from doi:10.2307/20070790.

utilization could be owned as private property protected by intellectual property (IP) rights.[5] Though local and indigenous communities that have lived in harmony with nature in megadiverse countries for centuries have developed knowledge regarding the use of such resources for various purposes, appropriation of such knowledge as private property has been an alien concept for them.[6] By claiming IP rights over such traditional knowledge, research institutions and commercial firms, predominantly from developed countries, have been able to appropriate products based on associated traditional knowledge as private property. As one scholar describes the misappropriation of plant genetic resources (PGRs) – "... PGRs leave the South as the "common heritage of mankind" and return as "individually owned" commodities for sale at prices that inhibit many citizens of … (the countries) from which the PGRs originated, from having access to them".[7]

At the multilateral level, the United Nations Convention on Biological Diversity (CBD) was adopted in 1992 to pursue the goals of conservation and sustainable use of biodiversity and ensure fair and equitable sharing of the benefits arising from the use of biological resources. Through the CBD, international law recognized the sovereignty of States over biological resources including GRs, and also the obligation of States to facilitate access to these resources to other States, upon mutually agreed terms (MAT) and the prior informed consent (PIC) of the providing State. The country receiving access is, in turn, required to share the benefits arising from the use of such resources. CBD also recognized that patents and other IP rights might have implications for the attainment of the objectives of the CBD and requires all States to cooperate so as to ensure that IP rights complement the objectives of the CBD. In 2010, Contracting parties to the CBD adopted the Nagoya Protocol on Access and Benefit-Sharing (hereinafter Nagoya Protocol) to elaborate on an international legal framework to advance the objective of the CBD to ensure fair and equitable benefit-sharing in respect of GRs. Contracting parties to the Nagoya Protocol are required to adopt access and benefit-sharing (ABS) regulations with specific measures to facilitate access to GRs, ensure benefit-sharing and compliance. However, both the CBD and the Nagoya Protocol do not provide a clear understanding of the interface between IP and ABS.[8]

Intellectual property issues in relation to GRs have arisen in various multilateral fora but remain unresolved till date. The negotiations for an international legal instrument to ensure balanced and effective protection of GRs and associated traditional knowledge through a mandatory disclosure requirement in IP applications about their source and country of origin have been on the agenda for a long time in the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). At the core of this debate lies the question whether applicants claiming IP rights over inventions that are based on the use of GRs or associated TK should be required to mandatorily submit to IP offices the information about the country of origin or source of such GR or associated TK. While several countries have introduced such a mandatory disclosure requirement, there is no obligation under international law for having such a requirement under national IP laws. Thus, there is considerable variance in the scope of disclosure requirement between countries that have such an obligation in their national laws, while some other countries that are major markets for innovative products that are derived from GRs or use associated TK do not have such a disclosure requirement at all. The variance in national laws also leaves them susceptible to

[5] Oluwatobiloba O. Moody, "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", PhD Thesis, Queen's University, 2016. Available from https://qspace.library.queensu.ca/bitstream/handle/1974/15302/Moody_Oluwatobiloba_O_201612_PhD.pdf?sequence=2; Gulati, *supra* note 1.
[6] Bratspies, *supra* note 4.
[7] Gulati, *supra* note 1.
[8] UNCTAD, *The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications* (Geneva, 2014), p.12. Available from https://unctad.org/en/PublicationsLibrary/diaepcb2014d3_en.pdf.

potential conflict with laws in foreign jurisdictions, with consequential legal uncertainty about their recognition and enforcement in foreign jurisdictions, as well as high costs of their enforcement.[9]

While national laws that include a mandatory disclosure requirement have diverse policy objectives, some of the key objectives which are broadly pursued by most countries having a disclosure requirement include prevention of misappropriation of GRs and associated TK; enhancing efficiency, legal certainty and transparency; and ensuring mutual supportiveness or complementarity with international ABS agreements. A mandatory disclosure requirement in IP laws could also help to monitor the utilization of GRs and associated TK and promote compliance with ABS law obligations.[10]

The issue of how to approach IP has also received attention in the discussions on the FAO International Treaty for Plant Genetic Resources for Food and Agriculture (hereinafter the Plant treaty), the WHO PIP Framework and the UN Convention on the Law of the Sea (UNCLOS) negotiations on marine genetic resources beyond areas of national jurisdiction. A coherent defensive protection outcome on IP in relation to GRs and associated traditional knowledge emanating from the negotiations in the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) could make the Nagoya Protocol more effective.[11] However, there is a sense of frustration among developing countries due to the lack of progress in achieving consensus towards an international understanding in WIPO and WTO.

Meanwhile, the practices implemented to extract genetic material from its place of origin has been evolving over the years, and today, new modes of utilizing GRs without physically accessing them have emerged as a result of new technologies and the development of sophisticated systems. The availability of the genetic sequence information and data of biological material and gene editing technologies have made it possible to avoid the need for physical access to the samples of biological or genetic material in order to utilize the same.

This paper discusses the use of IP and genetic sequence information and data as possible modes of misappropriation of GRs and associated TK. It shows the evolution of the different practices to commit such misappropriation. It maps the state of play of the current negotiations in the context of these issues in different fora and proposes possible alternative approaches for addressing these issues at the multilateral level. The paper is divided into five sections. Section II describes the issue of misappropriation of GRs and associated TK, as it relates to IP. It presents examples of prominent cases of misappropriation of GRs and associated TK through the acquisition of IP rights. It also demonstrates the evolution of practices in using new technologies in the domains of information communication and synthetic biology for utilizing GRs and the gaps in the current international regime of ABS in this context. Section III presents an overview of the existing global framework for GRs with regard to IP and ABS. Section IV maps the state of play of the current negotiations on the intersection of ABS and IP in different fora. To conclude, this paper explores in Section V possible alternative approaches towards finding solutions at the multilateral level.

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[9] See Joshua D. Sarnoff and Carlos M. Correa, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications: A contribution to UNCTAD's response to the invitation of the Seventh Conference of the Parties of the Convention on Biological Diversity* (New York and Geneva, United Nations, 2006), p. 20. Available from https://unctad.org/system/files/official-document/ditcted200514_en.pdf.

[10] Claudio Chiarolla and Burcu Kilic, *Developing Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge: Key Questions*, (Geneva, World Intellectual Property Organization, 2017) p. 23. Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2987820.

[11] Moody, *supra* note 5.

II. The Changing Face of Misappropriation of Genetic Resources and Associated Traditional Knowledge: From Physical Access to the Use of Genetic Sequence Information

The non-recognition of GRs and associated TK as formal knowledge systems[12] and the lack of clarity about the conditions under which such resources were accessed and used, created legal uncertainty about the ownership of these resources or products based on associated knowledge about their use. It is only recently that some countries enacted national legislation, attempting to set the conditions for access and the modalities to ensure benefit-sharing.

Samples of genetic material have been accessed over the years in two main ways:

1. Directly from their natural habitat (hereinafter *in-situ* conditions);
2. From collections accumulated over extended periods in institutional facilities where the resources are conserved outside their natural habitat (hereinafter *ex-situ* collections), e.g., gene banks, seed banks, etc.

By exploiting the opportunity for unbridled access to GRs over the past two centuries, much of the genetic material from the developing countries has been brought into *ex-situ* collections in developed countries. However, improvements over the genetic material so accessed have not been regarded as part of the "common heritage of mankind" to be universally accessible, but rather as products over which private property rights, such as IP rights, could be acquired, granting the IP owners the exclusive use, commercial exploitation and earning of financial benefits over the GRs and associated TK.[13] As described below, IP has thus served as a major mode for the misappropriation of GRs and associated traditional knowledge.

Even where IP rights are not taken, misappropriation may occur when genetic material is accessed without consent, or when consent is obtained based on inequitable contracts.[14] Since many of these contracts are private and confidential, it is difficult to verify compliance with the agreed terms and conditions and applicable ABS laws.

There are innumerable cases of misappropriation of GRs and associated traditional knowledge that can be traced back to the sixteenth century.[15] Annex 1 of this paper provides

[12] Through the application of a legal fiction, the traditional knowledge associated with GRs have not been accepted as a formal knowledge system. This legal fiction enabled botanical and zoological exploration of the flora and fauna of the colonized territories which facilitated the transfer of samples of genetic material and the associated traditional knowledge on their use for further innovations by the colonial powers. Establishment of botanical gardens in Europe and the colonies in the late nineteenth century acquired great scientific, agricultural and medical importance. See generally, John. Merson, "Bio-Prospecting or Bio-Piracy: Intellectual Property Rights and Biodiversity in a Colonial and Postcolonial Context", *Osiris*, vol. 15 (2000), pp. 282–96. Available from www.jstor.org/stable/301953.

[13] Naomi Roht-Arriaza, "Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities", *Michigan Journal of International Law,* vol.17, No.4 (1996), p. 919. Available from https://repository.law.umich.edu/mjil/vol17/iss4/2.

[14] See, e.g., Tak Jong Kim, "Expanding the Arsenal Against Biopiracy: Application of the Concession Agreement Framework to Prevent Misappropriation of Biodiversity", *Science and Technology Law Review,* vol.14, No.1 (2011), pp. 71–2. Available from https://cpb-us-w2.wpmucdn.com/smulawjournals.org/dist/8/7/files/2018/11/4_Expanding-the-Arsenal-against-Biopiracy_-Application-of-the-Conce.pdf.

[15] "Biopiracy in the Amazon began almost immediately after the "discovery" by the Portuguese in 1500, when they stole the secret – from the indigenous people of the region – how to extract a red pigment from pau-brasil

a list of prominent cases of patent applications related to GRs and associated traditional knowledge and the current status of the patents.

A. Cases of Misappropriation of GRs through Physical Access

The cases described below are illustrative of the systematic use of the patent system to gain ownership of GRs and associated TK. These illustrations are not exhaustive, but they show a pattern of extraction of GRs from the providing country and their patenting in other jurisdictions without compliance with the requirements established in the CBD and the Nagoya Protocol. They also show that in the successful cases where patents were revoked the main argument used to challenge the patent were related to IP and not ABS fulfilment. Some of these examples also illustrate the use of technology in the most recent cases to render misappropriation almost unnoticeable for the traditional mechanisms of prevention and control.

1. Turmeric

Turmeric or Curcuma is a flowering plant that is native to the Indian subcontinent and Southeast Asia and is cultivated primarily for the consumption of its roots in various forms. Turmeric powder has been traditionally used as an ingredient in traditional medicines for various conditions, food, cosmetic substances as well as a special dye. In 1995 a patent was granted in the United States to the University of Mississippi Medical Center for Wound Healing on both oral and topical use and administration of Curcuma powder for the healing of wounds, particularly skin ulcers. The patent application made no disclosure of well-known traditional use of turmeric for healing of wounds and thus the patent right over the associated traditional knowledge was misappropriated. The Indian Council for Scientific and Industrial Research objected to the granted patent and provided documentary evidence of the state of the art citing ancient ayurvedic texts. Although it was a well-known fact that the use of turmeric had been known in all households since ancient times in India, it became a difficult task to find written information, as required by the law, on the use of oral and topical turmeric powder for wound healing. After extensive research, 32 references were located in different Indian languages. Finally, after the evidence of the traditional use of turmeric for wound healing was brought before the USPTO, the patent was revoked in 1997 on the ground that the patent claims were obvious and lacked novelty. This case also demonstrates the challenges faced in mounting the patent opposition with documentary published evidence of prior art.[16] In fact the US patent law was amended in 2011 through the America Invents Act to expand the definition of prior art to include any form of public disclosure as evidence of prior art.[17]

2. Teff

Teff is a gluten-free cereal which has been grown in Ethiopia and Eritrea for at least 2000 years and used to prepare a traditional fermented sourdough flatbread called *Injera* which is consumed as a staple food in both countries. In 2005, a dozen varieties of teff seed were shared with a Dutch company—Crop Improvements (S&C)—by the Ethiopian Institute of

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(brazil wood). Emblematic of today's situation, in which flora and fauna continue to disappear, the wood that gave Brazil its name has completely disappeared, being preserved only in a few botanical gardens." See Ethical Boundaries of Registering Patents and Trade Marks on Biological Resources and Traditional Knowledge of the Amazon Rainforest, Biopiracy in the Amazon: Historical Facts. Available from https://www.amazonlink.org/biopiracy/biopiracy_history.htm.

[16] See Sangeeta Udgaonkar, "The recording of traditional knowledge: Will it prevent 'bio-piracy'?", *Current Science*, vol. 82, No. 4 (2002), pp. 414–5. Available from www.jstor.org/stable/24106653.

[17] See generally, Albert Tramposch, "The Global Impact of the America Invents Act", *WIPO Magazine*, December 2011, pp. 6–7. Available from https://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2011/wipo_pub_121_2011_06.pdf.

Biodiversity (IBC) and the Ethiopian Agricultural Research Organization (EARO) on the basis of a memorandum of understanding (MoU), which provided for the fair and equitable sharing of the benefits derived from the commercialization of teff. At the time, the deal was seen as a pilot case in the application of the CBD in terms of ABS.[18] Unfortunately, the MoU did not include a clause on IP rights, and S&C obtained patent rights in the Netherlands by claiming a novel way to store and process teff flour. The company also obtained a patent from the European Patent Office in 2007 for the processing of teff flour products and mixtures of flour containing teff. Though the patent applications disclosed that teff has been cultivated mainly in Ethiopia and Eritrea for more than 5000 years, it did not disclose Ethiopia specifically as the country of origin teff (contrary to a commitment in the agreement with the Ethiopian Institute of Biodiversity to acknowledge Ethiopia as the country of origin in all publications and applications). Moreover, while claiming novelty and inventiveness over the process of storage and making of teff flour, the patent application did not disclose that considerable traditional knowledge exists in Ethiopia regarding the storage time of teff after harvest and the making of teff flour.[19]

These patents effectively excluded Ethiopia from utilizing teff for most forms of production and marketing in Europe. The patents were subsequently assigned to its successor company—the Health and Performance Food International (HPFI). The patent rights were further transferred to a new group of five companies by HPFI before it was declared bankrupt in 2009.[20] These new companies expanded their markets to other countries and continents. Ethiopia only received from HPFI a research project that was later discontinued, and a payment of 4,000 Euros.[21]

On 21 November 2018, a Hague court revoked the teff patents,[22] asserting that they were invalid as the claimed inventions did not comply with the applicable patentability requirements. However, this decision was based on the argument that the claimed processes did not appear to be inventive as such. It did not revoke the patent on the ground of the existence of associated TK over storage of teff and making of teff flour. Hence, though this decision terminated the patent rights granted erroneously to HPFI, but it did not render justice to Ethiopia. Rather, the effect of the patent invalidation put the varieties of teff in the public domain in the Netherlands which allows anyone in the country to sell, market, and distribute teff flour and products without any recognition of the associated TK held by farmers in Ethiopia and the obligation of sharing benefits with Ethiopia. This deprives Ethiopia of any possibility to claim ABS in the Netherlands. The patent granted by the EPO is still valid in the rest of the European countries and will remain in force until 22 July 2024.[23]

The teff case demonstrates that a specific disclosure about the origin of teff in Ethiopia and the associated TK held in Ethiopia over storage and flour making processes using teff, could have enabled patent examiners to consider such associated TK as part of the prior art and thus avoid the erroneous grant of the patent.

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[18] See Regine Andersen and Tone Winge, *The Access and Benefit-Sharing Agreement on Teff Genetic Resources: Facts and Lessons* (Lysaker, Norway, Fridtjof Nansen Institute, 2012), p.vi. Available from https://www.fni.no/getfile.php/131843-1469869194/Filer/Publikasjoner/FNI-R0612.pdf.

[19] Ibid, pp. 131–2.

[20] Ibid.

[21] Ibid.

[22] See The Netherlands, Judiciary, Pronunciations, *Ancientgrain BV vs. Bakels Senior NV*. Available from https://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:RBDHA:2018:13960.

[23] See, Thamara Romero, "Misappropriation of genetic resources: Dutch Court revokes patents on teff for failure to meet patentability criteria", *SouthNews,* South Centre, 13 March 2019. Available from https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=13dbc46ed2.

3. Maca

Maca, also known as “Peruvian ginseng”, is a plant native to the central Andes of Peru, where it has been cultivated for many centuries for its edible roots. Maca has been used in the region traditionally for food and medicinal purposes and is well known in the Andean tradition for its effect on fertility. Products derived from maca have high demand as natural supplements in the United States, Europe and Japan. The Peruvian National Commission Against Biopiracy (NCAB) is considered as possibly the only institution of its kind in the world that actively seeks out cases of biopiracy in other countries and initiates proceedings to formally invalidate them and alert relevant authorities in those countries.[24] The NCAB has reported a number of cases of misappropriation of maca using the patent system since 1999.[25]It also successfully invalidated patent applications on different forms of use for maca in a number of countries.[26] However, in the absence of a mandatory disclosure requirement of the country of origin or source of a GR or associated TK as an international legal obligation, the reliance on this approach of "carving out Peruvian claims" has been dependent on the extent to which the patentability standards of the country where the application is filed enable mounting a successful opposition.[27] In particular, this can be significantly limiting if patentability standards as espoused in the Trans-Pacific Partnership Agreement that enable the grant of patents on new forms, uses or methods of use of a known product, even if they do not result in enhancement of the known efficacy of the product.[28] It is noteworthy that even after successful opposition resulting in invalidation of patent applications on maca in foreign territories in the past, patent applications have continued to be made on use of maca (see box below).

