Memorandum

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President/CEO
Public Interest Intellectual Property Advisors, Inc.

From: Joshua Sarnoff
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Re: Compatibility With Existing International Intellectual Property Agreements of Requirements for Patent Applicants to Disclose Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing

REQUEST FOR ANALYSIS

PIIPA has requested a legal analysis that could be made available for use by organizations seeking assistance from PIIPA. Specifically, PIIPA has requested evaluation of the compatibility of provisions that might be adopted in future bilateral or regional free-trade agreements (FTAs) with existing international patent law treaties, in particular the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),[2] the Paris Convention for the Protection of Intellectual Property (Paris Convention)[3], the Patent Cooperation Treaty (PCT),[4] and the Patent Law Treaty (PLT).[5] These FTA provisions would authorize – but would not mandate – national governments to require applicants for patent rights to disclose: (a) the source and origins of genetic resources or traditional knowledge used in developing

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[1] Daniel Gervais, Oslers Professor of Technology Law, Faculty of Law (Common Law), University of Ottawa, and Peter Jaszi, Professor of Law and Director of the IP Clinic provided helpful suggestions, and Elena Chan and Myriah Habeeb, students in the IP Clinic, Edith Deng, Nick Lewis, and Angela Malley, Deans' Fellows in the IP Clinic, and Kali Murray, Venable LLP provided research and analyses.

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, concluded Apr. 15, 1994, effective Jan. 1, 1995, available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

[3] Paris Convention for the Protection of Intellectual Property, concluded Mar. 20, 1883, effective 1884, as revised through July 14, 1967 at Stockholm and as amended Sept. 28, 1979 at Stockholm, available at http://www.wipo.int/clea/docs/en/wo/wo020en.htm.

[4] Patent Cooperation Treaty concluded June 19, 1970, Washington, as amended Sept. 28, 1979 and modified Feb. 3, 1984 and Oct. 3, 2001, effective Apr. 1, 2002, available at http://www.wipo.int/pct/en/texts/pdf/pct.pdf.

[5] Patent Law Treaty, concluded June 1, 2000, Geneva, not yet in force, available at http://www.wipo.int/documents/en/document/pt_dc/doc/pt_dc47.doc.

inventions; and (b) evidence of conformity to national access and benefit-sharing requirements regarding such resources or knowledge that implement the Convention on Biological Diversity (CBD)[6] or the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR)[7] (collectively referred to as CBD disclosures).[8]

SUMMARY OF CONCLUSIONS

The first part of this memorandum identifies the historic context for national laws that require CBD disclosures in patent applications. The analysis discusses the CBD and ITPGR requirements, and addresses positions taken by different countries and legal analyses performed for or by intergovernmental organizations in regard to: the need for CBD disclosure requirements; the need for amendments to international patent treaties to mandate CBD disclosure requirements; and the consistency of CBD disclosure requirements with existing international patent treaties.

The second part of the memorandum analyzes the consistency of national requirements for CBD disclosures with existing international patent treaties. CBD disclosure requirements could take different forms, having a range of potential consequences for the availability, validity, or enforceability of patents on inventions derived from genetic resources or traditional knowledge. Accordingly, the analysis identifies and evaluates a range of different options for such requirements. The analysis focuses on the most stringent requirements, which would result in abandonment of patent applications or denial of patent rights and invalidity or revocation of issued patents for failure to make the required CBD disclosures. The analysis also addresses alternatives having less adverse consequences for patent applications and issued patents, *i.e.,* curable or incurable unenforceability of the patent for failure to make the required CBD disclosures and civil or criminal sanctions imposed externally to patent laws. Finally, the analysis addresses some arguments regarding compatibility of CBD disclosure requirements with requirements for plant breeders' certificates under the Union for the Protection of New Varieties of Plants (UPOV)[9] and with accrual or application requirements for other intellectual property rights. To the extent that there is a need to address such non-patent issues in greater detail, subsequent drafts of this memorandum or additional memoranda may do so.[10]

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[6] Convention on Biological Diversity, opened for signature on June 5, 1992, at the United Nations conference on Environment and Development (the Rio "Earth Summit"), effective Dec. 29, 1993, available at http://www.biodiv.org/convention/articles.asp. Although 188 countries are signatories including the U.S. on June 4, 1993, the U.S. has not ratified the CBD. *See* Parties to the Convention on Biological Diversity/Cartagena Protocol on Biosafety, available at http://www.biodiv.org/world/parties.asp.

[7] International Treaty on Plant Genetic Resources for Food and Agriculture, concluded Rome Nov. 3, 2001, enters into force June 29, 2004, available at http://www.fao.org/ag/cgrfa/itpgr.htm#text.

[8] This discussion does not address policy arguments regarding the desirability of requiring CBD disclosures under domestic legislation, although it reviews various arguments regarding the desirability of mandating CBD disclosures by international agreement.

[9] Union for the Protection of New Varieties of Plants (UPOV), concluded Paris Dec. 2, 1961, entered into force Aug. 10, 1968, as revised at Geneva Nov. 10, 1972, Oct. 23, 1978, and Mar. 19, 1991 (entered into force Apr. 1998), available at http://www.upov.int/en/publications/conventions/index.html.

[10] This memorandum does not address requirements that might be imposed by national legislation of one country that would require other countries to deny or invalidate patents issued by other countries. Similarly, it

Contrary to the suggestions by some countries and some of the conclusions of the legal analyses performed for or by intergovernmental organizations, national requirements for CBD disclosures in patent applications are fully consistent with existing international patent law treaties. Specifically, such requirements should be understood as permissible substantive conditions on entitlement to apply for patent rights and to own patents, designed to prevent misappropriation of genetic resources or traditional knowledge. Nothing in the existing international treaties prohibits such additional substantive conditions of entitlement from being imposed in national patent applications, or from requiring the additional CBD disclosures that relate thereto. Similarly, nothing in those treaties prohibits the denial, invalidation, or unenforceability of issued patents based on the failure to comply with such substantive entitlement requirements or failures to demonstrate such entitlement through CBD disclosures. The arguments that have been advanced regarding inconsistency of CBD disclosure requirements with specific provisions of the TRIPS Agreement, the PCT, and the PLT do not survive close inspection.[11] Most of those arguments would not survive close inspection even if – contrary to this analysis – CBD disclosure requirements were not related to substantive conditions of entitlement. Because CBD disclosure requirements that impose sanctions of denial, invalidity, or revocation of patents are not inconsistent with existing international patent treaties, CBD disclosure requirements that render patents unenforceable or impose extra-patent sanctions also are not inconsistent with those treaties. Accordingly, an FTA that would authorize – but would not mandate – any of these forms of national requirements for CBD disclosures in patent applications should be fully consistent with existing international patent treaties.

Nevertheless, many different methods of implementing CBD disclosure requirements exist, and many different ways exist to characterize these requirements. Some of the implementing methods and characterizations are more likely than others to be viewed as consistent with international patent treaty provisions. It may help to avoid disputes over international patent treaty compliance by expressly adopting CBD disclosure requirements as substantive conditions of entitlement to apply for and own patents, and by assuring that such requirements apply only to national applications or at the national stage for PCT applications. It also may be prudent policy to allow applicants or patentees to cure even intentional failures to make the required CBD disclosures, without resulting in permanent denial of patent rights or in permanent invalidation, revocation, or unenforceability of issued patents.[12] Providing curable sanctions would minimize concerns that animate

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does not address national legislation of one country that would require extraterritorial recognition by other countries of contracts prohibiting application for, issuance, or validity of patents in other countries. In contrast, the analysis assumes that a country will implement requirements to deny or invalidate patents issued in that country based on: the failure to disclose the origins of genetic resources or traditional knowledge of other countries (from which the claimed inventions were derived); the failure to conform to national access and benefit-sharing legislation of other countries; and the recognition and enforcement of contracts regarding access and benefit sharing formed in other countries.

[11] An arguable but readily avoidable conflict of CBD disclosure requirements with PCT Art. 11(1) and PLT Art. 5(1) requirements relating to according filing dates for applications may exist in regard to international applications filed under the PCT system and national or regional applications filed under the PLT.

[12] Prior to issuance, patents could be denied unless and until applicants provided upon request of the patent office the required declarations and evidence, and unless and until the disclosed information were found adequate to demonstrate compliance with applicable access or benefit-sharing requirements of relevant

arguments regarding inconsistency of CBD disclosure requirements with international patent treaty provisions. Curable sanctions also may better assure commercialization of inventions subject to patents, which in turn may better assist countries and indigenous groups that are the intended beneficiaries of the CBD access and benefit sharing requirements.

Finally, as some countries have argued, misappropriation may not be fully prevented unless all parties to international patent treaties are willing to enforce other countries' national legislation implementing CBD access and benefit sharing requirements. The analysis provided here regarding compatibility of national requirements for CBD disclosures with international patent law treaties thus supports and is directly relevant to arguments for proposed patent law treaty amendments to require parties to mandate CBD disclosure requirements in patent applications. Legal analysis of such proposed treaty amendments is beyond the scope of this memorandum.[13]

DISCUSSION

1. Context, Proposals for Treaty Amendments, and Intergovernmental Analyses

1.1. CBD Provisions, Implementation, and Deliberations

1.1.1. Relevant Provisions of the CBD. The CBD was negotiated following world-wide concern over the loss of biological diversity, in the context of recognizing that sovereign nations possess both the right to manage and obligations to conserve and protect their biodiversity. *See, e.g.,* Preamble, ¶¶ 4-6, Arts. 3, 15.1. The objectives of the CBD "are the 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." Art. 1. Of specific relevance here are the objectives of fair and equitable benefit sharing and appropriate access, taking into account rights over the resources in question.

1.1.2. To accomplish the objective of appropriate access, the CBD requires that parties assure that "[a]ccess to genetic resources shall be subject to the prior informed

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countries. Issued patents could be presumed invalid, revocable or unenforceable based on the failure to comply with disclosure requirements in the patent office, subject to administrative or judicial procedures for curing disclosure deficiencies. This memorandum does not address whether to allow CBD disclosures to be based on retrospective authorizations or benefit sharing by applicants or patentees, for claimed inventions that were derived without complying with applicable CBD requirements.

[13] Analysis may be required of international legal principles regarding extraterritorial prescriptive and enforcement jurisdiction and recognition of judgments. Implementing national requirements for CBD disclosures in patent applications based on other countries' access and benefit sharing requirements also may trigger such considerations. These considerations are not avoided by relying on contractual approaches to implementing CBD disclosure requirements. However, sovereignty concerns should be less significant in regard to voluntary decisions by a country to enforce other countries' access and benefit sharing requirements through its patent system, particularly given that patent rights are territorial in scope. This memorandum does not analyze these issues further.

consent of the Contracting Party providing such resources, unless otherwise determined by that Party." Art. 15.5 (emphasis added). "Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article." Art. 15.4. Genetic resources are defined broadly to include biological materials containing hereditary information and having current or potential value.[14] Significantly, a Party providing such resources is defined as a country that supplies the genetic resources, whether or not the resources were originally native to that country.[15] However, for purposes of Article 15, the Party does not provide genetic resources unless it is also the country of origin of the resources or has acquired them consistently with the Convention.[16]

1.1.3. To accomplish the objective of fair and equitable benefit sharing, the CBD requires that Contracting Parties "shall take legislative, administrative or policy measures… with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms." Art. 15.7 (emphasis added). Similarly, the CBD requires that the Parties "shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms." Art. 19.2 (emphasis added).

1.1.4. The CBD recognizes "the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components." CBD, Preamble, ¶ 12. It was understood when negotiating the CBD that traditional and indigenous communities depend upon biological resources and have specialized knowledge of them. *See id.* In further effectuation of the goal of equitable sharing of benefits, the CBD also provides that Contracting Parties shall "respect, preserve and maintain" traditional knowledge of traditional and indigenous communities, and shall "encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations, and practices." Art. 8(j).

1.1.5. The CBD specifically acknowledges the overlap between its objectives and international intellectual property rights, in particular patent rights. The CBD requires that Parties shall provide access to and transfer of technology to developing countries "subject to patents and other intellectual property rights… on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights,"

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[14] "'*Genetic material'* means any material of plant, animal, microbial or other origin containing functional units of heredity. '*Genetic resources'* means genetic material of actual or potential value." Art. 2.

[15] *See* Art. 2 ("Use of Terms"). "'*Country providing genetic resources*' means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country." *Id.* The "Providing Country" is to be distinguished from the "Country of Origin." "'*Country of origin of genetic resources'* means the country which possesses those genetic resources in *in-situ* conditions." *Id.*

[16] "[T]he genetic resources being provided by a Contracting Party… are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention." Art. 15.3.

consistent with additional requirements. Art. 16.2. The most significant of these requirements is that the Parties shall seek to ensure that intellectual property rights support the CBD. "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives." Art. 16.5 (emphasis added). The CBD also provides that its provisions "shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity." Art. 22.1.

1.1.6. <u>Implementation of the CBD Requirements Through Disclosures In Intellectual Property Applications.</u> To effectuate the requirements for access and equitable benefit sharing, many Parties to the CBD have adopted by national legislation requirements for contracts with appropriate authorities and owners of genetic resources or traditional knowledge. The contracts must authorize access to genetic resources and traditional knowledge associated with use of the resources and must share the benefits of commercialization of inventions resulting from such access and/or traditional knowledge.[17] In 1998, the CBD Conference of the Parties (COP) created an Ad-Hoc Open-Ended Inter-sessional Working Group (WG8J) to evaluate mechanisms for implementing Article 8(j), particularly in regard to legal mechanisms to protect traditional knowledge and to assure benefit sharing.[18]

1.1.7. In 2000, the COP created an Ad-Hoc Open-Ended Working Group (WG-ABS) to provide recommendations to the parties on legislative, administrative, and policy measures to implement various provisions of the CBD (including Articles 8(j), 15, and 16) and to specify approaches to prior informed consent for access and to mechanisms for

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[17] *See, e.g.,* CBD COP 3, Decision III-15, Art. 1.(a), available at http://www.biodiv.org/doc/decisions/COP-03-dec-en.pdf (encouraging submission of country reports on adopted measures) (1996); Andean Community, Decision 391, Common Regime on Access to Genetic Resources (Decision 391), concluded Caracas, July 2, 1996, ¶ available at http://www.comunidadandina.org/ingles/treaties/dec/d391e.htm. Although the U.S. has not ratified the CBD, various agencies of the U.S. Government have developed guidelines or memoranda of understanding for funding that requires funded researchers to act consistently with the CBD access and benefit sharing requirements. *See, e.g.,* CBD UNEP/CBD/WG-ABS/2/INF/1, Compilation of Submissions on Access and Benefit Sharing As Related to Genetic Resources Received by the Secretariat Pursuant to Decisions IV/24 A-D of the Conference of the Parties, at 145-205, available at http://www.biodiv.org/doc/meetings/abs/abswg-02/information/abswg-02-inf-01-en.pdf (Submission of United States, including National Cancer Institute and U.S. Department of Agriculture, Agriculture Research Service model contractual agreements with foreign research partners, and National Institute of Health principles for accessing genetic materials).

[18] *See* CBD COP 4, Decision IV/9, ¶ 1, available at http://www.biodiv.org/doc/meetings/cop/cop-04/official/cop-04-11-en.pdf. *See also* CBD COP 5, Decision V/16, Annex, Task 12, available at http://www.biodiv.org/doc/decisions/COP-05-dec-en.pdf (adopting a program of work for the TK Working Group to develop guidelines to implement Article 8(j), containing definitions and provisions to safeguard traditional knowledge for indigenous and local communities); CBD COP 3, Decision III/14, ¶¶ 7, 10(a) available at http://www.biodiv.org/doc/meetings/cop/cop-03/official/cop-03-38-en.pdf (encouraging an inter-sessional process to produce a report on linkages between Article 8(j) and intellectual property rights); *id.,* Decision III/15, ¶ 8 (encouraging cooperation with WTO to explore linkages of Article 15 with the TRIPS agreement).

benefit sharing.[19] The COP also invited the WTO to "take into account" and "further explore" the interrelationship between the CBD and TRIPS.[20] In 2001, the Executive Secretary prepared a report reflecting the analysis of a Panel of Experts on Access and Benefit-Sharing (Experts Panel) on the role of intellectual property rights (Secretary's IP Report).[21] The Secretary's IP Report noted that the Experts Panel at its first meeting had not been able to reach conclusions about the role of intellectual property rights, although it had suggested that "'[i]ntellectual property rights application procedures could require that the applicant submit evidence of prior informed consent…. [to] create incentives for users to effectively comply with obligations to seek prior informed consent."[22] At its second meeting, the Experts Panel had suggested that "introducing requirements into existing intellectual property rights procedures, such as in the filing of patent applications… may be a possible way to track compliance with prior informed consent and mutually agreed terms on the basis of which access was granted."[23] The Secretary's IP Report also recognized that disclosure of origins of genetic resources and/or traditional knowledge related to claimed inventions in patent applications may be required to evaluate the state of prior art to determine if the invention is patentable.[24] The Experts Panel was aware, however, that disclosure of origins sometimes but not always was required to comply with traditional patent application disclosure requirements.[25]

1.1.8. In 2001, the WG-ABS met in Bonn, Germany and issued a report on implementing the access and benefit sharing provisions, for adoption at the sixth meeting of the COP.[26] The Report contained draft guidelines for legislative, administrative, or policy measures to implement the CBD access and benefit sharing requirements.[27] The Report also contained a proposed recommendation for the COP to encourage Parties and other governments to require disclosure of the origins of genetic resources or of traditional

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[19] *See* CBD COP 5, Decision V/26, Access to genetic resources, A. Access and benefit-sharing arrangements, ¶ 11, available at http://www.biodiv.org/doc/decisions/COP-05-dec-en.pdf.

[20] *See id.*, B. The relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention on Biological Diversity, ¶ 2.

[21] CBD, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, Report on the Role of Intellectual Property Rights in the Implementation of Access and Benefit Sharing Arrangements, UNEP/CBD/WG-ABS/1/4, available at http://www.biodiv.org/doc/meetings/abs/abswg-01/official/abswg-01-04-en.pdf.

[22] *Id.*, ¶¶ 1, 7, 10 (citing Report of the Panel of Experts on Access and Benefit Sharing, UNEP/CBD/COP/5/8, ¶¶ 127-38, and quoting ¶ 127, available at http://www.biodiv.org/doc/meetings/cop/cop-05/official/cop-05-08-en.pdf).

[23] *Id.*, ¶ 15 (quoting UNEP/CBD/WG-ABS/1/2, ¶ 77(a), available at http://www.biodiv.org/doc/meetings/abs/abswg-01/official/abswg-01-02-en.pdf).

[24] *See id.*, ¶ 33 (citing UNEP/CBD/WG-ABS/1/2, ¶ 77(c)).

[25] *See, e.g.,* UNEP/CBD/COP/4/INF.30, Patents Using Biological Source Material (I) and Mention of the Country of Origin in Patents Using Biological Source Material, reproduced in WIPO/GRTKF/IC/2/15, Annex, at 2, available at http://www.wipo.int/documents/en/meetings/2001/igc/pdf/grtkfic2_15.pdf (information submitted by Delegation of Spain, noting that disclosure of place of origin is not specified in patents if plant source material is widespread, but is specified where the plant is " 'rare'" or " 'exotic.'").

[26] *See* Report of the Ad-Hoc Open-Ended Working Group on Access and Benefit Sharing, UNEP/CBD/COP/6/6, available at http://www.biodiv.org/doc/meetings/cop/cop-06/official/cop-06-06-en.pdf.

[27] *See id.*, Annex, Recommendations Adopted by the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing, Recommendation 1, Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.

knowledge in applications for intellectual property rights, where the invention concerned or made use of the genetic resources or traditional knowledge in its development.[28] Similarly, a report by the WG8J recommended disclosing traditional knowledge and taking into account CBD provisions for prior informed consent and mutually agreed terms in applications for intellectual property rights.[29]

1.1.9. In 2002, at its sixth meeting, the CBD COP adopted the Bonn Guidelines.[30] The COP also adopted the WG-ABS recommendations to encourage countries to require disclosure of origins of genetic resources and traditional knowledge, and for the World Intellectual Property Organization (WIPO) to analyze the consistency of such disclosure requirements with international agreements.[31] In Decision VI/24C, the COP "1. *Invite[d]* Parties and Governments to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted; 2. *Also invite[d]* Parties and Governments to encourage the disclosure of the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge in its development."[32]

1.1.10. The Bonn Guidelines expressly "encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights."[33] The Guidelines similarly urge consideration of "[m]easures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting

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[28] *Id.,* Recommendation 3, Role of intellectual property rights in the implementation of access and benefit-sharing arrangements, ¶¶ 1, 2. The Report also recognized concerns over consistency of such requirements with existing international obligations and requested that WIPO provide a technical report on such consistency. *See id.*, ¶¶ 3, 4.

