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SYMPOSIUM COMMENTARY

Intellectual Property from a Global Environmental Law Perspective: Lessons from Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge[†]

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Abstract
This commentary considers the intellectual property (IP) system from a global environmental law perspective by exploring the extent to which patent-related treaties, such as the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and the World Intellectual Property Organization Patent Cooperation Treaty, can facilitate implementation of global environmental standards in the field of biodiversity law. It provides practical guidance to countries that wish to introduce patent disclosure-related mechanisms into their legal systems with a view to mainstreaming instances of global justice, fairness and equity, and raises awareness of the limitations arising from their extant IP obligations. Global environmental law standards have exercised an undeniable influence on the political discourse in international IP policy making in the field of patent disclosure. Still, many patent disclosure requirements that pre-date the Nagoya Protocol apply only to genetic resources the provenance of which is the same country that established the requirement. However, if a country designates its patent or IP office as a compliance checkpoint under the Nagoya Protocol, then the disclosure requirement should encompass at least the genetic resources originating from all countries that are contracting parties to this instrument. This could allow the fulfilment of a core monitoring obligation of the latter, while enabling wider synergies and transparency within the IP system.

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The views expressed in this commentary are solely those of the author and they are expressed in his personal capacity. The author would like thank Elisa Morgera, Alejandro Lago, and three anonymous reviewers for *Transnational Environmental Law* for feedback on previous versions of this commentary. Sections 2, 3 and 4 of the commentary are based on the World Intellectual Property Organization (WIPO) Study, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* (WIPO, 2017) by Claudio Chiarolla and Burcu Kılıç, used under CC BY 3.0 IGO.

Keywords: Intellectual property, Patents, Traditional knowledge, Disclosure requirements, Convention on Biological Diversity (CBD) Nagoya Protocol, Genetic resources

1. INTRODUCTION

There is growing interest in patent disclosure requirements concerning genetic resources and traditional knowledge. The use of genetic resources and associated traditional knowledge contributes invaluably to innovation in the fields of agriculture and horticulture, in the food and beverage, cosmetic, pharmaceutical and industrial biotechnology sectors, among others.[1] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol)[2] to the Convention on Biological Diversity (CBD)[3] points towards the achievement of a globally emergent form of sustainable development practice concerning the above uses, including in its legal dimensions, and aspires to global justice through fair and equitable benefit sharing. It does so by establishing a framework that aims to mitigate and correct, at least partly, inequalities and distributive injustices that have historically characterized the traditional business models and value chains of genetic resource utilization[4] (such as biotechnology development and biodiscovery) on the one hand, and the lack of recognition and protection of traditional knowledge on the other.[5] The latter is a symptom of the broader lack of recognition and protection of the rights of indigenous peoples, local communities, and small-scale farmers in many parts of the world.[6] Hence, the nexus between global environmental law and the global intellectual property (IP) system is the crossroads where instances of global justice,[7] trade and investment disciplines,[8]

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1 S.A. Laird, 'Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change' (CBD Secretariat, 2013), available at: https://www.cbd.int/abs/policy-brief.

2 Nagoya (Japan), 29 Oct. 2010, in force 12 Oct. 2014, available at: https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

3 Rio de Janeiro (Brazil), 5 June 1992, in force 29 Dec. 1993, available at: http://www.cbd.int/convention.

4 D.F. Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates* (Earthscan, 2010).

5 F. Papadopoulou, *The Protection of Traditional Knowledge on Genetic Resources* (Edward Elgar, 2018).

6 In her last report, the Special Rapporteur on the Rights of Indigenous Peoples was 'gravely concerned at the drastic increase in attacks and acts of violence against, criminalization of and threats aimed at indigenous peoples, particularly those arising in the context of large-scale projects involving extractive industries, agribusiness, infrastructure, hydroelectric dams and logging. These violations are occurring in the context of intensified competition for and exploitation of natural resources': V. Tauli-Corpuz, 'Report of the Special Rapporteur on the Rights of Indigenous Peoples to the 39th Session of the Human Rights Council, 10–28 Sept. 2018', UN Doc. A/HRC/39/17, 10 Aug. 2018, para. 4, available at: http://unsr.vtaulicorpuz.org/site/images/docs/annual/2018-annual-a-hrc-39-17-en.pdf. See also BeneLex Project, BeneLex Learning Module on Benefit-Sharing and the Rights of Indigenous Peoples over Natural Resources, Jan. 2019, available at: https://namati.org/resources/benelex-learning-module-benefits-rights-indigenous-peoples-natural-resources.

7 Global justice can be understood broadly as 'any conception of justice that treats the planet as a whole as the ultimate unit of assessment': N. Walker, 'The Gap between Global Law and Global Justice: A Preliminary Analysis', in A. Halpin & N. Roughan (eds), *In Pursuit of Pluralist Jurisprudence* (Cambridge University Press, 2017), pp. 216–38; also available in Edinburgh School of Law Research Paper No. 2016/30, 21 Dec. 2016, pp. 11–2, available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2888557.

8 B. Kılıç, 'Patent Disclosure Requirements in Free Trade Agreements', paper commissioned by the Centre for WTO Studies for the International Conference on TRIPS-CBD linkages, Geneva (Switzerland), 7–8 June 2018, available at: http://wtocentre.iift.ac.in/workingpaper/WorkingPaper49.pdf.

technology and development priorities, and international politics have met and created frictions around the issue of patent disclosure requirements over the last quarter of a century.

The Nagoya Protocol does not refer explicitly to patent disclosure requirements as such. However, these requirements represent one of the possible mechanisms that countries may choose to fulfil obligations concerning their duty to monitor the utilization of genetic resources within their jurisdictions. Therefore, patent disclosure requirements may help to address, at least partially, possible allegations of misappropriation and misuse of genetic resources and associated traditional knowledge. In the international policy debate, the distinct legal concepts of misappropriation and misuse have been referred to in more general terms as 'biopiracy'.[9] An example of the legal definition of biopiracy may be found in Peruvian law, in which it is stated:

> Biopiracy means unauthorized and non-remunerated access to and use of biological resources or collective knowledge of indigenous peoples by others, without the relevant authorization and in contravention of the principles established in the [CBD] and the rules in force on the matter. Such appropriation may occur by means of physical control, through ownership rights to products which incorporate such elements that were illicitly obtained or in some cases through invocation of such elements.[10]

One of the key pillars of the Nagoya Protocol – its *raison d'être* to be precise – concerns compliance in user countries with the domestic legislation or regulatory requirements on access and benefit sharing (ABS) of the contracting party which provides access to its genetic resources and associated traditional knowledge (Articles 15 and 16).[11] Researchers, companies and public research institutions that undertake research and development (R&D) or bioprospecting in any state party to the Nagoya Protocol must respect the applicable ABS obligations of the providing state party not only at the time of access, but also when the R&D cycle continues in another state. In order to monitor user compliance, the Nagoya Protocol stipulates that each party shall establish one or more 'checkpoints' (Article 17).[12] One such possible checkpoint can be the

[9] G. Dutfield, 'What is Biopiracy?', paper presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca (Mexico), 24–27 Oct. 2004, available at: http://moderncms.ecosystemmarketplace.com/repository/moderncms_documents/I.3.pdf.