Box 1: Best practice of institutional response against misappropriation

In 2018, the NCAB reported 24 applications for patents based on maca worldwide. For instance, a biotech company, JDS Therapeutics LLC, and the Yunnan Minzu University applied to patent two products containing maca with the aim of producing medicines. The first application was filed with the United States Patent and Trademark Office (USPTO) for the registration of a product called "Maca Compositions and Methods of Use," referring to two varieties of maca (black and yellow) that would be used for the treatment of the inflammatory syndrome. The second application was made to the Intellectual Property Office of China (CIPO) requesting the registration of a "New alkaloid of *Lepidium meyenii* Walp–Method of preparation and its application", referring to a process for the extraction of alkaloids from *Lepidium meyenii* and obtaining and identifying a specific metabolite called "Meyeniin A" with anti-tumor activity. The NCAB prepared opposition letters addressed to the patent offices of the United States and China arguing that these patent applications should be rejected, as they did not meet the requirements for patentability, i.e., lack of novelty and inventive step required by the respective patent laws. Pursuant to its intervention, more than 17 cases have been decided in favor of the Peruvian State. Some of the patent applicants abandoned the applications once they received the notice from the NCAB.

4. Sangre de Grado

Sangre de Grado is a latex extracted from the bark of a variety of species of the *Croton lechleri* tree in the Amazonian basin and is traditionally used in the region for its medicinal

[24] Simon E. Cortijo, "The successes and drawbacks of Peru's fight against biopiracy", *Biopirateria,* 25 June 2018. Available from https://biopirateria.org/the-successes-and-drawbacks-of-perus-fight-against-biopiracy/?lang=en.
[25] *See,* World Intellectual Property Organization, document WIPO/GRTKF/IC/5/13. Available from https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_5/wipo_grtkf_ic_5_13.pdf.
[26] Cortijo, *supra* note 24.
[27] Ibid.
[28] Ibid.

properties.[29] Patents have been granted in the United States on the method of extracting the latex, as well as on two medical products derived from it (an antiviral drug for respiratory disease and an anti-diarrhea drug).[30] In 1998, the United States also granted a patent for the compositions and methods for healing wounds using the *Croton lechleri*.[31] Around the time of the expiry of the patent in 2018, NCAB of Peru identified seventy new patent applications[32] related to *Sangre de Grado* and successfully prevented the processing of 25 patent applications by Jaguar Health.[33] However, in February 2020 Napo Pharmaceuticals, a subsidiary of Jaguar Health received the 2019 Varro E. Tyler Commercial Investment in Phytomedicinal Research Award in the United States for the successful development and commercialization of *Sangre de Grado*.[34] Even the other patents on anti-viral and antidiarrheal drugs developed from *Sangre de Grado* were assigned to Napo Pharmaceuticals and PS Pharmaceuticals, respectively, though the original patentee, Shaman Pharmaceuticals, has become bankrupt. These instances demonstrate that various patents related to *Sangre de Grado* continue to be commercially attractive[35] and the difficult task of NCAB to guarantee the protection of the Peruvian GRs against misappropriation in foreign territories, in spite of an active role it has tried to play in opposing such patents. An international mandatory disclosure requirement would thus make it easier for foreign patent offices to avoid erroneous grant of patents of Peruvian GRs such as *Sangre de Grado*, without awaiting a formal objection from NCAB.

5. Enola Yellow Beans

In 1994, Larry Proctor, a researcher from the United States, bought some beans in a market in Mexico while on a vacation. The beans, known by the population as Azufrado and Mayocoba, have been cultivated by Latin American farmers for centuries. The researcher planted the beans, allowed them to self-pollinate and selected the yellow beans successively for three generations. Then, he filed a patent application and for a certificate of plant variety protection in 1996 claiming that he had developed a new field bean variety that produces a

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[29] Julio Montero, "HEALTH-ECUADOR: The Miracle of "Dragon's Blood"", *Inter Press Service,* 16 November 1999. Available from http://www.ipsnews.net/1999/11/health-ecuador-the-miracle-of-dragons-blood/.

[30] *See* Jodie Chapell, "Biopiracy in Peru: Tracing Biopiracies, Theft, Loss & Traditional Knowledge", PhD Thesis, Lancaster University, September 2011, pp. 201–2. Available from https://eprints.lancs.ac.uk/id/eprint/133566/1/11003690.pdf.

[31] United States patent number US5932617A, Application US09/021,225 events 1998-02-06 filed by WoundFast Pharmaceuticals Inc.

[32] The applications were submitted to the European Patent Office (EPO), the Patent Cooperation Treaty (PCT), the Korean Intellectual Property Office, as well as to those of Mexico, Australia, Canada, China, Colombia, Costa Rica, Argentina, the United States and Uruguay. They related to methods for the treatment of gastrointestinal problems in pets, breeding animals, neonatal animals and young people, as well as to a composition for the treatment of ulcers and related symptoms.

[33] The NCAB sent non-patentability reports based on the lack of inventive step and the non-patentability of therapeutic methods to foreign patent offices and. The NCAB also coordinated with the Peruvian Ministry of Foreign Affairs to present patent opposition documents through the embassies of Peru. A total of 16 observations were presented. However, given the number of applications and that all were submitted by Jaguar Health Inc., the NCAB also sent decided to send through the Ministry of Foreign Affairs a letter to the same company that had applied for the patent, stating that it had become aware of the existence of the 25 patent applications filed in different intellectual property offices and that they were all related to a derivative of SDG. According to the NCAB, Jaguar Health Inc. abandoned the 25 patent applications following the issuance of that letter, in July 2018. *See, "*Indecopi impide latrocinio de patente de árbol amazónico de sangre de grado en varios países"*, Con Nuestro Peru,* 25 August 2018. Available from https://www.connuestroperu.com/consumidor/58135-indecopi-impide-latrocinio-de-patente-de-arbol-amazonico-sangre-de-grado-en-varios-paises ; "INDECOPI: Comisión Nacional contra la Biopiratería ganó 45 casos a nivel internacional", Gestión Economía, 1 February 2019. Available from https://gestion.pe/economia/indecopi-comision-nacional-biopirateria-gano-45-casos-nivel-internacional-257567-noticia/?ref=gesr.

[34] American Botanical Council, "ABC Varro E. Tyler Award for Excellence in Phytomedicinal Research to be Given to Jaguar Health/Napo Pharmaceuticals*", GlobeNewsWire,* 20 February 2020. Available from https://www.globenewswire.com/news-release/2020/02/20/1987862/0/en/ABC-Varro-E-Tyler-Award-for-Excellence-in-Phytomedicinal-Research-to-be-Given-to-Jaguar-Health-Napo-Pharmaceuticals.html.

[35] Chapell, *supra* note 30, p. 202.

uniform and distinctly colored yellow seed, which remains relatively unchanged by season. In 1999, the US Patent Office (USPTO) granted a patent for the claimed "Enola beans."[36]

The patent holder immediately started enforcing his rights against two Mexican and 16 US companies and farmers of Mexico and the US for exporting yellow beans. The International Center for Tropical Agriculture (CIAT),[37] which also holds similar beans in their international collection was also banned from sending its equivalent beans into the US. The patent holder also imposed a 6% royalty payment against yellow beans imported from Mexico. By 2001, the patent holder had sued 16 small bean seed companies and farmers that were selling Mexican yellow beans in the U.S.

The International Center for Tropical Agriculture (CIAT) in collaboration with Mexican farmers, and other civil society groups requested for the reexamination of the Enola patent in December 2000. This action was endorsed by the Consultative Group on International Agricultural Research (CGIAR) and the Food and Agriculture Organization of the United Nations (FAO). CIAT was able to dispute the inventor's claims to a unique color by providing evidence of 260 yellow beans. In addition, CIAT pointed out that the Mexican government released a version of the bean variety in question to the public in 1978 as Azufrado Pimono 87. After a long and difficult proceeding of eight years, the Enola beans were determined to be not inventive enough to be eligible for patent protection in 2008.

Generally, a patent remains in force until invalidated. Therefore, the patent holder could continue to enforce their patent rights against farmers and CIAT. He benefited from a "de facto" market exclusivity on a product that should never have been patented, as it was indicated by the final ruling.[38] In the United States, as well as some other countries, patents can be opposed only after they are granted.[39]

The Enola beans case also demonstrates how in the absence of disclosure of source or origin of the GR used or the associated TK, a patent was erroneously granted and was revoked after a considerably lengthy litigation.

6. Vaccines

Instances of misappropriation of GRs can be found in cases of accessing microbial genetic material for the research and development of new vaccines without compliance with ABS rules, as well as in not sharing the benefits of the results obtained from the research. This type of misuse has occurred when developing countries have shared samples of pathogens with research institutions in developed countries in order to develop vaccines. Many developing countries are dependent on developed countries' infrastructure for the production of vaccines. During pandemic influenza outbreaks in the recent past, countries such as Cambodia, Indonesia and Vietnam have supplied virus samples for preparation of vaccines, but their populations have not been able to benefit from them.[40]

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[36] See United States Patent no. 5,894,079.

[37] The International Center for Tropical Agriculture (CIAT) is a not-for-profit organization located in Palmira, Colombia, and has the world's largest bean collection – more than 35,000 varieties. See generally "About CIAT". Available from https://ciat.cgiar.org/about/.

[38] The final ruling indicated that there were several grounds to reject the patent. See, CIAT, "New legal decision against Enola bean", 22 July 2009. Available from http://www.ciatnews.cgiar.org/2009/07/22/new-legal-decision-against-enola-bean/.

[39] However, nothing under the TRIPS Agreement prevents any country from establishing a system allowing for opposition of patents before they are granted. A number of countries also allow third parties to oppose a patent during the examination of the patent application itself.

[40] See, Shawn Smallman, "Biopiracy and Vaccines: Indonesia and the World Health Organization's new Pandemic Influenza Plan", in *Journal of International & Global Studies*, vol. 4, No. 2 (2013), p. 22.

Prevention against the proliferation of influenza viruses through vaccines is of critical importance. However, the development of vaccines depends on the collaboration of the actors involved. Countries where a pathogen can be found can contribute by granting access to the original virus for research and more importantly, as a direct input for vaccines in the form of dead organisms.[41] On the other hand, technologically advanced countries can in return share the information found in their research and development of vaccines and provide access to the vaccines and other pandemic related supplies at an affordable price.

Every year scientists scour the planet looking for different forms of influenza pathogens in an effort to create new vaccines and solutions to prevent a pandemic. However, even successful research outcomes may not guarantee access to the vaccines for the populations in all countries. The priority for some rich countries has been securing first the needs of their population through negotiating bilateral advance purchase agreements with vaccine manufacturers, keeping the vaccines inaccessible for most developing countries.[42]

An emblematic case arose between 2005 and 2007 that involved Indonesia and WHO. In 2005, the WHO- global surveillance system network (WHO-GSS), originally established as an international public health collaboration system, was misused by the world's largest vaccine manufacturers as a free virus collection department for R&D of vaccines. It provided very little benefit to developing countries that did not have the technological capacity to develop their own vaccines. Faced with such inequity, in 2007 Indonesia decided to stop sharing virus samples with the WHO. Its action shocked the world and alerted many developing countries to the need for far-reaching reforms and caused major companies and developed countries to struggle to maintain the status quo. (See box 2).

Box 2: Indonesia's fight to change WHO rules on flu vaccines

In mid-2005 a new strain of H5N1 avian influenza emerged in Indonesia which also affected humans. Indonesia shared the H5N1 virus samples obtained from victims with the WHO-GSS. There was no material transfer agreement or other document specifying rights between the parties. Subsequently, one of the virus samples donated by Indonesia was selected by the WHO-GSS for use in vaccines. However, it emerged that the vaccines manufactured on the basis of this virus sample shared by Indonesia would not be available to Indonesians. This generated great concern and discontent among the population, which was increased when it was discovered that the pharmaceutical companies that were part of the WHO-GSS applied for patents on this and other types of H5N1, ensuring for them the monopoly on the production and sale of the vaccines.[43]

In 2007 Indonesian health authorities decided to stop sharing virus samples with the WHO and to directly make proprietary arrangements to exchange virus samples for vaccines with a pharmaceutical company called Baxter Healthcare.[44] Developing countries showed support for Indonesia and called for a new international framework to be set up for the sharing of avian influenza viruses, to review the existing WHO research system.[45] In May 2011, the World Health Assembly agreed upon a legal framework that provided clear rules for the sharing of virus samples in exchange for benefit sharing—The Pandemic Influenza

[41] Ibid., p. 315.
[42] Smallman, *supra* note 40, p. 23.
[43] Edward Hammond, "Indonesia lucha por cambiar las normas de la OMS sobre las vacunas contra la gripe", 17 April 2009. Available from https://www.grain.org/article/entries/727-indonesia-lucha-por-cambiar-las-normas-de-la-oms-sobre-las-vacunas-contra-la-gripe.
[44] Donald G McNeil Jr., "Indonesia to send bird flu samples, with restrictions", *New York Times,* 28 March 2007. Available from http://www.nytimes.com/2007/03/28/world/asia/28birdflu.html?_r1&oref=slogin@page2. See also Smallman, *supra* note 40, p. 23.
[45] Martin Khor, "Indonesia to share bird-flu samples only if there is a new system", *TWN Info Service on Health Issues*, 22 February 2007. Available from. https://www.twn.my/title2/health.info/twninfohealth078.htm.

Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits.[46] The framework seeks to ensure that the WHO could continue to collect and distribute viral samples to the developed world and pharmaceutical companies in exchange for providing more benefits (such as vaccines and medicines) to developing countries (WHO, "Benefit Sharing,").[47] Although there was consensus on the adoption of the Framework, concerns about the patenting of genetic material persisted. The delegation of Bolivia made its position clear by ensuring that the Annex 2, the "Standard Material Transfer Agreement outside WHO GISRS (SMTA2) does not prohibit the patenting of the influenza biological material and parts thereof shared with entities outside WHO GISRS.[48]

B. Misappropriation through New Technologies

A major transformation in the mode of accessing GRs today is through the use of new digital and synthetic biology technologies that eliminate the need for physical access to samples of a resource for bioprospecting. Scalable and electronic digital sequencing technologies such as MinION[49] can determine the full genome sequence of a biological resource and store the information of the genetic sequences. Genetic sequence information can also be obtained by using Artificial Intelligence-based technologies such as Google's DeepVariant[50] or by using mass spectrometry technologies. This information can be used to recreate a GR by using gene synthesis technologies. Moreover, information about genetic traits can be used to introduce similar traits in other varieties through gene-editing technologies such as CRISPR/Cas-9.[51]

An illustrative example of the use of synthetic biology as a means for biopiracy involves patent claims to a key vaccine-making piece of the H7N9 influenza virus.[52] A US biotech company Inovio Pharmaceuticals and its partner the University of Pennsylvania have applied for a patent[53] claiming a specific variant of an influenza gene called HA, which codes for the protein hemagglutinin. The patent application did not divulge the origin of the claimed HA gene, which is exactly the same as the gene of an H7N9 virus sample that was collected from a human male in China in 2013.[54] However, the patent examiner found that the claimed genetic sequence is a copy of the HA gene of a virus called A/Zejiang/DTID-ZJU01/2013.[55] This demonstrates that the process of gene synthesis from genetic sequence information poses challenges to the ABS system because of the difficulties of traceability of data. Furthermore, it shows that the ABS system risks becoming obsolete to prevent

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[46] See World Health Organization, Resolution WHA64.5. Available from https://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_8-en.pdf.

[47] See Smallman, *supra* note 30, p. 28.

[48] See World Health Organization, Resolution WHA64.8 Corr.1. Available from https://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_8Corr1-en.pdf.

[49] The MinION is a portable real-time device for DNA and RNA sequencing which can be used to obtain the sequence information of genetic material *in situ*. An even smaller handheld device – SmidgeION – is currently being developed. See Oxford Nanopore Technologies. Available from https://nanoporetech.com/about-us.

[50] Bernard Marr, "The Wonderful Ways Artificial Intelligence is Transforming Genomics and Gene Editing", *Forbes*, 16 November 2018. Available from https://www.forbes.com/sites/bernardmarr/2018/11/16/the-amazing-ways-artificial-intelligence-is-transforming-genomics-and-gene-editing/#14beff5442c1.

[51] Edward Hammond, "Gene sequences and biopiracy: Protecting benefit-sharing as synthetic biology changes access to genetic resources", Briefing Paper, No. 93 (Penang, Third World Network,2017). Available from https://www.twn.my/title2/briefing_papers/No93.pdf.