[29] *See* CBD, Report of the Ad-Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and related provisions of the Convention on Biological Diversity on the Work of its Second Meeting, UNEP/CBD/COP/6/7, Annex 2/6, Assessment of the effectiveness of existing subnational, national and international instruments, particularly intellectual property rights instruments, that may have implications for the protection of the knowledge, innovations and practices of indigenous and local communities, ¶¶ 18, 19, available at http://www.biodiv.org/doc/meetings/cop/cop-06/official/cop-06-06-en.pdf.

[30] *See* CBD COP 6, Decision VI-24, Access and Benefit Sharing as Related to Genetic Resources, A. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of Their Utilization (Bonn Guidelines), available at http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf.

[31] *See* CBD COP 6, Decision VI-24, Access and Benefit Sharing as Related to Genetic Resources, C. Role of intellectual property rights in the implementation of access and benefit-sharing arrangements, ¶¶ 1-4, available at http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf.

[32] *Id.*, ¶¶ 1, 2 (emphasis added).

[33] CBD COP 6, Decision VI-24, Access and Benefit Sharing as Related to Genetic Resources, A. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of Their Utilization (Bonn Guidelines), Annex, II. Roles and Responsibilities in Access and Benefit Sharing Pursuant to Article 15 of the Convention on Biological Diversity, C. Responsibilities, ¶ 16(d)(ii), available at http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf.

Party providing such resources."[34] The Guidelines suggest "establishing requirements regarding: (a) Reporting; and (b) Disclosure of information," and Parties may include national monitoring of "[a]pplications for intellectual property rights relating to the material supplied."[35] The Guidelines "should be applied in a manner that is coherent and mutually supportive of the work of relevant international agreements and institutions."[36] Finally, the Bonn Guidelines recognize that implementing the mutually agreed terms for benefit sharing should consider "[t]he possibility of joint ownership of intellectual property rights according to the degree of contribution."[37]

1.1.11. Country Submissions and CBD Evaluations of Compatibility of CBD Disclosures with International Intellectual Property Treaties. Following adoption of the Bonn Guidelines, the CBD Executive Secretary compiled submissions from countries on implementation, and commissioned a consultant's report on implementation issues relating to disclosure of origins in intellectual property applications.[38] The Consultant Report is discussed in detail here, but not because it constitutes an authoritative interpretation of the consistency of CBD disclosure requirements with international patent law treaties. Rather, it is discussed because it was produced at the request of the CBD, provides additional information regarding implementation of CBD disclosure requirements, and identifies relevant provisions of patent law treaties and arguments supporting compatibility or suggesting incompatibility of CBD disclosure requirements, which are addressed in the later analysis section.[39]

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[34] *Id.,* ¶ 16(d)(iii).

[35] *Id.,* V. Other Provisions, B. Accountability in implementing access and benefit-sharing arrangements, ¶ 53, C. National monitoring and reporting, ¶ 55(c). The guidelines also recognize for verification "[a] system of voluntary certification…. that the access and benefit-sharing provisions have been complied with," and that "Parties may take appropriate effective and proportional measures for violations of … measures implementing" the CBD requirements. *Id.*, D. Means for verification, ¶ 58, F. Remedies, ¶ 61.

[36] *Id.*, I. General Provisions, D. Relationship with relevant international regimes, ¶10.

[37] *Id.*, IV. Steps in the Access and Benefit Sharing Process, D. Mutually Agreed Terms, ¶ 43(d). Further, in implementing mutually agreed terms, users should "[m]aintain all relevant data regarding the genetic resources, especially documentary evidence of the prior informed consent and information concerning the origin and use of genetic resources and the benefits arising from such use." *Id.* II. Roles and Responsibilities in Access and Benefit Sharing Pursuant to Article 15 of the Convention on Biological Diversity, C. Responsibilities, ¶ 16(b)(vi).

[38] *See* CBD UNEP/CBD/WG-ABS/2/INF/1, Compilation of Submissions on Access and Benefit-Sharing as Related to Genetic Resources Received by the Secretariat Pursuant to Decisions VI/24 A-D of the Conference of the Parties, available at http://www.biodiv.org/doc/meetings/abs/abswg-02/information/abswg-02-inf-01-en.pdf. CBD UNEP/CBD/WG-ABS/2/INF/2, Measures, Including Consideration of their Feasibility, Practicality and Costs, to Support Compliance With Prior Informed Consent of the Contracting Party Providing Genetic Resources and Mutually Agreed Terms on Which Access Was Granted in Contracting Parties With Users of Such Resources Under Their Jurisdiction, Disclosure of origin and prior informed consent for applications of intellectual property rights based on genetic resources: a technical study of implementation issues, available at http://www.biodiv.org/doc/meetings/abs/abswg-02/information/abswg-02-inf-02-en.pdf (Consultant Report).

[39] The Consultant Report also addresses: the utility of CBD disclosures in assisting administrative evaluations of substantive patentability criteria (including identification of prior art and inventorship); the relation of CBD disclosures to traditional patent policies; concerns regarding over-extension of examiner capabilities; benefits and limitations of adopting CBD disclosures in patent systems; and methods of implementing an international certificate of origin. *See* Consultant Report, Sections IV-VI. Most of the exposition either is not relevant to the analysis of compatibility of CBD disclosures with treaty obligations or is similar to analyses of benefits and burdens of CBD disclosures provided by various countries and summarized elsewhere in this

1.1.12. In its submission to the CBD, the European Communities expressed the view that disclosure of origin requirements for genetic resources and traditional knowledge in intellectual property applications – as well as requirements for evidence of conformity to access and benefit-sharing requirements – are compatible with the TRIPS Agreement, "so long as the requirement does not constitute a patentability criterion and has no bearing on the patentability of the invention or the validity of the patent."[40] "[M]aking the patentability of an invention subject to the respect of a requirement to disclose… in cases where this information is not required under Art. 29.1 [of] TRIPS… constitutes a clear step beyond the current provisions of the TRIPS Agreement."[41] Accordingly, the European Communities recommended international adoption of a "self-standing" disclosure requirement for intellectual property applications that "should not act, de facto or de jure, as an additional formal or substantial patentability criterion."[42] Switzerland submitted a proposal to amend the PCT to authorize such disclosures,[43] which is discussed below in WIPO section. Mexico submitted a proposal for an international "certificate of legal origin," that would "contain information on the origin of genetic resources and related

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memorandum. Of particular importance, however, the Report notes that evidence of informed consent will rarely if ever be relevant to evaluations of substantive patentability (except possibly as a best mode disclosure if access to the resource is restricted). *See id.*, ¶ 4.2.4. The Report also notes that disclosure of origins of biological materials may sometimes be relevant to determining inventorship, but that patent offices rarely challenge claims of inventorship, particularly when supported by affidavits and in the absence of publications demonstrating the named inventor's derivation of the invention from another. *See id.*, ¶ 4.2.12 (citing United States Patent and Trademark Office Manual of Patent Examining Procedure (MPEP), §§ 602, 7.16(10, and 2137, 7.16 (8th ed. 2001), and European Patent Office Guidelines for Examination 5.2, Rule 17(2)). Although the relation between the improperly accessed genetic resources and the claimed invention and inventorship may be remote, it is directly relevant to entitlement (as discussed below in the analysis section). Disclosure of origins of traditional knowledge leading to an invention also is directly relevant to entitlement, and is more likely to be relevant to inventorship. The Report does not address practical considerations in determining entitlement of the applicant. National patent offices rarely evaluate substantive entitlement of the applicant, so long as formal assignments have been properly registered. *See, e.g.,* MPEP § 324 (8th ed. 2001) (discussing the need of assignees, in order to prosecute applications, to establish ownership to the satisfaction of the Commission under 37 C.F.R. § 3.73(b), by recording documentary evidence of a chain of title and providing a statement regarding where that evidence is found; noting that proof of ownership is not required for various application-related actions; and instructing examiners to rely for proof of ownership on the last submitted statement, unless there are conflicting statements of different parties in the record). Further, civil or criminal penalties for making false statements deter filing of false chain of title documents. *See, e.g.,* 18 U.S.C. § 1001 ("Statements or entries generally. (a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully: (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry; shall be fined under this title or imprisoned not more than 5years, or both.").

[40] CBD UNEP/CBD/WG-ABS/2/INF/1, at 103 (reproducing Communication from the European Communities), ¶ 48.

[41] *Id.,* at 104, ¶ 48.

[42] *Id.,* at 105, ¶ 55 (emphasis omitted). In this regard, Norway submitted information that it had adopted such a requirement, which "does not affect the handling of a patent application or the validity of a patent." *Id..,* at 115 (Communication from Norway).

[43] *See id.*, at 125-26 (Communication from Switzerland).

traditional knowledge and proof of prior informed consent with respect to the material accessed and related traditional knowledge, innovations and practices."[44]

1.1.13. The Consultant Report noted three general reasons for requiring enhanced disclosures in patent applications: strengthening intellectual property rights; preventing improper patents from issuing for biological materials by improving examination of (and identifying relevant sources of information regarding) substantive patentability criteria; and equitably remedying a lack of informed consent in the provision of genetic resources or assuring benefit sharing of the commercial rewards of those resources.[45] The Consultant Report concluded that a mandatory requirement for enhanced disclosures in patent applications – defined as a requirement "pursuant to which noncompliance results in *loss of patent,*" – "would be most problematic because of its likely inconsistency with the minimum requirements for patentability under TRIPS. In addition, even an optional requirement [where no patent or other sanctions accrue] might be problematic if it altered the examination of patents or resulted in discrimination as to field of technology."[46] Although within the scope of equitable considerations, the Consultant's Report did not address misappropriation of genetic resources or traditional knowledge and the relation of misappropriation to substantive criteria for entitlement to patents, nor whether intellectual property treaties limit national legislation addressed to substantive criteria of entitlement.

1.1.14. The Consultant Report further suggested that "[b]ecause TRIPS is considered to be an absolute minimum below which member states can not fall, patents *must* issue if they satisfy the requirements of TRIPS (unless TRIPS specifically permits an exception). Accordingly, if an enhanced disclosure requirement would bar the issuance of patents that presently satisfy the TRIPS criteria, there would seem to be an inconsistency."[47] Specifically, the Consultant Report concluded that mandatory CBD disclosure requirements that result in denial or invalidity of patents are inconsistent with TRIPS Arts. 27.1 and 29, because (and to the extent that) Art. 27.3(b) permissive exclusions from patent availability and Art. 29 permissive authorizations for additional disclosure requirements (in addition to the mandatory requirement for disclosure of information relating to substantive conditions of patentability) would not apply.[48] In contrast, the Consultant Report concluded that such CBD disclosure requirements are not

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[44] *See* CBD UNEP/CBD/WG-ABS/2/2, Further Consideration of Outstanding Issues Related to Access and Benefit Sharing: Use of Terms, Other Approaches and Compliance Measures, at ¶ 42, available at (citing CBD UNEP/CBD/WG-ABS/2/INF/1, at 113-14 (Communication from Mexico)). The Certificate could be issued by a competent national authority in a provider country, and would then allow other countries to recognize the adequacy of the demonstrations of source of origin and compliance with access and benefit-sharing requirements of the provider country "without the need for any additional verification process." *Id.,* ¶ 45. The international certification system would likely require national legislation and international harmonization, e.g., of minimum criteria and model certification documents. *See id.*, ¶¶ 46-48.

[45] *See* CBD UNEP/CBD/WG-ABS/2/INF/2, ¶¶ 2.2.1-2.2.6.

[46] *Id.,* Executive Summary, at 5.

[47] *Id.,* ¶ 3.1.11 (citing Nuno Pires de Carvalho, *Requiring Disclosure of Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution,* 2 Wash. U. J.L. & Pol'y 371, 394-96 (2000) (*Requiring Disclosure of Origin*), and Graham Dutfield, *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation* (2002), at 25, available at http://www.ictds.org/unctad-ictsd/docs/Dutfield2002.pdf) (*Protecting Traditional Knowledge*).

[48] *See id.*, ¶¶ 3.1.12-3.1.17.

discriminatory within the meaning of the Art. 27.1 prohibition on discrimination by field of technology, so long as the language of the CBD disclosure requirements is facially neutral and "'[s]o long as the broader application is not a sham.'"[49] In regard to TRIPS Art. 62.1, which permits member countries to impose "reasonable procedures and formalities" on patent application and maintenance, the Consultant Report noted the potential for inconsistency to the extent such procedures are not "'*tied to valid reasons required to ensure a proper examination.*'"[50] The Consultant Report also noted arguments that an enhanced disclosure requirement may be supported by TRIPS Arts. 7 and 8, given that: all TRIPS provision are to be read in light of these articles[51]; enhanced disclosure requirements would assist in ensuring that intellectual property rights "'should contribute to … social and economic welfare'"[52]; and such requirements may constitute permissible "'measures … to promote the public interest in sectors of vital importance'" to members.[53]

1.1.15. The Consultant Report also addressed consistency of enhanced disclosure requirements with the WIPO-administered patent treaties.[54] The Consultant Report noted that PCT Art. 27(1) prohibits parties from imposing requirements relating to the "'form and contents' of international applications, other than those explicitly set forth under the PCT."[55] The Report similarly noted that under PLT Art. 6(1) parties "are forbidden from requiring compliance [in national and regional applications subject to the PLT] with the form and contents of international applications that conflict with the PCT."[56] The Report also recognized that the PCT and the PLT do not prohibit members from establishing substantive patentability requirements.[57] The Report concluded that permissibility of enhanced disclosure requirements therefore depends on whether they constitute a "'substantive condition of patentability'" or "relate[] to the 'form and contents.'"[58]

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[49] *See id.,* ¶¶ 3.1.22-3.1.23 (quoting Canada – Term of Patent Protection, Report of the Panel, WT/DS170/R, ¶ 7.104 (May 5, 2000), and citing *id.,* ¶¶ 7.99-7.105)).
[50] *See id.*, ¶¶ 3.1.19-3.1.21 (quoting Canada – Term of Patent Protection, Report of the Panel, WT/DS170/R, ¶ 6.115 (May 5, 2000), and Nuno Pires de Carvalho, THE TRIPS REGIME OF PATENT RIGHTS, at 155, ¶ 27.21 (2002) (THE TRIPS REGIME OF PATENT RIGHTS).
[51] *See id.*, ¶ 3.1.25 (citing, inter alia, WTO WT/MIN(01)/DEC/2, Declaration on the TRIPS Agreement and Public Health, ¶ 5(a), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. *See also* WTO WT/MIN(01)/DEC/1, Doha Ministerial Declaration, ¶ 19, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (directing the TRIPS Arts. 27.3(b) and 71.1 reviews to proceed in light of the objectives of TRIPS Arts. 7 & 8).
[52] *See id.* (quoting WTO IP/C/W/403, The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge (Communication by Brazil on behalf of Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, and Venezuela), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm).
[53] *See id.* (quoting THE TRIPS REGIME OF PATENT RIGHTS, at 159 n.445).
[54] The Consultant Report also noted that the draft Substantive Patent Law Treaty contains a proposal that would expressly authorize such requirements. *See id.,* ¶¶ 3.1.34-3.1.35 (quoting WIPO SCP/9/2, Draft Substantive Patent Law Treaty, Arts. 13(2), 14(2) (grounds for refusal or invalidation, including "'*requir[ing] compliance with the applicable law on ….. access to genetic resources.*") (emphasis omitted).
[55] *See id.*, ¶ 3.1.40 (citing PCT Art. 27(1)).
[56] *Id.* (citing PLT Art 6(1)).
[57] *See id.*, ¶ 3.1.41 (citing PCT Art. 27(5) and PLT Art. 2(2)).
[58] *Id.*, ¶ 3.1.42 (citing Nuno Pires de Carvalho, *From Shaman's Hut to the Patent Office: In Search of Effective Protection for Traditional Knowledge,* at 45-47, available at http://law.wustl.edu/centeris/Confpapers/PDFWrdDoc/Fromshaman2.pdf, and WTO IP/C/W/400, Article

However, the Report also indicated that PCT Art. 27(2) permits applicants to provide in international applications additional supporting material to comply with required declarations of inventorship and "any document that relates to the applicant's entitlement to apply for a patent," and authorizes requirements for additional documentation at the national stage to prove allegations or statements made in the international stage.[59]

1.1.16. Finally, the Consultant Report addressed consistency of enhanced disclosure requirements with the UPOV Convention. Specifically, the Report suggested that UPOV requires plant variety certificates to issue if the technical requirements of novelty, distinctness, uniformity, and stability have been satisfied.[60] The Report also notes provisions of the UPOV Convention that preclude the breeder's right from being subject to any additional substantive conditions, although they do not prohibit national requirements relating to compliance with formalities.[61] Similarly, the Report notes provisions of the UPOV Convention that preclude certificates from being annulled or cancelled except on the specific grounds identified in the Convention.[62] The Report does not offer an opinion regarding whether CBD disclosure requirements are consistent with the UPOV Convention, but may imply that they are not to the extent they establish additional substantive conditions for plant variety certificates. Similarly, the Report notes the UPOV Secretariat's support for disclosures when necessary to provide information concerning the breeding history and genetic origin of the variety, and statement that "UPOV could '*not accept*

27.3(b), The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge (Communication from Switzerland), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1).

[59] *Id.,* ¶ 3.1.43 (citing PCT Art. 27(2) & PCT Rules 4.17(i)&(iv)).

[60] *See id.*, ¶ 3.2.8 (citing 1978 UPOV Art. 6 and 1991 UPOV Art. 5); 1978 UPOV Art. 6 ("The breeder shall benefit from protection provided for in this Convention when the following conditions are satisfied," *i.e.,* that the plant breed is (a) distinct from other varieties that are common knowledge at the time of protection, (b) not previously offered for sale under various conditions, (c) sufficiently homogeneous, (d) stable, and (e) given a denomination under Art. 13); 1991 UPOV Art. 5(1) ("[*Criteria to be satisfied]* The breeder's right shall be granted where the variety is (i) new, (ii) distinct, (iii) uniform, and (iv) stable.").

[61] *See* Consultant Report, ¶ 3.2.9 (citing 1978 UPOV Art. 6 and 1991 UPOV Art. 5); 1978 UPOV, Art. 6(2) ("Provided that the breeder shall have complied with the formalities provided for by the national law of the member State of the Union in which the application for protection was filed … the grant of protection may not be made subject to conditions other than those set forth above."); 1991 UPOV Art. 5(2) ("[Other Conditions] The grant of the breeder's right shall not be subject to any further or different conditions, provided that … the applicant complies with the formalities provided for by the law of the Contracting Party with whose authority the application has been filed ….").

[62] *See* Consultant Report, ¶ 3.2.9 (citing 1978 UPOV Art. 10(4) and 1991 UPOV Arts. 21(2) & 22(2)); 1978 UPOV Art. 10 (certificates "shall" be declared null and void if (1) they did not meet the conditions of Art. 6(a) or (b) at the time of issue, (2) the breeder is unable to provide the material, or (3) does not provide the material or documentation or allow inspection on request or fails to pay fees, and "(4) The right of the breeder may not be annulled or become forfeit except on the grounds set out in this Article."); 1991 UPOV Art. 21 (certificates "shall" be declared null and void (1) if they did not meet the conditions (i) of Art. 6 novelty or Art. 7 distinctness or (ii) Art. 8 uniformity or Art. 9 stability at the time of grant, and "(iii) that the breeder's right has been granted to a person who is not entitled to it, unless it is transferred to the person who is so entitled. (2) [*Exclusion of other reasons*] No breeder's right shall be declared null and void for reasons other than those referred to in paragraph (1)"); 1991 UPOV Art. 22 (certificates (1) "may" be cancelled (a) if Art. 8 uniformity or Art. 9 stability criteria are not longer met or (b) if the breeder (i) does not provide "information, documents or material" to verify the variety on request, (ii) fails to pay fees, or (iii) does not propose another suitable denomination if the original denomination is cancelled, and "(2) [*Exclusion of other reasons*] No breeder's right shall be cancelled for reasons other than those referred to in paragraph (1).").

