Preservation and Use of Genetic Resource Assets and the International Patent System

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The views expressed herein are solely those of the author.

I. Background, Methodology and Conclusion of the Study

In 1992 the Convention on Biological Diversity (CBD) was adopted at the Rio Conference.[1] In 1994 the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was adopted in Marrakech.[2] From the outset, questions were raised as to whether there are conflicts or potential conflicts between the objectives and rules of these two international undertakings. These questions have been on the agenda of the WTO TRIPS Council[3] and the Committee on Trade and Environment,[4] they have been raised in the context of work programs and negotiations at the World Intellectual Property Organization (WIPO),[5] they have been considered by the Conference of the Parties of the CBD,[6] and they are the subject of numerous studies and reports by

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[1] Convention on Biological Diversity (CBD), adopted June 5, 1992, available at http://www.biodiv.org/convention/articles.asp. As of March 26, 2005, there are 188 state parties to the CBD. The United States of America signed the CBD on June 4, 1993, but has not ratified the Convention. *See generally* Françoise Burhenne-Guilmin and Susan Casey-Lefkowitz, *The Convention on Biological Diversity: A Hard Won Global Achievement*, 3 (1992) YbIEL 43 (1993) and Edith Brown Weiss, *Introductory Note, United Nations Conference on Environment and Development*, 31 I.L.M. 814 (1992) (and agreement texts following, including Convention on Biological Diversity at 31 I.L.M. 818 (1992)).

[2] Agreement Establishing the World Trade Organization, adopted April 15, 1994, available at http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm. As of February 26, 2005, there are 148 Members of the WTO.

[3] *See, e.g.,* documents collected at WTO TRIPS Trade Topics web page for Article 27.3(b), traditional knowledge, biodiversity at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

[4] See, *e.g.*, Committee on Trade and Environment, Report to the Fifth Session of the Ministerial Conference in Cancún, WT/CTE/8, July 11, 2003, at paras. 25-29.

[5] *See, e.g.,* WIPO International Bureau, Draft Substantive Patent Law Treaty, SCP/10/2, Sept. 30, 2003, at article 14(3), and note 11, and; WIPO Secretariat, Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing, WIPO/GRTKF/IC/7/9, July 30, 2004.

[6] *See, e.g.,* Decision VII/19 of the COP of the CBD requesting technical assistance from WIPO on matters relating, *inter alia*, to the relationship between the CBD and international patent system disclosure which:

> "invited WIPO to examine, and where appropriate address, taking into account the need to ensure that this work is supportive of and does not run counter to the objectives of the CBD, issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, *inter alia*:
> (a) Options for model provisions on proposed disclosure requirements;

governments, intergovernmental and non-governmental organizations.[7] This study attempts to clarify the issues at stake in analysis of the relationship between the TRIPS Agreement, related international patent system rules and the CBD. It examines the conflicts or potential conflicts between the objectives and rules of these international undertakings, and it makes certain recommendations regarding the promotion of complementarity among these systems. In terms of subject matter, this study considers only genetic resources and does not address "traditional knowledge".

This study first identifies the objectives of the international patent system as it is embodied in the TRIPS Agreement and WIPO Conventions, and how these objectives are implemented. Second, it identifies the objectives of the CBD and its method of implementation. Third, it identifies conflicts or potential conflicts between the objectives and methods of implementation of the two rule systems. Fourth, it examines proposals that have so far been made to ameliorate or resolve conflicts. Fifth, it suggests means for promoting complementarity between the two systems, including rule changes where necessary or appropriate.