[52] See Edward Hammond, "Synthetic Biopiracy Gets Real with Inovio's Deceptive Patent Claim", *TWN Info Service on Biodiversity and Traditional Knowledge*, 16 November 2015. Available from https://www.twn.my/title2/biotk/2015/btk151101.htm.

[53] Patent application Wo2015023461, published 3 September 2015.

[54] Hammond, *supra* note 51.

[55] Ibid.

misappropriation, not only because of the use of new technologies but also because ABS obligations are typically implemented through the use of material transfer agreements that are linked to physical movement of samples of genetic material, that exclude movement of digital sequence information (DSI) from their scope.[56] Moreover, the possible variance in mutually agreed terms for ABS from contract to contract makes it impossible to be applied to the sharing of sequence information in databases. In some instances, such as pathogen sequence information, the need for expedited sharing of data is critical, and this requires an expedited solution to facilitate the same while complying with ABS rules.

The vast extent of *ex situ* collections of GRs in gene banks, seed banks, scientific research institutions, universities, companies, etc. have become even more important in the context of the application of new digital technologies. The sequence information of the genetic material held in some *ex-situ* collections have been or are in the process of being digitized. Some of this DSI from *ex situ* collections are being made available in public databases.[57] By using synthetic biology technologies, genes can be selected from the digitized information available in *ex situ* collections or in public databases and combined into an artificial DNA known as a "vector", which can then be injected into a host microorganism that can express the genes of the vector. It is noted that both the vector (artificial DNA) and the host microorganism can be owned by companies with associated IP rights over the same. The technology has evolved rapidly to the extent that genetic sequence information can be accessed in real-time even from *in situ* collections and transmitted to databases for further use in research.[58]

A recent study mapping the global patent landscape for synthetic biology points to 7,424 families of patent applications that constitute the core patent landscape for synthetic biology as of December 2017. The mapping shows that synthetic biology patents are most prevalent in the area of pharmaceutical and medical applications, followed by plant biotechnology, biocides and pesticides, diagnostic tools, animal husbandry and foodstuffs. A large majority of the patent applications are from the US.[59]

The use of synthetic biology technologies to create artificial microorganisms or edit the genetic traits of biologically originating microorganisms through the use of genetic sequence information obtained from genetic material *in situ* or *ex situ* without any physical collection of the sample can enable entities utilizing such information through the application of synthetic biology technologies to derive new products to do so without complying with any ABS requirement insofar as it is based on the occurrence of physical access. If a mandatory disclosure requirement that complements ABS rules is also similarly premised on the use of the genetic material in a physical sense, the disclosure requirement would not apply to synthetic biology patents that involve use of genetic sequence information instead of the physical sample of a genetic material. In this context, an important issue to reflect on is whether IP laws should include synthetic biology inventions within the scope of mandatory disclosure of origin or source obligation.[60]

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[56] Ibid.
[57] Sarah A. Laird and Rachel P. Wynberg, "A Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol", Convention on Biological Diversity Document CBD/DSI/AHTEG/2018/13, 12 January 2018 (with contributions from Arash Iranzadeh and Anna Sliva Kooser). Available from https://www.cbd.int/doc/c/e95a/4ddd/4baea2ec772be28edcd10358/dsi-ahteg-2018-01-03-en.pdf.
[58] Ibid.
[59] Paul Oldham and Stephen Hall, "Synthetic Biology – Mapping the Patent Landscape", *bioRxiv*, 30 November 2018. Available from https://www.biorxiv.org/content/biorxiv/early/2018/11/30/483826.full.pdf.
[60] Margo. A. Bagley, "Digital DNA: The Nagoya Protocol, Intellectual Property Treaties and Synthetic Biology", Public Law and Legal Theory Research Paper Series, No. 11, Emory Legal Studies Research Paper (Charlottesville, University of Virginia School of Law, 2016). Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2725986.

Genetic sequence information could also give rise to issues in certain jurisdictions about the rights over the database wherein the genetic sequence information is stored.[61] This can be the case particularly with regard to databases that are under the jurisdiction of countries that protect *sui generis* exclusive rights over databases.[62] These exclusive rights may restrict the extraction or re-utilization of the content of the databases without the authorization of the maker of the database.[63] An unsuccessful attempt was pursued in WIPO at the behest of the European Union to establish a globally harmonized system for the protection of non-original databases through the negotiation of a Treaty on Intellectual Property in Respect of Databases.[64] Insofar as the genetic sequence data is made available in a database in any country that recognizes a *sui generis* database protection right, such protection can also facilitate misappropriation of GRs.

A critical issue in this regard would be how the holders of GRs and associated TK can extend their control over genetic sequencing information and data taken from these resources and transmitted to databases in developed countries. It is possible that PIC and MAT on access and use of genetic material could exclude or restrict the taking or use of genetic sequence information of genetic material.[65] It could also be useful to draw from the experience of personal data privacy legislations adopted in different countries that seek to provide individuals the ability to control the acquisition and use of their personal data. Extension of this concept under ABS laws to the data over genetic material could imply a recognition of the authority of States and communities over such data, much like the authority of individuals over their personal data. For instance, access to such data can be subject to a data transfer agreement in place of a material transfer agreement which could lay down the terms for the downward use of the data. A bioprospector acquiring and transferring information to a database could be mandatorily required to also provide a certificate of compliance with ABS requirements provided by the biodiversity authority of the country from where the genetic sequence data has been obtained. However, any new mechanism would only apply to future transfer of genetic material or sequence information. It would not resolve the challenge in respect of material or sequence information already acquired. There is scope for considering in this regard mechanisms that are anchored to principles of open access to existing sequence information for scientific research purposes with possible limitations on taking of IP rights, as well as use of sequence information specific benefit-sharing for local innovation by the holders of GRs and associated TK.[66]

Traceability of the origin or source of the information contained in genetic sequence information databases is of fundamental importance for developing countries. Currently, most genetic sequencing information databases do not require data related to traceability to be submitted. Thus, there is a need to establish mechanisms for genetic databases to require the submission of standardized information necessary for the traceability of

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[61] World Intellectual Property Organization, "A Guide to Intellectual Property Issues in Access and Benefit-Sharing Agreements", 2018. Available from https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf.

[62] *Sui generis* protection of databases are currently available in EU, UK and Russia.

[63] Jerome H. Reichman, "Database Protection in a Global Economy", *La R.I.D.E.: Revue Internationale de Droit Economique,* vol. 16, No. 2 (2002), pp. 455–504. Available from. https://scholar.google.com/scholar_url?url=https://www.cairn.info/load_pdf.php%3FID_ARTICLE%3DRIDE_162_0455%26download%3D1&hl=en&sa=T&oi=ucasa&ct=ufr&ei=qjxAXbu9MsK-mwG3uYewAg&scisig=AAGBfm1wYxjqTacH84GRTGGpkMMkcJ6HPQ.

[64] The proposed treaty failed primarily due to the lack of support for the initiative from the US due to access concerns of the research and scientific community. An unsuccessful attempt was also made in the US in 1996 to enact a law for database protection.

[65] See Edward Hammond, "Finding Traditional Knowledge's Place in the Digital Sequence Information Debate", Discussion Paper (Third World Network, 2020). Available from https://twn.my/title2/briefing_papers/twn/TWB_EHamm_Jul2020_D03.pdf.

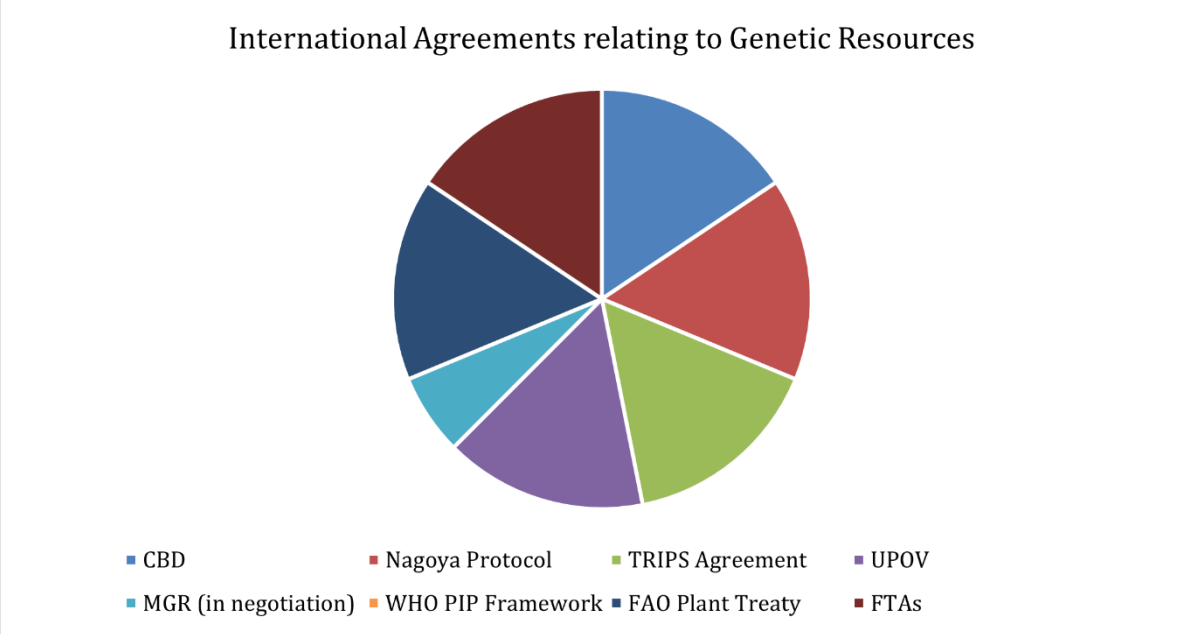
[66] Ibid, p. 8.

submitted sequences.[67] This could apply to future submissions of genetic sequence data from *in situ* as well as *ex situ* collections.

[67] Convention on Biological Diversity, Submission by Brazil to the CBD Secretariat, Digital Sequence Information", 18 August 2017. Available from https://www.cbd.int/abs/DSI-views/Brazil-DSI.pdf.

III. THE INTERNATIONAL LEGAL FRAMEWORK RELATING TO GRS

The international legal framework that is applicable to GRs and associated TK is a patchwork of different types of international legal instruments that constitute a "regime complex".[68] These include instruments that approach the subject from the perspective of IP, the environment (conservation and sustainable use), food security, health, and marine resources. From an IP perspective, the major international legal instrument that impacts GRs by enabling the acquisition of patent rights over microorganisms is the WTO TRIPS Agreement. The International Convention for the Protection of New Varieties of Plants (UPOV Convention) can also enable misappropriation of plant genetic resources through the acquisition of plant variety protection rights over new varieties developed by plant breeders by using existing plant genetic material.[69] A number of other IP instruments that are currently under negotiation, e.g., the WIPO negotiations for an international legal instrument on GRs and TK, as well as negotiations within the framework of the TRIPS Agreement, can also impact the international legal regime on GRs. On the other hand, environmental concerns of conservation and sustainable use of GRs has driven the establishment of an international legal framework that is built on the pillars of access and fair and equitable benefit sharing enshrined in the CBD and the Nagoya Protocol. Within this framework, specialized ABS regimes such as the FAO Plant Treaty have been recognized. Public health concerns such as the outbreaks of pandemic influenza have led to the establishment of mechanisms to facilitate ABS arising from use of virus samples to develop vaccines. Exploration of marine genetic resources beyond areas of national jurisdiction has also brought the international legal regime on the law of the sea into the fold of the regime complex of international legal instruments relating to GRs. The emergence of new technologies in the field of synthetic biology has also added a new dimension to the discussions in multiple fora.



[68] Kal Raustiala and David G. Victor, "The Regime Complex for Plant Genetic Resources", *International Organization*, vol. 58, No. 2 (2004), pp. 277–309. Available from https://pages.ucsd.edu/~dgvictor/publications/Faculty_Victor_Article_2004_Regime%20Complex_International%20Organization.pdf.

[69] See, e.g., Mohamed Coulibaly and Robert A. B. de la Perrière, "A Dysfunctional Plant Variety Protection System: Ten Years of UPOV Implementation in Francophone Africa" (APREBES and BEDE Working Paper, April 2019), pp. 28–9. Available from https://www.apbrebes.org/files/seeds/APBREBES_OAPI_EN_def_0.pdf.

A. Access and Benefit-Sharing Instruments

The global ABS system for GRs and associated traditional knowledge is established by the CBD and the Nagoya Protocol. These multilateral treaties require that access to GRs be based on conditions that seek to guarantee a balance of rights and obligations of the parties. Both instruments are based on an approach that assumes bilateral relationships between a provider country and a user and focuses on balancing the respective interests of access, on the one hand and benefit-sharing, on the other.[70] However, they leave much to national implementation measures establishing more precise obligations.

1. The Convention on Biological Diversity

The Convention on Biological Diversity (CBD) entered into force on 29 December 1993. The Convention has three principal objectives: (1) the promotion of the conservation of biological diversity, (2) the sustainable use of biological diversity,[71] and (3) the fair and equitable sharing of benefits from the use of GRs. CBD recognizes the sovereign rights of States to their natural resources and their right to determine the conditions of access.[72] It contains obligations related to *in situ*[73]and *ex situ*[74] conservation, and also seeks to protect indigenous peoples against unauthorized use of traditional knowledge pertaining to GRs and to secure compensation for commercial use of such knowledge.[75] CBD establishes that access to GRs shall be subject to the prior informed consent (PIC) of the country providing the GR and shall be based on mutually agreed terms (MAT) in cases where access is granted.[76] CBD does not require a country to enact any law or regulation in order to be able to require PIC and MAT. It only treats IP in the context of transfer of technology and does not specifically address IP issues in the context of misappropriation of GRs and associated traditional knowledge. It is silent about the possibility of enforcement at the international level. As a result, actual fulfilment with the PIC and MAT requirement of a provider country will depend on the goodwill of the user to comply with the legislation of the provider country. The governments in provider countries asserting complaints about “biopiracy” in user countries had to act through other mechanisms of pressure such as diplomatic representation rather than legal proceedings in domestic courts, as was revealed for instance by the case of Maca from Peru (see above).

2. The Nagoya Protocol

The Nagoya Protocol[77] further developed the objective in CBD of fair and equitable benefit-sharing, by establishing specific rules and mechanisms to that end. Three main ways are established to achieve fair and equitable sharing of the benefits arising from the utilization of GRs,[78] namely: 1) by appropriate access to GRs, 2) by transfer of relevant technologies and

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[70] See Henning G. Ruse-Khan, "The Private International Law of Access and Benefit-Sharing Contracts”, in *Intellectual Property and Development: Understanding the Interfaces*, Carlos Correa and Xavier Xeuba, eds. (Singapore, Springer, 2019), p. 321.

[71] According to art. 2, biological diversity means “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 and of ecosystems.

[72] See Convention on Biological Diversity, article 15.

[73] Article 2 of CBD defines *In Situ* as 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.

[74] *Ex Situ* is defined in article 2 of the CBD as the conditions where genetic resources exist outside their natural habitats, such as botanic gardens, zoological gardens and gene banks.

[75] The need to respect, preserve and maintain traditional knowledge and benefit-sharing is addressed in paragraph 12 of the preamble as well as in article 8, paragraph (j). A permanent working group of experts was established by the Conference of the Parties to address the implementation of article 8 (j) and related provisions of the CBD.

[76] Convention, *supra* note 73.

[77] The Nagoya Protocol entered into force on 12 October 2014 and to date has been ratified by 117 Parties.

[78] Nagoya Protocol, article 1.

3) funding. The Nagoya Protocol goes further than CBD by requiring countries to ensure that access is based on PIC and MAT and the benefits arising out of the utilization are shared. Unlike CBD, the Nagoya Protocol obliges countries to enact national legislation regulating access to GRs on the basis of PIC and MAT.[79] Furthermore, it requires countries to establish a national competent authority to implement the ABS system and checkpoints overseeing the entire product-chain.[80] IP Offices can act as provisory checkpoints to, inter alia, combat biopiracy as their already established infrastructure would facilitate access to the information provided in IP applications. Despite its importance, the role of IP offices as possible checkpoints and the interface between IP and the ABS regime are unclear in the Nagoya Protocol.

While CBD and the Nagoya Protocol recognize the sovereign authority of States over GRs in their territories, it is unclear whether their provisions apply to GRs accessed before the adoption of CBD,[81] which thus excludes much of the collections held *ex-situ*. The Nagoya Protocol also does not clearly state whether the use of GRs acquired before the adoption of a national ABS law compliant with the Protocol would be within its scope. There is a risk of individuals or corporations using broad IP claims to appropriate genetic material obtained from *ex-situ* collections.[82] For example, taking IP rights by accessing materials in *ex-situ* collections has not been uncommon in the context of plant genetic resources.[83]

3. International Treaty on Plant Genetic Resources for Food and Agriculture

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Plant Treaty) establishes a multilateral system for facilitating access to plant genetic material of a list of crops for farmers, breeders and scientists for research, breeding and training for food and agriculture. The Treaty prevents recipients of genetic material from this multilateral system from claiming IP over those resources and also obliges them to share any benefit arising from the use of the plant genetic resources through benefit-sharing mechanisms under the Treaty. It also calls for protecting the traditional knowledge of farmers, their participation in national decision-making processes, and also promotes the development and maintenance of diverse farming systems that allow for sustainable use of plant genetic resources. However, the scope of obtaining IP on plant genetic resources is ambiguous under the Plant Treaty,[84] and it does not establish any disclosure requirement regarding origin and source of the plant genetic material if the same is used in a patent or plant variety protection application.