[10] Act on the Protection of Access to Peruvian Biological Diversity and the Collective Knowledge of Indigenous Peoples, Law No. 28216, 30 Apr. 2004, para. 3 of the supplementary and final provisions, available at: https://wipolex.wipo.int/en/text/497328.

[11] In the context of the CBD and the Nagoya Protocol, the expression 'contracting party', whether in the singular or plural form, refers to any country that has consented to be bound by these treaties. In the above example, such providing party shall be also a 'legitimate provider' in the sense that it must be either 'the country of origin of such resources or a party that has acquired the genetic resources in accordance with the [CBD]': Art. 5.1 Nagoya Protocol.

[12] However, such monitoring obligations apply only to the utilization of genetic resources. The Nagoya Protocol does not include any obligation to monitor the use of traditional knowledge associated with genetic resources. From the perspective of developing countries and traditional knowledge holders, this is one of the most important gaps, which was left entirely unresolved during the negotiations of the Nagoya Protocol. For a critical account of how this gap came into being, see G.S. Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis* (Centre of Excellence for Biodiversity Law in collaboration with University of Malaya, 2011), pp. 3–4, 29 & box 3, available at: https://www.mybis.gov.my/pb/1631.

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patent (or IP) office, through the provision of additional disclosure requirements in patent (or other IP) applications.[13]

Approximately 25 countries and two regional organizations have adopted various kinds of (in some cases legally binding) patent disclosure requirements for genetic resources and traditional knowledge.[14] The academic literature and international policy making at the Secretariats of the CBD,[15] the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO) have focused prominently on whether a new legally binding obligation should be placed on all countries in the multilateral system to adopt or further harmonize patent disclosure requirements, as well as on the possible remedies for non-compliance.[16] However, despite the important and unsettled quest for international harmonization, there are several other practical reasons why the effective use of patent disclosure mechanisms to diffuse transparency across the IP system has been very limited.[17] These reasons include lack of knowledge and human resources, inadequate finance, and lack of capacity efficiently to coordinate government mandates and functions of different ministries (such as for the environment, industry and innovation).[18] Hence, there is still significant untapped potential for patent disclosure mechanisms to mainstream instances of global justice, fairness and equity.

This brief commentary does not aim to thoroughly review and assess the various proposals that have been tabled to promote the harmonization of patent disclosure requirements at the international level. A prolific literature has already considered this topic.[19] The aim is also not to analyze in fine detail the application of such

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[13] C. Chiarolla & B. Kılıç, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* (WIPO, 2017), p. 50, available at: https://www.wipo.int/publications/en/details.jsp?id=4194b.

[14] WIPO, 'Disclosure Requirements Table', in Chiarolla & Kılıç, n. 13 above, Annex, pp. 62–91; also separately available at: https://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf.

[15] CBD, n. 3 above.

[16] For instance, Correa argues that '[t]he incorporation of [patent disclosure] requirements into national laws has addressed some of the concerns of developing countries regarding the misappropriation of these resources and knowledge. However, their effectiveness is likely to be limited in the absence of an *international* rule that sets out the terms of the obligation and the consequences of non-compliance. This limitation is particularly problematic if the obligation is not recognized and enforced in the markets where the commercialization of the protected inventions may be most profitable': C.M. Correa, 'A Possible Plurilateral Framework to Address the Misappropriation of Genetic Resources and Traditional Knowledge', paper commissioned by the Centre for WTO Studies for the International Conference on TRIPS-CBD Linkages, Geneva (Switzerland), 7–8 June 2018, p. 1, available at: http://wtocentre.iift.ac.in/workingpaper/WorkingPaper50.pdf (emphasis in original).

[17] P. Oldham & G. Burton, 'Defusing Disclosure in Patent Applications', UN Doc. UNEP/CBD/COP/10/INF/44, 24 Oct. 2010, available at: https://www.cbd.int/doc/meetings/cop/cop-10/information/cop-10-inf-44-en.pdf; and P. Oldham, S. Hall & O. Forero, 'Biological Diversity in the Patent System', *PLOS ONE*, e78737, 12 Nov. 2013, available at: https://doi.org/10.1371/journal.pone.0078737.

[18] B. Pisupati, 'The Ten Questions to be Addressed while Developing National ABS Frameworks' (2015) *Forum for Law, Environment, Development and Governance*, pp. 16–7, available at: https://unctad.org/meetings/en/Contribution/ditc-ted-18102016-10-Questions-on-ABS.pdf.

[19] In the context of the WIPO Intergovernmental Committee (IGC) see, e.g., M.A. Bagley, 'Of Disclosure "Straws" and IP System "Camels": Patents, Innovation, and the Disclosure of Origin Requirement', in D. Robinson, P. Roffe & A. Abdel-Latif (eds), *Protecting Traditional Knowledge: The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*

requirements in any particular jurisdiction.[20] Instead, this commentary aims to provide further practical guidance to countries that wish to introduce new patent disclosure-related mechanisms into their national legal systems with a view to mainstreaming instances of global justice, fairness and equity, in line with the CBD and its Nagoya Protocol. While doing so, it raises awareness and pays due regard to the limitations arising from their extant IP obligations at the multilateral level by focusing on, inter alia, the effective use of available options under the WIPO Patent Cooperation Treaty (PCT).[21]

The next section of this commentary briefly introduces the origins of the frictions between global environmental law and the international IP system in the field of biodiversity. It then summarizes the essential features of patent disclosure requirements for genetic resources and traditional knowledge and reviews how to further possible synergies between the two. Section 3 then considers the relationship between ABS obligations under the Nagoya Protocol and additional patent disclosure requirements, and explains how the latter differ from conventional disclosure obligations under patent law. Section 4 provides the necessary background to understanding the specific features of extant patent disclosure requirements in national law by focusing on their subject matter, scope, and the triggers of disclosure. In so doing, it also illustrates the influence of global environmental law in the development of such features. Section 5 examines these additional patent disclosure-related mechanisms (and their implementation) by assessing their compatibility – or the absence thereof – with relevant international IP law treaties from a legal technical standpoint.