[disclosure of countries of origin or geographical origin of genetic resources] *as an additional condition of protection.*'"[63]

1.1.17. The CBD Executive Secretary also summarized issues relating to the role of intellectual property rights in CBD implementation, including disclosure of origin requirements in intellectual property applications, that were raised in country submissions, in the Consultant Report, and in a WIPO Technical Report that the CBD had requested (which is discussed below in the WIPO section).[64] The summary concluded that "[c]onsistency with international legal obligations will likely depend on the type of disclosure requirement established," and that an enhanced disclosure requirement (resulting in denial or invalidity of patents for failure to comply) would be more likely to be inconsistent.[65]

1.2. FAO ITPGR Provisions and Implementation.

1.2.1. Access and Benefit Sharing Requirements of the ITPGR. In 2001, the Food and Agriculture Organization (FAO) adopted the ITPGR. The ITPGR has as its objectives "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security." Art. 1.1. The ITPGR requires protection of Farmers' Rights and recognizes "the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments." Art. 9.2. Accordingly, the ITPGR requires that Parties "should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including: (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture." Art. 9.2(a)-(c).

1.2.2. The ITPGR also creates a multilateral system of access and benefit sharing for a specified list of plant genetic resources identified in Annex I and possessed by the Parties or contained in ex-situ collections of the International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR). *See* Arts.

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[63] *See* CBD UNEP/CBD/WG-ABS/2/INF/2, ¶ 3.2.9 (quoting WTO IP/C/W/347/Add.3, Review of the Provisions of Article 27.3, Relationship Between the TRIPS Agreement and the Convenetion on Biological Diversity and Protection of Traditional Knowledge and Folklore, Information from Intergovernmental Organizations, Addendum, International Union for the Protection of New Varieties of Plants (UPOV), at 4 (¶ 20), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1).

[64] *See* CBD UNEP/CBD/WG-ABS/2/3, The Role of Intellectual Property Rights in Access and Benefit Sharing Arrangements, Including National and Regional Experiences, available at http://www.biodiv.org/doc/meetings/abs/abswg-02/official/abswg-02-03-en.pdf (citing CBD UNEP/CBD/WG-ABS/2/Inf/2 and CBD UNEP/CBD/WG-ABS/2/Inf/4, available at http://www.biodiv.org/doc/meetings/abs/abswg-02/information/abswg-02-inf-04-en.pdf (reproducing WIPO WO/GA/30/7, Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, available as WIPO/GRTKF/IC/5/10, available at http://www.wipo.int/documents/en/meetings/2003/igc/pdf/grtkf_ic_5_10.pdf).

[65] *See* CBD UNEP/CBD/WG-ABS/2/3, at ¶ 72.

11.1, 11.2, 11.5.[66] The multilateral system is to provide facilitated access to the applicable plant genetic resources. Arts. 12.1, 12.2. Such access is subject to strict conditions under standard material transfer agreements (MTAs). Arts. 12.3, 12.4. "Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System." Art. 12.3(d). "Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws." Art. 12.3(f). Further, Art. 12.5 requires Parties to "ensure that an opportunity to seek recourse is available, consistent with applicable jurisdictional requirements, under their legal systems, in case of contractual disputes arising under such MTAs, recognizing that obligations arising under such MTAs rest exclusively with the parties to those MTAs."

1.2.3. The ITPGR also requires multilateral benefit sharing within the Multilateral System, including "the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization." Arts. 13.1, 13.2. "Access to these technologies, improved varieties and genetic material shall be provided and/or facilitated, while respecting applicable property rights and access laws, and in accordance with national capabilities," and payments "shall" be made to an international fund established under the Multilateral System under Art. 19.3f,[67] of "an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment." Art. 13.2(b)(i) & (d)(ii). Art. 21 requires the Governing Body of the ITPGR to "consider and approve cooperative and effective procedures and operational mechanisms to promote compliance with the provisions of this Treaty and to address issues of non-compliance."

1.2.4. Disclosure of Origin Requirements for Plant Genetic Resources Subject to the ITPGR. The first meeting of the Commission on Genetic Resources for Food and Agriculture (acting as the Interim Committee for the ITPGR) created an Open-Ended Expert Working Group to address procedures for compliance with the access and benefit sharing arrangements of the ITPGR, including terms for MTAs.[68] The FAO then solicited views of States on such procedures.[69] The United States has expressed its view that the compliance procedures of Art. 21 should not address non-compliance with specific MTAs.[70]

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[66] Art. 15.1 calls upon the IARCs to sign agreements to make their *ex situ* collections of plant genetic resources available under the terms of the Multilateral System.

[67] Art. 19.3(f) provides for the Governing Body of the ITPGR to "establish, as needed, an appropriate mechanism, such as a Trust Account, for receiving and utilizing financial resources."

[68] FAO, CGRFA-MIC-1/02/REP, First Meeting of the Commission on Genetic Resources for Food and Agriculture acting as Interim Committee of the International Treaty on Plant Genetic Resources for Food and Agriculture, ¶ 13, available at ftp://ext-ftp.fao.org/ag/cgrfa/mic1/m1repe.pdf.

[69] *See* FAO LE-67, International Treaty on Plant Genetic Resources For Food and Agriculture, Effective Procedures and Operational Mechanisms to Promote Compliance with the Treaty, at 2, available at ftp://ext-ftp.fao.org/ag/cgrfa/CSLs/compliance.E.pdf.

[70] *See* Communication of United States, available at http://www.fao.org/ag/cgrfa/compliance.htm#usa.

1.2.5. The IPGTR prohibits intellectual property protection on genetic resources in the form received from the multilateral system.[71] Nevertheless, plant genetic resources from the multilateral system may be the source of origin or of knowledge leading to inventions that may become the subject of intellectual property protection. The prohibition on intellectual property rights thus may conflict with Art. 27.3 of the TRIPS Agreement, because the IPGTR prohibition is not limited to exclusions from patent protection and TRIPS requires at least *sui generis* protection of plant varieties.[72] However, the ITPGR Preamble states that "nothing in this Treaty shall be interpreted as implying in any way a change in the rights and obligations of the Contracting Parties under other international agreements."[73] Unlike the CBD, the ITPGR post-dates the TRIPS Agreement and other relevant intellectual property law treaties, and thus the ITPGR provisions should control in the event of a conflict.[74]

1.2.6. Disclosure in patent applications or applications for plant breeders' certificates under the UPOV Convention of the source of origins of plant genetic resources from which new breeds are derived, and of evidence of compliance, may lead to greater compliance with multilateral system access and benefit sharing requirements. Such disclosures also may assist enforcement of the prohibition on acquiring intellectual property rights in multilateral system source materials and – as with disclosures relating to CBD access requirements – may prevent intellectual property rights on plant genetic resources derived from source materials misappropriated in violation of MTAs.

1.3. WIPO Deliberations.

1.3.1. Country Proposals and WIPO Evaluations and Analyses of Proposals for CBD Disclosures in Patent Applications. WIPO has addressed the issue of disclosing the origin of genetic resources in patent applications since 1998.[75] In the context of negotiating the draft PLT in 1999, the Delegation of Columbia proposed to require countries to guarantee protection of biological and genetic heritage, by making patents or registrations "that relate to elements of that heritage" conditional on "their having been

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[71] *See* ITPGR, Art. 12.3(d) ("Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System"). The scope of the prohibition on acquiring intellectual property rights is subject to dispute, particularly in regard to whether isolated or purified genetic resources obtained from the multilateral system are patentable under the ITPGR. *See, e.g., See* FAO Legal Papers Online #31, Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments., at § 4.3.2.4, available at http://www.fao.org/Legal/Prs-OL/lpo31.pdf.

[72] *Cf.* TRIPS, Art. 27.3(b) (Parties may exclude from patent protection "(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."). Another potential conflict is the requirement to assure benefit sharing in regard to commercialization of inventions resulting from source materials provided by the multilateral system, which may be thought to discriminate by field of technology in the enjoyment of patent rights in violation of Art. 27.1 of TRIPS. *See* FAO Legal Papers Online #31, at § 4.3.3.2. The Art. 27.1 prohibition against discrimination is addressed in the analysis section below.

[73] ITPGR, Preamble, § 10.

[74] *See* Vienna Convention on the Law of Treaties, May 23, 1969, Arts. 31(2) & (3), 1155 U.N.T.S. 331.

[75] *See* CBD COP 6, Decision VI-24, ¶ 94.

acquired legally."[76] Further, each patent application or registration would be required to "specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin."[77] (Following the Columbian Proposal, the Andean Community adopted requirements for such disclosures.[78]) The WIPO Standing Committee on the Law of Patents (SCP) noted opposition to the proposal (because the PLT negotiations were not addressed to substantive measures) and recommended that the issue be addressed at the 1999 meeting of the Working Group on Biological Inventions and at a subsequent meeting specific to the topic.[79] WIPO held the special meeting addressing these issues in April 2000, following which Diplomatic Conference negotiating the Patent Law Treaty recommended continued discussions and the Director General proposed to create a special committee – the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC) – which proposal the WIPO General Assembly (GA) subsequently adopted.[80]

1.3.2. Following a request from the CBD COP to WIPO,[81] the IGC developed and WIPO transmitted to the CBD a draft technical study of disclosure of origins of genetic resources and traditional knowledge and evidence of compliance with access and benefit sharing requirements, and their relationship to international intellectual property agreements (Technical Study).[82] The Technical Study is discussed in detail here, but not

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[76] WIPO, SCP/3/10, Protection of Biological and Genetic Resources (Proposal by Delegation of Columbia 1999), ¶ 1. available at http://www.wipo.int/scp/en/documents/session_3/pdf/scp3_11.pdf.

[77] *Id.,* ¶ 2.

[78] *See* Andean Communities, Decision 486, Common Intellectual Property Regime, available at http://www.comunidadandina.org/ingles/treaties/dec/D486e.htm, (concluded Sept. 16, 2000). Decision 486 requires disclosure in patent applications of member States of any contracts for access for genetic resources if the products or processes that are the subject of the applications were obtained or developed from genetic resources originating in a member State. *See id.,* Art. 26(h). Similarly, Decision 486 requires disclosure of any applicable documents certifying the license or authorization to use traditional knowledge of indigenous, African-American, or local communities in the member State, where the products or processes were obtained or developed from such traditional knowledge, pursuant to Decision 391. *See id.,* Art. 26(i). Decision 391 prohibits recognition of intellectual property rights that were obtained in violation of Decision 391 access requirements, and member countries may request nullification of granted rights. *See* Decision 391, Complementary Provisions, Second.

[79] *See* WIPO, SCP/3/11, Report (3rd Session), ¶¶ 205, 208, available at http://www.wipo.int/scp/en/documents/session_3/pdf/scp3_11.pdf.

[80] *See* WO/GA/26/10, ¶ 71 (adopting proposal for committee); WO/GA/26/6, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, ¶¶ 5-18, available at http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/ga26_6.pdf (discussing history and proposing committee). *See also* WG-ABS Report, ¶¶ 96, 97 (discussing this history).

[81] *See* CBD COP 6, Decision VI/24/C, ¶ 4, available at http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf.

[82] *See* WIPO, WO/GA/30/7 Add.1, Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge (August 2003), available as WIPO/GRTKF/IC/5/10, available at http://www.wipo.int/documents/en/meetings/2003/igc/pdf/grtkf_ic_5_10.pdf, also incorporated in UNEP/CBD/COP/7/INF/17, available at http://www.biodiv.org/doc/meetings/cop/cop-07/information/cop-07-inf-17-en.pdf. (Citations are to WO/GA/30/7 Add. 1). *See also* WIPO, WO/GA/30/7, Convention on Biological Diversity: Disclosure Requirements Concerning Genetic Resources and Technical Knowledge, available at http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_30_7.pdf (transmitting the WIPO Draft Technical Study); WIPO, WIPO/GRTKF/IC/6/9, Genetic Resources and Patent

because it constitutes a binding interpretation by WIPO of the consistency of CBD disclosure requirements with international patent law treaties. Rather, it is discussed because it was produced by the relevant body in WIPO with technical competence over the subject matter, because WIPO is the most definitive authority on interpretation of the WIPO-administered patent law treaties, and because it provides the most comprehensive analysis of these issues to date.

1.3.3. The Technical Study followed circulation by the IGC of a questionnaire regarding national laws and practical experience, and compilation of the responses.[83] The questionnaire asked about requirements for disclosure of origins of genetic resources (from any country) used to develop or used in inventions, including: (a) information about the resources; (b) their geographic origins; (c) indication or evidence of prior informed consent; (d) any traditional knowledge employed to isolate or distinguish the claimed genetic resources; (e) nature and sources of such traditional knowledge; and (f) indication or evidence of prior informed consent for the traditional knowledge.[84] Country submissions informed many of the analyses in the Technical Study.

1.3.4. In the Technical Study, the IGC noted that disclosure of origins of genetic materials or traditional knowledge sometimes but not always was required under existing domestic patent systems, in order to enable skilled practitioners to carry out the invention for which protection is sought or because the information constitutes relevant prior art.[85] The IGC summarized various national laws addressing CBD disclosures, noting that the failure to conform to required disclosure of origins and traditional knowledge requirements could lead to different results, including: (a) a lack of consequence for patents; (b) rejection of patent applications; (c) loss or transfer of patent rights; (d) revocation or invalidation of patents; and (e) civil or criminal sanctions for false submissions in the patent application

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Disclosure Requirements: Transmission of Technical Study to the Convention on Biological Diversity, available at http://www.wipo.int/documents/en/meetings/2004/igc/pdf/grtkf_ic_6_9.pdf (discussing transmission and subsequent developments); WIPO, WIPO/GRTKF/IC/4/11, Initial Report on the Technical Study on Disclosure Requirements Related To Genetic Resources and Traditional Knowledge, available at http://www.wipo.int/documents/en/meetings/2002/igc/pdf/grtkf_ic_4_11.pdf.

[83] *See* Technical Study, ¶ 3; WIPO/GRTKF/IC/Q.3 (WIPO Questionnaire), available at http://www.wipo.int/tk/en/questionnaires/ic-q3/index.html.

[84] *See* WIPO Questionnaire, ¶ 3.

[85] *See, e.g.,* Technical Study, ¶¶ 57-64 (discussing responses to Question 12, which asked whether countries required disclosure of the categories of information addressed by Question 3 in requiring enabling disclosures for determining patentability of inventions; summarizing the responses of Span, Germany, Burundi, Switzerland, the European Patent Office (EPO), France, the European Union (EU), and New Zealand); WIPO Questionnaire, ¶ 12. Although not addressed by the Questionnaire, disclosure of such information also may be required by existing patent law standards, to the extent it constitutes relevant prior art known to the applicant. *See, e.g.,* Technical Study, ¶ 85(iv) (noting that some traditional knowledge may need to be disclosed in jurisdictions requiring disclosure of known prior art); ¶ 88 (noting "severe consequences" for failing to disclose known prior art). Many categories of information addressed by Question 3, however, would not be considered prior art that would have to be disclosed under traditional patent application standards. *See id.,* ¶ 100. *See also* PCT Rule 33(1) ("relevant prior art shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step"). *See generally* WIPO, WIPO/GRTKF/IC/2/6, Progress Report on the Status of Traditional Knowledge as Prior Art, available at http://www.wipo.int/documents/en/meetings/2001/igc/pdf/grtkfic2_6.pdf.

process. The remedies depended on the specifics of the national laws, which took into consideration, *inter alia*: the nature, importance, and facial appearance of the false or incomplete information; and the relationship of the information to the inventor(s), to the invention, and to substantive criteria for patentability.[86] Further, the IGC summarized that ownership and non-ownership information may be required to be disclosed as part of ownership recordation systems, including recordation systems for licenses and security interests as contemplated by Article 14(1)(b)(iii) of the PLT, and that failure to disclose such information may affect the ability to enforce patents or lesser interests or transfer ownership in them.[87]

1.3.5. The IGC identified general objectives for requirements to disclose (and to certify[88]) various kinds of information relating to genetic resources and traditional knowledge in intellectual property applications, including "transparency and monitoring, and … enforcing compliance with legal obligations governing access."[89] The IGC recognized that the link between the type of information required to be disclosed and the invention itself may be remote from patentability considerations, and that disclosure requirements may reflect either "existing patent law mechanisms" or "new requirements based on separate legal principles."[90] The IGC noted the complex jurisdictional considerations involved in assessing compliance with national CBD access and benefit-sharing legislation or with contractual provisions through mandated CBD disclosures and evaluation thereof in different jurisdictions, particularly if demonstrations of compliance with such access and benefit-sharing legislation or contractual provisions were prerequisites to grants of patents in the different jurisdictions.[91] The IGC also discussed: contractual obligations to disclose information[92]; ordre public prohibitions on patenting in violation of CBD requirements[93]; general equitable principles that would render patents unenforceable

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[86] *See* Technical Study, ¶68-72, 85-88 (discussing responses to Questions 2 and 13, which asked for consequences of failing to disclose information required by existing patent laws and for submitting false and misleading information, and discussing the relationship between the invention, the disclosure requirements, and patentability requirements); WIPO Questionnaire, ¶¶ 2, 13.
[87] *See* Technical Study, ¶¶ 74-79.
[88] *See id.,* ¶ 82.
[89] *Id.*, ¶ 80. *See also id.*, ¶¶ 90-91 (discussing patent and extra-patent sanctions for failure to comply and whether they are necessary and sufficient to accomplish specified objectives).
[90] *Id.*, ¶ 111. *See id.*, ¶ 80(i)-(vi) (listing types of disclosures suggested by the CBD in UNEP/CBD/SBSTTA/2/7, ¶ 93 Knowledge, Innovations and Practices of Indigenous and Local Communities, available at http://www.biodiv.org/doc/meetings/sbstta/sbstta-02/official/sbstta-02-07-en.pdf); *id.*, ¶¶ 92-94, 99-100 (discussing various legal requirements or proposals for disclosures, from the Group of Countries of Latin America and the Caribbean (GRULAC), Andean Community, Brazil, Costa Rica, India, Egypt, and their proximity to traditional patent disclosures) (citations omitted); *id.*, ¶ 98 (discussing categories of varying relations between genetic resources or traditional knowledge and patentable inventions); *id.,* ¶¶ 106-110 (discussing linkages between CBD implementation mechanisms and patent disclosures).
[91] *See id.*, ¶¶ 117-21, 156-60. Like the Consultant Report, the Technical Study also discussed some practical considerations in performing such determinations. *See id.,* ¶¶ 132-40 (discussing: formal or substantive requirements for disclosure, including whether and when examination is made into substance of allegations; extent of the obligations on the applicant, including requirements to use best efforts to obtain information; burdens of proof; relevance of the intentions of the applicant; and the potential for conflicting obligations, such as contractual secrecy duties imposed as conditions of access). *Cf.* Consultant Report, Section V (discussing problems with and benefits of examination of CBD disclosures).
[92] *See* Technical Study, ¶ 129.
[93] *See id.,* ¶¶ 122-23.

when the invention was developed with illegitimately acquired inputs or when the information about the inputs was fraudulently withheld[94] (which is analyzed in greater detail below); the nature of the obligation imposed on applicants and the potential for conflicting disclosure and non-disclosure obligations[95]; methods and evaluations of determining compliance[96]; and methods of implementing, verifying, and monitoring compliance with disclosure requirements.[97]

1.3.6. <u>WIPO Evaluations Of Conformity to Intellectual Property Law Treaties of CBD Disclosures In Patent Applications.</u> In the Technical Study, the IGC analyzed conformity with existing international intellectual property law treaties of various forms of national CBD disclosure requirements. The Technical Study reaches conclusions that in some ways differ from those of the Consultant Report. In particular, as discussed in more detail below, the Technical Study: raised the potential for additional conflict with PLT Art. 5(1) and implied that only certain types of CBD disclosure requirements would pose a conflict with Art. 5(1)[98]; recognized "'differing views' of the distinction between substantive requirements and requirements as to form and contents," as relevant to determining consistency with PLT Art. 6(1) and PCT Art. 27(1)[99]; raised the potential for additional conflict with PLT Art. 10(1) and implied that PLT Arts. 6(1) and 10(1) and PCT Art. 27(1) may not pose a conflict to the extent that CBD disclosures relate to conditions of substantive entitlement to apply for and own patents[100]; and identified the relevance of Art. 32 of TRIPS in addition to Arts. 27.1, 29, and 62.1, without suggesting an actual conflict of

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[94] *See id.,* ¶¶ 124-28 (citing, inter alia, Commission on Intellectual Property Rights, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY, at 87 (2002), available at http://www.iprcommission.org/graphic/documents/final_report.htm (CIPR Report); *Requiring Disclosure of Origin*; and *Protecting Traditional Knowledge*). In particular, the Technical Study discussed the equitable doctrine of "unclean hands," and cited to an early United States case that held that fraudulent declarations regarding the date and independent invention by the applicant justified refusal to enforce the patent. *See id.,* ¶ 125 (citing *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806 (1945), and *Keystone Driller Co. v. General Excavator,* 290 U.S. 240 (1933)). The Technical Study also refers to "inequitable conduct that contributed to the patent grant," for which "general equitable principles [would] deny the patent holder theentitlement to enforce patent rights on the invention." *Id.,* ¶ 127. *See Requiring Disclosure of Origin,* at 399 ("Actually, the determination that the concealment of information might lead to the implementation of public policies concerning benefit sharing is fraudulent is a matter of law. Consequently, any attempt to enforce patent rights thus obtained would be an abuse of rights.").