The study concludes that promotion of the objectives of the CBD would be furthered by multilateral adoption of a mandatory requirement for the disclosure of the source and origin of genetic resources in patent applications. Such a requirement is appropriate to protect the interests of developing and developed countries which house genetic resource stocks. This requirement would be consistent with existing rules of the TRIPS Agreement. However, to give it effect it should be adopted as a new TRIPS Agreement rule. While national action to give effect to such a requirement is permitted under existing WIPO administrative treaties, establishing a mandatory multilateral standard under such treaties would also require amendment. The strength of any set of legal rules is dependent upon its enforceability. Therefore, it is important that states be obligated to provide for the effective enforcement of a mandatory disclosure requirement. Existing patent law standards among advanced legal systems impose upon patent applicants affirmative duties with respect to the disclosure of information and establish penalties which include determinations of invalidity or provision for revocation of

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(b) Practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements;
(c) Options for incentive measures for applicants;
(d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties;
(e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance;
and regularly provide reports to the CBD on its work, in particular on actions or steps proposed to address the above issues, in order for the CBD to provide additional information to WIPO for its consideration in the spirit of mutual supportiveness."

See WIPO Secretariat, Patent Disclosure Requirements Relating to Genetic Resources and Traditional Knowledge: Update, WIPO/GRTKF/IC/7/10, at para. 11.

[7] *See, e.g.,* Carlos Correa, *Establishing a Disclosure of Origin Obligation in the TRIPS Agreement*, Quaker United Nations Office (QUNO) Occasional Paper No. 12, 2003 and *The Politics and Practicalities of a Disclosure of Origin Obligation,* QUNO, Occasional Paper 16, January 2005.

patents. Because the failure to disclose information regarding the source and origin of genetic resources may be relevant to the issue of patentability, including inventorship, it is appropriate that existing equitable doctrines that protect the integrity of the international patent system be extended to this area. It should not be an objective of prospective remedial measures to introduce insecurity into the international patent system, recognizing that patents are inherently insecure. Rather, the objective of prospective remedial measures should be to effectively encourage compliance with agreed upon rules, in this case designed to promote the objectives of the CBD.

II. The Goals of the International Patent System and Methods of Implementation

A. The Objectives of the Patent System

In his seminal work, Fritz Machlup identified three fundamental objectives of a patent system for a developed country. These are: (1) to encourage innovation; (2) to encourage investment in innovation, and; (3) to promote the disclosure of technical information.[8] Machlup observed that that there was limited empirical evidence to support the proposition that patents encourage innovation.[9] This circumstance remains true today.[10] He considered that the most viable function of the patent system is to encourage investors to risk their capital in bringing products to market by encouraging a belief that the patent would establish a profitable market opportunity. Machlup was skeptical of the need for patents to encourage disclosure since patent applicants generally seek protection because they could not otherwise market their products without risking appropriation of their inventive activity. Machlup also pointed out that the reasons why a developed country might choose to maintain a patent system might well not be persuasive for a developing country.

There is a conceptual conflict between the grant of the patent and the maintenance of competitive markets. A patent grants its holder the right to exclude others from the market. Market economics, on the other hand, promotes competition between economic actors as the best means for creating efficiencies and promoting consumer welfare. The patent can be justified as a restriction on the market if it encourages the creation of new products which seek to displace existing products on the market, thereby promoting competition between new and older products.[11]

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[8] Fritz Machlup, *An Economic Review of the Patent System***,** Subcomm. on Patents, Trademarks and Copyrights, of the Committee on the Judiciary, 85th Congress, 2d Sess. (excerpts reprinted in F. ABBOTT, T. COTTIER AND F. GURRY, THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS, at 224-46). Another school of thought considers patents to protect a human right in a person's creative efforts.

[9] Referring, among others, to J. JEWKES, D. SAWERS AND S. STILLERMAN, THE SOURCES OF INVENTION (1958).

[10] *See, e.g.*, Josh Lerner, *150 Years of Patent Protection*, AM. ECON. REV. PAPERS AND PROC. 92 (May), 2002: 221-25, and Lee Branstetter & Mariko Sakakibara, *Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms*, RAND J. Econ. 32: 77-100 (2001).