4. WHO Pandemic Influenza Preparedness (PIP) Framework

In 2011, WHO Member States adopted the Pandemic Influenza Preparedness Framework (PIP Framework) for enabling the sharing of influenza viruses of pandemic potential and for facilitating access to vaccines and sharing of other benefits. The PIP Framework exhorts WHO Member States to share biological material (virus samples) relating to influenza of human pandemic potential with WHO for the onward transfer and use of the biological

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[79] Ibid, article 5.
[80] Ibid, article13 and 17 (1) (a).
[81] UNCTAD, *supra* note 8, p. 18.
[82] Catherine Monagle and Aimee T. Gonzalez, "Biodiversity and Intellectual Property Rights: Reviewing Intellectual Property Rights in the Light of the Objectives of the Convention on Biological Diversity", WWF-CIEL Joint Discussion Paper (Gland, World Wide Fund for Nature and Geneva, Centre for International Environmental Law, 2001). Available from https://www.ciel.org/Publications/tripsmay01.PDF.
[83] Chidi Oguamanam, "Intellectual Property Rights in Plant Genetic Resources: Farmers' Rights and Food Security of indigenous and Local Communities", *Drake Journal of Agricultural Law*, vol.11, No.3 (2006), p.282. Available from https://aglawjournal.wp.drake.edu/wp-content/uploads/sites/66/2016/09/agVol11No3-Oguamanam.pdf.
[84] The Plant Treaty prohibits taking IP rights over the material accessed through the multilateral system under the treaty "in the form received." See International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA), Article 12.3 (d).

material to institutions, organizations or entities in accordance with the terms of Standard Material Transfer Agreements (SMTAs). The transfer of PIP biological material under the Framework is governed by either of two kinds of SMTA—SMTA 1 which applies to transfer of material within the WHO Global Influenza Surveillance and Response System (GISRS) which includes a number of specific research institutions and laboratories from different countries; and SMTA 2 which applies to transfer of material to entities outside GISRS. Thus, SMTA 2 will apply to material transfer to private entities that seek to develop vaccines and other treatments with regard to influenza outbreaks of pandemic potential. However, while there is a provision that under SMTA 1 no IP should be taken on the materials, this stipulation is absent in SMTA 2. In addition, even the stipulation under SMTA 1 appears to be limited to the material itself that is transferred and does not per se restrict the taking of IP on products developed therefrom.

B. IP Treaties that Impact ABS Regimes

1. WTO TRIPS Agreement

One of the most fundamental changes introduced through the TRIPS Agreement was the requirement for all WTO members to grant patents in all fields of technology, and to also grant patents on microorganisms and certain biotechnological processes.[85] These requirements established under the TRIPS Agreement brought much of the products derived from GRs within the scope of patent protection for a minimum term of 20 years. This made it possible to claim patent protection on biotechnological inventions[86] wherein use of GRs is most common. The language of article 27.3(b) attempted to strike a balance between the interests of developed countries that have a strong interest in protecting biotechnological inventions, allowing for variance in scope of such protection under national laws, while developing countries were concerned about extending patentability to life forms. Nevertheless, a comparison of the draft negotiating texts with the final provision adopted reflects that the provision echoed the interests of developed countries to a large extent.[87] Developing countries have contended that article 27.3 (b) of the TRIPS Agreement does not require patent applicants to comply with obligations under the CBD and the Nagoya Protocol, and have called for a revision of the provision to include a mandatory disclosure requirement and exclude all life forms, including microorganisms, from patenting. These issues have been on the agenda of the TRIPS Council for a number of years (see below).

2. The UPOV Convention

The TRIPS Agreement requires WTO members to protect plant varieties either through patents or through a *sui generis* (unique) system of plant variety protection. Thus, countries could develop their own unique systems of plant variety protection to meet this requirement of the TRIPS Agreement. One kind of system of plant variety protection that has been sought to be promoted globally by developed countries is the system of plant variety protection (PVP) under the UPOV Convention. The Convention was originally adopted in 1961 and further revised in 1972, 1978 and 1991 to strengthen the rights conferred by PVP to plant breeders while restricting the traditional rights of farmers to save, use and exchange seeds.[88] At the time of the entry into force of the TRIPS Agreement, only 30 countries had

[85] See TRIPS Agreement, Article 27.3(b).
[86] See Geoff Tansey, *Trade, Intellectual Property, Food and Biodiversity: Key Issues and Options for the 1999 Review of the TRIPS Agreement*, Discussion Paper (London, Quaker Peace & Service, February 1999). Available from, http://www.tansey.org.uk/docs/TRIPS%20English%20.pdf.
[87] UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge, Cambridge University Press, 2005), p. 391.
[88] Carlos M. Correa, Sangeeta Shashikant and Francois Meienberg, "Plant Variety Protection in Developing Countries: A Tool for Designing a Sui Generis Plant Variety Protection System: An Alternative to UPOV 1991",

joined UPOV, and most of these were developed countries.[89] Following the adoption of the TRIPS Agreement, the membership of UPOV has increased rapidly to the current level of 72 member countries, with some developing countries acceding to it. In many cases, the accession of developing countries to UPOV was the result of unilateral pressures exerted by developed countries or of obligations imposed through free trade agreements, without a thorough assessment of the benefits and costs of acceding to the UPOV system.[90] Prior to acceding to UPOV, a country has to first implement a PVP law that is compliant with the standards set under the UPOV Convention.[91] However, the UPOV Convention does not provide any scope for a member to have a disclosure requirement regarding country or source of origin of a plant genetic resource from which a new plant variety that is sought to be protected may be derived.[92] In contrast, countries that are not parties to UPOV can and do have such disclosure requirement in their PVP laws. [93] In a reply to the CBD Secretariat in 2003, the UPOV Secretariat stated that a disclosure requirement should not be introduced as a condition for plant variety protection, and that the breeders' rights under the UPOV Convention should not be subjected to any condition other the conditions of novelty, distinctiveness, uniformity and stability (NDUS).[94] In 2005, for instance, the UPOV Council reviewed the PVP law of Malaysia for determining its compatibility with UPOV 1991 and refused to approve of the disclosure requirements in the Malaysian PVP law.[95]

3. IP Related Provisions in Free Trade Agreements

IP related provisions in FTAs can also play a significant role in addressing the interface between IP and the misappropriation of GRs and associated traditional knowledge. A number of FTAs contain IP provisions that require parties to accede to IP treaties such as the UPOV Convention, that does not allow for introducing misappropriation prevention measures such as a disclosure requirement in national PVP laws. Some FTAs also require parties to undertake reasonable efforts to make patent protection available to plants, though there is no obligation under the TRIPS Agreement to do so. Moreover, some FTAs, largely involving the United States, lay down standards of sufficiency of disclosure in patent applications that effectively make any mandatory disclosure requirement of the country or source of origin of GR non-applicable to the determination of the patentability of claimed invention based on such GR. Some countries have concluded memorandums of understanding on IP and GRs and associated traditional knowledge within the framework of FTAs with the United States, but these are non-binding[96] and also exclude the application of a mandatory disclosure requirement in preference to use of contractual agreements and prior art databases favored by the United States.[97] At the same time, some other FTAs have

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Working Paper, (APBREBES, October 2015), p. 10. Available from https://www.xn--untergrund-blttle-2qb.ch/dokumente/Plant_Variety_English.pdf.

[89] David S. Tilford, "Saving the Blueprints: The International Legal Regime for Plant Genetic Resources", *Case Western Reserve Journal of International Law*, vol. 30, No. 2 (1998), p. 406. Available from https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1527&context=jil.

[90] Carlos M. Correa et al., *supra* note 89, p. 11.

[91] Ibid, p. 24.

[92] Ibid, p. 25.

[93] Ibid.

[94] International Union for the Protection of New Varieties of Plants, document C/37/20. Available from https://www.upov.int/edocs/mdocs/upov/en/c/37/c_37_20.pdf. Also see International Union for the Protection of New Varieties of Plants, document C/37/21(for decision of the UPOV Council adopting the report by the UPOV Secretariat as a reply to the CBD Secretariat). Available from https://www.upov.int/edocs/mdocs/upov/en/c/37/c_37_21.pdf

[95] Carlos M. Correa et al., *supra* note 89.

[96] See David Vivas-Eugui and Maria Julia Oliva, "Biodiversity Related Intellectual Property Provisions in Free Trade Agreements", Issue Paper No. 4 (Geneva, International Centre for Trade and Sustainable Development,2010), pp. 7–9. Available from https://www.peacepalacelibrary.nl/ebooks/files/ICTSD_Vivas-Eugui_Biodiversity-related-IP.pdf.

[97] See Burcu Kilic, "Patent Disclosure Requirements in Free Trade Agreements", Working Paper No. 49 (New Delhi, Centre for WTO Studies, 2018). Available from http://wtocentre.iift.ac.in/workingpaper/WorkingPaper49.pdf.

also included provisions that enable countries to introduce or retain a mandatory disclosure requirement under their national laws[98] without making it an obligation for parties to introduce such a requirement.

[98] Ibid.

IV. Genetic Resources and Associated TK Related Negotiations in Multilateral Fora

Setting of new global norms pertaining to the use of the IP system in relation to GRs has been on the negotiating agenda of the WIPO and WTO for a number of years. Though IP rights in the form of PVP are also relevant to PGRs, no specific normative proposal in relation to the same has been made by any country that is party to the UPOV convention. However, the members of the FAO Plant Treaty have tried to initiate an engagement with UPOV and WIPO secretariats on the issue of interrelations with the UPOV and WIPO instruments with the provisions of the Plant Treaty.

GRs have also featured in the discussions in a number of other fora. These are - the FAO International Treaty on Plant Genetic Resources for Food and Agriculture ("Plant Treaty"), the WHO PIP Framework and the negotiations on a binding treaty on Marine Genetic Resources under the UN Convention on the Law of the Sea (UNCLOS). The question of how to address the use of genetic sequence information has emerged as a major issue of discussion in the context of the CBD and the Nagoya Protocol, the WHO PIP Framework, the FAO Plant Treaty and the FAO Commission on Genetic Resources for Food and Agriculture. Some countries have also raised concerns on this issue in the WIPO IGC negotiations for an international legal instrument on IP and GRs. The issue of genetic sequence information for marine genetic resources in areas beyond national jurisdiction has also been included in the draft UNCLOS convention.

A. Negotiations in WIPO

In WIPO, developing countries are currently engaged in negotiations for a draft text of an international legal instrument on IP and GRs. These negotiations are ongoing in the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC). The mandate of IGC has been renewed for the 2020–2021 biennium by the WIPO General Assembly.[99]

The biggest obstacle to advancing the work in IGC is the lack of genuine interest among some developed countries in reforming their national IP laws. They deny any need for reforming the IP system to address issues related to GRs and associated traditional knowledge. While some developing countries have advanced proposals on a disclosure requirement informed by their experience in implementing such a requirement in their national laws, there are many other developing countries that lack experience with related national legislation and play a passive role in the negotiations.[100] This means that the fundamental proposals in the IGC negotiations reflect a) a contention between countries that seek a disclosure requirement and those that are absolutely opposed to the idea, and b) a difference of views between countries that agree to a disclosure requirement but differ on its scope and extent. While progress has been made towards reaching agreement among the countries that are in principle supportive of the disclosure requirement, consensus has been blocked by countries like the United States and Japan that fundamentally view the disclosure

[99] Assemblies of the Member States of WIPO, List of Decisions – 2019, pp. 11–13. Available from https://www.wipo.int/export/sites/www/about-wipo/en/assemblies/pdf/2019_decisions.pdf.

[100] Viviana M. Tellez, "The WIPO Negotiations on IP, Genetic Resources and Traditional Knowledge: Can it Deliver?", Policy Brief No. 22, South Centre, September 2015. Available from https://www.southcentre.int/wp-content/uploads/2015/10/PB22_The-WIPO-Negotiations-on-IP-Genetic-Resources-and-Traditional-Knowledge-Can-It-Deliver_EN_rev.pdf.

requirement as an attempt to weaken the patent system and are thus strongly opposed to it.[101] As of the last session of IGC in 2018 that discussed the GRs text, this fundamental opposition has blocked consensus on a text which enjoyed broad support from most countries.

For developing countries, the key objectives to pursue through an international legal instrument on IP and GRs are: 1) establishing an obligation for all countries to adopt a mandatory disclosure requirement regarding the origin or source of GRs utilized in an IP application, and 2) ensuring mutual supportiveness of IP laws with obligations under ABS laws.

In the current version of the consolidated draft text on GRs[102] the objective of the proposed instrument is to contribute to the protection of GRs and associated traditional knowledge within the IP system by ensuring mutual supportiveness between international instruments relating to GRs, such as CBD and the Nagoya Protocol, and instruments relating to IP; enhance transparency in the IP system in relation to GRs; and, ensure access to appropriate information relating to GRs to IP offices in order to prevent erroneous grant of IP rights (draft art.2).[103] This provision also enjoyed broad support from most countries at the conclusion of the latest round of negotiations on the GRs text in 2018.

However, there is a divergence of views on whether GRs in the context of all IP rights should be within the scope of this instrument or whether the scope should be limited to protection of GRs in the context of patent rights. Developing countries favor a broad application of the instrument to all kinds of IP protection (draft art.3),[104] while developed countries favor a very restrictive scope of this instrument and limit it to patent applications for inventions directly based on GRs (draft art.3 alternative).[105] Thus, the disclosure requirement about the source and origin of GRs used in IP applications is at the heart of the proposed instrument. Developing countries have proposed that where a subject matter of an IP application includes utilization of GRs and associated traditional knowledge, the applicant shall be required by each country to disclose the country of origin and/or source of the GR and associated traditional knowledge. Developed countries which prefer a softer disclosure requirement have sought to limit the scope of the disclosure requirement to only claimed inventions in patent applications that are directly based on GRs and associated traditional knowledge.

The GRs text is based on two pillars—establishing a mandatory disclosure requirement about the origin and source of the GRs and adopting complementary measures for defensive protection of GRs from misappropriation. These two pillars reflect two mechanisms that are sought to be addressed through the GRs text for preventing misappropriation of GRs and associated TK—disclosure requirements and databases. These mechanisms also reflect the respective preferences of the countries that generally are providers of GRs (developing countries) and the countries that primarily utilize the GRs to develop inventions based on them (developed countries). While the disclosure requirement is essential to the former, databases that provide information to avoid erroneous grant or registration of IP rights are the preferable option for the latter.[106]

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[101] Catherine Saez "WIPO IP and Genetic Resources Committee Makes Progress Despite Block at End", *Intellectual Property Watch,* 2 July 2018. Available from https://www.ip-watch.org/2018/07/02/wipo-ip-genetic-resources-committee-makes-progress-despite-block-end/.

[102] World Intellectual Property Organization, document *IGC/GRTKF/IC/41/4*. Available from . https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_41/wipo_grtkf_ic_41_4.pdf

[103] Ibid.

[104] Ibid.

[105] Ibid.

[106] David Vivas-Eugui, "Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC)", Issue Paper No. 34; (Geneva, International Centre for Trade and

As noted, there is a fundamental divergence of views between the proponents of a disclosure requirement and the US in particular. While there are differences about the framing of the disclosure requirement between some countries, the US completely rejects any disclosure requirement on GRs in addition to the standard disclosures to be made in patent applications. The alternative proposal from the US states that the disclosure of the source location of the GR may be required of the patent applicant only where such disclosure is relevant to the determination of the novelty, inventive step or industrial applicability of the GR for which the patent is applied. This mirrors a similar approach pursued by the US under bilateral FTAs with developing countries.

Developing country proponents of the disclosure requirement have also sought to enable States that would be parties to the instrument to require applicants to provide relevant information regarding compliance with ABS requirements, including prior informed consent, in particular from indigenous peoples and local communities, where appropriate. However, developed countries that support the disclosure requirement prefer to keep compliance with ABS requirements outside the scope of the instrument.

Draft art. 4 of the consolidated text is focused on exceptions and limitations to the disclosure requirement. It presents two alternative options. One option is to introduce a general enabling provision allowing State parties to adopt justifiable exceptions and limitations necessary to protect public interest provided that these exceptions and limitations do not unduly prejudice the implementation of the instrument on GRs, or mutual supportiveness with other instruments. The alternative option is to introduce specific exceptions for human genetic resources including human pathogens, derivatives of GRs, use of GRs as commodities, GRs beyond national jurisdictions and economic zones (an expression which applies to marine genetic resources in the high seas and in the international seabed), GRs acquired before the entry into force of the CBD and the Nagoya Protocol, and GRs necessary to protect human, animal or plant life or health.