[95] *See id.*, ¶¶ 131-40.

[96] *See id.*, ¶¶ 141-55.

[97] *See id.*, ¶¶ 156-60.

[98] *See id.*, ¶ 167 (noting that some proposals for CBD disclosures would result in return of applications for resubmission of information).

[99] *Id.,* ¶ 170.

[100] *See id.*, ¶ 148 (distinguishing potential consequences of failure to comply with examination of substantive legal issues during the application process, and noting that issues relating to entitlement to apply for a patent may be "fully weighed when contested (e.g., when a third party claims a share in ownership or inventorship)."); *id.,* ¶ 153 (noting that granted patents may be challenged on substantive grounds, including "the entitlement to hold or exercise the patent right"); *id.*, ¶ 175 (noting that PCT Art. 27 provides that the PCT and its implementing regulations do not prescribe freedom to impose substantive conditions on patentabilty and to requireapplicants to furnish evidence in regard thereto). Unlike the Consultant Report, the Technical Study also expressly discussed the fact that substantive entitlement to apply for patent rights is not normally evaluated in patent offices, but rather only when specific issues arise or only in courts. *See id.*, ¶¶ 148, 183.

CBD disclosures with any of these provisions, particularly given considerations of substantive entitlement.[101]

1.3.7. In regard to the **Paris Convention,** the IGC noted, *inter alia,* the requirements for national treatment under Art. 2 and for the independence of patents in different countries (including for purposes of nullity or forfeiture) under Art. 4bis. The IGC did not suggest conflicts between CBD disclosures and these provisions.[102]

1.3.8. In regard to the **Patent Law Treaty,** the IGC noted that the PLT "does not establish a completely uniform procedure for all Contracting Parties" and that Article 2(2) expressly preserves the freedom "'to prescribe such requirements of the applicable substantive law relating to patents as it desires.'"[103] The IGC, however, found a potential conflict of certain types of CBD disclosure requirements with Art. 5(1), which requires applicants to be provided with a filing date if specific categories of information are provided. The potential for conflict exists if failure to disclose would result in abandonment and resubmission of an application that resulted in the failure to accord a filing date that otherwise would be provided.[104]

1.3.9. The IGC noted a potential for conflict with that Art. 6(1) of the Patent Law Treaty, which prohibits national patent laws from mandating compliance with additional requirements for the "'form or contents'" of patent applications different from those required for international applications under the PCT.[105] However, the "form or contents" prohibition of Article 6(1) should not be understood to apply to disclosures such as search reports or identification of assistance in preparation, nor to substantive requirements of patentability or of entitlement to a patent.[106] The IGC at various points also recognized that the PLT (like PCT Rules 51bis.2(a)(i)&(ii)) authorizes Parties to require "that evidence in respect of any matter referred to in paragraph (1) or (2) be filed with its Office in the course of the processing of the application only where that Office may reasonably doubt the veracity of that matter."[107]

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[101] *See id.*, ¶¶ 180-81.
[102] *See id.*, ¶¶ 162-64 (discussing Paris Convention Arts. 2, 4bis, 4ter, and 4^{quater}).
[103] *Id.,* ¶ 165 (quoting Art. 2(2), and citing Explanatory Notes on the PLT and Regulations under the PLT, WIPO Publ. No. 258, 2000, originally issued as WIPO PT/DC/48 Prov., Explanatory Notes on the Patent Law Treaty and Regulations Under the Patent Law Treaty Adopted by the Diplomatic Conference on June 1, 2000, ¶ 10.01, available at http://www.wipo.int/scp/en/documents/pt_dc/pdf/pt_dc_48p.pdf, ¶ 2.01 (Explanatory Notes)).
[104] *See id.*, ¶¶ 166-67 (citing Art. 5(1)).
[105] *See id.*, ¶¶ 168-70 (citing Art. 6(1)).
[106] *See id.* (citing Explanatory Notes, ¶¶ 6.01, 6.02, and WIPO SCP/6/5, Study on the Interface Between the SPLT, the PLT, and the PCT, ¶ 8, available at http://www.wipo.int/scp/en/documents/session_6/pdf/scp6_5.pdf)).
[107] PLT, Art. 6(6). *See* PCT Rules 51bis.2(a)(i)&(ii) (prohibiting requirements for additional documentation except in cases of reasonable doubt, regarding the identity of the inventor – if the inventor is not required to apply – or regarding the applicants' entitlement to the patent – if a declaration is provided under Rule 4.17(ii)), available at http://www.wipo.int/pct/en/texts/pdf/pct_regs.pdf; Technical Study, ¶ 91 (discussing Art. 6(6) and its relationship to PCT Rule 51bis.2); *id.,* ¶¶ 177 (discussing language of PCT Rule 51bis.2); *id.*, ¶ 196 (discussing language of Art. 6(6) in context of specifying confirming requirements for demonstrating entitlements to apply for patents); PLT, Art. 6(7) (requiring that "the Office shall notify the applicant, giving the opportunity to comply with any such requirement" of PLT Arts. 6(1) through 6(6)).

1.3.10. The IGC identified an additional, related potential for conflict with Art. 10(1) of the PLT of various remedies for failures to disclose. Art. 10(1) prohibits revocation or invalidation of a patent for failure to comply with "'formal requirements referred to in Articles 6(1), (2), (4) and (5), and 8(1) to (4)… except where the non-compliance with the formal requirements occurred as a result of a fraudulent intention.'"[108] Further, the IGC noted that Art. 10(1) "limitations on revocation and invalidation are 'intended to also cover sanctions which are equivalent effect to revocation or invalidation, such as non-enforceability of rights.'"[109] Similarly, Art. 10(2) requires provision to patent owners of an opportunity to "'make amendments or corrections where permitted by applicable law.'"[110]

1.3.11. In regard to the **Patent Cooperation Treaty,** the IGC identified a potential for conflict of CBD disclosures with PCT Art. 27(1) regarding the "form and contents" of applications, similar to the potential conflict of PLT Art. 6(1).[111] PCT Art. 27(1) of the PCT provides that "[n]o 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."[112] However, the IGC also noted that, under PCT Art. 27(2)(ii), the language of PCT Art. 27(1) "does not 'preclude any national law from requiring, once the processing of the international application has started in the designated Office, the furnishing … of documents not part of the international application but which constitute proof of allegations or statements made in that application….'"[113] Similarly, Art. 27(5) states that "nothing in the PCT or its 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….'"[114] In particular, the IGC noted that a PCT applicant may be required by national law to provide a declaration of an entitlement to apply for and be granted a patent, and that national patent offices can require additional documents or evidence concerning both the entitlement and the identity of the inventor in cases of reasonable doubt as to the indications or declaration.[115]

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[108] Technical Study, ¶ 171 (quoting PLT Art. 10(1)).
[109] *Id.,* ¶ 127 (quoting Explanatory Notes, ¶ 10.01).
[110] *Id.*, (quoting PLT Art. 10(2)).
[111] *See id.*, ¶¶ 174-77.
[112] PCT Art. 27(1) (emphasis added). The language of PCT Art. 27(1) is ambiguous in regard to whether it refers to international applications at the international stage or at the national stage. *See* PCT Arts. 2 Definitions (vi) ("national application"), (vii) ("international application"), (viii) ("application"). Because PCT Art. 27(2)(ii) makes clear that parties are free to require additional documentation proving allegations or statements in international applications once they are processed in the "designated Office," PCT Art. 27(1) (unlike PLT Art. 6(1)) may apply only to additional form or content requirements of international applications at the international stage.
[113] Technical Study, ¶ 175 (quoting PCT, Art. 27(2)).
[114] *Id. (*quoting PCT, Art. 27(5)).
[115] *See id,* ¶ 177 (citing PCT Rules 51bis.2(a)(i)&(ii)).

1.3.12. In regard to the **TRIPS Agreement**, the IGC identified the relevance of Articles 27.1, 29, 32, and 62.[116] After quoting Art. 27.1, which provides that "'subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology,'"[117] the IGC noted that Art. 27.1 refers to technical patentability "and does not make specific provision for the entitlement of the applicant, which is separately determined."[118]

1.3.13. The IGC also discussed Art. 29.1, which codifies various disclosure requirements necessary for determining substantive patentability, but did not suggest a conflict with Art. 29.[119] The IGC also noted Art. 32, which provides for "'an opportunity for judicial review of any decision to revoke or forfeit a patent.'"[120] Finally, the IGC discussed Article 62, which authorizes Members to "'require, as a condition of the acquisition or maintenance of [specified] intellectual property rights … compliance with reasonable procedures and formalities" that are consistent with other TRIPS provisions.'"[121] The IGC, however, did not discuss potential conflicts based on these provisions.

1.3.14. Country Proposals For Permissive and Mandatory CBD Disclosure Requirements. Following the adoption of CBD COP Decision VI/24 and the suggestions in the Plan of Implementation of the World Summit on Sustainable Development for an "international regime" within the CBD for benefit sharing and the successful conclusion of the WIPO IGC's efforts,[122] **Switzerland** proposed at the fourth session of the Working

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[116] *See id.,* ¶ 180 (citing WIPO WIPO/GRTKF/IC/I/3, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore – An Overview, ¶ 45, available at http://www.wipo.int/documents/en/meetings/2001/igc/pdf/grtkfic1_3.pdf).

[117] *See id.* (quoting TRIPS, Art. 27.1).

[118] *Id.*

[119] *See id. See also id.,* ¶¶ 32, 134-35 (discussing Art. 29, distinguishing formal from substantive information disclosure requirements, noting that Art. 29 disclosures are evaluated during substantive examination of the patent application, and recognizing that failure to provide adequate substantive disclosures under Art. 29 to support the claims or to demonstrate entitlement to the patent may result in denial of grant, invalidity or revocation of the patent, or cancellation or transfer of the patent).

[120] *Id.,* (quoting TRIPS, Art. 32). In contrast, PLT Art. 10(2) requires that an applicant be given an opportunity to make "observations" on an intended revocation or invalidation, and "to make amendments or corrections where permitted under the applicable [national] law, within a reasonable time limit." PLT Art. 10(3) provides that PLT Arts. 10(1) & (2) do not create obligations to require specialized judicial procedures regarding patent rights.

[121] *Id.,* (quoting TRIPS, Art. 62).

[122] World Summit on Sustainable Development, Plan of Implementation, ¶ 42(o) & (p), available at http://www.johannesburgsummit.org/html/documents/summit_docs/2309_planfinal.doc **(check).** *See also* CBD COP 7, Decision VII/19, Access and Benefit Sharing as Related to Genetic Resources (Article 15), D. International regime on access to genetic resources and benefit-sharing, ¶ 1 & Annex (d)(xiii) & (xiv), available at http://www.biodiv.org/doc/meetings/cop/cop-07/official/cop-07-21-part2-en.pdf (directing the WG-ABS and the WG8J "to elaborate and negotiate an international regime" to implement CBD Arts. 8(j) and 15, taking into account, *inter alia,* an international certificate of origin/source/legal provenance and disclosure in intellectual property applications). Further, the COP directed the WG-ABS to identify issues relating to disclosure of origins and a proposed international certificate of origin/source/legal proveneance and transmit the results to WIPO, and invited WIPO to examine issues relating to, *inter alia,* disclosure requirements in intellectual property rights application procedures. *See* Decision VII/19, E. Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was

Group on Reform of the Patent Cooperation Treaty (WG-PCT) to amend the PCT Regulations to authorize (but not to require) CBD disclosures in patent applications.[123] Specifically, Switzerland proposed to amend PCT Rule 51bis.1 to add a new paragraph (g), which would allow national law to require (in accordance with PCT Art. 27(1)) applicants to declare: (i) the source of specific genetic resources for inventions "directly based" on such resources or that the source is unknown; and (ii) the source of traditional knowledge for inventions "directly based" on such knowledge or that the source is unknown.[124] Switzerland also proposed to amend PCT Rule 4.17 by adding a new paragraph (iv) to allow parties to include such declarations at the international stage of PCT applications.[125] Because PCT Rule 4.18(a) currently prohibits the application request from containing matter other than as specified in PCT Rules 4.1 through 4.17, and PCT Rule 4.18(b) requires the international stage receiving Office to delete any such additional matter, it is only possible to include such information at the international stage as part of the patent specification.[126] By amending the PCT Rules, corresponding changes will be made to Art. 6(1) of the PLT, which prohibits additional requirements relating to form and contents at the national stage for PCT applications. Similarly, the PCT Rule changes would allow Parties to impose sanctions for non-compliance prior to granting of patents, and (consistent with PLT Art. 10(1)) to authorize invalidation of patents issued when non-compliance results from "a fraudulent intention."[127] Further, declarations made during the international phase would not be subject to further documentation or evidence unless the designated office reasonably doubts the veracity of the declaration.[128] The WG-PCT reflected a divergence of opinions on the Swiss proposal, which has been deferred until the next session.[129]

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granted in Contracting Parties with users of such resources under their jurisdiction, ¶¶ 7, 8. The IGC subsequently considered the referral from the COP, but after failure to reach consensus on an approach referred the matter to the WIPO General Assembly. *See* WIPO WIPO/GRTKF/IC/6/14, Report, ¶¶ 183-84, available at http://www.wipo.int/documents/en/meetings/2004/igc/pdf/grtkf_ic_6_14.pdf.

[123] WIPO PCT/R/WG/4/13, Proposals by Switzerland Regarding the Declarations of the Source of Genetic Resources and Traditional Knowledge in Patent Applications, available at http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_4_13.pdf. *See also* WIPO PCT/R/WG/5/11 Rev., Proposals By Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge, available at http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_5_11_rev.pdf (reproducing PCT/R/WG/4/13 for discussion at the Fifth Session of the WG-PCT); PCT/R/WG/6/11, Additional Comments By Switzerland on Its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications, available at http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_6_11.pdf (discussing the terminology of the proposal).

[124] *See* WIPO PCT/R/WG/4/13, ¶ 21.

[125] *See id.,* ¶ 26.

[126] *See id.,* ¶¶ 13-14.

[127] PLT Art. 10(1). *See* WIPO PCT/R/WG/4/13, ¶¶ 15-16.

[128] *See* WIPO PCT/R/WG/6/11, ¶25.

[129] *See* WIPO PCT/R/WG/6/12, Summary of the Session, ¶¶ 82-107, available at http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_6_12.pdf. In particular, the United States expressed its views that the Swiss proposal: would sanction denial of patent rights, increase litigation, create a disincentive for innovation, and reduce any benefits to be shared; was based on disclosures outside of patent law and that patent laws are inappropriate means for addressing misappropriation of genetic resources and traditional knowledge; and that the IGC was the appropriate forum for addressing these issues. *See id.*, ¶¶ 94-96.

1.3.15. The African Group of countries submitted a proposal to the Sixth Session of the IGC containing, which suggested the outlines of an international regime to address intellectual property in regard to genetic resources.[130] Specifically, the African Group proposal would introduce "a disclosure requirement in patent laws as well as evidence of compliance with national access and benefit sharing laws of the country of origin of genetic resources" including source and origins of genetic resources and traditional knowledge "used in the invention."[131]

1.4. WTO Deliberations.

1.4.1. Country Submissions and Evaluations Regarding CBD Disclosures In the Context of the Art. 27.3(b) Review. The WTO has addressed the relationship of the CBD to the TRIPS Agreement since 1997.[132] Art. 27.3(b) of TRIPS authorized Members to exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[133] It also provided for a review of the exclusion provision four years after entry into force.[134] As part of that review (initiated in 1999 and intensified in 2001 after the Doha Ministerial Meeting[135]), the TRIPs Council invited submissions by Members of information on how Art. 27.3(b) was being implemented. Some of these submissions considered the TRIPS Agreement and the CBD to be incompatible, and contained recommendations for amending Art. 27.3(b) to prohibit patents for inventions developed in violation of the CBD Art. 15 access or benefit sharing provisions.[136] Others considered TRIPS and the CBD to be compatible, as having different

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[130] *See* WIPO WIPO/GRTKF/IC/6/12, Submission by the African Group: Objectives, Principles and Elements of an International Instrument, or Instruments, on Intellectual Property in Relation to Genetic Resources and on the Protection of Traditional Knowledge and Folklore, available at http://www.wipo.int/documents/en/meetings/2004/igc/pdf/grtkf_ic_6_12.pdf.

[131] *Id.,* Annex. After consideration of the African Group submission, the IGC took note of it. WIPO WIPO/GRTKF/IC/6/14, ¶ 230.

[132] *See* WTO WT/CTE/W/65, The Relationship Between the TRIPS Agreement and the Convention on Biodiversity (Communication from India), ¶¶ 1, 2, available at (citing WTO WT/CTE/W/17, Summary of Activities of the Committee on Trade and Environment (1995) Presented by the Chairman of the Committee, at 7, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1, and WTO WT/CTE/1, Report (1996) of the Committee on Trade and the Environment, ¶ 208, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1).

[133] TRIPS, Art. 27(b).

[134] *See id. See also id.*, Art. 71.1 (providing for general review of TRIPS provisions following the end of transition periods of Art. 65.2, or an additional four years after the year following entry into force, *i.e.,* in 2000).

[135] *See* WTO WT/MIN(01)/DEC/1, Doha Ministerial Declaration, ¶ 19, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (directing the Arts. 27.3(b) and 71.1 reviews to proceed "guided by the objectives set out in [TRIPS] Articles 7 and 8").

[136] *See* WTO IP/C/W368, The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, Summary of Issues Raised and Points Made, ¶¶ 6-8, available at http://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf (Secretariat's Summary) (citing IP/C/W/196 (Communication from India), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1); WTO IP/C/W/369, Review of the Provisions of Art. 27.3(b) Summary of Issues Raised and Points Made, ¶ 9, available at http://www.wto.org/english/tratop_e/trips_e/ipcw369_e.pdf (same). *See also* WTO IP/C/W370, The Protection of Traditional Knowledge and Folklore, Summary of Issues Raised and Points Made, ¶¶ 17-18, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1 (noting similar suggestions in

objectives and not addressing the same subject matter.[137] The premise of these discussions was the need for an international system that would prevent violations of access and benefit sharing conditions, and thus the discussions did not directly address compatibility with the TRIPS Agreement of national legislation unilaterally imposing such disclosure obligations.

1.4.2. Country Proposals to Amend TRIPS to Require CBD Disclosures. Recent proposals offered in the WTO would amend the TRIPS Agreement to require member countries to adopt legislation to mandate CBD disclosure requirements in patent applications. For example, the submission by **Brazil on behalf of various countries** would amend TRIPS to require "as a condition to acquiring patent rights" that applicants for inventions relating to biological materials or traditional knowledge provide: "(i) disclosure of the source and country of origin of biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin."[138] Similarly, **the African Group** has suggested amending TRIPS Art. 29 to add a new paragraph 3, specifying that "Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin."[139]

1.4.3. Country and WTO Evaluations of Compatibility of CBD Disclosure Requirements with TRIPS Provisions. The Secretariat of the WTO recently summarized the issues raised by countries in regard to the relation of the TRIPS Agreement to CBD disclosure requirements in the context of proposed amendments to TRIPS, without

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regard to traditional knowledge, citing IP/C/W/228 Review of Article 27.3(b) (Communication from Brazil), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1,and IP/C/W/195 (Communication from India), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1).