In the transnational context of biodiscovery and its globalized R&D value chains, the final section (Section 6) concludes by drawing key lessons learned from the national implementation of additional patent disclosure requirements. In light of the unsettled debate on the need for mandatory disclosure requirements (and harmonized remedies)

(Routledge/Earthscan Press, 2017), pp. 85–107; D. Muyldermans, 'Genetic Resources, Traditional Knowledge and Disclosure Obligations: Some Observations from the Life Science Industry', in Robinson, Roffe & Abdel-Latif, ibid., pp. 230–6; G. Bauer, C.M. Berger & M. Girsberger, 'Disclosure Requirements: Switzerland's Perspective', in Robinson, Roffe & Abdel-Latif, ibid., pp. 244–52. See also WTO, 'Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the Convention on Biological Diversity', WTO Doc. TN/C/W/59, 19 Apr. 2011, available at: http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/tn/c/W59.doc; and WIPO, 'Consolidated Document Relating to Intellectual Property and Genetic Resources', second revision, as at the close of IGC 36 on 29 June 2018), available at: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=433262.

[20] For such analysis, see Chiarolla & Kılıç, n. 13 above. However, this commentary does provide selected examples of relevant national or regional laws to illustrate some general features of extant patent disclosure requirements in Sections 2, 3 and 4 below.

[21] Washington, DC (US), 19 June 1970, in force 24 Jan. 1978, modified 3 Oct. 2001, available at: https://wipolex.wipo.int/en/text/288637. Admittedly, the WIPO PCT system has an undeniable economic importance: see Section 5.2 below. However, the PCT system has attracted only limited interest in this area, mainly because the main proposal to amend the PCT (and the WIPO Patent Law Treaty) is associated with the idea that the introduction of such disclosure requirements would remain voluntary and without any (mandatory) consequences for non-compliance: WIPO, 'Proposals by Switzerland regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications', WIPO Doc. PCT/R/WG/5/11 Rev., 19 Nov. 2003, available at: https://www.wipo.int/edocs/mdocs/pct/en/pct_r_wg_5/pct_r_wg_5_11_rev.pdf. See also Bauer, Berger & Girsberger, n. 19 above. Furthermore, developing country *demandeurs* of patent disclosure have a preference for addressing this issue in the WTO, where a mandatory dispute settlement system is readily available to enforce compliance.

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at the international level, this commentary puts into perspective the challenges and opportunities that arise from the adoption of patent disclosure measures that are immediately implementable. It finally considers their implications for the emergence and enforcement of the global environmental law exigencies and standards of transparency, fairness, equity and global justice under the CBD and its Nagoya Protocol.

2. GLOBAL ENVIRONMENTAL LAW AND THE INTERNATIONAL IP SYSTEM: FRICTIONS AND SYNERGIES AT THE BIO-BASED MARKETPLACE

Global law – and by inference, global environmental law – may be understood as a distinct and significant subset of transnational law, which 'embraces any practical endorsement of or commitment to the universal or otherwise global-in-general warrant of some laws or some dimension of law'.[22] Hence, global law tends to look beyond state sovereignty as the exclusive meta-principle of legal authority and, in doing so, it explicitly considers some 'general ethical principles and purposes in search of a legitimate grounding for its authority'.[23] The CBD is the first comprehensive international agreement dedicated to biological diversity, which was adopted in 1992 at the Rio Earth Summit[24] and has by now achieved almost global coverage with 196 parties, the United States (US) being the most notable non-party. Its objectives are:

> [T]he conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.[25]

It also reaffirms 'the sovereign rights of States over their natural resources', including genetic resources. In particular, the CBD provides that 'the authority to determine access to genetic resources rests with the national governments and is subject to national legislation' and that 'access, where granted, shall be on mutually agreed terms … and subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party'.[26]

Historically, there have been tensions between IP law, particularly relating to patents and plant breeders' rights, and biodiversity-related legislation such as the CBD.[27] Where the invention disclosed in a patent application is shown to have some

[22] N. Walker, *Intimations of Public Law* (Cambridge University Press, 2015), pp. 1–28.

[23] Walker (2016), n. 7 above, p. 11.

[24] CBD, n. 3 above.

[25] Art. 1 CBD.

[26] Art. 15 CBD.

[27] C. Lawson, 'Patents and Access and Benefit-Sharing Contracts: Conservation or Just More Red Tape?' (2011) 30(2) *Biotechnology Law Report*, pp. 2–3, available at: https://research-repository.griffith.edu.au/handle/10072/44925. In the field of agriculture see C. Chiarolla, *Intellectual Property, Agriculture and Global Food Security: The Privatisation of Crop Diversity* (Edward Elgar, 2011), pp. 74–109.

degree of dependence on the acquisition and use of genetic resources or associated traditional knowledge, or appears to include one or both of them in its scope, several developing countries have expressed concerns regarding their misappropriation or misuse,[28] and the possible violation of ABS legislation.

In an emblematic case, the patented product 'Brazzein' was derived from the Oubli berry, a West African fruit of the climbing plant Oubli (*Pentadiplandra brazzeana Baillon*).[29] The protein derived from the berry is between 500 to 2,000 times sweeter than sugar and is used as a natural low-calorie sweetener.[30] Brazzein is a substitute for currently available low-calorie sweeteners and is suitable for diabetics.[31] It is also thermostable, which makes it suitable for heat processes used in food processing.[32] The West African people of Gabon originally discovered and nurtured the plant, which was used to help nursing infants 'forget' their mother's milk.[33] A researcher from the University of Wisconsin observed people and animals eating the berries in West Africa and brought them to the attention of the university. The latter was granted three US patents[34] and one European patent[35] for isolating and reproducing the protein in a laboratory.[36] One claim for the berry in the US patents is to 'provide Brazzein in large quantities, at low cost, by artificial means'. The researchers have since concentrated on the reproduction of the protein in a laboratory, obviating the need to collect and cultivate the plant in Gabon.[37] The University of Wisconsin maintained that Brazzein is 'an invention of a UW-Madison researcher'[38] and offered no recognition or benefit sharing to the people of Gabon. It was subsequently argued that the synthetic substitution has caused a significant fall in the price of natural Brazzein products, and

[28] E.g., in the context of the outstanding revision of Art. 27.3(b) of the WTO TRIPS Agreement (n. 65 below), a group of countries led by Brazil and India – which includes also Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and supported by the African Group and other developing countries – have requested the amendment of the TRIPS Agreement to require patent applicants 'to disclose the country of origin of genetic resources and traditional knowledge used in the inventions, evidence that they received "prior informed consent", and evidence of "fair and equitable" benefit sharing': see WTO, n. 19 above. See also Chiarolla, n. 27 above, pp. 135–7.

[29] This example is adapted from Chiarolla & Kılıç, n. 13 above, p. 10.