[11] *See* Robert Anderson*, The Interface Between Competition Policy And Intellectual Property In The Context Of The International Trading System*, 1 J. INT'L ECON. L. 655 (1998).

The patent is an instrument of industrial and social policy. It reflects a balance between the interests of society in innovation and other social welfare interests. Traditionally, the balance has been understood in terms of competing interests of producers in securing monopoly rents and interests of consumers in lower prices. Other interests, such as interest in protecting biodiversity are certainly relevant. The balancing inherent in the patent system changes over time. The negotiation of the TRIPS Agreement in the GATT Uruguay Round was evidence of such a change. Prior to negotiation of the TRIPS Agreement countries differed widely in the scope of subject matter protection of their patent systems, the term of protection, and so forth. The TRIPS Agreement represented a rebalancing that eliminated a substantial degree of the flexibility previously maintained by GATT Contracting Parties in the implementation of their patent regimes, elevating the interests of producers in securing rents by innovating products over competing stakeholder interests. The conclusion of the CBD reflected the emergence of a new social welfare interest that must be balanced within the international intellectual property rights system, just as other consumer interests.

As an industrial policy instrument, the patent does not reflect an inherent right to property. The nature of patent protection embedded in international legal instruments continues to evolve and to reflect changes in collective perceptions of appropriate social welfare balancing.

B. Implementation of the International Patent System

The Paris Convention on the Protection of Industrial Property of 1883 established the basic principles of the international patent system, including national treatment, independence of patents and right of priority. The Paris Convention did not define the patent, the criteria of patentability, the subject matter scope of patent protection, the term of patent protection or other basic substantive norms. The Paris Convention left substantial discretion with respect to these matters in the hands of its contracting states, essentially reflecting a heterogenous international patent system. The WTO TRIPS Agreement, which entered into force on January 1, 1995, prescribed minimum substantive rules of patent protection, including subject matter scope, term of protection and rights of the patent holder, as well as making provision for exceptions. Nonetheless, the substantive rules of the TRIPS Agreement are drafted in general terms, still allowing flexibility in matters such as defining the criteria of patentability.

The negotiators of the TRIPS Agreement recognized that the adoption of minimum substantive standards of intellectual property protection might create a level playing field in terms of legal rules, but that the capacity of countries and their enterprises to take advantage of such rules would not be equal. The OECD countries maintain the vast preponderance of ownership of technology as well as the capital resources required to commercialize such technology. The TRIPS Agreement took account of the differential capacity of countries to develop and make use of technology by including transition periods in favor of developing and least developed countries, as well as encouraging the transfer of technology.

While the WTO assumed substantial responsibility for basic substantive patent norms, WIPO remained responsible for the administration of treaties regulating the acquisition of patent protection. The Patent Cooperation Treaty (PCT), administered by WIPO, is intended to provide a mechanism for securing multiple national and regional patents in a relatively efficient manner. It also effectively extends the Paris Convention priority period, giving an additional advantage to patent applicants who are the first to file. The Patent Law Treaty (PLT), also administered by WIPO, is designed to enhance efficiencies by limiting differences among the form of patent application. The PLT operates in tandem with the PCT. Neither the PCT nor the PLT is intended to establish substantive patent law standards.

The major current effort to modify the international patent system is taking place under the auspices of the WIPO Standing Committee on the Law of Patents in the form of negotiations toward a Substantive Patent Law Treaty. The SPLT seeks, *inter alia*, to define the criteria of patentability. While such definition is characterized by some negotiators as a "technical exercise", it would necessarily result in diminishing the level of discretion among governments in implementing international patent obligations. For this reason, a number of developing countries have urged a careful approach to substantive harmonization taking into account their own economic and social interests.