[137] *See, e.g.,* WTO IP/C/W/383, Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore: "A Concept Paper" (Communication from the European Communities and their Member States), ¶¶ 34-36, available at (summarizing the European Communities' position articulated in WTO IP/C/W/254 Review of the Provisions of Article 27.3(b) of the TRIPS Agreement (Communication from the European Communities and their Member States), ¶¶ 5-30 (noting the lack of inherent conflict between the TRIPS Agreement and the CBD and "not favour[ing] incorporating into the TRIPS Agreement" requirements for disclosure or certification in patent applications), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1).

[138] *See* WTO IP/C/W/356, The relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of traditional knowledge (Communication from Brazil on behalf of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, Venzuela, Zambia, and Zimbabwe), at 1 (Summary), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1). *See also* WTO IP/C/W/228, ¶ 25 (earlier proposal to amend Art. 27.3(b) to this effect); WTO IP/C/W 196 (Communication from India), at ¶ 4 (proposing amendment of the TRIPS Agreement to prohibit granting of patents in violation of Article 15 of the CBD).

[139] WTO IP/C/W/404, Taking Forward the Review of Art. 27.3(b) of the TRIPS Agreement (Joint Communication from the African Group), at 6, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm. *See also id.,* Annex, Draft Decision on Traditional Knowledge, ¶¶ 2(e), (f) (prohibiting intellectual property rights and requiring their cancellation for inventions derived from traditional knowledge or *in situ* genetic resources of any Member, unless CBD access requirements have been complied with).

attempting to provide a definitive legal interpretation of whether CBD disclosure requirements are compatible with the TRIPS Agreement.[140] The Secretariat's Summary is discussed in detail here, not because it constitutes a binding interpretation by the WTO. Rather, the Secretariat's summary analyzes policy considerations regarding the need for and alternatives to CBD disclosure requirements, which could be relevant to interpretation of particular TRIPS provisions and to determinations of compatibility of CBD disclosures with TRIPS requirements. In particular, the Secretariat's Summary noted that various Members: (a) had suggested that the TRIPS Agreement should be amended because it does not prohibit the grant of intellectual property rights obtained in violation of CBD requirements[141]; (b) had opposed amendment as unnecessary and undesirable, and had noted that contractual approaches are preferable and that funding approaches also can accomplish benefit sharing[142]; (c) had argued that contractual approaches do not address situations where authorization for access is intentionally avoided and imbalances exist in negotiating power, and that mandatory disclosure requirements would provide predictability, facilitate contracts, provide certainty in regard to existing legislation, and provide a dispute mechanism to assure implementation of CBD access and benefit sharing requirements[143]; (d) had responded that additional requirements would be unduly burdensome and costly to applicants and would encourage trade secrecy over patent disclosures and would not ensure benefit sharing, that contracts could require applicants to disclose, the civil and criminal enforcement can address violations of access requirements, that the intellectual property system and the TRIPS Agreement are not appropriate instruments for regulating access and benefit sharing, that the amendment would be inconsistent with the TRIPS Agreement, and that it would go beyond the CBD by mandating an international approach rather than national approaches to access and benefit sharing requirements[144]; (e) had further responded that the additional requirements would be no more burdensome than other patent evaluations, could be administered by national biodiversity authorities, and applied selectively only when there was reason to doubt compliance[145]; and (f) had suggested an alternative stand-alone regime for enforcing CBD compliance, following which the TRIPS Agreement might be amended to supplement the direct enforcement regime.[146]

1.4.4. Various WTO members have suggested that certain forms of CBD disclosure requirements may be incompatible with existing obligations under the TRIPS

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[140] *See* Secretariat's Summary, ¶¶ 5-28. One sub-paragraph of the Summary notes that, in response to arguments for CBD disclosures, arguments have been made for the inconsistency with the TRIPS Agreement of proposals to amend the TRIPS Agreement to require CBD disclosures. *See id.*, ¶ 26.
[141] *See id.*, ¶ 20 (citations omitted).
[142] *See id.* ¶¶ 21-23 (citations omitted).
[143] *See id.*, ¶¶ 24-25 (citations omitted).
[144] *See id.,* ¶ 26 (citations omitted). Specifically, the proposed amendment was argued to be inconsistent with the Art. 27.1 prohibition on discrimination by field of technology, the Art. 29 mandatory disclosure requirements, and the Art. 62.1 authorization for reasonable procedures and formalities. *See id.* (citing IP/C/M/29, Minutes of Meeting of TRIPS Council, ¶ 155 (Comments of Japan), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1, and IP/C/M/30, Minutes of Meeting of TRIPS Council, ¶ 177 (Comments of the United States), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1).
[145] *See id.*, ¶ 27 (citations omitted).
[146] *See id.,* ¶ 28 (citations omitted).

Agreement. For example, the **European Communities** has expressed the view that "the TRIPS Agreement does not prevent Members from requiring the disclosure of origin in cases where this information is not essential in the meaning of Article 29 [of] TRIPS, or the production of evidence of respect of access and benefit-sharing rules to patent applicants, as long as this requirement does not constitute a patentability criterion and has no bearing on the patentability of the invention or the validity of the patent. Substantive patentability criteria are set out in Article 27.1 of the TRIPS Agreement, while Article 29 lays down obligations that can or must be imposed on the patent-holder in order to check whether the patentability criteria are met. Compatibility with TRIPS depends on the consequences arising from non-compliance."[147] The European Communities would support a free-standing CBD disclosure obligation in patent applications, the failure to comply with which would not result in invalidity of the patent.[148]

1.4.5. For another example, the **United States** has expressed the view that the TRIPS Agreement itself is not inconsistent with the CBD itself, because "Article 16(2) of the CBD stated that in case of the access and transfer of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognized and were consistent with the adequate and effective protection of intellectual property rights."[149] Nevertheless, the United States has firmly opposed amendments to require inclusion of CBD disclosure requirements in patent applications, suggesting that implementation of such CBD disclosure requirements would be extremely burdensome and ineffective.[150] The United States also has suggested that such requirements are inconsistent

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[147] WTO IP/C/W/383, ¶ 48.
[148] *See id.,* ¶ 55.
[149] WTO IP/C/M/29, Minutes of Meeting of TRIPS Council, ¶ 193, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1. *See also* WTO IP/C/W/162, Review of the Provisions of Article 27.3(b) (Communication from the United States), VI. The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, at 5-6, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1 (noting the lack of any specific example of conflict and the failure of any country to claim its implementation violates either agreement); WTO IP/C/W/209, Review of the Provisions of Article 27.3(b), Further Views of the United States (Communication from the United States), 5. Compatibility of the Provisions of the CBD and the TRIPS Agreement, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1 (noting that Art. 22 of the CBD prevent the CBD provisions from affecting rights or obligations of existing treaties, and in the event provisions of treaties are mutually exclusive, the later-in-time provisions prevail).
[150] *See, e.g.,* WTO IP/C/W/162, at 5-6; WTO IP/C/M/29, ¶ 166 (Statement of United States). *But cf.* WTO IP/C/W/356 The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge (Communication of Brazil on behalf of various countries), ¶¶ 12-13, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1 (noting the need for international requirements to avoid systemic conflicts between implementation of the CBD and the TRIPS Agreement, the greater cost-effectiveness of an international solution to biopiracy, and the lack of substantial additional burdens in fulfilling CBD disclosure requirements in patent applications); Secretariat's Summary, ¶ 24 (summarizing WTO IP/C/M/32, Minutes of Meeting, ¶128 (Statement of Brazil), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1, regarding inadequacies of a voluntary contract system); David Vivas, Eugui, Center for International Environmental Law, Issues Linked to the Convention on Biological Diversity in the WTO negotiations: Implementing Doha Mandates, at 7-8 (noting the avoided costs of judicial actions to revoke patents that will result from such disclosures), available at http://www.ciel.org/Publications/Note_CBD_EDITEDversion.pdf.

with TRIPS Article 29.[151] Similarly, **Japan** has suggested that CBD disclosure requirements are inconsistent with Article 29, the Article 62.1 authorization for reasonable procedures and formalities, and the Article 27.1 prohibition on discrimination by field of technology.[152]

1.4.6. **Brazil (on behalf of various countries)** has not expressed a view regarding TRIPS compatibility of existing national laws requiring disclosure within patent applications of origins of genetic resources and traditional knowledge and evidence of compliance with access and benefit sharing requirements. Nevertheless, **Brazil (on behalf of those countries)** may have implied that the TRIPS Art. 27.3(b) exclusions from patentability – and by extension the TRIPS Art. 27.1 requirements for patentability – do not currently include permit CBD disclosures, when proposing to amend Art. 27.3(b) "to include the possibility of Members requiring, whenever appropriate, as a condition to patentability" various CBD disclosures.[153] In contrast, **India** has suggested that national legislation to require CBD Disclosures is consistent with existing TRIPS Art. 29.[154]

1.4.7. **Brazil** also has expressed the view that there is a potential for conflict in implementing the CBD and the TRIPS Agreement.[155] **Brazil (on behalf of various countries)** has expressed the view that disclosures of origins in patent applications are desirable and serve the following purposes: "(a) reducing instances of bad patents; (b) enabling the patent office to ascertain more effectively the 'inventive step' claimed in a particular patent application; (c) enhancing the ability of countries to track bad patents in the instances where they are granted and challenge the same; (d) improving compliance with their national laws on PIC and fair and equitable benefit sharing prior to accessing a biological resource/associated traditional knowledge."[156] Brazil (on behalf of various countries) also has expressed a view that its proposed amendment to TRIPS to require such disclosures would be consistent with TRIPS, particularly with Art. 7.[157]

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[151] *See* Secretariat's Summary ¶ 26 (citing IP/C/M/30, Minutes of Meeting, ¶ 177, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1).
[152] *See id.* (citing IP/C/M/29, ¶ 155 (Statement of Japan)).
[153] *See* WTO IP/C/W/228, ¶ 25.
[154] *See* WTO IP/C/M/29, Minutes of Meeting, ¶ 165 (Statement of India); WTO IP/C/W/195 (Communication from India), ¶ 16, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1 (proposing amendments to TRIPS Art. 29 to require countries to enforce CBD disclosures in patent applications, and stating that "[s]uch a provision in the domestic law [to require CBD disclosures] should be considered compatible with the TRIPS Agreement.").
[155] *See, e.g.,* Secretariat's Summary, ¶ 11 (citing, e.g., IP/C/M/28, Minutes of Meeting ¶¶ 146, 148, and 234 (Statements of Brazil), available at http://docsonline.wto.org/gen_home.asp?language=1&_=1); WTO IP/C/M/29, ¶ 194 (Statement of Brazil). Some countries find an inherent conflict between the CBD and the TRIPS Agreement in that the TRIPS Agreement allows for patenting if genetic material without assuring that CBD requirements are respected. *See* Secretariat's Summary, ¶ 7 (citing IP/C/M/28, ¶ 144 (Statement of Kenya)).
[156] WTO IP/C/W/356, ¶ 7.
[157] *See id.,* ¶ 8. *See also* IP/C/W/293 (Communication from Norway), 6. The question of requiring the disclosure of origin of the genetic resources to be included in patent applications, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1 (noting that such provisions "could make it easier for parties to enforce their rights to their own genetic resources, could make the CBD provisions on prior informed consent more effective, and could effectuate Art. 16.5 of the CBD).

1.4.8. **The African Group** has suggested that disclosure of origins requirements in patent applications are consistent with TRIPS, the CBD, and the ITPGR. Specifically, the African Group requested the TRIPS Council confirm that "the TRIPS Agreement and the Convention on Biological Diversity as well as the International Treaty on Plant Genetic Resources should be implemented in a mutually supportive and consistent manner. In this regard, Members retain the right to require, within their domestic laws, the disclosure of sources of any biological material that constitutes some input in the inventions claimed, and proof of benefit sharing."[158]

1.4.9. As noted above, **Switzerland** has recently proposed amendments to the PCT Regulations, that would expressly authorize countries to impose CBD disclosure requirements in national stage PCT applications, the effect of which would make CBD disclosures expressly permitted under PLT Art. 6(1) and similarly permit revocation or invalidation for intentionally fraudulent failures to make required CBD disclosures under PLT Art. 10(1). The proposed rule changes also would allow for applicants to fulfill the CBD disclosure obligations at the international stage of PCT applications.[159] Switzerland has expressed the view that the TRIPS Agreement and the CBD can be implemented without conflict, presumably including the proposed changes to PCT.[160]

1.5. Bilateral and Regional FTA Provisions.

1.5.1. Various recent bilateral and regional FTAs concluded by the United States contain additional requirements on grant and revocation of patents that are potentially relevant to whether the parties to those agreements may adopt CBD disclosure requirements in patent applications. For example, the Central American Free Trade Agreement, Art. 15.9.4 provides that "Without prejudice to Article 5.A(3) of the Paris Convention, each Party shall provide that a patent may be revoked or cancelled only on grounds that would have justified a refusal to grant the patent. However, a Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking, canceling, or holding a patent unenforceable."[161]

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[158] *See* WTO IP/C/W/404, II. Possible Areas Of Agreement, (c), at 3.

[159] *See* WTO IP/C/W/400R1, Article 27.3(b), The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge (Communication from Switzerland), ¶¶ 7, 8, available at http://docsonline.wto.org/gen_home.asp?language=1&_=1.

[160] *See id.*, V. The Relationship Between The TRIPS Agreement and the Convention on Biological Diversity.

[161] Central American Free Trade Agreement, concluded Washington May 28, 2004, Art. 15.9.4, available at http://www.ustr.gov/new/fta/Cafta/final/15-ipr.pdf. *See also, e.g.,* Morocco Free Trade Agreement, Art. 15.9.5, concluded March 2, 2004, draft text available at http://www.ustr.gov/new/fta/Morocco/text/15.pdf ("Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking or holding a patent unenforceable. Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available prior to the grant of the patent."). Art. 5.A.(3) of the Paris Convention provides that (3) "[f]orfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses." This limitation on forfeiture, however, is intended to apply to forfeiture in response to "the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." Art. 5.A.(2).

1.5.2. Parties to such bilateral or regional agreements may not adopt requirements for revocation or invalidity of patents based on failures to disclose, if the failures would not authorize denial of the patent in the first instance. These agreements, however, do not themselves prohibit requirements for CBD disclosures that would result in denial of patents for failures to make disclosures. The quoted language from these agreements – contrasting the reference in the first sentence to revocation or cancellation with the reference in the second sentence to revocation, cancellation, and unenforceability – leaves open the possibility that national laws may prescribe additional conditions of unenforceability (to the grounds specified for denial of patents) even in the absence of fraud, misrepresentation, or inequitable conduct.

2. Compatibility of National CBD Disclosure of Origins and Evidentiary Requirements with International Intellectual Property Law Treaties.

2.1. CBD Disclosure Requirements As Substantive Requirements of Entitlement.

2.1.1. Substantive Entitlement Conditions to Prevent Misappropriation. The premise of CBD disclosure obligations is to assist in assuring that genetic resources and traditional knowledge are not misappropriated, by precluding the results of such misappropriation from being commercially exploited in the absence of conformity to CBD requirements for access and benefit sharing. CBD disclosure obligations operate by requiring disclosure of origins of genetic resources and traditional knowledge and disclosure of evidence of compliance with access and benefit sharing requirements as conditions for accrual or grant and validity of intellectual property rights. In this way, CBD disclosure requirements may prevent those who have misappropriated genetic resources or traditional knowledge from acquiring exclusive rights to commercialize the "ill-gotten" subject matter that could be protected by intellectual property rights. Accordingly, CBD requirements for disclosure of origins and evidence of conformity should be understood to establish permissible, substantive conditions for entitlement to accrue or to acquire intellectual property rights, including but not limited to patents.

2.1.2. National legislation may prohibit acquisition or application for intellectual property rights, when the applicant misappropriated the information on which the subject matter to be protected was based. For example, the United States has taken a very protective approach to misappropriation in copyright law, denying copyrights to original works that include misappropriated, copyrighted expression when the misappropriated expression cannot easily be severed from the rest of the original work.[162]

2.1.3. National legislation or judge-made requirements of substantive intellectual property laws or equitable doctrines also may render intellectual property rights invalid, revocable, or unenforceable as a result of misappropriation. For example, in the United

[162] *See* 17 U.S.C. § 103(a) (Copyright Act of 1976) (copyright protection "for a work employing preexisting material in which copyright subsists does not extend to any part of the work in which such material has been used unlawfully"); *Pickett v. Prince,* 207 F.3d 402 (7th Cir. 2000) (noting that a derivative work made without authorization necessarily infringes the copyright and that "Section 103(a) means only, at least so far as bears on this case, that the right to make a derivative work does not authorize the maker to incorporate into it material that infringes someone else's copyright.").

States, the judicial doctrine of "unclean hands" has been used to preclude those who misappropriate information from enforcing their patent rights, on the premise that governmental bodies should not be used by patent owners to perpetuate or to derive additional benefits from inequitable conduct.[163] More specifically, the patent-law "inequitable conduct" doctrine will render a patent unenforceable as to all potential defendants, if the patent was procured by intentional, materially false statements or material omissions.[164] Judicial remedies may differ in regard to the timing and nature of the improper conduct. False or fraudulent statements and omissions in the Patent and Trademark Office (PTO) are most likely to result in incurable unenforceability of patents.[165]

2.1.4. Misappropriation also may lead to errors in naming the true originators of subject matter to be protected by intellectual property rights, and may thereby prevent accrual or grant of rights or may render those rights invalid, revocable, or unenforceable. For example, the intentional failure to name the correct inventors in patent applications in the United States will prevent correction of inventorship in the PTO, which may then result in a denial of the patent grant or may cause invalidity of an issued patent. [166] False designations of inventorship thus may or may not be curable.

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[163] *See Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 809-10, 815, 819-20 (1945) (upholding dismissal of action to enforce patents which were obtained based on fraudulent statements in an interference regarding the date of invention – and probably also involved incorrect inventorship – noting that an equity court should "withhold its assistance … [to] prevent[] a wrongdoer from enjoying the fruits of its transgression [and] averts an injury to the public"); *Seismograph Service Corp. v. Offshore Raydist,* 135 F. Supp. 342, 347-48, 353-56 (E.D. La. 1955) (invalidating on prior art grounds a patent based on misappropriated information and possible false inventorship, and suggesting an equitable remedy of a royalty free license had the patent been valid), aff'd in pertinent part, 263 F.2d 5, 22 (5th Cir. 1959).

[164] *See, e.g., Kingsdown Medical Consultants, Ltd.,v. Hollister Inc.,* 863 F.2d 867 (Fed. Cir. 1988) (requiring for a finding of inequitable conduct a failure to disclose or submission of false information material to patentability criteria and an intent to deceive).

[165] *See, e.g., Aptix Corp. v. Quickturn Design Sys., Inc.,* 269 F.3d 1369, 1376-77 (Fed. Cir. 2001) (upholding dismissal of legal action for post-issuance fraudulent conduct but reversing a finding of unenforceability of the patent under the "unclean hands" doctrine; noting that unclean hands is typically limited to the matter in litigation, whereas inequitable conduct during procurement of a patent taints the property right *ab initio* and affects subsequent cases; and stating that inequitable conduct in procurement comprise conduct broader than common-law fraud). *Cf. Hoffman-La Roche, Inc. v. Promega Corp.,* 2004 WL 1192709, at * 5 (N.D. CA May 13, 2004) (distinguishing the related doctrines of "infectious unenforceability" and "unclean hands from "inequitable conduct," and suggesting that inequitable conduct is a species of the unclean hands doctrine applied to conduct before the Patent and Trademark Office) (citing *Consolidated Aluminum Corp. v. Foseco Int'l Ltd.,* 910 F.2d 804, 810-11 (Fed. Cir. 1990) (holding patent unenforceable based on both the inequitable conduct doctrine and the unclean hands doctrine; refusing to limit the unclean hands doctrine to fraud before courts).