[30] A. Pollack, 'Patenting Life: A Special Report. "Biological Products Raise Genetic Ownership Issues"', *The New York Times*, 26 Nov. 1999, available at: https://www.nytimes.com/1999/11/26/business/patenting-life-special-report-biological-products-raise-genetic-ownership-issues.html.

[31] G.G. Birch, *Ingredients Handbook: Sweeteners*, Ingredients Handbook Series (Leatherhead Food Research Association, 2000).

[32] B.G. Hellekant & D. Ming, 'Brazzein Sweetener', U.S. Patent 5326580, issued 5 Jul. 1994.

[33] See 'Pentadiplandra Brazzeana' in *World Heritage Encyclopedia* (online), available at: http://www.gutenberg.us/articles/pentadiplandra_brazzeana#cite_note-doc-2.

[34] Patents 5,326,580, 5,346,998 and 5,527,555.

[35] Patent 684,995.

[36] GRAIN, 'Of Patents & Pirates', *GRAIN Reports*, 25 July 2000, available at: https://www.grain.org/article/entries/53-of-patents-pi-ates?print=true.

[37] J. Madeley, *Hungry for Trade: How the Poor Pay for Free Trade* (Zed Books, 2000), pp. 101–3.

[38] House of Commons, Select Committee on Environmental Audit Appendices to the Minutes of Evidence, Nov. 1999, available at: http://www.publications.parliament.uk/pa/cm199900/cmselect/cmenvaud/45/4502.htm#evidence.

many Gabonese women, who used to harvest the fruit, have lost their source of income.[39]

Several other cases of alleged misappropriation or misuse of genetic resources and associated traditional knowledge are well documented in the literature.[40] This has led to the introduction of additional disclosure obligations for genetic resources and associated traditional knowledge in the national patent systems in both developed and developing countries.[41] Thus, several countries now require or invite patent applicants to disclose, among other things:[42]

- the origin and/or source of genetic resources and/or traditional knowledge;
- evidence of prior informed consent for their use from the provider country and, where applicable, from indigenous peoples and local communities;[43] and
- evidence of having established mutually agreed terms for the fair and equitable sharing of the benefit derived from such use, if so required by the national legislation of the provider country.

Many megadiverse countries[44] regard patent disclosure requirements as a crucial measure to encourage patent applicants to comply with requirements for prior informed consent and mutually agreed terms.[45] Such new patent disclosure requirements – especially when mandatory – may lead to changes in the attitudes and behaviour of inventors. Thus, they may reinforce the effects of an ABS system and reduce the free-riding incentives to freely obtain a benefit from someone else's genetic resources or traditional

[39] P. Carmody, *The New Scramble for Africa* (Polity Press, 2011), p. 1970.

[40] Robinson, n. 4 above.

[41] For an account of various pre-Nagoya Protocol attempts to modify patent law in European countries to meet various objections and public concerns regarding the patenting of traditional knowledge, see G. van Overwalle, 'Holder and User Perspectives in the Traditional Knowledge Debate: A European View', in C. McManis (ed.), *Biodiversity and the Law: Intellectual Property, Biotechnology and Traditional Knowledge* (Earthscan, 2007), pp. 355–72, at 364–6.

[42] For a full list of countries that provide patent disclosure provisions related to genetic resources and associated traditional knowledge, see WIPO, n. 14 above.

[43] On the use of the term 'indigenous peoples' in the Nagoya Protocol context, see UN Environment Programme, 'Decision on the Use of the Term "Indigenous Peoples and Local Communities"', UN Doc. CBD/NP/MOP/DEC/2/7, 10 Dec. 2016, available at: https://www.cbd.int/doc/decisions/np-mop-02/np-mop-02-dec-07-en.pdf.

[44] 'Megadiverse countries' is a term used to refer to the world's top biodiversity-rich countries: UNEP World Conservation Monitoring Centre, 'Megadiverse Countries', available at: http://www.biodiversitya-z.org/content/megadiverse-countries.

[45] In the CBD context, the term 'prior informed consent' refers to the permission given from the competent national authority of a provider country to a user prior to accessing genetic resources or associated traditional knowledge, in line with the applicable legal and institutional framework. The term 'mutually agreed terms' refers to an agreement reached between the providers of genetic resources or associated traditional knowledge and the users on the conditions of access and use of such resources and knowledge, and the benefits to be shared between both parties: WTO, 'The TRIPS Agreement and Convention on Biological Diversity', WTO Doc. IP/C/W/368/Rev.1, revised 8 Feb. 2006, pp. 28–31, available at: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=71013,62129,31989,25697,49523&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True.

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knowledge without adequate compensation or proper authorization. Ultimately, this should help in preventing their misappropriation.

Admittedly, the major limitation of such patent disclosure mechanisms is that there is no international legally binding obligation to use them.[46] Hence, in most user countries a large majority of patent applications associated with biological or genetic resources do not divulge their origin.[47] Furthermore, it would be unfair not to acknowledge that the lack of fair and equitable benefit sharing is also, at least partly, a consequence of poorly regulated access in the provider countries. Despite these various factors, there are other important limitations to the effective use of extant patent disclosure requirements, which could be more easily mitigated. At present, many patent disclosure requirements that pre-date the Nagoya Protocol apply only to genetic resources and traditional knowledge the provenance of which is the same country that has established the patent disclosure requirement. Indeed, under the Nagoya Protocol, if a party designates its patent/IP office as a compliance checkpoint under Article 17, then the (geographical) scope of the requirement should at least encompass all genetic resources originating from any other contracting parties. This relatively simple fine-tuning of existing legislation could allow the fulfilment of a core monitoring requirement of the Nagoya Protocol on ABS, while also enabling wider synergies with the IP system.

3. THE RELATIONSHIP BETWEEN ABS OBLIGATIONS AND PATENT DISCLOSURE REQUIREMENTS FOR GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

Given the concerns about illegal access to genetic resources and traditional knowledge under the CBD and its Nagoya Protocol, new patent disclosure requirements focus primarily on the legal status of genetic resources and traditional knowledge – that is, whether they have been acquired legally, subject to prior informed consent and mutually agreed terms, if that is required by the provider country. However, a conventional duty of disclosure already exists within the patent system with regard to information that is 'material' to the examination of each patent claim. This conventional disclosure does not normally require disclosure of the origin or source of genetic resources and traditional knowledge, because such information is often not strictly relevant to enable the invention or support the claims.[48]

[46] Correa, n. 16 above.

[47] E. Hammond, *Patent Claims on Genetic Resources of Secret Origin* (Third World Network (TWN), 2014), and E. Hammond, *More Patent Claims on Genetic Resources of Secret Origin: An Update on Disclosure of Origin in Patent Applications under the [WIPO] Budapest Treaty* (TWN, 2016), available at: https://www.twn.my/title2/series/bkr/bkr004.htm.