A major issue of contention with regard to the disclosure requirement is the question of sanctions and remedies to ensure compliance with the disclosure requirement. The draft text presents three alternate approaches in this regard. One approach is that of setting general principles or standards of remedy that must be satisfied while leaving States free to determine the specific means of ensuring compliance in accordance with those standards. Another approach presents specific remedies and sanctions that are set as desirable measures that national laws should adopt. The third alternative approach is to have a very weak enforcement provision which safeguards IP rights obtained without complying with the disclosure requirement.

In addition to the textual proposal completely rejecting the disclosure requirement, the US has also rejected any reference to the protection of GRs and associated traditional knowledge as an objective of the instrument. Rather, the US has proposed that the objective of the instrument should be restricted to the prevention of grant of patent rights for inventions that do not meet the criteria of patentability.

The US also suggests making the disclosure requirement subject to the terms of an agreement between the patent applicant and the provider of the GR. This is in line with the US approach of addressing the terms of acquisition and use of GRs through contractual agreements between the bioprospector and the country or community which have legal rights over the GR.

Sustainable Development, 2012). Available from https://www.files.ethz.ch/isn/144518/bridging-the-gap-on-intellectual-property-and-genetic-resources-in-wipos-intergovernmental-committee-igc.pdf.

In view of the divergent objectives pursued by different parties in the IGC negotiations on the GRs text, in May 2019 the Chair of the IGC, Prof. Ian Goss from Australia, advanced a proposal[107] on the way forward with a view to bridging the differences and balancing the rights and interests of users' vis-a-vis that of the providers and holders of GRs and associated traditional knowledge. The Chair's draft text advances two objectives of the instrument: 1) enhance the efficacy, transparency and quality of the patent system; and 2) prevent the erroneous grant of patents that are not novel or inventive with regard to GRs and associated traditional knowledge. Thus, the text lacks a clear acknowledgement of the problem of misappropriation which is the core issue that developing countries are seeking to address through a disclosure requirement in IP or more specifically patent applications. Instead, the Chair's text proposes objectives such as enhancing transparency and quality of the patent system and compliance with patentability requirements with regard to GRs. For instance, those who wish to avoid an obligation to introduce a mandatory disclosure requirement could still be accommodated under such an objective insofar as those countries adopt other, even though less satisfactory means, that could in a limited way be said to be in compliance with such broad objectives.

The explanatory note to this draft provision in the Chair's proposal states that the provision does not make any reference to misappropriation or ABS as these issues are dealt with under international instruments such as the CBD, Nagoya Protocol, the FAO Plant Treaty, and the WHO PIP Framework. However, the fact that misappropriation has been addressed in other international instruments does not mean that the issue of misappropriation is not relevant for the WIPO instrument because the instrument should specifically address IP related issues concerning misappropriation. Unless this core issue concerning GRs and associated traditional knowledge is specified in the objectives provision of the instrument, this will create uncertainty about the problem that the instrument seeks to resolve through the promotion of transparency and prevention of erroneous grant of patents. In the event of ambiguity in interpretation of the text, the preamble can be referred to for guidance. However, it should be noted that even the preamble in the Chair's text does not mention any recognition of the problem of misappropriation of GRs and associated traditional knowledge. Article 31 of the Vienna Convention on the Law of Treaties states that the provision of a treaty shall be interpreted in the light of its objects and purposes. Thus, it is critical that the preamble and the provision on the objectives of the WIPO instrument recognize the problem of misappropriation and state the intent to resolve the IP related aspects of this problem as the main objective of the instrument.

Definitions that are unique in this instrument are the expressions "materially/directly based on", "source of GRs" and "source of TK associated with GRs". The most critical of these is the expression "materially/directly based on." The European Union in particular has been seeking to limit the scope of disclosure requirement in patent applications to inventions that are "directly" based on GRs. The Chair has proposed to use the expression "materially based on" as an alternative to the expression "directly based on", because the latter signifies the need to establish physical access to GRs in order to trigger the disclosure requirement. However, the expression "materially" literally means the extent to which something is present or involved in the development of something. Therefore, this expression means that the disclosure requirement can only be triggered if the GRs in question are materially or substantially present in a claimed invention. This would give significant discretion to patent offices to determine whether any GR is substantially present in a claimed invention. Thus, countries that seek to limit the disclosure requirement could adopt very high thresholds for determining whether the invention is materially based on GRs, thus limiting the instances where the disclosure requirement could be triggered. This would frustrate the very purpose

[107] World Intellectual Property Organization, Document IGC/GRTF/IC/41/5, 30 December 2020. Available from https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_41/wipo_grtkf_ic_41_5.pdf.

of a disclosure requirement. Therefore, it would be pertinent to have any use of a GR in a patent application as a trigger for the disclosure requirement rather than setting a fictional threshold of the extent to which an invention is materially based on GRs. Perhaps, the disclosure can be made a requirement on any use of a GR in an invention, but countries could still retain the policy space to determine the extent to which the use of the GR is material to the invention in assessing the patentability of the invention. This would ensure that disclosure is made in all countries if a GR is used in an invention, but all countries may not rely on that disclosure in deciding on the application unless they regard the use of the GR to be materially significant.

With regard to the definitions of source of GRs and associated traditional knowledge, the Chair's proposal refers to any source from which the applicant has obtained the GR or associated traditional knowledge, but then gives examples of the kind of sources referred to with the expression "such as." In accordance with the principle of *ejusdem generis* that is applied in interpretation of legal texts, the nature of specific examples given can determine the kind of source which is included within the definition. When applied in respect of the definition of source of associated traditional knowledge, this suggests that only published material on the associated traditional knowledge will be within the scope of the definition of sources. Therefore, instead of referring to specific examples, the definition should make the examples inclusive and read "Source of associated traditional knowledge means any source from which the applicant has obtained the associated traditional knowledge including both written and oral sources."

The draft provision on exceptions in the Chair's proposal is also very broad. It provides considerable flexibility to any country to significantly limit the scope of the disclosure requirement, particularly when read in conjunction with the provision on objective which does not specifically make disclosure an objective of the instrument.

The provision on remedies states that each Contracting Party shall put in place appropriate, effective and proportionate legal, administrative, and/or policy measures to address an applicant's failure to provide the information in terms of the disclosure requirement. It would be better to use the expression "adequate" instead of "appropriate" as a standard of the legal, administrative or policy measures to remedy failure to comply with the disclosure requirement. The provision also excludes revocation as a possible remedy for non-compliance with disclosure requirement, except in circumstances where non-disclosure or wrongful disclosure with fraudulent intent can be established. In the minimum, the option of revocation as a sanction should be available for countries that wish to make revocation a possible remedy for non-disclosure.

B. Negotiations in WTO

The issue of the relationship between IP and GRs was taken up in WTO from the very beginning of the organization's existence. In 1995, several WTO members discussed the relationship between the TRIPS Agreement and CBD in the Committee on Trade and Environment (CTE). While some developed countries felt that there is no inconsistency or conflict between the objectives of TRIPS and CBD, some developing countries specifically pointed to the need for modifying the provisions relating to disclosure requirement in patent applications under art. 29 of the TRIPS Agreement with respect to biotechnological inventions, such that the disclosure in patent applications should have "… a clear mention of the biological source material, the known country of origin and all known information pertaining to knowledge and practices of the use of biological source material by indigenous communities in the country of origin. This part of the patent would be open to full public

scrutiny immediately after filing of the application."[108] It was also proposed that to remedy the lack of a prior informed consent mechanism within the TRIPS Agreement for obtaining GRs and associated traditional knowledge, material transfer agreements (MTA) and information transfer agreements (ITA) between the users and providers of the material and the associated traditional knowledge would be necessary, and that patent owners should be required to execute ITAs for any traditional knowledge which is already in the public domain or part of recorded or otherwise publicly accessible knowledge systems. It was also proposed that the CTE should also examine the pros and cons of establishing a system of IP protection for traditional knowledge and folklore.[109] Subsequently, these debates have also been taken up in the WIPO discussions, but the issue of a mandatory disclosure requirement regarding the source and country of origin of GRs and associated traditional knowledge has continued to feature in WTO.

Since 1999, the issue of establishing a mandatory disclosure requirement has been on the agenda of the WTO TRIPS Council as part of the agenda item on the review of article 27.3(b) of the TRIPS Agreement. In 2001, the Doha WTO Ministerial Declaration mandated the TRIPS Council to specifically examine the relationship between TRIPS and CBD, and also the issue of protection of traditional knowledge and folklore. In 2008, a coalition of 106 countries (including many developing countries and the European Union) submitted a proposal calling for the amendment of the TRIPS Agreement to enable mandatory disclosure of origin and source of GRs and associated traditional knowledge, and to facilitate the disclosure of evidence of prior informed consent and ABS in patent applications. Following the adoption of the Nagoya Protocol, a revised version of this proposal aligning it to the Nagoya Protocol was submitted by 73 countries in 2011.[110] However, there has been no discussion on the proposals. The proposals suggest the adoption of a protocol establishing a new Art.29 *bis* under the TRIPS Agreement.

Fundamentally, some developed countries such as the Unites States, Japan and Australia are opposed to any amendment to the TRIPS Agreement. These countries do not acknowledge any conflict between TRIPS and CBD and are only agreeable to limiting the discussions to prevention of erroneous grant of patents, which, in their view, can be addressed adequately through databases documenting the associated traditional knowledge. Another group of countries are of the view that although there is no inherent conflict between TRIPS and CBD, international action is desirable for a disclosure requirement. A third group of countries view TRIPS and CBD to be in conflict and propose an amendment to Article 27.3(b) of the TRIPS Agreement, in addition to a disclosure requirement, to ban all patents on life forms, protect innovations of indigenous and local farming communities and their farming practices, prevent anti-competitive practices, protect the rights of indigenous communities and prevent any IP claims over traditional knowledge.[111] This proposal, presented by Bolivia, has not been discussed in detail so far in the TRIPS Council.

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[108] World Trade Organization, Document WT/CTE/1, 12 November 1996. Available from https://docs.wto.org/dol2fe/Pages/FE_DownloadDocument.aspx?Symbol=WT/CTE/1&Language=English&CatalogueId=58544&Context=ShowParts.

[109] Ibid.

[110] World Trade Organization, Document TN/C/W/59, 19 April 2021.

[111] See World Trade Organization, Document IP/C/W/545, 26 February 2010. Available from https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=77859,102965&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True. The proposal requests the urgent review of Art. 27.3(b) to "Prohibit the patenting of all life forms, including plants and animals and parts thereof, gene sequences, micro-organisms as well as all processes including biological, microbiological and non-biological processes for the production of life forms and parts thereof…"

The "no disclosure" group of countries regard that the objectives of CBD, including ensuring access and benefit-sharing through PIC and MAT should be addressed through contracts rather than through the IP system.

The 2008 and 2011 proposals have been submitted to the WTO Trade Negotiations Committee (TNC) which was mandated by the Doha Ministerial Declaration to establish appropriate negotiating mechanisms for the negotiations on issues agreed under the Doha work program. The issue of disclosure requirement is related to the relationship between TRIPS and CBD, which is a TRIPS implementation issue as identified by the Doha work program. In 2005, the Hong Kong WTO Ministerial Conference requested the Director-General (DG) of WTO to intensify consultations on these issues with a view to take action no later than 31 July 2006. The consultations led by the DG have, however, also been discontinued since 2011. Though the issues continue to feature on the agenda of the TRIPS Council, there have been no formal negotiations on them.

During the 2017 WTO Ministerial Conference, some developing countries had suggested that a work program on the relationship between TRIPS and CBD should be included as part of a deal on continuation of the moratorium on zero tariffs on electronic commerce transactions. These countries stated that the TRIPS Council must hold dedicated discussions on the relationship between TRIPS and CBD and the protection of traditional knowledge and folklore, with the objective of reaching agreement on a legally binding outcome by the WTO Ministerial Conference in 2019. However, the 2019 ministerial conference failed to reach agreement on many key issues, including the issue of TRIPS-CBD linkage. The outcome of the WTO Ministerial Conference in 2019 has rendered the future of the entire Doha round of negotiations uncertain, including the future of the issues on the TRIPS-CBD relationship and protection of traditional knowledge and folklore.

Another approach that has been proposed by developing countries as part of the review of article 27.3(b) of the TRIPS Agreement is to seek an absolute prohibition on the patenting of all life forms. In 1999 and 2003, the African Group made submissions to the TRIPS Council calling for amendment of article 27.3(b). In 2010 Bolivia submitted a proposal for prohibiting patenting of all life forms including plants, animals, parts of plants and animals, genetic sequences, microorganisms, as well as biological, microbiological or non-biological processes for the production of life forms and their parts.[112] During the discussions on this proposal in the TRIPS Council, Bolivia had specifically stated that article 27.3(b) fosters biopiracy by facilitating appropriation of life forms or parts thereof that originate in, or are sourced from developing countries,[113] However, there has been little discussion on the issue of patentability of life forms in the TRIPS Council since the submission of the proposal.

It will be important for developing countries to intensify discussions on the issue of patentability of life forms based on the proposals that have been made to the TRIPS Council. Article 27.3(b) allows patent offices to apply legal fictions to expand the interpretation of microorganisms to include human, animal and plant cells which could be patented, contrary to the ordinary meaning of microorganisms as unicellular organisms such as bacteria, fungi, etc.[114] In this sense, a prohibition on patenting of all life forms per se could limit the proliferation of questionable patents on genetic material, sequences, etc. and thus prevent their misappropriation.

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[112] Ibid.

[113] Kanaga Raja, "Bolivia submits detailed paper on TRIPS Article 27.3(b)", *TWN Info Service on Intellectual Property Issues (Mar11/05)*, 10 March 2011. Available from https://twn.my/title2/intellectual_property/info.service/2011/ipr.info.110305.htm.

[114] See, *e.g.,* Carlos M. Correa, *Patent Examination and Legal Fictions: How Rights are Created on Feet of Clay,* Research Paper No. 58 (Geneva, South Centre, 2014), p.13. Available from https://www.southcentre.int/wp-content/uploads/2014/12/RP58_Patent-Examination-Legal-Fictions-rev2_EN.pdf.

C. Discussions in the CBD and the Nagoya Protocol

In respect of IP, although the Nagoya Protocol allows the possibility to establish national IP offices as a designated checkpoint for ABS compliance, the Contracting Parties to the Nagoya Protocol have been unable to provide guidance on how the adoption of an international legal instrument on IP and GRs could contribute to the implementation of the Nagoya Protocol. The first assessment and review of the Protocol undertaken by the COP/MOP in 2018 specifically stated that in view of the ongoing WIPO IGC negotiations it would be premature to assess how the outcome of that process would contribute to the implementation of the Protocol.[115] It merely invites Contracting Parties to take note of the relevant work undertaken by WIPO in the context of implementation of Article 16 of the Protocol which requires them to take appropriate, effective and proportionate legislative, administrative or policy measures to ensure that traditional knowledge associated with GRs utilized within their jurisdiction has been accessed in accordance with prior informed consent and on mutually agreed terms, in compliance with the ABS legislation of the provider country.

The 2018 session of the COP/MOP of the Nagoya Protocol also adopted a decision which requested the CBD Executive Secretary to continue to engage with relevant ongoing processes and policy debates, and liaise with other conventions, international organizations and initiatives to provide and collect information on discussions related to ABS in such fora, particularly on public health issues.[116] In January 2020 the CBD Secretariat invited the CBD Contracting Parties to participate in a survey conducted by WHO on pathogen sharing practices and arrangements and implementation of ABS measures, pursuant to a decision taken by the World Health Assembly (see below).

The COP/MOP has also discussed the question of the criteria to be used for identifying what constitutes a specialized international ABS instrument in accordance with Article 4.4 of the Nagoya Protocol, which states that the Protocol will not apply where such a specialized instrument applies and the same does not run counter to the objectives of the CBD and the Nagoya Protocol. The second session of the COP/MOP requested the Executive Secretary of the CBD Secretariat to undertake a study on this issue. On the basis of the study that was conducted accordingly, the CBD Secretariat had proposed to the Subsidiary Body on Implementation (SBI) of the CBD possible criteria for specialized international ABS instruments to be adopted by the COP/MOP and to be disseminated to other intergovernmental organizations and parties to apply the same in the development of a specialized ABS instrument by them.[117] The SBI recommended the COP/MOP to adopt a decision taking note of the study and invite parties and other governments to submit information on how specialized international ABS instruments are addressed in their domestic measures, as well as their views on the potential criteria recommended in the study.[118] The decision was adopted by the COP/MOP in 2018 as recommended.[119] Since then, the issue of criteria for identifying specialized international ABS instruments in terms of Article 4.4 of the Nagoya Protocol has been under discussion and there has been no agreement on the same by the Parties. In the intersessional period since the 2018 COP/MOP, submissions have been made on this topic by four Contracting Parties (the

[115] Convention on Biological Diversity, Document CBD/NP/MOP/DEC//3/1, 30 November 2018. Available from https://www.cbd.int/doc/decisions/np-mop-03/np-mop-03-dec-01-en.pdf.
[116] Convention on Biological Diversity, Document CBD/NP/MOP/DEC/3/7, 30 November 2018. Available from https://www.cbd.int/doc/decisions/np-mop-03/np-mop-03-dec-07-en.pdf.
[117] Convention on Biological Diversity, Document CBD/SBI/2/6, 14 May 2018. Available from https://www.cbd.int/doc/c/f688/67e0/4b1b877f664a29ac256bba5a/sbi-02-06-en.pdf
[118] Convention on Biological Diversity, Document CBD/SBI/REC/2/5, 13 July 2018. Available from https://www.cbd.int/doc/recommendations/sbi-02/sbi-02-rec-05-en.pdf
[119] Convention on Biological Diversity, Document CBD/NP/MOP/DEC/3/14, 30 November 2018. Available from https://www.cbd.int/doc/decisions/np-mop-03/np-mop-03-dec-14-en.pdf.