[166] *See* 35 U.S.C. § 116, ¶ 3 ("Whenever through error a person is named in an application for patent as the inventor, or through an error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Director may permit the application to be amended accordingly, under such terms as he prescribes."); 35 U.S.C. § 256 ("Correction of named inventor. Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error. The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section.

2.1.5. As recognized by the WIPO Technical Study, countries may establish equitable restrictions on misappropriation by legislation or by judge-made doctrines that deprive applicants of the ability to enforce intellectual property rights when such rights are procured by fraud or other inequitable conduct.[167] However, remedies for fraud or misappropriation need not be limited to unenforceability of issued intellectual property rights. National patent laws may provide requirements implementing CBD access and benefit sharing obligations that also establish grounds for denial, invalidation, or revocation of patents if CBD disclosure requirements are not met.[168]

2.1.6. Substantive Entitlement Conditions Within or External to the Patent System. Restrictions on eligibility for or enjoyment of intellectual property rights may be imposed either in the intellectual property laws themselves or in separate misappropriation laws. For example, United States patent law itself imposes limitations on the entitlement to apply for patents, by requiring assignees of patent-application rights to record their assignments and to file sworn declarations regarding their entitlement to the invention.[169]

The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.); *Stark v. Advanced Magnetics, Inc.,* 119 F.3d 1551, 1552-56 (Fed. Cir. 1997) (a court has permissive authority to order correction for misjoinder or nonjoinder of inventors to avoid invalidity of the patent, even in the case of deceptive intention, so long as the deceptive intent was not that of the inventor to be joined, but the Patent Office cannot allow correction in the case of deceptive intention); *Perspective Biosystems, Inc. v. Pharmacia Biotech, Inc.,* 225 F.3d 1315-1323 (Fed. Cir. 2000) (upholding inequitable conduct for false statements regarding co-inventorship, but allowing correction of inventorship following initial refusal to allow correction, following the decision in *Stark* and based on the lack of evidence of fraudulent intent of the true inventor).

[167] *See* Technical Study, ¶ 127. *See also id.,*, ¶ 128 (noting the potential for development of unfair competition, liability or misappropriation regimes that would create a more explicit linkage between access to genetic resources and traditional knowledge and inventions).

[168] *See* WIPO WIPO/GRTKF/IC/3/7, Review of Existing Intellectual Property Protection of Indigeneous Knowledge, ¶ 11, available at http://www.wipo.int/documents/en/meetings/2002/igc/pdf/grtkfic3_7.pdf (discussing Columbian and New Zealand laws providing protection in patent and trademark laws against misappropriation of genetic resources – implementing CBD disclosure requirements – and of traditional names); *id.*, ¶ 24 (discussing Peru's then-proposed sui-generis system of protection and the potential for denial or revocation of patents and plant breeders certificates for failure to comply with access and benefit sharing conditions for traditional knowledge).

169 See 35 U.S.C. § 152 ("Issue of patent to assignee. Patents may be granted to the assignee of the inventor of record in the Patent and Trademark Office, upon the application made and the specification sworn to by the inventor, except as otherwise provided in this title."); 35 U.S.C. § 261("Ownership; assignment. Subject to the provisions of this title, patents shall have the attributes of personal property. Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing…. An assignment, grant, or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage."); 37 C.F.R. §1.47(b) ("Whenever all of the inventors refuse to execute an application for patent, or cannot be found or reached after diligent effort, a person to whom an inventor has assigned or agreed in writing to assign the invention, or who otherwise shows sufficient proprietary interest in the matter justifying such action, may make application for patent on behalf of and as agent for all the inventors."); 37 C.F.R. § 3.71 ("Prosecution by assignee… (c) Patents. Becoming of record. An assignee becomes of record either in a national patent application or a reexamination proceeding by filing a statement in compliance with § 3.73(b) that is signed by a party who is authorized to act on behalf of the assignee."); 37 C.F.R. § 3.73(b)(1) ("Ownership is established by submitting to the Office a signed statement identifying the assignee, accompanied by either: (i) Documentary evidence of

Absent such sworn declarations, only inventors may apply for patents.[170] Substantive entitlement conditions on accrual or application for intellectual property rights also may be based in national legislation other than intellectual property laws, such as laws implementing the CBD to require access and benefit sharing.[171]

2.1.7. The mechanisms adopted by national legislation to implement the CBD disclosure requirements in patent laws may add additional substantive conditions of entitlement to apply for or own patents. For example, such laws may require all applicants to file a "negative" declaration if no genetic resources or traditional knowledge subject to access and benefit sharing requirements were involved in developing the invention. The failure to provide the negative declaration would result in denial of the patent right, as might submission of a false or fraudulent negative declaration. Conversely, filing of a positive declaration may trigger an obligation to provide evidence demonstrating that the genetic resources or traditional knowledge were obtained in conformity with access requirements and that benefit sharing is being provided in conformity with applicable requirements. The failure to provide the required evidence or the submission of false or fraudulent evidence or statements in the positive declaration also may result in denial of the patent right if discovered in the patent office or provide grounds for invalidity, revocation, or unenforceability if discovered later.

2.1.8. Conformity of CBD Disclosures With International Patent Treaties. International patent treaties do not address, and therefore do not prohibit, CBD disclosure obligations as substantive conditions of entitlement. As noted by the WIPO Technical Study, TRIPS Art. 27.1 refers to substantive criteria for the patentability of inventions "and does not make specific provision for the entitlement of the applicant, which is separately determined."[172] As held by the WTO Appellate Body in regard to corresponding trademark provisions of the TRIPS Agreement, "the definition of the conditions of ownership has been left to the legislative discretion of individual countries…."[173] The TRIPS Agreement

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a chain of title from the original owner to the assignee (e.g., copy of an executed assignment). The documents submitted to establish ownership may be required to be recorded pursuant to § 3.11 in the assignment records of the Office as a condition to permitting the assignee to take action in a matter pending before the Office; or (ii) A statement specifying where documentary evidence of a chain of title from the original owner to the assignee is recorded in the assignment records of the Office (e.g., reel and frame number). (2) The submission establishing ownership must show that the person signing the submission is a person authorized to act on behalf of the assignee by: (i) Including a statement that the person signing the submission is authorized to act on behalf of the assignee; or (ii) Being signed by a person having apparent authority to sign on behalf of the assignee, e.g., an officer of the assignee.").

[170] *See* 35 U.S.C. § 111(a)(1) ("WRITTEN APPLICATION.—An application for patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title, in writing to the Director."); 35 U.S.C. § 117 (filing by legal representative in case of death of inventor); 35 U.S.C. § 118 (filing by assignee, person to whom invention is agreed in writing to be assigned, or person "who otherwise shows sufficient proprietary interest in the matter justifying such action," if the inventor refuses to apply).

[171] *See, e.g.,* Andean Communities, Decision 391 Complementary Provisions, Second.

[172] Technical Study, ¶ 180.

[173] WTO WT/DS176/AB/R, United States – Section 211 Omnibus Appropriations Act of 1998, ¶ 189, available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm. *See also id.,* at ¶¶ 122-148 (analyzing TRIPS Art. 2, which incorporates by reference Paris Convention Art. 6 and Art. 6^{quinquies}, and concluding that the Paris Convention does not prohibit national legislation establishing "conditions for filing and registration," and that the obligation to register marks "as is" under Art. 6^{quinquies} does not prohibit imposition

simply does not address or otherwise restrict substantive conditions of entitlement to apply for or own intellectual property rights. Nor do the Paris Convention, the PCT or the PLT address the substantive entitlement of the applicant to apply for and obtain patent rights.[174]

2.1.9. Because these treaties do not address substantive entitlement conditions, they should not be interpreted to restrict national legislation that would impose on patent applicants or owners additional procedures or formalities designed to demonstrate substantive entitlement. As noted by the WIPO Technical Study, there is no clear agreement over the difference between substantive requirements and procedures or formalities.[175] But even if characterized as procedures or formalities, the TRIPS Agreements in Art. 62.1 specifically authorizes members to "require, as a condition of the acquisition or maintenance of the intellectual property rights … compliance with reasonable procedures and formalities," so long as they are consistent with other requirements of the TRIPS Agreement.[176] Although PCT Art. 27(1) and PLT Art. 6(1) do restrict additional requirements for the "form and contents" of patent applications, the treaties were not negotiated with substantive conditions of entitlement in mind and should not be interpreted to restrict parties from imposing additional procedures and formalities (particularly at the national stage) designed to implement substantive entitlement requirements.[177] As discussed further below, PCT Art. 27(1) and PLT Art. 6(1) do not prohibit such requirements.

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of additional conditions). Specifically, the Appellate Body reviewed additional conditions on registration of trademarks, determining that by disestablishing ownership they "relate to" substantive conditions of ownership, and determined that such conditions are consistent with TRIPS Art. 15.1, which addresses "protectable subject matter" and requires only that various signs be "capable of" and "eligible for" registration, and with Art. 16.1, which confers rights on "owners." *See id.*, ¶¶ 114, 154-55, 166, 187. The Appellate Body held that ownership measures, including the filing requirements at issue, do "not in any way concern those issues that are addressed by Art. 15.1." *Id.,* ¶ 166.

[174] *See id.,* ¶¶ 122-48; Technical Study, ¶ 177. *See also* Consultant Report, ¶ 3.1.43 (recognizing that PCT Art. 27(2) authorizes inclusion of information in international application to satisfy national requirements for documentation of substantive entitlement to apply for patents, notwithstanding the Art. 27(1) prohibition on additional 'form and contents' requirements in international applications).

[175] *See* Technical Study, ¶¶ 132-35. *Cf.* Carlos M. Correa, Quaker United Nations Office, *Establishing a Disclosure of Origin Obligation in the TRIPS Agreement,* Occasional Paper 12, at 9 available at (noting that the distinction "may not be crucial," because non-substantive conditions may result in denial or revocation of patents, and treating CBD disclosure obligations as non-substantive); *id.* at 11 (treating CBD requirements as "reasonable" formalities under TRIPS Art. 62.1).

[176] Because it failed to address substantive conditions of entitlement, the CBD Consultant Report erroneously treated TRIPS Art. 62.1 as a potential limitation on CBD disclosure requirements, rather than as an express authorization therefore. *See* Consultant Report, ¶¶ 3.1.19-3.1.21 (implying that procedures not limited to examination of substantive criteria of patentability may be unreasonable).

[177] Treaties are to be interpreted where possible to avoid absurd or unreasonable results. *See* Vienna Convention on the Law of Treaties, Art. 32 ("Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion… to determine the meaning when the interpretation according to article 31…
(b) leads to a result which is manifestly absurd or unreasonable."). Were the PCT and PLT interpreted to prohibit additional requirements imposed by national legislation to establish entitlement of applicants to apply for international patents under the PCT, most national legislation requiring additional procedures to establish entitlement to apply in regard to international applications would be invalid. For example, the United States' requirements for a sworn statement by the assignee and for recording of the chain of title to prosecute international applications would be impermissible. *See, e.g.,* 35 U.S.C. § 364(a) (procedures for international applications are subject to requirements of the Patent Act); 35 U.S.C. § 373 (prohibiting acceptance of

2.1.10. Article 27.2 of the TRIPS Agreement also does not prohibit additional requirements relating to entitlement to apply for protection. Art. 27.2 provides that "Members may exclude from patentability inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law." [178] Art. 27.2 "makes clear that the fact that a national law prohibits the exploitation of an invention is not sufficient to render such invention ineligible for patentability."[179] However, Art. 27.2 does not in any way address entitlement to obtain or own patents. It only prohibits limiting the availability of patents based on regulatory prohibitions on commercializing inventions. In any event, CBD disclosures may reflect requirements "necessary to protect" *ordre public* or morality, because allowing patents on misappropriated genetic resources and traditional knowledge may constitute violations of *ordre public* or morality.[180] If existing patent treaties – including the TRIPS Agreement, the PCT, and the PLT – prohibited national requirements to prohibit granting rights on misappropriated inventions that constitute violations of *ordre public* or morality, it might be "necessary" to amend them.[181] The same is true for the UPOV Convention.

2.1.11. In sum, existing international patent law treaties do not address substantive conditions of entitlement to apply for patents or plant breeders certificates. These treaties should not be interpreted to prohibit what they do not address, particularly when principles of national sovereignty are taken into consideration.[182]

2.2. Conformity of CBD Disclosures With the TRIPS Agreement.

2.2.1. Conformity of CBD Disclosures With TRIPS Art. 27.1. Requirements for the disclosure of origin of genetic resources or traditional knowledge and of evidence of

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international applications at the national stage if submitted by an "[i]mproper applicant," which is to be determined pursuant to the requirements for national applications).

[178] *See* Daniel Gervais, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS at 223, ¶ 2.262 (2d ed. Sweet & Maxwell 2003) (hereinafter TRIPS DRAFTING HISTORY) (noting that "necessary" has been interpreted in the context of Article XX (b) of the GATT to be objectively justifiable and there must be no less GATT-restrictive reasonable, alternative measure available) (citing the DSB Panel Report in Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes, BISD 37S/200 (Nov. 7, 1990), and United States – Restrictions on Import of Tuna, BISD 39S/155 (Sept. 3, 1991)).

[179] *Id.* at 223, ¶ 2.262.

[180] *See, e.g.,* WTO IP/C/W/369, ¶ 18 (citing WTO IP/C/W/228); WTO IP/C/W/228, ¶ 17.

[181] *See* WTO IP/C/W/228, ¶ 26. *See id.,* ¶ 25.

[182] *See* Vienna Convention on the Law of Treaties, Art. 31(1) ("A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."); WTO WT/DS2/9, United States – Standards for Reformulated and Conventional Gasoline, Appellate Body Report and Panel Report, at 20, available at http://www.wto.org/english/tratop_e/dispu_e/gasoline.wp5 ("The Appellate Body considers that the basic international law rule of treaty interpretation, discussed earlier, that the terms of a treaty are to be given their ordinary meaning, in context, so as to effectuate its object and purpose"). *See also id.* at 17-19 (focusing on both the text and the context, and accepting interpretation that was "not itself treaty language" but was agreed to by all parties); *id.* at 22 (noting relevance of drafting history to understanding of the "purpose and object" of a specific provision).

conformity with access and benefit sharing requirements do not violate Art. 27 of the TRIPS Agreement. The relevant language of TRIPS Art. 27.1 provides that "[s]ubject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions… in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to Paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether patents are imported or locally produced." The CBD's Consultant Report overstates the stringency of this provision when suggesting that Art. 27.1 requires Parties to grant patents to inventions that meet the specified substantive patentability requirements and prohibits parties from imposing different conditions by field of technology on patent applications or on the enjoyment of patent rights.[183] Art. 27.1 is not so demanding. CBD disclosure requirements do not violate Art. 27.1, even if they resulted in denial or invalidity of patents and (contrary to the analysis above) even if they did not qualify as permissible conditions on entitlement of applicants or patents owners.

2.2.2. The final text of the TRIPS Agreement adopted only a general principle that all fields of technology be available (or eligible) for patent protection.[184] The TRIPS Agreement specifically rejected a mandatory requirement to grant patents meeting the specified substantive patentability criteria, when refusing to adopt bracketed language to require grant of patents in the Draft of July 23, 1990 (W/76): "Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable."[185] TRIPS Art. 27.1 simply does not require members to grant patents without regard to meeting additional requirements, much less additional requirements that differ based on the field of technology.[186] The second sentence of TRIPS Art. 27.1 reinforces that the first sentence does not prohibit denial of patents based on additional or differential conditions, as the second sentence prohibits only

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[183] *See* Consultant Report, ¶¶ 3.1.6, 3.1.11, 3.1.19, 3.1.22-23.

[184] *See* TRIPS DRAFTING HISTORY, at 220, ¶ 2.257 ("one might say that a general principle of eligibility to be patented is established. Any exclusion from patentability would therefore be looked upon as an exception to that rule.").

[185] *See id.* at 219, ¶ 2.255.

[186] *See* UNCTAD/ICTSD Intellectual Property Rights and Sustainable Development, TRIPS AND DEVELOPMENT: RESOURCE BOOK, Part II: Substantive Obligations, 2.5 Patents, 2.5.2 Non-Discrimination (Art. 27.1), at 31, 35 (TRIPS RESOURCE BOOK) (distinguishing "discrimination" from "differentiation" and noting that "patent laws in many countries currently allow for a differentiation based on field of technology," such as term extension based on pharmaceutical product regulatory reviews). Further, the interpretive maxim *expressio unius est exclusio alterius* is applicable here, indicating that other forms of discrimination may be permissible. *See* WTO IP/C/W/403, ¶ 10 ("There would be discrimination only if the three criteria of patentability (novelty, inventiveness and usefulness) are applied differently to different fields of technology."); RESOURCE BOOK, at 29 (noting the limitation to the three substantive conditions and stating that "[d]iscrimination based on other factors is not banned."). TRIPS Art. 27.1 should not be understood to prohibit additional and different requirements even with regard to the three substantive patentability conditions. It is widely accepted that various facially neutral substantive patentability criteria in fact impose different standards by field of technology, particularly for biotechnology. *See* Dan L. Burk and Mark A. Lemley, *Is Patent Law Technology Specific?,* 17 BERKELEY TECH. L. J. 1155 (2002). TRIPS Art. 27 itself recognizes this point by authorizing exclusions from Art. 27.1 availability and non-discrimination requirements by various fields of technology in Art. 27.3.

three specific forms of discrimination when making patents available. Similar provisions of the TRIPS Agreement relating to trademarks have similarly been interpreted by the Appellate Body to require only that parties make particular types of signs "capable of" and "eligible for" protection.[187]

2.2.3. The CBD Consultant's Report noted that the WTO Panel Report in Canada –Patent Protection of Pharmaceutical Products determined that facially neutral, additional criteria imposed on availability of patents or enjoyment of patent rights do not constitute "discrimination" within the meaning of Art. 27.1.[188] "The broader scope of the measure usually reflects an important legal principle that rules being applied in the area of primary interest should also be applied to other areas where the same problem occurs. Indeed, it is a common desideratum in many legal systems that legislation apply its underlying principles as broadly as possible. So long as the broader application is not a sham, the legislation cannot be considered discriminatory."[189]

2.2.4. The nature of the purported discrimination suggested to result from CBD disclosure requirements is the establishment of neutral conditions of entitlement on applicants for patents. CBD disclosure requirements apply to products and processes, which may be derived from genetic resources or traditional knowledge, in all fields of technology. Genetic resources and traditional knowledge may lead to inventions that include but are not limited to research tools, biotechnology, pharmaceuticals, medical techniques, new or isolated microbial, plant, or animal species, industrial chemicals, production methods, etc. Nothing suggests that CBD disclosure requirements would be a sham to discriminate against particular fields of technology, even if they would more frequently apply to pharmaceutical and biotechnological inventions.[190] It was precisely such an argument that the WTO Panel Report rejected.

2.2.5. Further, the Panel Report in the Canada – Patent Protection of Pharmaceutical Products interpreted "discrimination" to require more than just the imposition of differential conditions on patents, at least if the conditions are not limited by their express language to a particular field of technology and apply to some other fields.[191] The Panel Report also suggested that discrimination requires both relative disadvantage by

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[187] WTO WT/DS176/AB/R, ¶¶ 154-55.

[188] *See* Consultant Report, ¶¶ 3.1.22-3.1.23 (citing Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R, ¶¶ 7.99-7.105 (Mar. 17, 2000), available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm). *See also* TRIPS DRAFTING HISTORY, at 227, ¶ 2.268 (also noting that the Art. 27(1) prohibition on discrimination by field of technology applies to exceptions to patent rights under Art. 30) (citing WT/DS114/R, ¶¶ 7.88-7.93).

[189] WT/DS114/R, ¶ 7.104.

[190] For this reason, it is unnecessary to consider whether Art. 27(3), by allowing exclusions from patentability for "plants and animals … and essentially biological processes" would authorize CBD disclosures in regard to patents for inventions derived from plants, animals, and other genetic resources.