[48] Information about the origin or source of genetic resources and traditional knowledge may be disclosed voluntarily in a patent application if the applicant believes that it would be required to meet the requirements for patentability, such as novelty, inventive step, and industrial application. It is only in such cases that this information may be considered to be 'material' to the patentability of the claimed invention. On conventional disclosure under patent law, see WIPO, 'Technical Study on Disclosure Requirements

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Thus, the distinctive feature of additional patent disclosure requirements related to genetic resources and traditional knowledge is their primary focus on information or documentation that may concern the legal status of genetic resources and traditional knowledge and the circumstances under which such resources or knowledge have been acquired by the applicant. Since this information is not typically required for the substantive examination of patentability, in most cases it is not considered requisite to satisfy the 'sufficiency of disclosure' requirement under conventional patent law. On the other hand, new patent disclosure requirements relating to genetic resources and traditional knowledge may enhance compliance with standard requirements for patent protection, in particular, the requirement of 'novelty'. A proper scope of disclosure of information related to genetic resources and traditional knowledge may help to ensure that relevant 'prior art' is considered in the examination of the patent application, so reducing the risk that patents are erroneously awarded for inventions that lack novelty.

A core issue to be considered when introducing new patent disclosure requirements is how to frame an appropriate interface between ABS legislation and the patent system. How might disclosure requirements be designed to promote mutual supportiveness, synergies and complementarity between the implementation of ABS mechanisms and obligations, on the one hand, and the innovation incentives of the patent system, on the other? Countries vary in terms of their biodiversity endowment, research and biotechnology capacity, level of public and private R&D spending and biocultural sensitivities, as well as their national IP examination capacities. While there is clearly no one-size-fits-all approach, a growing number of countries have been demanding some degree of harmonization through a new legally binding international IP instrument or instruments, which have been under discussion since 2000 at the WIPO Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.[49]

In the context of global biodiversity law, as anticipated in the previous section, patent disclosure requirements can be used principally as a tool to monitor the utilization of genetic resources and associated traditional knowledge, namely as a compliance checkpoint under Article 17 of the Nagoya Protocol. They can help in promoting user compliance with ABS obligations. In doing so, they may facilitate the diffusion of a quasi-extraterritorial application of the ABS standards adopted by the provider countries in the user countries,[50] as an emerging global environmental law practice that aspires to achieve a higher standard of global fairness and justice between countries, and with indigenous peoples and local communities alike.

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in Patent Systems Related to Genetic Resources and Traditional Knowledge', 2004, p. 2, available at: https://www.wipo.int/publications/en/details.jsp?id=282&plang=EN.

[49] For an overview of the WIPO IGC, see D. Robinson, P. Roffe & A. Abdel-Latif, 'Introduction: Mapping the Evolution, State-of-Play and Future of the WIPO IGC', in Robinson, Roffe & Abdel-Latif, n. 19 above, pp. 3–9.

[50] C. Chiarolla, 'The Role of Private International Law under the Nagoya Protocol', in E. Morgera, M. Buck & E. Tsioumani (eds), *The Nagoya Protocol in Perspective: Implications for International Law and Implementation Challenges* (Brill/Martinus Nijhoff, 2013), pp. 423–49.

4. THE ABC OF PATENT DISCLOSURE REQUIREMENTS: SUBJECT MATTER, SCOPE, AND TRIGGERS

In national patent or IP legislation, various concepts are used to define the subject matter of disclosure. Diverse terms are used, such as genetic resources, biological resources, traditional knowledge, traditional knowledge associated with genetic resources, indigenous knowledge, as well as processes or products derived from or developed with them. The use of such terms and their definitions parallels or is directly derived from national biodiversity legislation on ABS, which, in turn, implements global environmental law standards. Hence, biodiversity law exerts an important influence on the development of IP legislation in this area,[51] despite the fact that the communities of practitioners operating in the technical legal fields of IP and ABS are quite far apart.

At the international level, genetic resources are defined in the CBD as 'genetic material of actual or potential value', and 'genetic material' as 'any material of plant, animal, microbial or other origin containing functional units of heredity'.[52] The latter expression is commonly understood to require the presence of coding DNA in the genetic material,[53] so may exclude many gene products at the sub-organism level, non-DNA molecules as well as proteins, which do not contain 'functional units of heredity'.[54]

On the other hand, the term 'traditional knowledge' may refer generally to knowledge resulting from intellectual activity in a traditional context and include know-how, practices, skills, and innovations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.[55] For example, South Africa defines traditional knowledge as 'the knowledge that an indigenous community has regarding the use of an indigenous biological resource or a genetic resource'.[56]

The Nagoya Protocol also defines the term 'derivative' as 'a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.[57] Thus,

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[51] See, e.g., the Patents Amendment Act 2005 of South Africa, Art. 2, available at: https://www.wipo.int/tk/en/databases/tklaws/articles/article_0021.html (which states that an 'indigenous biological resource' means an indigenous biological resource as defined in section 1 of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004)).

[52] See Art. 2 CBD and Art. 2 Nagoya Protocol, as well as the definitions in the document WIPO, 'Second Revision of the Consolidated Document Relating to Intellectual Property and Genetic Resources (as at the close of IGC 30 on June 3, 2016)', WIPO/GRTKF/IC/34/4, available at: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=368344.

[53] L. Glowka et al. (eds), *A Guide to the Convention on Biological Diversity* (International Union for the Conservation of Nature (IUCN), 1994), pp. 21–2.

[54] C. Chiarolla, 'Genetic Resources', in E. Morgera & K. Kulovesi (eds), *Research Handbook on International Law and Natural Resources* (Edward Elgar, 2016), pp. 218–42.

[55] WIPO Glossary, available at: www.wipo.int/tk/en/resources/glossary.html#49.

[56] Patents Amendment Act 2005 of South Africa, n. 51 above, Art 2.

[57] T. Greiber et al., *Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing* (IUCN, 2012), p. 67, available at: https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf (stating that 'the biochemical components of genetic resources … are the non-modified chemical components, other than DNA or RNA, formed by the organisms' metabolic processes that exist in samples of biological materials (that is, active biological components found in collected material) and that have yet to be modified and used in technological applications').

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some countries would rely on the above definition of 'derivative' to expand the range of biochemicals that are covered by ABS provisions beyond those that are genetic resources in a strict sense (such as a naturally occurring protein).[58] Similarly, user countries may decide to monitor also the utilization of derivatives through a patent disclosure requirement.