European Union, Japan, Norway, Switzerland), two other governments (Canada and New Zealand) and one submission by the African Union.[120] All the developed country submissions have specifically stated their recognition of the Plant Treaty and the WHO PIP Framework as specialized international ABS instruments and have remained ambivalent or questioned the exercise of setting any criteria by the Nagoya Protocol parties for specialized ABS instruments.

Genetic Sequence Information and Data

By eliminating the need for physical access to a GR to utilize its traits, digital and synthetic biology technologies have created a challenge for existing legal mechanisms that regulate ABS, as these mechanisms are premised on the occurrence of physical access to such resources. The Nagoya Protocol does not define GRs,[121] nor does it clarify whether digital data about the genetic sequence information of a GR is within the scope of the Nagoya Protocol[122] and hence subject to ABS obligations under it. According to Nijar, "Because most parties assumed that the treaty was based on physical access, most countries enacted (ABS) laws and policies predicated on the physical transfer of material."[123] If physical access is considered to be the basis for triggering ABS obligations as well as the disclosure requirement in IP applications based on the utilization of such resources, the use of digital and synthetic biology technologies can result in the evasion of ABS and disclosure obligations, while in essence promoting digital biopiracy.

In 2018, the Conference of the Parties (COP) to the CBD discussed a fact-finding and scoping study[124] on DSI[125] and GRs in the context of CBD and the Nagoya Protocol, and adopted a decision which invited parties to CBD, other governments and indigenous and local communities, to submit information and views to clarify the concept of DSI on GRs and on benefit-sharing arrangements from commercial and non-commercial use of DSI, as well was information on capacity-building needs regarding access, use, generation and analysis of DSI.[126] The COP also requested the Executive Secretary of the CBD Secretariat to commission a science-based, peer-reviewed fact finding study on the concept and scope of digital sequencing information, as well as peer reviewed studies on ongoing developments regarding traceability of digital information, private and public databases of DSI and the terms and conditions on which access to such databases is granted, and domestic measures to address benefit-sharing arising from commercial and non-commercial use of DSI.[127] The COP further established an extended Ad Hoc Technical Expert Group (AHTEG) to consider the compilation and synthesis of the information and views submitted and the peer-reviewed studies, develop options on operational terms and their implications to provide conceptual clarity on DSI, identify key areas of capacity-building, and submit its outcomes for consideration by an open-ended working group to support the preparation of

[120] See Convention on Biological Diversity, "Submissions on Article 4, paragraph 4, of the Nagoya Protocol pursuant to decision NP - 3/14", 30 September 2019. Available from https://www.cbd.int/abs/specialized-instruments/2019-2020/.
[121] The Nagoya Protocol applies to GRs that are within the scope of the CBD, which defines GRs as genetic material of actual or potential value. Genetic material is further defined as material of plant, animal, microbial or other origin containing functional units of heredity.
[122] Myrna E. Watanabe, "The Nagoya Protocol: The Conundrum of Defining Digital Sequence Information", *BioScience*, vol. 69, No. 6 (2019). Available from https://doi.org/10.1093/biosci/biz034.
[123] Gurdial S. Nijar, "Digital twist to biopiracy", *The Sun Daily*, 26 November 2018. Available from https://www.thesundaily.my/opinion/digital-twist-to-biopiracy-JC163380.
[124] Laird and Wynberg, *supra* note 57.
[125] Digital sequence information is a placeholder term used in the CBD discussions to include different terms used to refer to the varied types of information about the genetic makeup of a genetic material that is used by the scientific community, databases and different policy processes. See Laird and Wynberg, *supra* note 57, p.8.
[126] Convention on Biological Diversity, document CBD/COP/DEC/14/20, paragraphs 9-10. Available from https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf.
[127] Ibid., paragraph 11.

the post-2020 global biodiversity framework, prior to the next meeting of the COP.[128] Thus, the discussion in CBD at this stage is exploratory in nature and there is no proposed amendment to CBD or the Nagoya Protocol to include, if necessary, DSI on GRs within its scope.

Following the decision taken at the Fourteenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP14) in 2018, the Ad Hoc Technical Expert Group (AHTEG) was constituted with 37 experts selected by the CBD Secretariat based on nominations received. Peer reviewed studies on the concept and scope of DSI, traceability and databases, and domestic measures on DSI was presented at a virtual meeting of AHTEG in March 2020. AHTEG also received a synthesis of views and information relating to DSI from governments as well as indigenous peoples and local communities.

The issue of concept and scope of what kind of data and information relating to GRs is included within the term “digital sequence information” will be critical to the determination of whether legal rules relating to ABS and prevention of misappropriation of GRs and associated traditional knowledge will apply to the use of such information.[129] The expert study has proposed a categorization of data and information on GRs into four groups based on the proximity of the same to a GR. The submissions from members and observers pointed to a clear difference of views between developed and developing countries on the concept and scope of DSI. While developed countries preferred restricting the scope of DSI to DNA, RNA and nucleotide sequence information, developing countries favored a broader scope to include processed sequence information and not just information about natural arrangement of DNA or RNA strands in a genetic resource. Importantly, traditional knowledge associated with GRs is presented in the expert study as being most distant from the information about the makeup of a genetic material and hence is proposed to be excluded from the scope of DSI. AHTEG also agreed to this in its last meeting in March 2020.[130]

D. Governing Body of the FAO Plant Treaty

In the Governing Body of the FAO Plant Treaty, discussions have been pursued on the interrelations between the international IP instruments of UPOV and relevant WIPO treaties, in respect of implementation of the provisions of Art.9 of the Plant Treaty on farmers’ rights. Art. 9 of the Plant Treaty recognizes the past and future contribution of local and indigenous communities and farmers to the conservation and development of plant genetic resources which constitute the basis of food and agricultural production throughout the world, and encourages parties to the Treaty to protect and promote farmers’ rights including protection of traditional knowledge relevant to plant genetic resources, right to equitably participate in benefit sharing arising from the utilization of plant genetic resources, and the right to participate in decision making at the national level on the conservation and sustainable use of plant genetic resources. Art.9 also alludes to the right of farmers to save, use, exchange and sell farm-saved seed or propagating material, subject to national laws. However, existing international IP instruments that shape national laws could limit the scope of farmers’ rights as spelled out under the Plant Treaty, because the recognition of such’ rights is made subject to national laws. Thus, for countries that are parties to the 1991 act of the

[128] Ibid.
[129] See Edward Hammond, "Finding Traditional Knowledge's Place in the Digital Sequence Information Debate", Discussion Paper (Third World Network, 2020). Available from https://twn.my/title2/briefing_papers/twn/TWB_EHamm_Jul2020_D03.pdf.
[130] Convention on Biological Diversity, document CBD/DSI/AHTEG/2020/1/7, paragraph 9. Available from https://www.cbd.int/doc/c/ba60/7272/3260b5e396821d42bc21035a/dsi-ahteg-2020-01-07-en.pdf.

UPOV Convention that shape the national laws in these countries on plant variety protection, the scope of farmers' rights can be significantly constrained.[131]

In 2013, the Governing Body of the Plant Treaty adopted a resolution which requested the Secretariat of the Plant Treaty to invite UPOV and WIPO to jointly identify possible areas of interrelations between their respective international instruments. The 2019 session of the Governing Body requested the Secretary of the Plant Treaty to continue exploring the issue of interrelations with UPOV and WIPO.[132] However, there has been limited discussion of this issue in UPOV and WIPO. The UPOV Secretariat considers that there is no conflict between the Plant Treaty and UPOV and that both should be implemented in a mutually supportive manner. The WIPO Secretariat has merely informed the Secretary of the Plant Treaty about the status of discussions in the WIPO IGC negotiations, but there has not been any focused discussion on the issue among WIPO Member States.

In this context, it is noteworthy that WIPO technical assistance to countries on the issue of IP and plant variety protection tends to present the UPOV system as the desirable form of protection of PVP. In the WIPO IGC negotiations, there is resistance on the part of developed countries to include plant varieties within the scope of a disclosure requirement in GRs.

Discussions on Genetic Sequence Information

In May 2014, FAO presented the Diversity Seek (DivSeek) Initiative,[133] to contribute to the continuous development of the Global Information System (GIS) on Plant Genetic Resources for Food and Agriculture (art. 17 ITPGRFA). This treaty provision aims to strengthen cooperation among the Contracting Parties, in order to facilitate the exchange of information related to plant genetic resources for food and agriculture. GIS includes the Contracting Parties and the knowledge-sharing platforms belonging to the Commission on Genetic Resources (CGRFA) and the CBD. However, Art. 17.2 ITPGRFA also specifies that Contracting Parties shall, upon notification by them, be alerted to the dangers that threaten the effective maintenance of plant genetic resources for food and agriculture, in order to safeguard the material. The DivSeek Initiative was originally developed by the Global Crop Diversity Trust[134] in 2012 to sequence the genetic information of the seeds found in the national germplasm banks, in order to make that information more accessible to everyone. The initiative was promoted in the context of discussions within the Governing Body of the Plant Treaty.[135] The collaboration of many seed industries with the DivSeek Initiative led to concerns among farmers' groups that the DivSeek Initiative would enable access to the genetic sequence information of seeds that are collected from farmers without any adherence to ABS obligations arising from physical access to plant genetic resources.[136] In

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[131] Carlos M. Correa, *Access to and Benefit-Sharing of Marine Genetic Resources Beyond National Jurisdiction: Developing a New Legally Binding Instrument*, Research Paper No. 79 (Geneva, South Centre, 2017). Available from https://www.southcentre.int/wp-content/uploads/2017/09/RP79_Access-to-and-Benefit-Sharing-of-Marine-Genetic-Resources-Beyond-National-Jurisdiction_EN.pdf.

[132] The International Treaty on Plant Genetic Resources for Food and Agriculture, resolution 6/2019. Available from http://www.fao.org/3/nb784en/nb784en.pdf.

[133] The International Treaty on Plant Genetic Resources for Food and Agriculture, document GB6-017-DivSeek Initiative. Available from http://www.fao.org/3/a-bc757e.pdf.

[134] The Global Crop Diversity Trust is an intergovernmental organization established in 2004, in the nature of an international fund to ensure conservation and availability of plant genetic resources for food and agriculture. See "Crop Trust". Available from https://www.croptrust.org/about-us/governance-policy/establishment/.

[135] In September 2015, the Sixth Session of the Governing Body of the Treaty was held, and Resolutions were published on the Vision for the Global Information System Work Programme. Contracting Parties were invited to submit assessment reports on the impacts of participation in DivSeek on the principles and objectives of the Treaty before the 7th Governing Body of the Treaty.

[136] During the Global Consultation on Farmers' Rights held in Bali, Indonesia in September 2016, participants concluded that the DivSeek initiative did not consider farmers' rights at all. See Food and Agriculture Organization of the United Nations and The International Treaty on Plant Genetic Resources for Food and

view of these concerns, the Governing Body of the Plant Treaty decided to end its collaboration with the DivSeek Initiative.[137]

E. Discussions in WHO

In WHO, the discussions on GRs in the context of ensuring rapid access to virus samples for developing vaccines and benefit-sharing arrangements for the same have focused on the following issues—the inclusion of genetic sequence data within the scope of the existing WHO PIP Framework for influenza viruses of pandemic potential, the expansion of the PIP Framework to include seasonal influenza viruses, and the implementation of the Nagoya Protocol with respect to the PIP Framework.

As described in this paper, the PIP Framework of WHO establishes norms relating to access to influenza viruses of human pandemic potential, and fair and equitable sharing of benefits arising from their use. However, the PIP Framework does not apply to sharing of seasonal influenza viruses and other pathogens (such as the coronavirus). At the recommendation of the PIP Framework Review Group that was established as part of in-built review of the PIP Framework, the WHO Member States had requested the WHO Director General to study the implications and desirability of including seasonal influenza viruses in the scope of the PIP Framework.[138]

The question of whether the sharing of seasonal influenza viruses should be organized through a framework such as the PIP Framework is important as seasonal influenza viruses are shared within the WHO GISRS as well as bilaterally. While the rules of the CBD and the Nagoya Protocol can apply to regulate access and benefit-sharing of seasonal influenza viruses, there is divergence in country practices on including seasonal influenza viruses within the scope of ABS legislations implementing the Nagoya Protocol. Thus, the development of a framework in WHO that regulates ABS with regard to seasonal influenza viruses could be useful to ensure that such pathogens are accessed and the benefits from their utilization are shared in accordance with the Nagoya Protocol. However, a decision on whether to expand the PIP Framework itself to include seasonal influenza viruses may be premature without further knowledge about the similarities and differences in seasonal viruses and PIP biological material. Moreover, there is also lack of clarity on what would constitute a specialized instrument for pandemic influenza preparedness and response that could be recognized as such under the Nagoya Protocol. Hence, though some developed countries specifically desired to provide a mandate to the WHO Secretariat to identify and address the challenges and uncertainties related to the sharing of seasonal influenza viruses, the 2019 World Health Assembly requested the WHO Secretariat to collect, analyze and present data on influenza virus sharing in a way that enables a deeper understanding of the challenges, opportunities and public health implications associated with virus sharing under the GISRS.[139]

The WHO discussions on the PIP Framework have also focused on the relationship between the PIP Framework and the Nagoya Protocol. The general understanding among the WHO Member States is that the PIP Framework can be implemented harmoniously with the

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Agriculture, "Global Consultation on Farmers' Rights 2016, Summary of presentations and discussions", 27-30 September 2016, Bali, Indonesia, Recommendation 41. Available from: http://www.fao.org/3/a-bs767e.pdf.

[137] See, e.g., Press release by Food Sovereignty, available from http://www.foodsovereignty.org/divseek-initiative-loses-support-international-treaty-plant-genetic-resources-food-agriculture/.

[138] World Health Organization, Decision WHA 70(10). Available from https://apps.who.int/gb/ebwha/pdf_files/WHA70-REC1/A70_2017_REC1-en.pdf.

[139] World Health Organization, Decision WHA 72(12). Available from https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(12)-en.pdf.

Nagoya Protocol. Nevertheless, some developed countries have echoed a hypothetical concern raised by the vaccines industry that some countries could refuse to share PIP biological material through the PIP Framework in preference to providing access under the terms of the Nagoya Protocol, which could restrict access to the biological material required to develop vaccines against influenza viruses of pandemic potential. Though such concerns are addressed under the provisions of the Nagoya Protocol, some countries have proposed in the WHO that the PIP Framework be declared a specialized instrument for ABS under the Nagoya Protocol. The implication of this would be that the PIP Framework would be the instrument that would govern all matters relating to access and benefit-sharing of PIP biological material.

Developed countries have been seeking to carve out a broad exception from the obligations under the Nagoya Protocol for securing access to pathogens for development of health products. The WHO Secretariat submitted a report at the 2019 World Health Assembly which sought a broad mandate from the WHO Member States for the Secretariat to explore possible options for pathogen access and benefit-sharing. The options proposed to be explored include codes of conduct, guidelines, best practices and global multilateral mechanisms for access to pathogens and benefit-sharing. However, many developing countries expressed reservations about this proposal and instead requested the Secretariat to share information on the current modalities for pathogen sharing. The World Health Assembly adopted a decision which requested the WHO Secretariat to provide information on current pathogen sharing practices and arrangements, implementation of access and benefit-sharing measures, as well as potential public health outcomes and other implications.[140]

The decision by the World Health Assembly requesting for more information by the WHO Secretariat on pathogen sharing practices and arrangements is important in the light of a number of instances of misappropriation of biological resources such as pathogens through the IP system. These include filing of patent applications on the SARS coronavirus and the virus genome and its parts,[141] as well as patent applications on the MERS coronavirus.[142]

In order to follow up on the mandate for data collection, the WHO Secretariat prepared a survey from which it sought to extract relevant information. WHO Member States expressed concern with regard to the survey questionnaire. Some members led by Finland have requested that the right contained in Article 8(b) of the Nagoya Protocol to regulate the exchange of pathogens through national legislation be removed from the Nagoya Protocol, thus calling for the imposition of immediate access to pathogens from any country without the need for access to be authorized by the donor country.[143]

This position is in line with the opinion expressed by the pharmaceutical industry, which has openly called for the amendment of the Nagoya Protocol to exclude pathogens.[144] The civil

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[140] World Health Organization, decision WHA 72(13). Available from https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(13)-en.pdf.