[191] *See* WT/DS114/R, ¶¶ 7.101-7.105 (analyzing provisions of Canadian law for de facto, rather than de jure, discriminatory effects or discriminatory purpose; finding no discriminatory purpose and suggesting that in the absence of discriminatory purpose the application of disadvantageous conditions beyond a particular field of technology will preclude a finding of discrimination by field of technology). Further, the Panel Report noted that the United States and Australia had argued that mere differential effect should not be considered discrimination. *See id.*, ¶ 7.100.

field of technology and lack of justification for differential conditions. "The ordinary meaning of the word 'discriminate' is potentially broader than the[] more specific definitions [in TRIPS Art. 3 and 4, requiring national treatment and most favored nation treatment, respectively.[192]] It certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment…. The standards by which the justification for differential treatment is measured are a subject of infinite complexity. 'Discrimination' is a term to be avoided whenever more precise standards are available, and, when employed, it is a term to be interpreted with caution, and with care to add no more precision than the concept contains."[193]

2.2.6. CBD disclosure requirements would be justifiable requirements even if they were not considered (contrary to this analysis) to constitute legitimate, neutral conditions of entitlement for patents. CBD disclosure requirements apply facially neutrally beyond particular fields, even if they may have differential application to particular inventions within the same or different fields. Further, CBD disclosure requirements would have sufficient justification to avoid being considered discrimination in the pejorative sense suggested by the Panel Report, even if (contrary to their nature) they were to facially impose differential conditions solely within a particular field. It would be extremely odd to view Art. 27.1 as prohibiting CBD disclosure requirements, given recognition that the substantive criteria of patentability in many cases will require such disclosures.[194] CBD disclosure requirements thus cannot be considered to impermissibly discriminate by field of technology.[195] For the same reasons, CBD disclosure requirements cannot be considered to discriminate by place of invention or by status of the invention in regard to local production (which forms of discrimination also are prohibited by Art. 27.1).

2.2.7. Finally, the CBD disclosure requirements derive from a treaty directing implementation of intellectual property rights to be consistent with CBD access and

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[192] TRIPS Art. 3.1 requires "treatment no less favourable" than corresponding treatment of nationals. TRIPS Art. 4 requires that "any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded …." The Panel Report noted the various interpretations of language in the GATT identical to TRIPS Art. 3.1 and 4, but specifically avoided reliance on those cases because the difference in terminology from Art. 27.1 "discrimination" made such reliance inappropriate. See WT/DS114/R, ¶ 7.98 (citing Japan — Taxes on Alcoholic Beverages, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (adopted 1 November 1996); European Communities - Regime for the Importation, Sale and Distribution of Bananas, WT/DS27/AB/R (adopted 17 November 1997); EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R, WT/DS48/AB/R (adopted 15 February 1998); United States - Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R (adopted 6 November 1998).

[193] WT/DS114/R, ¶ 94.

[194] *See, e.g.,* Technical Study, at ¶¶ 39- (discussing CBD disclosure obligations in regard to patentability criteria of enabling use of claimed inventions, determining the scope of prior art, and assuring access to microorganisms and biological materials); *id.,* at ¶¶ 50-52, (discussing requirements to disclose origins and access in regard to inventorship, and noting that under Paris Convention Art. 4ter the inventor has the right to be mentioned in the patent); *id.,* ¶¶ 74-79 (discussing disclosure requirements in regard to registration of security interests and ownership, which may be directly relevant to access and benefit sharing contracts).

[195] Because Art. 27.1 does not prohibit additional substantive conditions of entitlement for patents, Art. 27.3(b) is not an exclusive list of exceptions to Art. 27.1 that could result in denials of patents.

benefit-sharing obligations of parties.[196] The Vienna Convention on the Law of Treaties (which the WTO recognizes as applicable) requires that treaties such as the TRIPS Agreement be interpreted to take account of other principles of international law (including implementation provisions of other treaties).[197] Accordingly, Art. 27.1 cannot be read so as to conflict with TRIPS' Art. 7 and Art. 8 to preclude accomplishment of Art. 7 objectives and Art. 8 purposes (which are discussed further below).

2.2.8. <u>Conformity of CBD Disclosure Requirements With TRIPS Art. 29.</u> As recognized by the WIPO Technical Study, TRIPS Art. 29 addresses information disclosures that are required to establish substantive validity of the invention under the three conditions for patent protection.[198] The Art. 29.1 disclosure requirement may sometimes but will not always require disclosure of origins of genetic resources or traditional knowledge, and will rarely if ever require proof of compliance with access and benefit sharing requirements.[199] Art. 29 simply does not address substantive entitlement of the applicant for patent protection. Accordingly, and contrary to the suggestion by the CBD Consultant Report,[200] Art. 29 should not be understood to prohibit additional requirements for disclosure of entitlement to apply for patents. Nothing in the language or negotiating history of Art. 29 suggests that it was intended to regulate disclosures other than disclosures relevant to substantive conditions of patentability.

2.2.9. Art. 29.1 was intended to and does establish the minimum required substantive disclosure of the invention that assures the public is enabled to carry out the invention claimed.[201] Art. 29.1 and 29.2 authorize members to require disclosure, respectively, of the best mode of practicing the invention and information on foreign applications and grants (which is principally relevant to searching prior art and thus to substantive patentability). Even more than TRIPS Art. 27.1, Art. 29 cannot be interpreted as restricting disclosures regarding substantive conditions of entitlement by negative implication from requiring minimum disclosure relating to substantive conditions of patentability. Nor could it reasonably be interpreted to do so, given that the PCT and national laws require patent applicants to make various additional disclosures demonstrating their entitlement to apply for patents.[202]

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[196] *See* CBD, Art. 16.5 (requiring Parties "to ensure that such [intellectual property] rights are supportive of and do not run counter to its objectives.").

[197] *See* Vienna Convention on the Law of Treaties, Art. 31(3) ("There shall be taken into account, together with the context… (c) any relevant rules of international law applicable in the relations between the parties."); Gabrielle Marceau, *WTO Dispute Settlement and Human Rights,* at 51, available at http://www.ejil.org/journal/vol13/No4/art/.pdf ("Article 31(3)(c) of the Vienna Convention aims at promoting some 'coherence' in international law, so that the treaty is interpreted so as to avoid conflicts with other treaties.").

[198] Technical Study, ¶ 177.

[199] *See id.*¶¶

[200] *See* Consultant Report, ¶ 3.1.15 (suggesting that because Art. 29 mandates one form of disclosure requirement and permissively authorizes two other disclosure requirements, Art. 29 excludes imposition of other types of disclosures).

[201] *See* TRIPS DRAFTING HISTORY, at 239, ¶ 2.287.

[202] *See, e.g.,* PCT, Arts. 4(1)(iii)-(v) (the international application request "shall contain … the name of and other prescribed data concerning the applicant and agent (if any)… the title of the invention… [and] the name of and other prescribed data concerning the inventor" where required by a designated state); PCT Rules 4(a)(ii)-(iv) (same); PCT Rules 4(c)(i) & (iii) (request may contain indications concerning the inventor when

2.2.10. Further, Art. 29 should not be interpreted as restricting even additional disclosures addressing substantive conditions of patentability. The permissive language regarding disclosures of the best mode and foreign applications and grants was most likely employed to contrast with the required substantive disclosure for these two specific forms of disclosure, rather than to prohibit requirements for additional disclosures. As with Art. 27.1, nothing in Art. 29 suggests a prohibition on national requirements imposing additional, non-discriminatory conditions for patent applicants. Art. 29 should not be interpreted to preclude what it does not require.

2.2.11. Conformity of CBD Disclosures With TRIPS Art. 32. TRIPS Art. 32 provides that an "opportunity for judicial review of any decision to revoke or forfeit a patent shall be available." The TRIPS Agreement specifically rejected a proposed limitation in Art. 32 on revocation or forfeiture to cases where a patent had failed to meet the criteria for grant.[203] Because Article 32 does not restrict the substantive grounds on which patents may be invalidated or revoked, national legislation may provide for invalidation, revocation (or forfeiture), or unenforceability of patents based on failures to comply with CBD disclosures or on the making of false statements or omissions in such disclosures, even if substantive conditions of patentability are met.[204]

2.2.12. Conformity of CBD Disclosures With TRIPS Art. 62.1. As noted above, TRIPS Art. 62.1 supports rather than prohibits CBD disclosure requirements. Art. 62.1 expressly authorizes "reasonable procedures and formalities," so long as "[s]uch procedures and formalities shall be consistent with the provisions of this Agreement." CBD disclosure requirements should be considered reasonable, because as conditions of substantive entitlement they either are necessary to or help to implement CBD provisions against misappropriation. Because such conditions of entitlement are not inconsistent with other provisions of the TRIPS Agreement, they are authorized by Art. 62.1.[205]

2.2.13. Even if CBD disclosure requirements were not considered substantive conditions of entitlement (contrary to the above analysis), they would be authorized by Art. 62.1. As discussed above, such CBD disclosure requirements do not conflict with Art. 27.1, which does not prohibit additional procedures or formalities but only requires that all fields of technology be available for patenting. CBD disclosure requirements also do not

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not required by a designated state and a declaration under Rule 4.17); PCT Rules 4.17(i)-(iii) (request may contain declarations regarding the inventor and the applicant's entitlement to apply); 35 U.S.C. § 115 (applicant "shall make oath" regarding belief in his original and first invention and "shall" identify his citizenship).

[203] *See* TRIPS DRAFTING HISTORY, at 254, ¶ 2.312.

[204] Even if Article 32 were to limit revocation or forfeiture to the grounds for denial, the TRIPS Agreement does not preclude conditioning issuance of patents on CBD disclosures and the absence of false or fraudulent statements and omissions. Further, Art. 32 does not address unenforceability of patents, but only revocation or forfeiture; Art. 32 thus would not prohibit patents from being declared unenforceable on additional grounds to those for denial. In contrast, Art. 10(1) of the PLT, as reflected in Explanatory Note ¶ 10.01 thereto, would preclude such additional grounds for unenforceability.

[205] For similar reasons to those discussed in regard to discrimination and reasonableness, CBD disclosure requirements that render patents invalid, revocable, or unenforceable should be considered "fair and equitable" procedures for enforcement within the meaning of TRIPS Art. 41.2.

conflict with Art. 29, which does not restrict additional disclosure requirements but only mandates the minimum disclosures relevant to substantive patentability criteria. Again, by implementing the CBD, such requirements should be considered reasonable.

2.2.14. Consistency of CBD Disclosures With TRIPS Arts. 7 and 8. As noted by the Consultant Report, TRIPS Arts. 7 and 8 may authorize the imposition of CBD disclosure requirements.[206] The WTO in the Doha Ministerial Declaration on Public Health held that "each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."[207] Art. 7, which identifies these objectives, states that "[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." Art. 8.2 provides as a TRIPS principle that "[a]ppropriate measures … may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which … adversely affect the international transfer of technology."

2.2.15. CBD access and benefit sharing requirements self-consciously seek to promote innovation and technology transfer in a manner conductive to social and economic welfare. CBD disclosure requirements also promote technology transfer and economic welfare,[208] as well as assure a balance between intellectual property rights and obligations in regard to misappropriation. For these and additional reasons, the CBD in adopting the Bonn Guidelines expressly encouraged countries to adopt CBD disclosure requirements. Accordingly, TRIPS provisions should be interpreted to effectuate, rather than to prohibit, CBD disclosure requirements in patent applications. Specifically, Art. 27.1 and Art. 29 should not be interpreted to preclude effectuation of CBD disclosure requirements, which are calculated to effectuate TRIPS Art. 7 welfare promotion and balancing objectives.[209]

2.3. Conformity of CBD Disclosures With the Paris Convention.

2.3.1. Conformity of CBD Disclosures With Paris Convention Arts. 2 & 3.

Art. 2(1) of the Paris Convention provides that "Nationals of any country of the Union shall … enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals." Art. 2(2) provides that "no requirement as to domicile or establishment in the country where protection is claimed may be imposed upon nationals of countries of the Union…." Art. 3 provides that "[n]ationals of countries

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[206] *See* Consultant Report, ¶ 3.1.25 (citing WTO IP/C/W/403 and THE TRIPS REGIME OF PATENT RIGHTS, at 155 n. 445).

[207] WT/MIN(01)/DEC/2, ¶ 5(a).

[208] CBD Art. 17.1 requires Parties to "facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries." CBD disclosure requirements for intellectual property applications thus not only reinforce access and benefit sharing obligations but also promote collection and exchange of relevant information.

[209] *Cf. Requiring Disclosure of Origin,* at 395-96 (noting the "comparative advantage of developing countries" in biodiversity and knowledge of its use in a sustainable manner, which may constitute sectors of vital importance under TRIPS Art. 8(1) warranting additional measures under Art. 8(2)).

outside the Union who are domiciled or who have real and effective industrial or commercial establishments in the territory of one of the countries of the Union shall be treated in the same manner as nationals of the countries of the Union." These national treatment and similar treatment obligations impose narrower but more restrictive requirements than the TRIPS Art. 27.1 prohibitions against discrimination and are similar to the TRIPS Art. 3 national treatment and TRIPS Art. 4 most-favored-nation treatment requirements discussed above.

2.3.2. CBD disclosure requirements should be fully consistent with the Paris Convention Art. 2 and Art. 3 obligations. CBD disclosure requirements can and should be applied without distinction to nationals of all countries and without domicile requirements, and should apply uniformly whenever the relevant access and benefit sharing requirements are triggered.[210] The neutral application of CBD disclosure requirements should be sufficient for conformity with Art. 2 and Art. 3 obligations, even if there may be some difference in effect in the application of the CBD disclosure requirements.[211]

2.3.3. Conformity of CBD Disclosures With Paris Convention Art. 4. Art. 4 of the Paris Convention addresses rights to claim priority to foreign intellectual property applications. Because Art. 4 does not address substantive validity of applications, CBD disclosure requirements (as substantive conditions on entitlement to apply for a patent) should be fully consistent with Art. 4. Further, Art. 4 does not address or prohibit imposition of other substantive or procedural conditions on the processing of patent applications.[212]

2.3.4. Conformity of CBD Disclosures With Paris Convention Art. 4^{bis} and Art. 4^{ter}. Art 4^{bis}(1) of the Paris Convention provides that patent applications shall be independent of patents obtained in other countries. Art. 4^{bis}(2) provides that such independence extends for patents subject to priority claims to nullity and forfeiture, as well as to term of protection. 4^{bis}(5) requires that patents claiming priority shall have the same term as they would without claiming priority. Art. 4^{ter} provides that inventors shall have the right to be identified in the patent. It should be apparent that CBD disclosure requirements are consistent with these provisions. These provisions do not restrict grounds

[210] The national of the country imposing CBD disclosure requirements will be subject to those requirements to the same extent as the national of any other country, whether the acquisition of genetic resources or traditional knowledge and the inventive activities occur in the country imposing the disclosure requirements or in other countries.

[211] For example, nationals of highly biodiverse countries and highly developed countries may be more likely than nationals of less biodiverse countries and less developed countries, respectively, to access genetic resources or traditional knowledge and to develop patentable inventions derived from such resources. Accordingly, nationals of highly biodiverse countries and highly developed countries may be more likely to be required to provide evidence of compliance with access and benefit sharing requirements.

[212] An argument might be constructed that national patent offices cannot prohibit acceptance of applications lacking required CBD disclosures, because Art. 4 requires that "equivalent" national applications meeting the specified criteria be accorded priority to the corresponding foreign applications. In particular, Art. 4(d) provides that (4) "[n]o other formalities [than those specified] may be required for the declaration of priority at the time of filing the application." Although such an argument is absurd or unreasonable, as it would prevent national patent offices from refusing applications without payment of fees or submission of required inventor's oaths, it also may be avoided by the simple expedient of accepting the application, according it foreign priority, and refusing to process it.

for nullity or forfeiture based on national criteria of substantive entitlement to apply for patents, and do not otherwise prohibit national legislation imposing conditions on grant or validity of patent rights. Rather, 4ter provides additional support for CBD disclosures, in order to assure that the correct inventor is identified in cases where the contributor of genetic resources or traditional knowledge should be considered an inventor. Accordingly, CBD disclosure requirements are consistent with these provisions.

2.3.5. Conformity of CBD Disclosures With Paris Convention Art. 4quater. Art. 4quater of the Paris Convention provides that "[t]he grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law." As discussed above in regard to TRIPS Art. 27.2, this provision does not address or prohibit requirements regarding the substantive entitlement to apply for patents. Accordingly, CBD disclosure obligations are consistent with Art. 4quater.

2.3.6. Conformity of CBD Disclosures With Paris Convention Art. 5. Art. 5(A) of the Paris Convention addresses additional conditions on enjoyment of patent rights and compulsory licensing for abuses of those rights. Of greatest relevance, Art. 5(A)(1) provides that "[i]mportation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent." In context, "articles manufactured" refers to the patented inventions, and the Art. 5(A)(1) prohibition on forfeiture would not be triggered by import of genetic resources or traditional knowledge from which the inventions may be derived. Art. 5(A)(3) provides that "[f]orfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses" for which compulsory licenses can be granted under Art. 5(A)(2), including failure to work the patent. Again, these provisions are not addressed to and do not prohibit requirements regarding substantive entitlement to apply for patents. Accordingly, CBD disclosure obligations are consistent with Art. 5.

2.4. Conformity of CBD Disclosures With the PCT.

2.4.1. Conformity of CBD Disclosures With PCT Art. 11(1). Art. 11(1) requires the receiving office to accord an international filing date to applications after determining that applications: (i) do not have an obvious defect in the right to file the application in the receiving office based on nationality or residence of the applicant; (ii) use the prescribed language; and (iii) contain information establishing (a) an intent to be an application, (b) a designation of a contracting state, (c) the name of the applicant, (d) a description, and (e) a claim. Art. 11(3) provides that, "[s]ubject to Art. 64(4) [allowing reservations from the treaty for treatment of patents as prior art from their filing date while excluding foreign application priority dates from being considered prior art filing dates], any international application fulfilling the requirements listed in items (i) to (iii) of paragraph (1) and accorded an international filing date shall have the effect of a regular national application in each designated State as of the international filing date, which date shall be considered to be the actual filing date in each designated State." A potential exists for CBD disclosure requirements to conflict with PCT Art. 11, to the extent that the CBD disclosures were imposed at the international stage of PCT applications, if applications

failing to contain required CBD disclosures were refused without first according the application an international filing date. Although PCT Art. 11 does not address and thus should not be interpreted to limit additional conditions on processing of PCT applications, it was intended to assure that applications would be received and examined further. Accordingly, any conflict could easily be avoided, simply by accepting the application, according it an international filing date, and refusing to process it further (but not withdrawing it in a manner that would result in loss of the filing date) without provision of the required disclosures.

2.4.2. Nevertheless, it may be prudent to avoid imposing CBD disclosure requirements at the international stage of PCT applications. Unless CBD disclosure requirements are mandated by amending intellectual property treaties, they will be imposed voluntarily by particular countries only in regard to their own patent laws. It therefore makes sense to impose those requirements only when applications enter the national stage of countries requiring the CBD disclosures and for which patent protection is sought. Limiting CBD disclosure requirements to the national stage of PCT applications also avoids extraterritorial jurisdiction concerns regarding the application of CBD disclosure requirements of the receiving office (as well as countries of origin of genetic resources or traditional knowledge or particular countries designated in the international application) to different countries designated in the international application.[213]

2.4.3. Conformity of CBD Disclosures With PCT Arts. 3(2), (4), 14, and 26.
PCT Art. 3(2) provides that "an international application shall contain … a request, a description, one or more claims, one or more drawings (where required), and an abstract." As discussed above, PCT Art. 4(1)(iii)-(v) provides that the international application request shall contain information regarding the name and prescribed data regarding the applicant, the title of the invention, and the name and prescribed data regarding the inventor where required by a designated state. PCT Art. 14(1) requires the receiving office to check for specific information, to notify the applicant of deficiencies (including (ii) the prescribed indications concerning the applicant), and to treat the application as withdrawn if corrections are not timely made. Similarly, Art. 14(4) requires the receiving office to treat the application as withdrawn if corrections are not made to deficiencies in the application under Art. 11(1)(i)-(iii). PCT Art. 26 requires countries at the national stage to allow applicants to correct errors in their applications to the same extent as permitted for national applications.

2.4.4. Although some of these provisions address substantive entitlement to apply for the patent, they are written either as mandatory minimum requirements or as discretionary requirements for equal treatment of international and national applications.