With regard to the scope of a patent disclosure requirement, many countries require only the disclosure of genetic resources and traditional knowledge that originate within their own territory[59] or region.[60] The impact of such patent disclosure requirements may be rather limited, since a patent applicant who files an application for an invention that is based on a genetic resource or traditional knowledge originating from a another country (or region, as applicable)[61] will not be subject to checks. A majority of compulsory patent disclosure requirements of a substantive nature enacted prior to the entry into effect of the Nagoya Protocol belong to this category.[62]

In countries that are party to the Nagoya Protocol the introduction of new patent disclosure requirements as a checkpoint mechanism is only one of several possible options to enable fulfilment of their monitoring obligations. However, if such requirements are introduced, then their scope must at least encompass genetic resources that originate from any other contracting party. Thus, the designation of a country's

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[58] See, e.g., the Namibian Access to Biological and Genetic Resources and Associated Traditional Knowledge Act 2 of 2017, available at: http://www.lac.org.na/laws/annoSTAT/Access%20to%20Biological%20and%20Genetic%20Resources%20and%20Associated%20Traditional%20Knowledge%20Act%202%20of%202017.pdf.

[59] E.g., Costa Rican law provides that '[b]oth the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior consent. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation': Law No. 7788 on Biodiversity of Costa Rica (as last amended by Law No. 8686 of 21 Nov. 2008), Art. 80, available at: https://wipolex.wipo.int/en/text/208691. South African law provides that '[e]very applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use': Patents Amendment Act of South Africa (Act No. 20 of 2005), s. 30, available at: https://www.wipo.int/tk/en/databases/tklaws/articles/article_0021.html.

[60] At the regional level, the Common Industrial Property Regime of the Andean Community states that the patent applicant, where applicable, shall provide 'a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin; [and] a copy of the document accrediting the licensing or the authorization of the use of the traditional knowledge of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force': Decision No. 486 (2000) Establishing the Common Industrial Property Regime of the Andean Community, Art. 26, available at: https://www.wipo.int/tk/en/databases/tklaws/articles/article_0027.html.

[61] Ibid.

[62] Chiarolla & Kılıç, n. 13 above, pp. 21–2.

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patent/IP office as a compliance checkpoint under Article 17 of the Nagoya Protocol is an example of a situation where the geographical scope of a patent disclosure requirement must be defined based on reciprocity.[63]

Finally, it is important to consider the possible trigger of a disclosure obligation. The function of the trigger is to identify markers of 'proximity' that create a boundary within which benefit-sharing requirements and any related compliance-monitoring obligations will apply. Under what circumstances should a patent examiner or other receiving office demand additional disclosure related to genetic resources or traditional knowledge from the applicant? Three possible triggers can be identified in national laws: when the patent application or claimed invention (i) *includes the utilization* of genetic resources and/or traditional knowledge; or (ii) is *derived from* genetic resources and/or traditional knowledge; or (iii) is *based on* genetic resources and/or traditional knowledge or *directly based* on them.[64]

5. IMPLEMENTING GLOBAL BIODIVERSITY LAW EXIGENCIES AND STANDARDS: MONITORING ABS COMPLIANCE VIA THE INTERNATIONAL IP SYSTEM

The above sections have succinctly examined the key policy objectives and the principal features of new patent disclosure requirements for genetic resources and associated traditional knowledge, and their relation to global biodiversity law. The remainder of this commentary considers the question of their compatibility with two of the most important international intellectual property law treaties, which have contributed to globalizing substantive and procedural patent standards, respectively: the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[65] and the WIPO PCT.[66]

5.1. *The WTO TRIPS Agreement*

In 1994, a critical milestone for the development of the international IP system as we know it today was the adoption of the WTO TRIPS Agreement.[67] This Agreement required, for the first time, members of the multilateral trade system to introduce harmonized intellectual property rules within their domestic law. In particular, it required, inter alia:

- the application of the general provisions and basic principles of the multilateral trading system to international IP, such as national treatment and most-favoured-nation treatment principles;

[63] Ibid., p. 33.
[64] Ibid., pp. 36–8.
[65] Marrakesh (Morocco), 15 Apr. 1994, in force 1 Jan. 1995, available at: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[66] N. 21 above.
[67] N. 65 above.

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- the application of minimum standards of protection for IP rights; and
- the introduction of enforcement-related provisions, while also affording the possibility of resolving IP-related disputes between member states through the WTO dispute settlement mechanism.

Under the TRIPS Agreement, patent protection must be available for eligible inventions that are *new*, involve an *inventive step*, and can have an *industrial application*. Article 27 of the TRIPS Agreement calls on WTO members to provide patent protection for both products and processes, and forbids discrimination among different fields of technology. Patent protection must be provided for at least 20 years. WTO members have also agreed that plants, animals and all essentially biological processes for their production may be excluded from patentability. However, if members do so, they are required to provide for the protection of plant varieties either by patents or by an effective *sui generis* system. Therefore, countries are free to choose either to provide patent protection for new plant varieties or to adopt a *sui generis* system, for which the most successful and widely disseminated model is the Convention of the International Union for the Protection of New Plant Varieties (UPOV Convention).[68] Furthermore, the mainstream interpretation of Article 27 of the TRIPS Agreement is that governments would generally be required to issue patents for microbiological inventions and for microbiological processes for the production of plants and animals.[69]

Interestingly, Article 27.3(b) of the TRIPS Agreement also presents a built-in review mechanism, which was triggered in 1998. In 2001, paragraph 19 of the Doha Ministerial Declaration instructed the WTO TRIPS Council 'to examine, *inter alia*, the relationship between the TRIPS Agreement and the [CBD], the protection of traditional knowledge and folklore, and other relevant new developments raised by members'.[70] Under this negotiating mandate, most developing countries supported the proposal to amend the TRIPS Agreement to include a mandatory obligation in patent applications to disclose the origin of genetic resources and traditional knowledge. The most recent proposals and discussions of the WTO TRIPS Council have focused on amending Article 29 of the TRIPS Agreement – instead of Article 27.3(b) – with the view to including a requirement that the applicant submit evidence of compliance

[68] Paris (France), 2 Dec. 1961, in force 10 Aug. 1968, available at: http://www.upov.int/ upovlex/en/upov_-convention.html. See C. Chiarolla, 'Commodifying Agricultural Biodiversity and Development-related Issues' (2006) 9(1) *Journal of World Intellectual Property*, pp. 25–60. A key difference between patents and plant breeders' rights is that the latter have broader exemptions for research and plant breeding as well as for farmers' use for their subsistence compared with patents.