C. Substantive Patent Law

1. General requirements of invention

The protection of genetic resources by patent involves several uncertainties at the international level. First, the patent law of advanced legal systems has traditionally excluded laws of nature and natural phenomenon from the scope of patent protection. Second, the TRIPS Agreement at its Article 27.3(b) permits WTO Members to exclude plants and animals other than microorganisms from the scope of patent protection, while requiring the protection of microbiological processes. The question whether WTO Members should be obligated or permitted by the TRIPS Agreement to provide patent protection for genetic resources, and the scope of any such obligation, is the source of debate.[12]

A number of countries have resolved uncertainty concerning the patenting of genetic resources by adoption of specific legislation or authoritative judicial decision. The European Union in its Biotechnology Directive has, for example, provided that genetic resources in the form of biological materials may be patented provided that they are transformed, for example, through isolation or purification.[13] The Court of Appeals

[12] Compare Communication from Kenya on behalf of the African Group dated 29 July1999, Review of the Provisions of Article 27.3(b), IP/C/W/163, 8 Nov. 1999, and Communication from the European Communities and Their Member States, 16 Sept. 2002, 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", IP/C/W/W383, 17 Oct. 2002.

[13] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213 , 30/07/1998 p. 0013 – 0021, provides:

for the Federal Circuit in the United States has consistently permitted the patenting of genetic resources based on activities of patent applicants such as the isolation, purification or synthetic reproduction of materials.[14] In the EU and United States gene sequences are patentable. Despite these actions, it is not self-evident that genetic resources are or should be subject to patenting depending on the nature of the patent application.

There are ethical barriers to certain forms of patenting of genetic resources. The EU Biotechnology Directive, for example, specifically precludes patenting with respect to human cloning or modification of the human germ line.[15]

Despite theoretical objection to patenting of genetic resources in a form found in nature or substantially similar to a form found in nature, it is generally accepted that inventions consisting of recombined genetic resources, such as recombined DNA, are subject to patent protection because these inventions have been subject to substantial human intervention.

2. Criteria of patentability

The criteria of novelty, inventive step, capability of industrial application and sufficiency of disclosure each present complex technical issues in relation to the patenting of genetic resources.[16]

To meet the criteria of novelty an invention must not have been anticipated by the prior art. Generally speaking, a worldwide standard of novelty is applied, although some

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"Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application *shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used*.

2. *Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature*."

"Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application." [Italics added]

[14] *See, e.g.*, Amgen v. Chugai Pharmaceutical, 927 F. 2d 1200 (CAFC 1991).

[15] EU Biotechnology Directive, at art. 6(2).

[16] On the criteria of patentability, *see generally* F. ABBOTT, T. COTTIER & F. GURRY, THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM, ch. 1 (1999).

countries apply different standards with respect to disclosures of anticipating art made within the national territory and disclosures occurring abroad. Thus, a country may recognize oral and written disclosures occurring within the national territory, and written disclosures occurring abroad. A limited number of countries continue up to apply national standards of novelty. Patent applicants are required to advise the patent office of anticipating prior art of which they have knowledge.[17] Failure to provide such information may constitute misrepresentation or "fraud on the patent office" and serve as the basis for revocation of the patent.

A genetic resource, such as a biological material, may not meet the standard of novelty as it exists in nature either because of its character as a natural phenomenon or because it has disclosed itself as prior art. An invention that has been "derived from" a genetic resource may not have disclosed itself as prior art and therefore be capable of patenting. However, with respect to inventions derived from genetic resources found in nature, the question remains whether claims are sufficiently different from the resources in their natural state so as to meet the criterion of inventive step.

Inventive step requires a sophisticated analysis in the context of inventions constituting or derived from genetic resources. A traditional framing of the criterion of inventive step is that the invention would not be obvious to a person reasonably skilled in the art based on the prior art at the time the invention is claimed. The criterion of inventive step is also defined by the distance between the claimed invention and the prior art in terms of technical advance.[18] The field of biotechnology is sufficiently sophisticated and specialized that the answer to the question what is "obvious" will vary significantly depending on what group of individuals is selected as those "reasonably skilled in the art". Moreover, because courts and juries are unlikely to be able to assess the degree of inventiveness needed to move between new developments in the field of biotechnology the role of experts in inventive step determinations becomes particularly important.