[141] James H. M. Simon, Eric Claassen, Carmen E. Correa and Albert D.M.E. Osterhaus, "Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling", *Bulletin of the World Health Organization*, September 2005. Available at https://www.who.int/bulletin/volumes/83/9/707.pdf.

[142] Erasmus University in the Netherlands has admitted to having applied for a patent on use of the MERS coronavirus. See Edward Hammond, "Sovereignty and patents at the fore in debate over MERS virus", *TWN Info Service on Health Issues*, 31 May 2013. Available from https://www.twn.my/title2/health.info/2013/health130510.htm.

[143] Statement of the Finnish delegation during the Informal Consultation on Implementation of WHA72(13) Public Health Implications of Implementation of the Nagoya Protocol, held on 27 January 2020.

[144] The Pharma Industry demands the amendment of the Nagoya Protocol to exclude pathogens because this impedes their sharing. See interview T. Cueni, Director General of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). In Health Policy Watch: Over 30 Antiviral Drugs Being Tested Against

society, on the other hand, proposes that the PIP framework should be considered as a model. The debate should not only be focused on access to samples but also take into consideration the need to access the result of the research, mainly the treatments or the vaccines.[145]

Developing countries, for their part, hope that the outcome of the negotiations will lead to a clearer definition of the modalities for sharing the benefits obtained from the research on pathogens, including the case where pharmaceutical companies privatize knowledge obtained through patents. The current COVID-19 pandemic has brought to light the most controversial aspects of this debate. Even after the complete genetic sequence information of the samples of the virus was shared by China, the multinational pharmaceutical industry has taken advantage of the situation to put pressure on the WHO about the irrelevance of the Nagoya Protocol in the context of the pandemic.[146] However, the fundamental question for developing countries is whether they will have affordable access to a potential COVID-19 vaccine when it is developed? The WHO PIP Framework only applies to access to virus samples and benefit-sharing relating to influenza pathogens of pandemic potential and does not apply to coronavirus pathogens of pandemic potential.[147] Hence, it will be important for WHO and its Member States to address this issue as a matter of priority.

Genetic sequence data

In WHO, discussions concerning genetic sequence data[148] have taken place in the context of implementation of the PIP Framework. The fundamental issue here is that while the PIP Framework requires the sharing by WHO Member States of both PIP biological material and their genetic sequence information,[149] benefit-sharing obligations on the part of users are only triggered for access to PIP biological material and not the genetic sequence information of such material. Thus, if an influenza vaccine manufacturer accesses the genetic sequence data and uses the same to manufacture influenza vaccines, it will not be bound by any benefit-sharing obligation in terms of the applicable Standard Material Transfer Agreements (SMTAs) under the PIP Framework. This means that laboratories that access genetic sequence data, including laboratories under the WHO Global Influenza Surveillance and Response System (GISRS), can potentially claim IP rights over products developed by using the genetic sequence information.[150]

Novel Coronavirus – As WHO Convenes Global Innovation Forum. Available from https://www.healthpolicy-watch.org/over-30-antiviral-drugs-being-tested-against-against-novel-coronavirus-as-who-convenes-global-innovation-forum/.

[145] Statement of the Third World Network delegation during the Informal Consultation on Implementation of WHA72(13), Public Health Implications of Implementation of the Nagoya Protocol, held on 27 January 2020.

[146] See Thomas Cueni, "Novel coronavirus 2019-nCoV exposes a flaw in the Nagoya Protocol", *STAT News*, 5 February 2020. Available from https://www.statnews.com/2020/02/05/novel-coronavirus-exposes-nagoya-protocol-flaw/.

[147] See, e.g., Andrew E. Bollinger, "E-MERS-GENCY: An Application and Evaluation of the Pandemic Influenza Preparedness Framework to the Outbreak of MERS-COV", *Temple International Comparative Law Journal*, vol. 29, No.1 (2015). Available from https://sites.temple.edu/ticlj/files/2017/02/29.1.Bollinger-TICLJ.pdf

[148] The WHO PIP Framework has mandated the WHO Director-General to consult the PIP Advisory Group on the best process for further discussion and consideration of issues related to the handling of genetic sequence data of influenza viruses of pandemic potential under the PIP Framework. Accordingly, the PIP Advisory Group has undertaken deliberations on developing options on handling genetic sequence data.

[149] The PIP Framework mandates that genetic sequence data and analysis arising from that data, relating to H5N1 and other influenza viruses with human pandemic potential, should be shared in a rapid, timely and systematic manner with the originating laboratory and among the WHO GISRS laboratories. See World Health Organization, *Pandemic Influenza Preparedness Framework for the Sharing of influenza Viruses and Access to Vaccines and other Benefits* (Geneva, World Health Organization, 2011), paragraph 5.2.1. Available from https://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082_eng.pdf;jsessionid=D24B60560FB2415AD41D788BFEE3B11C?sequence=1.

[150] In terms of SMTA 1 that applies to them, the GISRS laboratories cannot claim IP rights over products developed by using physical PIP biological material. However, it is unclear whether this restriction also extends to claiming IP rights over products developed by using genetic sequence information instead of the physical PIP

In terms of SMTA 1 that applies to them, the GISRS laboratories cannot claim IP rights over products developed by using physical PIP biological material. However, it is unclear whether this restriction also extends to claiming IP rights over products developed by using genetic sequence information instead of the physical PIP biological material. Moreover, there is no restriction at all on taking IP rights under SMTA 2 which applies to entities outside the GISRS such as commercial firms that develop influenza vaccines. Significantly, the WHO Secretariat has acknowledged that as technologies mature and major influenza vaccine manufacturers increasingly rely on genetic sequence data, their need for access to physical material may no longer be necessary, and this may reduce the WHO access to certain benefits and potentially jeopardize implementation of the PIP Framework.[151]

In this context, in 2016 a WHO Expert Review Group recommended that WHO Member States should include genetic sequence data within the definition of PIP biological material. This would help to ensure that the PIP Framework applies access and benefit-sharing on an equal footing to both physical PIP biological material as well as associated genetic sequence data. However, till date there has been no agreement among WHO Member States on this issue.

The 2019 World Health Assembly adopted a decision requesting the Director-General of WHO to amend a footnote to the PIP Framework to clarify that the obligations under SMTA 2 would also extend to entities that engage with recipients of PIP biological material (such as industry and research institutions that have received such material from a WHO GISRS laboratory in terms of SMTA 2). By virtue of this amendment the PIP Framework now extends the SMTA 2 obligations to entities that use genetic sequence data to develop an influenza product, but only insofar as they also engage with a recipient of PIP biological material under SMTA 2 from a WHO GISRS laboratory. This amendment will not apply to entities that fully develop and commercialize an influenza product by using genetic sequence data without engaging with a recipient of the physical material from a WHO GISRS laboratory.

The 2019 World Health Assembly also requested the Director-General to continue to provide information on new challenges and opportunities presented by new technologies in the context of the PIP Framework. Hence, the WHO Secretariat has been given the mandate to continue its deliberations on the issue of new technologies such as genetic sequence data.

F. UNCLOS Negotiations on Marine Genetic Resources

In 2004, the UN General Assembly established an *ad hoc* open-ended informal working group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction. Nine annual sessions of the working group were held from 2006 to 2016. In 2015, the working group recommended the General Assembly to take a decision to develop an international legally binding instrument under the United Nations Convention on the Law of the Sea (UNCLOS). It also recommended that the negotiations for such an instrument should include the topic of conservation, sustainable use and benefit-sharing of marine genetic resources. A preparatory committee commenced work on developing a draft text in 2018 and an intergovernmental conference was convened in August 2019 to consider the recommendations of the preparatory committee on the draft text of a UN convention on the law of the sea on the conservation and sustainable use of marine

biological material. Moreover, there is no restriction at all on taking IP rights under SMTA 2 which applies to entities outside the GISRS such as commercial firms that develop influenza vaccines.

[151] World Health Organization, "Approaches to Seasonal Influenza and Genetic Sequence Data under the PIP Framework", 14 December 2018. Available from https://www.who.int/influenza/pip/WHA70108b_Analysis.pdf.

biological diversity of areas beyond national jurisdiction. On the issue of marine genetic resources, progress was made on the temporal scope of the agreement, the inclusion of benefit sharing modalities in the text of the instrument, and on including a definition of marine genetic resources. However, further consideration is still required on whether to limit the scope of the instrument to marine genetic resources collected *in situ* or to also include *ex situ* collections, DSI, and derivatives of marine genetic resources. The definition and conditions of access to marine genetic resources, the scope, triggers and modalities of benefit-sharing arrangements also require further discussion. There is also no consensus on whether to include IPRs in the instrument and the modalities of the same.[152]

A critical issue concerning marine genetic resources beyond areas of national jurisdiction is that the CBD and the Nagoya Protocol apply only to GRs (including marine and aquatic GRs) insofar as they are within national jurisdictions. This means that currently there is no legal regime governing ABS relating to marine genetic resources that are in the high seas, beyond the national jurisdiction of States. Many of such resources have been noted to be of potentially immense value in pharmaceuticals, food and beverage, agrochemicals, biotechnology, etc.[153] However, there is huge asymmetry in the capacities of developed and developing countries to undertake bioprospecting and R&D over marine genetic resources to tap into their potential. In this context, a major issue in the negotiations has been the extent to which the provisions of UNCLOS can apply to bioprospecting of marine genetic resources, particularly provisions regarding the freedom of the high seas, the use of the resource as common heritage of mankind, and the freedom of scientific research. Moreover, the scope of benefit-sharing and IP rights on innovations developed from marine genetic resources in areas outside national jurisdiction will also be critical issues in the negotiations.

The draft text of the convention defines access to marine genetic resources to include access to *in situ* as well as *ex situ* collections and also access to the DSI concerning such resources. It applies to resources in the high seas and the seabed, the ocean floor and its subsoil. The draft convention defines marine genetic resources as marine genetic material, which is defined as material of marine plant, animal, microbial or other origin. However, there is a divergence of views on whether derivatives and information describing the material such as genetic sequence information and data should also be considered to be part of marine genetic material. This mirrors the fundamental division between developed and developing countries in other fora such as the WIPO IGC negotiations where similar differences exist on the inclusion of derivatives within the definition of GRs.

There are also fundamental differences on inclusion of a provision on IP in the draft convention, which is currently present in square brackets as draft art. 12.[154] Countries that have the capability to undertake bioprospecting for marine genetic resources in the high seas and the international seabed area have objected to any inclusion of a provision on IP, contending that the matter should be addressed in WTO and WIPO. Some developed countries particularly pointed to ongoing work in WIPO in this context, though the issue of marine genetic resources beyond areas of national jurisdiction is outside the scope of the draft text on GRs discussed in the WIPO IGC. Rather, a proposed provision on exceptions to

[152] IISD, "Summary of the Third Session of the Intergovernmental Conference (IGC) on the Conservation and Sustainable Use of Marine Biodiversity of Areas Beyond National Jurisdiction", *Earth Negotiations Bulletin (ENB)*, 2 September 2019. Available from https://enb.iisd.org/vol25/enb25218e.html

[153] Jesus M. Arrieta, Sophie Arnaud-Haond and Carlos M. Duarte, "What lies underneath: Conserving the oceans' genetic resources", *Proceedings of the National Academy of Sciences of the United States of America*, vol. 107, No. 43, pp. 18318–24. Available from https://doi.org/10.1073/pnas.0911897107.

[154] Revised draft text of an agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, 27 November 2019. Available from https://www.un.org/bbnj/sites/www.un.org.bbnj/files/revised_draft_text_a.conf_.232.2020.11_advance_unedited_version.pdf.

the disclosure requirement in the GRs text in WIPO IGC negotiations seeks to exclude the application of the disclosure requirement to patent applications relating to genetic resources from areas beyond national jurisdictions and economic zones.

Currently, the draft provision on IP presents alternative approaches. One approach is to defer IP considerations to WIPO and WTO instruments. However, IP considerations relating to marine genetic resources are currently not part of the discussions in WIPO or WTO. Therefore, the implication of not addressing the question of IP relating to marine genetic resources within the UNCLOS instrument would effectively be a continuation of the status quo to the advantage of countries that can derive commercial gains by taking IP rights over marine genetic resources and genetic sequence.[155] There is also a draft provision to establish a general obligation among State parties to cooperate to ensure that IP rights do not run counter to the objectives of the treaty, and that no action is taken in the context of IP that would undermine benefit-sharing and traceability of marine genetic resources in areas beyond national jurisdiction. Another approach is to have an absolute exclusion of marine genetic resources from patents except where the same are modified through human intervention resulting in a product capable of industrial application. A fourth option is to establish a disclosure requirement about the origin of marine genetic resources for patent applicants of inventions that utilize marine genetic resources beyond areas of national jurisdiction.[156] Such a disclosure would enable authorities to identify whether a marine genetic resource utilized in an IP application originates within the national jurisdiction or in the area outside national jurisdiction.[157] Even though a declaration of origin of a marine genetic resource in the area beyond national jurisdictions would not be able to attribute the origin of such resource to a specific country, it would be essential to the traceability of the origin of the resource to the areas beyond national jurisdiction, and operationalize benefit-sharing mechanisms applicable to such resources,[158] such as a possible monetary fund to support research funding on marine genetic resources.[159]

[155] See Siva Thambisetty, " Biodiversity Beyond National Jurisdiction: (Intellectual) Property Heuristics", working draft paper presented at the 43rd Centre for Oceans Law and Policy Annual Conference, World Maritime University, Malmo, Sweden, 14–17 May 2019. Available from https://dx.doi.org/10.2139/ssrn.3483670.
[156] Ibid.
[157] Claudio Chiarolla, "Intellectual property rights and benefit sharing from marine genetic resources in areas beyond national jurisdiction: Current discussions and regulatory options", *Queen Mary Journal of Intellectual Property*, vol. 4, No. 3 (2014), pp. 171–94 at 179. Available from https://www.elgaronline.com/view/journals/qmjip/4-3/qmjip.2014.03.01.xml.
[158] Siva Thambisetty, "Marine Genetic Resources Beyond National Jurisdiction: Elements of a New Internationally Legally Binding Instrument", LSE Law Policy Briefing Series. Policy Briefing No. 32, 2018. Available from http://eprints.lse.ac.uk/100081/1/SSRN_id3219995.pdf.
[159] See, e.g., Jane E. Collins, Thomas Vanagt and Isabelle Huys, " Stakeholder Perspectives on Access and Benefit-Sharing for Areas Beyond National Jurisdiction" *Frontiers in Marine Science*, vol. 7, 5 May 2020. Available from https://www.frontiersin.org/articles/10.3389/fmars.2020.00265/full.

V. CONCLUSIONS AND RECOMMENDATIONS

While misappropriation of GRs through the IP system remains a major problem for developing countries, decades of multilateral negotiations have so far been unsuccessful in reaching agreement on any effective mechanism for resolving the problem. The emergence of new technologies in the field of synthetic biology has also made it possible to circumvent ABS laws that are premised on physical access to GRs from provider countries, through the use of genetic sequence information as a substitute for physical access to genetic material. In order to overcome this problem, developing countries have to respond to multifaceted challenges. These include strategic considerations on how to strengthen multilateral negotiations in order to attain meaningful progress, identifying minimum objectives to achieve in specific fora in coherence with approaches in other related fora, and preventing the circumvention of proposed mechanisms through new technologies in synthetic biology.

Strengthening Multilateral Negotiations

Fundamental differences on the need for a mandatory disclosure requirement about the country or source of origin of a GR used in an IP application, as well as on the scope of the disclosure requirement itself, have continued to stifle meaningful progress in the multilateral negotiations. While the discussions in WTO have effectively been in a state of suspended animation with no formal engagement on the proposals in the TRIPS Council, the very need for a disclosure requirement has been questioned in WIPO negotiations. In particular, developed countries that are opposed to a disclosure requirement in any form have argued that such a requirement would stifle innovation, and have called for evidence on the impact of mandatory disclosure requirements on innovation. At the same time, these countries have been opposed to any discussion on IP in the context of GRs in other treaties, as evident from the successful objection to include IP offices as specific checkpoints under the Nagoya Protocol, as well as the objection to include a provision on IP in the UNCLOS draft convention on marine genetic resources beyond areas of national jurisdiction. These objections are often accompanied by suggestions that IP issues related to GRs are being considered in the WIPO IGC negotiations, and hence IP issues should addressed in WIPO.