[69] United Nations Conference on Trade and Development (UNCTAD) – International Centre for Trade and Sustainable Development (ICTSD), *Resource Book on TRIPS and Development* (Cambridge University Press, 2005), p. 389, available at: https://www.ictsd.org/themes/innovation-and-ip/research/resource-book-on-trips-and-development. For a narrow interpretation of these TRIPS provisions, see C.M. Correa, 'TRIPS-Related Patent Flexibilities and Food Security: Options for Developing Countries', QUNO-ICTSD Policy Guide, Sept. 2012, pp. 5–6, available at: https://www.ictsd.org/sites/default/files/research/2012/10/trips-related-patent-flexibilities-and-food-security.pdf.

[70] WTO, Doha Ministerial Declaration, WTO Doc. WT/MIN(01)/DEC/1, 14 Nov. 2001, available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

with the prior informed consent and benefit-sharing provisions of the CBD.[71] The Council has also recently considered the possibility of pursuing plurilateral initiatives to overcome almost two decades of standstill on this issue at the multilateral level.[72]

In the absence of an amendment to the TRIPS Agreement that would expressly regulate how to introduce new patent disclosure obligations related to genetic resources and associated traditional knowledge, if any, in the multilateral trading system, the question of their current compatibility with the TRIPS Agreement is a critical issue. In general, patent disclosure requirements can be provided either as substantive or procedural requirements.[73] Substantive requirements broadly relate to the actual nature of the invention, including considerations for assessing compliance with the standards set for patentability. As we have seen earlier, there are three patentability requirements under TRIPS: novelty, inventive step, and industrial application. Therefore, it is unlikely that a new patent disclosure requirement on genetic resources and traditional knowledge, added as a 'fourth' substantive standard for the patentability of gene-based inventions, could be compatible with the TRIPS Agreement *as such*. However, not all 'substantive' requirements have strictly to do with the qualities of the invention. Some deal with such issues as inventorship, entitlement to apply for or be granted a patent and other interests in a patent right. Hence, if it were crafted within the latter category, even a substantive patent disclosure requirement on genetic resources and associated traditional knowledge (that is, not concerned directly with the examination of the qualities of the invention as such) could be permissible under the TRIPS Agreement. Similarly, patent disclosure requirements regarding genetic resources and associated traditional knowledge that are framed as formality requirements are also generally acceptable – and accepted – under the TRIPS Agreement.[74]

5.2. *The WIPO PCT*

New patent disclosure requirements on genetic resources and associated traditional knowledge should also be considered in light of their possible compatibility with the PCT.[75] As we will see, an analysis of relevant PCT provisions leads to altogether different – even rather spectacularly contrary – conclusions regarding the compatibility of patent disclosure requirements with international IP law from those resulting from scrutiny under the TRIPS Agreement.

According to WIPO, the PCT 'assists applicants in seeking patent protection internationally for their inventions, helps Patent Offices with their patent granting decisions,

[71] WTO, n. 19 above.

[72] Correa, n. 16 above.

[73] Chiarolla & Kılıç, n. 13 above, p. 23.

[74] At the time of writing, no complaint has ever been brought before the WTO dispute settlement body for a violation of the patent-related provisions of the TRIPS Agreement because of their alleged incompatibility with a national patent disclosure requirement on genetic resources and associated traditional knowledge. Other formality requirements may include, e.g., the need to disclose the names of inventors and their addresses, to submit certain documents such as priority documents (i.e., copies and translations of foreign patent applications that form the basis of a claim for priority), and to submit the application in a prescribed format.

[75] N. 21 above.

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and facilitates public access to a wealth of technical information relating to those inventions. By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in [152] countries'.[76] The PCT is very widely used by international patent applicants and the fees generated by the PCT system amounted to nearly 300 million Swiss francs in 2016 and 2017.[77]

As regards the possibility of introducing additional patent disclosure requirements in conformity with relevant PCT provisions, due regard must be given to Article 27 PCT, which stipulates the conditions under which 'special' national requirements can be introduced. The above article states:

> (1) No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.
>
> […]
>
> (5) Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires . . . . any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications.
>
> (6) The national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law.

The face value of the above provisions is that under the PCT additional *substantive* patent disclosure requirements related to genetic resources and associated traditional knowledge are generally allowed. For example, India has included special requirements in its national 'chapter' to be complied with during the national phase.[78] In particular, the applicant shall declare if '[t]he invention as disclosed in the specification uses the biological material from India' and must confirm that 'the necessary permission from the competent authority shall be submitted … before the grant of the patent'.[79]

In contrast, in accordance with Rule 51*bis* of the PCT Regulations,[80] only a closed list of additional national requirements would be allowed, which leaves a relatively narrow margin for manoeuvre to argue that an additional *procedural* or *formality* patent disclosure requirement would be compatible with the PCT. In particular, Rule 51*bis* of the PCT Regulations states that 'the national law applicable by the designated office may, in accordance with Article 27 [of the PCT] require the applicant to furnish [*inter alia*, …] (ii) any document relating to the applicant's entitlement to apply for or be granted a patent'.

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[76] WIPO, 'PCT: The International Patent System', available at: http://www.wipo.int/pct/en/index.html.

[77] WIPO, 'Annual Financial Report and Financial Statements 2017', WO/PBC/28/9, Annex II, p. 76, available at: http://www.wipo.int/edocs/mdocs/govbody/en/wo_pbc_28/wo_pbc_28_9.pdf.

[78] India National Chapter, PCT National Phase, available at: http://www.wipo.int/pct/guide/en/gdvol2/annexes/in.pdf.

[79] Ibid.

[80] Geneva (Switzerland), 1 July 2018, in force 1 July 2018, available at: https://wipolex.wipo.int/en/text/494065.

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Arguably, *legal* access – or the absence thereof – to a genetic resource or associated traditional knowledge, which underpins or is used in the claimed invention, can have implications for the applicant's entitlement to apply for or be granted a patent. However, despite the above argument – and the possibility of requiring additional documentation or evidence only if the receiving office reasonably doubts the veracity of the indications or declaration concerned – Article 27(4) PCT further provides:

> Where the national law provides, in respect of the form or contents of national applications, for requirements which, from the viewpoint of applicants, are more favorable than the requirements provided for by this Treaty and the Regulations in respect of international applications, the national Office, the courts and any other competent organs of or acting for the designated State may apply the former requirements, instead of the latter requirements, to international applications, except where the applicant insists that the requirements provided for by this Treaty and the Regulations be applied to his international application.