The criterion of utility has taken on particular significance in respect of biotechnological inventions because of the possibility for the generation of new materials in the laboratory the potential uses of which remain unknown until subjected to further research. In order to limit the wholesale claiming of new biological materials, which might impede future research, judicial and administrative authorities have required a demonstration of credible uses for such materials. Nonetheless, there is question whether such tests in their present form are adequate because they tend to establish a relatively low threshold for demonstration of utility.

The foregoing three criteria of patentability are recognized in Article 27.1 of the TRIPS Agreement. The fourth criterion of patentability, "sufficiency of disclosure" or "enablement", is recognized in Article 29.1 of the TRIPS Agreement. Enablement requires the patent applicant to claim and describe the invention in a manner sufficiently clear to allow third persons reasonably skilled in the art to practice the invention without

[17] *See* §156 of Consolidated Patent Rules of the US PTO.
[18] *See* Friedrich-Karl Beier, *The European Patent System*, 14 VAND. J. TRANSNAT'L L. 1 (1981).

undue experimentation. Enablement assures that the patent applicant has actually made the invention, and separates science from science fiction. Enablement is a controversial criterion in respect to genetic resources because inventors often do not understand the biological mechanics that cause the genetic invention to function. Therefore, the patent applicant is not able to explain "why" the invention functions, but only that it does. Thus, the Canadian Supreme Court was unwilling to grant patentability to inventions claiming "higher life forms" because, *inter alia*, the applicants could not describe what causes such higher life forms to be made or function.[19]

The decision to grant patents for genetic resources has been based as much on considerations of industrial policy as on the traditional concepts of patentability. There is good reason to doubt that a court considering the matter objectively would regard genetic materials found in nature as anything other than a product of nature and unpatentable. However, as in the case of the EU Biotechnology Directive, legislatures and courts have elected to determine outcomes based on industrial policy considerations.

3. Ownership of invention

Fundamental to the rights of an inventor is "ownership" of the invention. That is, a patent is granted to the true inventor and not to a third person who has misappropriated the invention. The critical concept of ownership is specifically acknowledged in the Paris Convention, the European Patent Convention and guidelines of the European Patent Office and the U.S. Patent Act and PTO regulations. Article 4ter of the Paris Convention establishes the right of the "inventor" to be mentioned as such in the patent. Article 81 of the EPC provides that:

> "The European patent application shall designate the inventor. If the applicant is not the inventor or is not the sole inventor, the designation shall contain a statement indicating the origin of the right to the European patent."[20]

The US Patent Act provides:

> *"35 U.S.C. 102. Conditions for patentability; novelty and loss of right to patent.*
> A person shall be entitled to a patent unless
> *****
> (f) he did not himself invent the subject matter sought to be patented."[21]

The Consolidated Patent Rules of the US PTO require an oath or declaration from the patent applicant as follows:

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[19] Harvard College v. Canada (Commissioner of Patents), Supreme Court of Canada, 2002 SCC 76 File No.: 28155 2002: May 21; 2002: December 5.
[20] *See also* Rule 5.1 of the EPO Guidelines for Examination.
[21] *See also* MPEP Rule 2137.

"§ 1.63 Oath or declaration.

…

(4) State that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought."

In evaluating claims to genetic resources it is important to consider who the "owner" or true "inventor" of such material may be.[22] If, for example, the CBD identifies the country of origin as the owner of a genetic resource, a patent applicant should be able to demonstrate how he or she came into possession of that resource as inventor.

III. The Goals of the Convention on Biological Diversity and Related Treaties Governing Genetic Resources

A. Preservation of Genetic Resource Stocks

The first objective of the CBD is preservation of the diversity of genetic resources found in nature, including in animals and plants.[23] There are various reasons for promoting such preservation, including to allow continuity in the natural evolution of species (including adaptation to new environmental conditions), for use in research and development as a source of primary material for direct and recombinant use (taking advantage of natural development and adaptation of biological systems), and maintaining the quality of life from the presence of a diverse biological environment.