[213] The concern over extraterritorial jurisdiction is addressed in PCT Art. 25(2)(a), which provides relief for errors by receiving offices that would adversely affect applicants' rights in designated states. Specifically, it requires the designated states to review (upon request by the applicant and payment of fees) decisions by the receiving office refusing to process international applications, and authorizes the designated states to treat what it believes were errors as if they had not occurred (but only "as far as effects in the State of the designated Office are concerned"). In contrast, PCT Art. 41(3) requires application of the national laws of the state in which a preliminary examination is elected to amendments to the application, even though such law may differ from the laws of designated states.

Accordingly, these provisions should not be interpreted to prohibit the imposition of additional substantive conditions of entitlement to apply by designated countries. Nor do these provisions appear to prevent receiving offices from imposing under their own laws additional substantive entitlement conditions and corresponding requirements for disclosure on international applications under the PCT, or from recognizing and applying at the international stage additional substantive criteria of entitlement of designated countries. Nevertheless, the premise of the PCT is that applications meeting the mandated minimum requirements would be afforded an international search and search report under PCT Arts. 16-18, and, upon request, a preliminary examination under PCT Arts. 31-36. Again, absent amendment of international patent treaties to require CBD disclosure obligations, it may be prudent to limit application of CBD disclosure requirements to the national stage of PCT applications.

2.4.5. Conformity of CBD Disclosures With PCT Art. 27(1). PCT Art. 27(1) provides that "[n]o 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." At first blush, Art. 27(1) would appear to prohibit CBD disclosures requirements being imposed on PCT applications either at the international stage or at the national stage. However, Art. 27(3) expressly provides that "[w]here the applicant, for the purposes of any designated State, is not qualified according to the national law of that State to file a national application because he is not the inventor, the international application may be rejected by the designated Office." Art. 27(2)(ii) further provides that Art. 27(1) does not "preclude any national law from requiring once the processing of the international application has started in the designated Office, the furnishing … of documents not part of the international application but which constitute proof of allegations or statements made in that application."[214] The PCT restricts such national qualification requirements only based on residence and nationality under Art. 9.[215]

2.4.6. Because CBD disclosure requirements are substantive conditions of entitlement to apply authorized under Art. 27(3), and because Art. 27(2)(ii) expressly authorizes requirements for submission of additional documentation relating thereto, Art. 27(1) should not be interpreted to preclude countries from imposing CBD disclosure

[214] PCT Art. 22(1) further allows delay in national-stage provision of information regarding the inventor when not supplied in the request and where delay is allowed by national law, but not later than a specified time following the priority date accorded the application.

[215] *See* PCT Art. 9 ("The Applicant. (1) Any resident or national of a Contracting State may file an international application. (2) The Assembly may decide to allow the residents and the nationals of any country party to the Paris Convention for the Protection of Industrial Property which is not party to this Treaty to file international applications. (3) The concepts of residence and nationality, and the application of those concepts in cases where there are several applicants or where the applicants are not the same for all the designated States, are defined in the Regulations."). *See also* PCT Rule 18(4)(c) ("The International Bureau shall, from time to time, publish information on the various national laws in respect of the question who is qualified (inventor, successor in title of the inventor, owner of the invention, or other) to file a national application and shall accompany such information by a warning that the effect of the international application in any designated State may depend on whether the person designated in the international application as applicant for the purposes of that State is a person who, under the national law of that State, is qualified to file a national application.").

requirements on international PCT applications.[216] This is particularly true given that CBD disclosure requirements are substantive conditions of entitlement to apply for patents, and that Art. 27(5) provides that "[n]othing 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."[217] For this reason, as suggested by the WIPO Technical Study, CBD disclosure requirements should not be considered precluded by PCT Rule 5bis.2(a)(ii), which prohibits national laws from requiring any additional declarations or evidence to establish "the applicant's entitlement, as at the international filing date, to apply for and be granted a patent [as expressly authorized by Rule 51*bis*.1(a)(ii)], except in cases where the patent office "may reasonably doubt the veracity of the indications or declaration concerned."

2.4.7. The language of Art. 27(3) does not by its own terms prohibit a designated office from imposing substantive conditions on entitlement and disclosures relating thereto at the international stage for PCT applications.[218] Further, because the language of Art.27(3) is a permissive authorization, it should not be interpreted to prohibit receiving offices from doing so (under domestic law or by recognizing and applying the law of designated offices). Nevertheless, imposing such obligations at the international stage may pose a conflict with the PCT Regulations. PCT Rule 4.1(a)(iii) requires the international request to contain only "indications concerning the applicant and the agent, if there is an agent," and PCT Rule 4.5 does not include within the mandatory information regarding applicants in the international request evidence of substantive entitlement to apply for the patent.[219] Although under PCT Rule 4.17(ii) an applicant may voluntarily include at the international stage a declaration of entitlement to apply, for the purposes of satisfying

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[216] As noted above by the Technical Study, a PCT applicant may be required by national law to provide a declaration of an entitlement to apply for and be granted a patent, and national laws can require additional documents or evidence concerning both the entitlement and the identity of the inventor in cases of reasonable doubt as to the indications or declaration. *See* Technical Study, ¶ 177 (citing PCT Rules 51bis.2(a)(i)&(ii)).
[217] *See* Technical Study, ¶ 179 (noting the likely application of this language to substantive conditions on entitlement to apply for patents).
[218] Unlike Art. 27(2), Art. 27(3) does not contain introductory language implying that it is an exception to the "form and contents" limitation of Art. 27(1). Similarly, the caption to Art. 27 ("National Requirements") does not suggest that Art. 27(3) is an exception to Art. 27(1). PCT Arts. 27(5) and (6) also preserve authority to impose national requirements relating to "substantive conditions of patentability" and to require furnishing of evidence in regard thereto. Although Art. 27(5) discusses PCT Treaty and PCT Regulatory definitions of prior art in regard to "the international procedure," nothing in either subsection limits the preserved authority from applying at the international stage of PCT applications. Nor does Art. 27(4) appear to be limited to the national stage, although that was clearly its focus. Art. 27(4) authorizes application of more-favorable national-application treatment to international applications (so long as the applicant does not object). Only Art. 27(7), which addresses national law regarding authorization of agents to practice before the office, is limited (for designated but not receiving offices) to the national stage.
[219] *See* PCT Rule 4.5 ("4.5 *The Applicant.* (a) The request shall indicate: (i) the name, (ii) the address, and (iii) the nationality and residence of the applicant or, if there are several applicants, of each of them. (b) The applicant's nationality shall be indicated by the name of the State of which he is a national. (c) The applicant's residence shall be indicated by the name of the State of which he is a resident. (d) The request may, for different designated States, indicate different applicants. In such a case, the request shall indicate the applicant or applicants for each designated State or group of designated States. (e) Where the applicant is registered with the national Office that is acting as receiving Office, the request may indicate the number or other indication under which the applicant is so registered.").

national laws of designated offices,[220] PCT Rule 4.18(a) prohibits national laws from requiring more information at the international stage than is required under the PCT Regulations.[221]

2.4.8. At the national stage, the PCT does not require national legislation to provide the opportunity for applicants to correct erroneous information contained in international applications. Rather, PCT Art. 26 requires only that any opportunity to correct an international application must be available to the same extent as for national applications.[222] Thus, CBD disclosure requirements may, consistent with the PCT, prohibit applicants from curing false or fraudulent initial disclosures or failures to disclose origins of genetic resources or traditional knowledge. The PCT also does not contain any provisions prohibiting CBD disclosure requirements from imposing invalidity, revocation, or unenforceability of patents as sanctions for disclosure failures.

2.5. Conformity of CBD Disclosures With the PLT.

2.5.1. Conformity of CBD Disclosures with PLT Art 5(1). PLT Art. 5(1)(a) provides that "[e]xcept as otherwise prescribed in the Regulations, and subject to paragraphs (2) to (8), a Contracting Party shall provide that the filing date of an application[223] shall be the date on which its Office has received all of the following elements … (i) an express or implicit indication to the effect that the elements are intended to be an application; (ii) indications allowing the identity of the applicant to be established or allowing the applicant to be contacted by the Office; (iii) a part which on the face of it appears to be a description."[224] PLT Art. 5(1) thus requires parties to accord a filing date to applications containing such information.[225] Similarly to PCT Art. 11(1) as discussed above, a potential exists for CBD disclosure requirements to conflict with PLT Art. 5(1) to the extent that the applications failing to contain required CBD disclosures were refused without first according the application a filing date. As with PCT Art. 11(1), the conflict

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[220] *See* PCT Rule 4.17(ii) ("The request may, for the purposes of the national law applicable in one or more designated States, contain one or more of the following declarations, worded as prescribed by the Administrative Instructions…. (ii) a declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent, as referred to in Rule 51*bis*.1(a)(ii)).

[221] *See* PCT Rule 4.18 ("*Additional Matter.* (a) The request shall contain no matter other than that specified in Rules 4.1 to 4.17, provided that the Administrative Instructions may permit, but cannot make mandatory, the inclusion in the request of any additional matter specified in the Administrative Instructions. (b) If the request contains matter other than that specified in Rules 4.1 to 4.17 or permitted under paragraph (a) by the Administrative Instructions, the receiving Office shall *ex officio* delete the additional matter.").

[222] *See* PCT Art. 26 ("Opportunity to Correct Before Designated Offices. No designated Office shall reject an international application on the grounds of non-compliance with the requirements of this Treaty and the Regulations without first giving the applicant the opportunity to correct the said application to the extent and according to the procedure provided by the national law for the same or comparable situations in respect of national applications."). In contrast, PCT Arts. 41(1)&(2) require that an opportunity be provided to amend the description in the specification during preliminary examination in an elected office.

[223] PLT Arts. 3(1) and (2) provide that the PLT and the PLT Regulations apply only to original and divisional national or regional applications that would be permitted to be filed as international PCT applications, to PCT international applications in regard to time limits for national stage entry and procedures after the dates for national stage entry, and to granted patents. *See* Explanatory Notes, ¶ 3.05.

[224] PLT Art. 5(1)(c) provides that parties may require either or both indications of Art. 5(1)(a)(ii).

[225] *See* Explanatory Notes, ¶ 5.01.

may be avoided by accepting the application, according it a filing date, and refusing to process it further (but not withdrawing it in a manner that would result in loss of the filing date) without provision of the required disclosures. This approach may be required by PLT Arts. 11 and 12.[226]

2.5.2. Conformity of CBD Disclosures With PLT Art. 6(1). **PLT** Art 6(1) provides that "[e]xcept where otherwise provided by this Treaty, no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to: (i) the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty; (ii) the requirements relating to form or contents compliance with which, under the Patent Cooperation Treaty, may be required by the Office of, or acting for, any State party to that Treaty once the processing or examination of an international application, as referred to in Article 23 or 40 of the said Treaty, has started; (iii) any further requirements prescribed in the Regulations." As noted above by the Technical Study, the Explanatory Notes to Art. 6(1) clarify that this provision does not apply to certain additional indications, such as disclosure of foreign applications or of assistance of an invention marketing company.[227] The Explanatory notes further clarify that Art. 6(1)(ii) "permits a Contracting Party to require that a national or regional application comply with any requirements relating to the 'form or contents' that any State party to the PCT is allowed to apply in the 'national phase' of an international application, in particular, the requirements that are allowed under PCT Rule 51*bis*. It is to be noted that this item is not restricted to the particular 'national phase' requirements under the PCT applied by the Contracting Party concerned, but rather applies to any 'national phase' requirements allowed under the PCT."[228]

2.5.3. As discussed above in regard to PCT Art. 27(1), PCT Rule 51bis.2 should not be understood to preclude CBD disclosure requirements, because they constitute substantive conditions on entitlement to apply for patents. Similarly, PLT Art. 6(1), which limits requirements relating to the "form and contents" of applications should not preclude CBD disclosure requirements. Nor should CBD disclosure requirements be precluded by PLT Rule 3(2), which provides that a "Contracting Party shall accept the presentation of the contents referred to in Article 6(2)(a)" -- if presented on a request form corresponding to a PCT request form or on a PCT request form, with any modifications allowed under Rule 20(2). PLT Art. 6(2)(a) authorizes but does not require parties to require presentation of information on an application form, and (as with PCT Rule 51bis.2) should not be

[226] Art. 11(1) authorizes a party to extend upon timely request the time limits for applicants and patentees to comply with requirements . Art. 11(2) provides that parties shall provide for continued processing of applications or patents and if needed for restoration of rights upon request and subsequent compliance (and payment of fees). Art. 11(3) provides exceptions from the obligations as provided in the PLT Regulations. Art. 11(5) prohibits additional requirements on such extension or restoration except as provided in the PLT Regulations (Rule 12). Art. 12 provides that parties shall restore upon request and subsequent compliance (and payment of authorized fees and compliance with authorized requirements for declarations and evidence regarding the reasons for non-compliance) any rights that are lost by applicants or patentees as a result of failures to comply with requirements within specified time limits, after a finding that in spite of "due care" the delay was unintentional and except in regard to specific conduct identified by a list of exceptions in the PLT Regulations (Rule 13).

[227] *See* Technical Study, ¶ 169 (citing Explanatory Notes, ¶ 6.03).

[228] Explanatory Notes, ¶ 6.07.

understood to prohibit additional substantive conditions of entitlement or disclosure requirements relating thereto.

2.5.4. Conformity of CBD Disclosures With PLT Art. 10(1). PLT Art. 10(1) provides that "[n]on-compliance with one or more of the formal requirements referred to in Articles 6(1), …. May not be a ground for revocation or invalidation of a patent … except where the non-compliance with the formal requirement occurred as a result of fraudulent intention." PLT Art. 10(2) requires an opportunity "to make observations on [any] intended revocation or invalidation, and to make amendments or corrections where permitted under the applicable law." As discussed immediately above, CBD disclosure requirements should be considered substantive conditions of entitlement to apply that are not subject to the prescriptions of Art. 6(1) and thus are not subject to the provisions (by reference) of Art. 10(1).[229] Accordingly, even stringent CBD disclosure requirements resulting in invalidity of patents should not conflict with PLT Art. 10(1).

2.6. Conformity of CBD Disclosures With the UPOV Convention.

2.6.1. Conformity of CBD Disclosures as Substantive Conditions of Entitlement. As with patent law treaties, the UPOV Convention should not be understood to prohibit CBD disclosures intended to assure entitlement to apply for plant breeder certificates. The relevant provisions of the UPOV cited by the Consultant Report address substantive conditions for issuance of certificates and compliance with formalities, not substantive conditions of the entitlement of applicants or owners.[230] Although the relevant provision of the 1978 UPOV Convention addressing nullification of rights does not address substantive conditions for entitlement, the 1991 UPOV Convention expressly contemplates cancellation based on national requirements regarding such conditions for entitlement (subject to potential transfer to a person entitled to the right).[231] Accordingly, the UPOV Convention should not be understood to prohibit Parties from imposing CBD disclosure requirements on plant breeder certificate applications as substantive conditions of entitlement. However, even if CBD disclosure requirements were not considered substantive conditions of entitlement (contrary to this analysis), CBD disclosures resulting in denial or invalidity of certificates may not necessarily be inconsistent with the relevant UPOV provisions, for reasons similar to the analysis of TRIPS Art. 27.1 and PLT Art. 6(1) provided above.[232] This memorandum does not analyze the UPOV issues further.

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[229] Because Explanatory Notes ¶¶ 10.01 and 10.08 extend the meaning of revocation and invalidity under Art. 10(1) to unenforceability of patents, were Art. 10(1) to apply to CBD disclosures it also would prohibit unenforceability except when the required information was submitted or withheld with fraudulent intent. *See* Technical Study, ¶ 135. *See also id.* ¶ 153 (noting entitlement to challenge patent when formalities address patentability or entitlement, but that Article 10 restricts invalidation when violations of formalities occur without fraudulent intent).

[230] *See* Consultant Report, ¶¶ 3.2.8-3.2.9 (citing 1978 UPOV Arts. 6 & 10(1)-(2), and 1991 UPOV Arts. 5 & 21).

[231] *See* 1978 UPOV, Art. 10; 1991 UPOV, Art. 21(1)(iii).

[232] However, the relevant language and application of the patent treaties and UPOV Convention differ, and thus careful analysis of the provisions is required. TRIPS Art. 27.1 requires only that patents be "available for any inventions … in all fields of technology" when the specified substantive conditions are met. In contrast, 1978 UPOV Art. 6 requires that "the breeder shall benefit from the protection provided" when the specified substantive conditions are met, and 1991 UPOV Art. 5 requires that "[t]he breeder's right shall be granted" on

2.7. Additional Considerations on Implementing CBD Disclosures.

2.7.1. Unenforceability and Independent Remedies. As indicated in the analyses of conformity to particular provisions of international patent treaties, CBD disclosure requirements are permissible even when they require denial or invalidity of patents in the absence of fraud. To the extent that such stringent requirements are consistent with international patent law treaties, less stringent requirements resulting in unenforceability of issued patents or imposing remedies through civil or criminal sanctions external to the patent system also should be permissible. However, such additional civil or criminal sanctions may be limited to fraudulent statements and omissions, and thus may not themselves create prohibitions on substantive entitlement to apply for patent protection in cases of misappropriation. Accordingly, if a country wishes to rely on such sanctions, it should also provide either in its access and benefit-sharing legislation or in its patent legislation requiring such disclosures to be made that such misappropriation deprives applicants of the substantive entitlement to patent rights.

2.7.2. Curing Failures to Disclose or Fraudulent Conduct. As indicated by the discussion above, CBD disclosure requirements are compatible with existing patent law treaties even if they result in incurable denial, invalidity, revocation, or unenforceability of patents. However, it may be prudent policy to allow applicants or patentees to cure even intentional failures to provide required CBD disclosures, or fraudulent submissions of omissions in those disclosures, without resulting in permanent denial of patent rights or in permanent invalidation, revocation, or unenforceability of issued patents. Providing curable sanctions would minimize concerns that animate arguments regarding inconsistency of CBD disclosure requirements with international patent treaty provisions. In particular, such curable sanctions would be in greater harmony with provisions of the PLT authorizing or requiring remedial actions to protect applicants' and owners' patent rights.[233]

2.7.3. Curable sanctions also may better assure commercialization of inventions subject to patents. Adopting curable sanctions for CBD disclosure requirements would allow applicants to proceed to acquire or owners to retain enforceable patent rights. Applicants and owners thereby may be better able to commercialize and disseminate the inventions that derive from genetic resources or traditional knowledge. In this way, applicants and owners may better assist countries and indigenous groups that are the intended beneficiaries of the CBD access and benefit sharing requirements.

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meeting the conditions. Similarly, PLT Art. 6(1) prohibits national requirements regarding "form and contents" of applications, whereas 1978 UPOV Art. 6 prevents grants from being subject to substantive "conditions other than those set forth" and not national formalities, and 1991 UPOV Art. 5 prevents grants from being subject to "any further or different [substantive] conditions" and not national formalities. In particular, the language of PLT addressing grounds for invalidity of patents differs dramatically from the corresponding language in UPOV. PLT Art. 10(1) prohibits revocation for failure to comply with formalities, except in cases of fraud, whereas 1978 UPOV Art. 10 requires nullification on and limited to specified substantive grounds, 1991 UPOV Art. 21 requires nullification on and limited to specific substantive (including elibility) and procedural grounds, and 1991 UPOV Art. 22 permits cancellation on specified substantive and procedural grounds.

[233] *See* PLT Arts. 11, 12.

2.7.4. Disclosure failures may cured administratively or judicially. For example, reissue proceedings in the United States PTO exist to correct non-fraudulent errors that would otherwise invalidate patents based on substantive patentability conditions,[234] and inventorship may be corrected during the application process or after issuance at the direction of courts.[235] Alternatively, national law could authorize judges to cure CBD disclosure failures without returning patents to patent offices. To effectuate disclosure obligations and to avoid permanent denial of rights, patents applications could be withheld from processing unless and until applicants provided the required information upon request, and unless and until the disclosed information were found adequate to demonstrate compliance with applicable access or benefit-sharing requirements of relevant countries. Issued patents could be presumed invalid, revocable or unenforceable based on the failure to comply with disclosure requirements in the patent office, subject to administrative or judicial procedures for curing disclosure deficiencies.

[234] *See* 35 U.S.C. § 251("Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less then he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.").
[235] *See* 35 U.S.C. §§ 116 ¶3, 256.