In sum, even if a new *formality* requirement related to patent disclosure of genetic resources and associated traditional knowledge is allowable under the PCT,[81] an international applicant may always refuse, at least in principle, to be subject to such less favourable requirement, including in the context of post-grant opposition or invalidation proceedings, where applicable.[82]

6. CONCLUSIONS: IMPLICATIONS FOR GLOBAL ENVIRONMENTAL LAW

This commentary concludes that a balanced and proactive use of current mechanisms and flexibilities that are available within the international IP system can further its synergetic implementation with key biodiversity-related instruments such as the CBD and its Nagoya Protocol. However, it also argues that several 'systemic' limitations will persist. These include the elusive multilateral consensus on priorities for the unaccomplished reform of the multilateral trading system and, via the mandate of the WTO TRIPS Council, the review of provisions concerning the patentability of plant and animal inventions, the protection of new plant varieties, and the relationship between the TRIPS Agreement and the CBD.[83]

Similarly, there are no compromises within easy reach at the WIPO IGC on IP and genetic resources, traditional knowledge and folklore, including on the subject of its normative work on IP and genetic resources. In an attempt to consider some form of global minimum standards for harmonized patent disclosure requirements, protracted IGC negotiations have now stretched over almost two decades.[84] No significant concessions are in sight, particularly from entrenched corporate interests and opponents in a

[81] See above in this section the discussion on Rule 51*bis* 1(a)(ii) of the PCT Regulations.

[82] On available remedies and sanctions, see Chiarolla & Kılıç, n. 13 above, pp. 39–43.

[83] Art. 27.3(b) TRIPS Agreement.

[84] W. Wendland, 'The Evolution of the IGC from 2001 to 2016: An Insider's Perspective', in Robinson, Roffe & Abdel-Latif (eds), n. 19 above, pp. 31–55.

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few developed countries.[85] Hence, the current top-down approach for such harmonization has not yet fully proven its worth, at least for those countries and stakeholders waiting to achieve, within a reasonable time, a multilateral outcome of a legally binding nature.

However, new global standards of transparency, fairness, equity and justice may already be construed through a bottom-up approach at the national and regional levels. The adoption and diffusion of implementable common standards and 'best practices' concerning the disclosure of genetic resources and associated traditional knowledge in patent applications are crucially important elements in this endeavour. The globalization of such standards and 'best practices' can immediately be brought to fruition by the countries that have already adopted some form of patent disclosure through relatively minor fine tuning of their national disclosure measures.

At present, many pre-Nagoya patent disclosure requirements apply only to genetic resources and traditional knowledge the provenance of which is the same country that established the patent disclosure requirement. Indeed, under the Nagoya Protocol, if a contracting party designates its patent or IP office as a compliance checkpoint under Article 17, then the geographical scope of the requirement should at least encompass all genetic resources originating from any other parties. This relatively simple fine tuning of existing legislation could allow the fulfilling of a core monitoring requirement of the Nagoya Protocol, while also enabling wider synergies with the IP system. The pervasive effects of such bottom-up harmonization[86] and an improved interface with the ABS system, in turn, can ease an effective user-compliance monitoring system for ABS checkpoints and Competent National Authorities in user and provider countries alike.

Efforts to support the implementation of the Nagoya Protocol and related regulatory instruments are well under way at the national level.[87] National and regional level initiatives can provide a powerful impulse for the development of a new generation of patent disclosure requirements that are directly connected to ABS legislation, such as in France[88] and Ethiopia,[89] among others. Likewise, the progressive development and reform of domestic IP systems that have introduced additional disclosure

[85] C. Saez, 'WIPO IP and Genetic Resources Committee Makes Progress Despite Block at End', *Intellectual Property Watch*, 2 July 2018, available at: http://www.ip-watch.org/2018/07/02/wipo-ip-genetic-resources-committee-makes-progress-despite-block-end.

[86] E.g., if additional patent disclosure requirements were more widely introduced via the WIPO PCT system, notably in the national phase, as in the Indian example: see Section 5.2 above.

[87] United Nations Development Programme (UNDP) & Global Environmental Facility (GEF), 'ABS is Genetic Resources for Sustainable Development', 7 Nov. 2018, available at: https://www.undp.org/content/undp/en/home/librarypage/poverty-reduction/abs-is-genetic-resources-for-sustainable-development.html.

[88] Loi n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages, available at: https://www.legifrance.gouv.fr/eli/loi/2016/8/8/2016-1087/jo/texte. See also C. Chiarolla, 'Commentary on the ABS Provisions of the Draft Biodiversity Law of France', in T. Dedeurwaerdere et al. (eds), *Implementing the Nagoya Protocol: Comparing Access and Benefit-Sharing Regimes in Europe* (Brill/Martinus Nijhoff, 2015), pp. 56–76.

[89] Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006 of Ethiopia, Art. 17, available at: https://www.wipo.int/tk/en/databases/tklaws/articles/article_0009.html.

requirements, coupled with duly designed interfaces with international IP treaties, particularly the WIPO PCT system, hold potential for diffusing the effects of any single national disclosure on a much wider scale across multiple jurisdictions. This is because inventions that belong to the same *patent family*,[90] for which an initial single disclosure of origin is triggered, can technically be traced in all countries where a subsequent filing is made. This potentially pervasive effect of disclosure not only supports efforts to monitor user compliance under the Nagoya Protocol, but also enables defensive protection strategies of other provider countries.[91] Such strategies can effectively be used against the misappropriation of genetic resources and traditional knowledge that occurs in any other country – regardless of whether or not such country is a party to the Nagoya Protocol.

A global environmental law practice that aspires to achieve a higher standard of global fairness and justice between countries and with indigenous peoples and local communities is developing progressively. The global environmental law standards of transparency, fairness, equity and global justice, which have emerged in the field of biodiversity law, have exercised an undeniable influence and attraction on the international political discourse in international IP policy making at WIPO and the WTO. However, their impetus has still to travel a long way towards global justice and the realization of more inclusive development pathways for indigenous peoples and local communities (IPLCs) who help us to conserve 80% of biodiversity on our planet.[92] By examining the key challenges and opportunities arising from the implementation of additional patent disclosure requirements, this commentary reaches the conclusion that, in the long run, they are an important technical stepping-stone in helping IPLCs and biodiversity-rich developing countries to benefit from the dividends arising from the commercial use of biodiversity.

[90] European Patent Office, 'Patent Families', available at: http://www.epo.org/searching-for-patents/helpful-resources/first-time-here/patent-families.html ('A patent family is a collection of patent applications covering the same or similar technical content. The applications in a family are related to each other through priority claims').

[91] WIPO, 'Developing a National Strategy on Intellectual Property, Traditional Knowledge and Traditional Cultural Expressions', Background Brief No. 3, 2016, available at: https://www.wipo.int/publications/en/details.jsp?id=3864.

[92] C. Sobrevila, *The Role of Indigenous Peoples in Biodiversity Conservation: The Natural but Often Forgotten Partners* (World Bank, 2008), p. 5, available at: http://documents.worldbank.org/curated/en/995271468177530126/pdf/443000WP0BOX321onservation01PUBLIC1.pdf.