Determining the "economic value" of genetic resource stocks is a problematic exercise because it involves anticipating what technological capacities will evolve to exploit such resources, as well as what technological capacities will evolve as alternatives to the exploitation of genetic resources. The world community remains at early stages in assessing the economic value of genetic resource stocks and strong assumptions concerning their future value should be avoided.[24] Anecdotal references to a comparatively small number of "biopiracy" cases are not a proper framework for evaluating the economic value of genetic resource stocks. The economic value of genetic resources may remain stable, or increase or decrease dramatically in the future. Notwithstanding caveats regarding indeterminacy in valuing genetic resources, there is a reasonable likelihood that such resources are of "material" value.

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[22] *See* further discussion of inventorship *infra* text at note [].

[23] *a See, e.g.,* Secretariat of Convention on Biological Diversity, Sustaining life on Earth, April 2000 ("CBD Secretariat Summary").

[24] *See, e.g.,* Thomas Cottier, *The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law*, 1 J. INT'L ECON. L. 555 (1998) and Joshua P. Rosenthal, Fogarty International Center, National Institutes of Health, United States of America, *A Benefit-sharing case study for the Conference of Parties to Convention on Biological Diversity*, The International Cooperative Biodiversity Groups Program (ICBG).

Developing countries are the preponderant owners of diverse genetic resources.[25] The special interest of the international community in encouraging development suggests that a presumption in favor of recognizing rights in genetic resources on the part of developing countries is appropriate. In other words, to the extent that developing countries are able to effectively exploit economic interests in genetic resources it is in the interests of the wider international community to support this.

B. Recognizing Ownership and Control

1. CBD-based rules

The second objective of the CBD is to recognize state ownership and control over genetic resources located within territorial boundaries. This basic objective has at least two grounds: first, to provide an economic incentive to countries for preserving genetic resources by assuring compensation for their use, and; second, to enhance economic welfare in countries that house existing stocks of genetic resources by assuring compensation for genetic assets.

These objectives are implemented by (i) broadly recognizing sovereignty over genetic resources,[26] (ii) requiring prior informed consent (PIC) of the host country as a condition of access to genetic resources,[27] and (iii) providing for the equitable sharing of benefits from the exploitation of such resources.[28] Methods for implementation of PIC

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[25] *See* FIC - Economic Development and Biodiversity, Table - Economic Development and Biodiversity, available at http://www.fic.nih.gov/programs/countries.html and UN list of Megadiverse countries.

[26] The CBD provides:

> "Article 15. Access to Genetic Resources
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> 1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."

[27] The CBD provides:

> "Article 15. Access to Genetic Resources
>
> 5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

[28] The CBD provides:

> "Article 15. Access to Genetic Resources
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> "7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

and equitable benefit sharing are elaborated in the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization.

The CBD is implemented in national and regional legislation in various ways. Explicit legislation has been adopted by the Andean Community, Brazil, Costa Rica and India, among other countries.[29] In addition, a number of countries through regulatory guidance offer some form of protection for genetic resources.

2. Public international law

Because some countries are not parties to the CBD, and particularly from an economic standpoint the United States which has signed but not ratified the agreement, it is important to clarify that the principle of sovereignty of states over resources located within their territory did not arise in the CBD but was only codified in that agreement.[30] The United States has in multilateral fora acknowledged its acceptance of this principle.[31] Therefore, to the extent that the rules of the international patent system are reviewed for promoting compliance with the objective of national sovereignty over genetic resource stocks, the review is not directed only to countries that are party to the CBD.