In this context, it is important to note that while WIPO is the UN Specialized Agency in the area of IP and its competences on IP issues are leading within the UN system, the impact of IP on GRs and associated TK goes far beyond technical IP. It concerns the preservation of biodiversity, marine resources, and especially fair ABS, and should therefore benefit from expertise that is not available in WIPO. The relationship agreement between the UN and WIPO clearly specifies that the competence of WIPO in the area of IP is **subject to** the competence of the UN and its organs.[160] Therefore, just because IP issues in relation to GRs are being discussed in WIPO does not mean that they cannot be discussed in other UN bodies where negotiations related to GRs are taking place. Indeed, if UN instruments establish specific rules on IP in relation to GRs, it could be expected that these would be complemented and supported by related WIPO instruments, as WIPO should be guided by the UN instruments, being subject to the competence of the UN.

[160] Nirmalya Syam, *Mainstreaming or Dilution? Intellectual Property and Development in WIPO*, Research Paper 95, (Geneva, South Centre, 2019). Available from https://www.southcentre.int/wp-content/uploads/2019/07/RP95_Mainstreaming-or-Dilution-Intellectual-Property-and-Development-in-WIPO_EN.pdf.

In view of the lack of progress in the WTO and WIPO, some developing countries are also contemplating pursuing a plurilateral approach outside WTO or WIPO.[161] However, a multilateral approach offers advantages over a plurilateral approach, such as ensuring a broader membership, support of a treaty secretariat to mobilize technical and financial resources.[162] Moreover, even under a plurilateral approach, agreement on substantive issues would entail significant time and effort, given the variance in national approaches even among developing countries.[163] Hence, developing countries should continue to pursue an effective multilateral legal instrument that addresses the problem of misappropriation of GRs and associated traditional knowledge through the IP system.

The lack of progress in WIPO and WTO does not mean that all possible multilateral options have been exhausted for developing countries. For instance, developing countries could also consider raising the need for a mandatory disclosure requirement in relation to IP applications, as well as the need to address the challenges to ABS arising from new technological developments such as genetic sequencing data/digital sequencing information, gene editing, and other synthetic biology technologies for a high-level discussion in the UN. Indeed, a number of SDG goals are related to the use of GRs. A high-level declaration in the UN could provide some impetus to overcome the political obstacles to progress in WIPO and WTO.

Fresh Impetus in WTO TRIPS Council

In WTO, developing countries should insist on commencing formal negotiations in the TRIPS Council on the basis of the proposal for an amendment to the TRIPS Agreement introducing a mandatory disclosure requirement. Since 2011, the informal consultations led by the WTO DG have not taken place, and at the same time, there has been no substantive engagement on the proposals in the TRIPS Council. At the special session of the TRIPS Council held before the WTO Ministerial Conference in Buenos Aires many WTO members expressed their willingness to discuss the issue of GRs and IP, but it was felt that the issue could not be addressed through a Ministerial Declaration due to the political issues around the Ministerial Conference. However, there has been no discussion on this issue since the Buenos Aires Ministerial Conference. Developing countries could consider seeking a ministerial declaration at the 12th WTO Ministerial Conference, to revive the discussions on the proposal for a mandatory disclosure requirement and its modalities. Developing countries should also intensify discussions in the TRIPS Council on the proposals for prohibition of patenting on life forms with the objective of ensuring robust patentability standards prevent the grant of patents of genes, cell lines, sequences, etc.

Minimum Requirements to Ensure in a WIPO Instrument

A WIPO agreement on IP and GRs with an effective disclosure requirement will be ideal, but the fundamental problem is that a small group of countries, that also constitutes territories where IP applications based on use of GRs are most frequent, are opposed to any form of mandatory disclosure requirement. In effect, this has rendered the outcome of the negotiations uncertain. In the current situation, if there is any agreement at all, it is likely to be one with a very weak and ineffective disclosure requirement.

[161] Saez, *supra* note 102.
[162] Ibid.
[163] Ibid.

Even so, developing countries should seek to ensure that in the minimum an international legal instrument negotiated in WIPO IGC acknowledges and recognizes the problem of misappropriation of GRs and associated traditional knowledge through the IP system. Even if it is not possible to have consensus on including all types of IP protection within the scope of a disclosure requirement, to be effective the instrument must include patents and PVP within its scope. The instrument should also be consistent with the Nagoya Protocol to allow countries to include any subject matter that is derived from the utilization GRs within the scope of a disclosure requirement in an IP application. Moreover, the source or origin of the GRs disclosed should not be limited to published sources and should include even unpublished or undocumented sources that the applicant is aware of or should be reasonably aware of. The instrument should also require parties to provide for adequate remedies where the disclosure requirement is not complied with. Even if revocation of a granted IP right cannot be agreed to as a specific obligation, the instrument should not limit interested parties from adopting remedies including revocation, monetary fines, or making an IP right non-enforceable.

Any use of a GR for the registration of an IP right covered under the instrument should be a trigger for the disclosure requirement rather than setting a fictional threshold of the extent to which an invention is directly or materially based on GRs that has been proposed by developed countries in WIPO negotiations. Disclosure should be a mandatory requirement for applications submitted to IP offices in all countries that are party to the instrument, even if the instrument allows national IP offices the discretion to decide on the material relevance of the disclosed information in the process of examination of the application. The disclosed information could be shared with other national IP offices through an information sharing mechanism, similar to information sharing mechanisms relating to search and examination reports between patent offices.

Developing countries should also ensure coherence with CBD, the Nagoya Protocol, and specialized ABS instruments like the FAO Plant Treaty, or related mechanisms or fora like WHO and the UNCLOS negotiations on marine genetic resources in areas beyond national jurisdiction, in the normative discussions in WIPO and WTO. Specific exceptions and limitations have been proposed which can limit the application of a disclosure requirement under an international instrument on IP and GRs in WIPO, in respect of marine genetic resources, pathogens, use of GRs as derivatives and commodities. It should be noted that an instrument on IP and GRs will essentially create exceptions and limitations to the scope and modalities of grant of IP rights over products derived from GRs. Hence, exceptions and limitations to such an instrument should be extremely restricted as overly broad exceptions could be creatively applied to defeat the very objective of prevention of misappropriation of GRs and associated traditional knowledge through IP protection.

Review of WIPO Technical and Legislative Assistance

Coherence with the relevant international instruments should also be ensured in technical and legislative assistance provided by WIPO. Under the TRIPS Agreement, WTO members are required to provide for protection of new plant varieties either through the patent system or a *sui generis* system. While a *sui generis* system of PVP could include a mandatory disclosure requirement of the origin and source of plant genetic resources and associated traditional knowledge used for the development of a new plant variety, WIPO technical assistance to its Member States and WTO has been focused on promoting the system of plant variety protection under the UPOV Convention, which does not allow its members to introduce the disclosure requirement. Though the Governing Body of the FAO Plant Treaty requested the Secretary of the Plant Treaty to continue exploring the issue of interrelations of the Plant Treaty with UPOV and WIPO instruments, there has been no discussion of this issue in WIPO. Given the major role that the WIPO Secretariat plays in promoting the UPOV

system through its technical and legislative assistance, developing countries should review WIPO technical assistance in this regard and request the WIPO Secretariat to present a report reflecting the findings of the review by WIPO Member States to the Secretary of the FAO Plant Treaty. This could be discussed by the Member States under the related discussion on WIPO technical assistance in the WIPO Committee on Development and Intellectual Property (CDIP).

Strengthening Existing and Future WHO Mechanisms

In WHO, developing countries should focus on strengthening the SMTAs, particularly SMTA 2, which applies to transfer of genetic material (pathogen samples) to private entities that seek to develop vaccines and other treatments with regard to influenza outbreaks of pandemic potential. Currently, there is no restriction to the taking of IP on products developed from the use of material transferred to private entities under SMTA 2 of the PIP Framework. Moreover, such restrictions to the taking of IP should also be pursued for the development of any mechanism in WHO for the sharing of samples of pathogens for seasonal influenza or other diseases such as coronavirus infections like COVID-19. Moreover, in the absence of any specific mechanism like the PIP Framework for other pandemics like COVID-19, developing countries should also insist that the WHO members comply with the ABS obligations under the Nagoya Protocol instead of taking the prejudiced view held by some developed countries that sees the Nagoya Protocol as an obstacle to timely and expeditious sharing of pathogens in order to develop necessary medical products like vaccines, which has been attempted by some developed countries. A sustainable framework for sharing of pathogens must comply with ABS obligations to ensure not only expeditious sharing of pathogen samples, but adequate benefit-sharing, including sharing of technology and knowhow, for the local production of such medical products in developing countries, without being restricted by IP rights.

A Disclosure Requirement for Marine Genetic Resources Beyond Areas of National Jurisdiction

In the UNCLOS negotiations on marine genetic resources in areas beyond national jurisdiction, inclusion of a provision restricting the taking of IP rights over marine genetic resources has been opposed by some countries with the capacity to engage in bioprospecting in such areas in the high seas. However in the minimum, developing countries should establish a disclosure requirement for IP applications on inventions that utilize marine genetic resources from areas beyond national jurisdiction, in order to enable traceability of marine genetic resources utilized in claimed IP applications and the implementation of any benefit-sharing mechanism. As national laws, or international instruments such as a future WIPO instrument, could apply the disclosure requirement in respect of all GRs within national jurisdiction including marine genetic resources within areas of national jurisdiction, a complementary disclosure requirement in respect of the origin of such resources beyond areas of national jurisdiction would be beneficial.

Addressing the use of Digital Sequencing Information in Different Fora

Finally, across different fora including CBD and the Nagoya Protocol, WIPO, WTO, the FAO Plant Treaty, WHO, the UNCLOS negotiations on marine genetic resources, developing countries must address the challenges posed by technological developments in the field of synthetic biology wherein access to genetic sequence data of the genetic material from both *in situ* locations and *ex situ* collections, can be used to circumvent any disclosure requirement relating to IP, if such a requirement is anchored to the occurrence of physical

access to the genetic material. To that end, developing countries should seek to revise and update their existing proposals on the relevant provisions under the instruments being negotiated in different fora. Another critical issue for developing countries would be to ensure that the holders of GRs and associated traditional knowledge can extend their control over genetic sequencing data that is held by databases in developed countries. Access to such data can be subjected to a data transfer agreement in place of a material transfer agreement which could lay down the terms for the downward use of the data, including provisions relating to IP. Traceability of the origin or source of the information contained in genetic sequence information databases will also be critical for developing countries. Thus, there is a need to establish mechanisms for genetic databases to require the submission of standardized information necessary for the traceability of submitted sequences.

ANNEX 1: CASES OF MISAPPROPRIATION USING THE PATENTS REGIME

N°	Genetic resource & other identifiers	Endemic to	Patents and Status
1	Ayahuasca (*Banisteriopsis Caapi and Psychotria viridis)*	Amazonian Region	Patent US PP 5,751 granted to International Plant Medicine Corporation (IPMC) for developing psychiatric drugs. Patent application pending in Germany DE102016014603A1
2	Basmati Rice (*Oryza Sativa*)	India	Patent US 5,663,484 granted to RiceTec for long grain, aromati. No longer active
3	Cunani (*Clibadium sylvestre*) and Tipir (*Ocotea rodiaei*)	Guyana	Patent EP 0610059A1 granted in Europe to Conrad Gorinsky's, 1994. Withdrawn. Closed
4	Endod or Soapberry (*Phytolacca dodecandra*)	Ethiopia	Patent US 5252330A granted to Lee, Fraleigh, Lemma. No longer active. Anticipated expiration on 12/10/2010.
5	Yellow Bean (product 'Enola bean')	Mexico	Patent US 5894079A granted to Larry M. Proctor. First worldwide family litigation field on 26/09/2005. Anticipated expiration on 15/11/2016.
6	Tricolor Frog (*Epipedobates tricolor*)	Ecuador	More than 42 patent applications. For instance, US20130281482A1 granted to Richard W. Fitch, Thomas F. Spande, H. Martin Garraffo, Herman J.C. Yeh, John W. Daly. Granted. Expiration expected 2031.
7	Kalahari Hoodia *Hoodia gordonii*	Namibia, RSA	More than 7 worldwide patent applications. Among them: Application filed for Patent US 20060159773A1 by Stephen Holt on 20/07/2006. Abandoned Application filed by Pharmaceutical Grade Health Products LLC for Patent US 20080138447A1 on 06/12/2006. Granted Patent China CN101888785A granted to Unilever Netherlands Ltd. on 17/11/2010. Abandoned Application filed for Patent US 20090155388A1 by Jose Angel Olalde on 19/09/2010. Withdrawn Application filed by AQUAPHARM HEALTH & NUTRITION for patent in Germany DE 102006024885A1 on 24/05/2006

8	Extremophiles	Kenya	2715 results of patent application. For instance, patent ES2542177T3 granted to Jean Prof. Dr. Krutmann. Patent granted.
9	Maca (*Lepidium meyenii)*	Peru	823 patent applications around the world. Among them: Patent US 6267995B1 by Pure World Botanicals granted in 31/07/2001 Anticipated expiration 03/03/2019 Patent CN102526161B by Zhao Bing Wang Liwei Liang Chen granted. Patent valid 6/11/2013
10	Nap Hal (Wheat variety used in chapatis)	India	11084 patent applications. For instance: US5763741A granted to Peter Ivor Payne. Expired.
11	Neem Tree (*Azadirachta indica*)	Asia	Patents US5,411,736; US5,409,708; EP436,257 granted to W R Grace, Native Plant Institute, Japanese Terumo Corporation, for pesticide and Toothpaste, etc. Decided 2002
12	Pozol	Mexico	One of 214 results of patent applications. For instance: Patent US9814242B2 granted to Felipe A. Rubio Roberto Contreras J. Fernando Ramirez. Anticipated expiration 2031-09-14
13	Swartzia Madagascariensis	Zimbabwe	One of 20 results, sample: patent EP2295031B1 granted to Imke Meyer Oskar Koch Nadine Hillebrand Martina Herrmann Holger Joppe. Anticipated expiration 2030-07-22
14	Turmeric (*Curcuma longa*)	India	Patent US5,401,504 granted to the University of Mississippi Medical Centre for wound healing property. Decided 1998
15	Acai Euterpe precatoria	Amazon region	8 patent applications. For instance: patent US20130095195A1 granted to Kenneth A. Murdock Alexander G. Schauss. Adjusted expiration 2024-09-07
16	J'oublie Berry (patented products name "Bazzein")	West Africa (GABON)	2 patent applications: patent US20100021533A1 granted to Mohammad A. Mazed Sayeeda Mazed. Anticipated expiration 2028-07-08
17	Philippine Snail *Conus magnus*	Philippines	13 patent applications. For instance, patent US6767896B1 granted to J. Michael McIntosh Baldomero M. Olivera Lourdes J. CruzGloria P. Corpuz Robert M. JonesJames E. Garrett. Anticipated expiration 2020-01-28
18	Copaiba Copaifera sp.	Amazon region	305 patent applications. For instance: EP2788011A1 granted to Daniele PIETRA Alice BORGHINI Simone DEL CORSO Marcello IMBRIANI Anna BIANUCCI. Anticipated expiration 2032-12-05

19	Cupuacu *Theobroma grandiflorum*	Amazon region	87 applications: patent GB2500662A granted to Albertus Bernardus Eskes. Application status is Withdrawn
20	Jamun *Syzygium cuminii*, Karela *Momordica charantia* Lin and Brinjal Solanum melongena L	India	21 patent applications. For instance, patent US20100021533A1 granted to Mohammad A. Mazed Sayeeda Mazed. Anticipated expiration 2028-07-08
21	Hom Mali (Jasmine Rice)	Thailand	1940 patent applications. For instance, patent granted in Japan JP5154610B2 to Apichart, Banabichit Sombong, Tragornlung Thirayut, Tozinda Samat, Huachana Winthai, Kamolskjung Yong. Anticipated expiration 2026-01-25
22	Kemekus *Piper cubeba* and Sambiloto *Andrographis panicurata*	Indonesia	8 patent applications. For instance, patent US20110111067A1 granted to Vijay Singh Chauhan Kavita Sujeet Salkar. Anticipated expiration 2029-06-25
23	General seeds collection (Millennium Seed Bank)	Kenya	21732 patent applications. For instance, patent US7879611B2 granted to Alex Liu George Wadsworth Helena Mathews Ry Wagner Jill Van Winkle Sandra Peters Stephanie Clendennen. Adjusted expiration 2023-05-12
24	Snake Gourd	China	33751 patent applications. For instance, patent: JPS6210007A granted to Toyoko Yonezawa. Application status is Pending 2019-09-14
25	Teff	Ethiopia and Eritrea	574 patent applications. For instance, patent US10264790B2 granted to Mohamed ELSHERIF Thomas Wilde. Anticipated expiration 2037-03-22
26	Kampô, kambô, kampu frog (*Phyllomedusa bicolor*)	Amazonian region (Brazil and Perú)	27 patent applications. For instance, patent US20040073977A1 granted to Santosh Misra William Kay. Adjusted expiration 2020-06-04

Compiled from: IUCN Analysis of Claims of “unauthorized Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge” pp. 5–6; and “South Asian Yearbook of Trade and Development (New Delhi: Centad, 2005), p. 268. Updated 30 July 2019.

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