IV. Complementarity and Potential Conflicts in Implementation of the CBD with the TRIPS Agreement and WIPO Conventions

A. Complementarity and Its Limits

In adopting the CBD and in development of public international law states have decided that ownership and control over genetic resources is vested in the territory where those resources are located.[32] The CBD is intended to protect rights in genetic resources and promote the equitable sharing of benefits from the exploitation of such resources. The patent is an instrument that provides legal protection for intangible interests in inventive activity. It facilitates the commercialization of such interests. At a fundamental level the objectives of the CBD and international patent system are complementary. The international patent system should facilitate the objectives of the CBD by allowing states to legally protect their recognized interests in genetic resources,

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[29] *See* WIPO database of CBD implementing legislation.

[30] The United States is a signatory to the CBD. Therefore, in accordance with the Vienna Convention, it has an obligation not to take measures inconsistent with the object and purpose of the agreement even if it is not obligated to specifically comply with the agreement.

[31] *See, e.g.,* Communication from the United States, Views of the United States on the Relationship between the Convention on Biological Diversity and the TRIPS Agreement dated 24 April 2001, IP/C/W/257, 13 June 2001 (implicitly acknowledging right of state to control access to genetic resources). *See also* US statements in WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

[32] An argument may be made in favor of treating genetic resources as the "common heritage of mankind" over which no state or person exercises ownership or control. Since the parties to the CBD have rejected that premise, this study does not analyze whether a regime based on common heritage may be preferable.

including inventions derived from genetic resources, including through commercialization.

However, to recognize that rule systems are conceptually complementary does not mean that they are properly aligned so as to achieve that complementarity. For example, if the international patent system as currently implemented facilitates circumvention of the CBD by allowing patent applicants to secure patents based on incomplete or misleading information, this may undermine the objectives of the CBD. Similarly, if the CBD is implemented in a way which adds an unnecessary level of insecurity to patent rights, this may undermine the commercial value of patents and incentives for the development of new products. The CBD and the international patent system have not been subject to "conscious alignment" and that is the reason for the present international dialogue.

The protection of genetic resource stocks presupposes the capacity of countries to enforce the sovereign right of ownership and control recognized by the CBD. The CBD adopts PIC and equitable benefit sharing as the mechanism for protecting and exploiting ownership interests. The commercial exploitation of genetic resources may (but does not necessarily) entail securing patent protection. With respect to patents, options for enforcing CBD-based rules include providing evidence of compliance with the requirements of that agreement as a condition of patentability.

A. Criteria of Patentability

1. Novelty and inventive step

The TRIPS Agreement provides that patents should be made available for inventions which meet the criteria of novelty, inventive step and capability of industrial application. In determining the novelty of an invention claiming or based on a genetic resource, whether the claimed invention is found in nature or derived from a material found in nature is relevant in establishing the prior art. The Rules of the US PTO frame the inquiry as follows when identical products are sought to be patented:

> "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada,* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." [33]

The patent applicant must disclose information relevant to the question of novelty. Claims may be made with respect to genetic resources as found in nature or genetic resource-based inventions derived from nature. Determining whether such inventions are

[33] MPEP Rule 2112.01.

anticipated by the prior art requires identifying the inventions in their natural state; that is, if a material in its natural state constitutes anticipating prior art it must be identified in order to determine whether the claimed invention is different from that prior art. Similarly, a determination as to inventive step is predicated on an appreciation of the distance between the prior art and the claimed invention.[34] Determining whether a newly claimed invention would be obvious to a person skilled in the art necessitates a determination as to what constituted the prior art. For reasons both with respect to determinations of novelty and inventive step information regarding genetic resources in their natural state is important to the patent examiner.

It is possible for a patent applicant to disclose the composition and structure of genetic material claimed in an invention either by description of the composition and structure or by deposit of the genetic material.[35] It is possible for a patent applicant to describe the prior art as a form of genetic material found in nature without specifically disclosing the country of source or origin of that material. It does not follow, however, that a requirement of disclosure of the source and origin is not reasonably related to a determination of novelty and inventiveness even if genetic material might be described in writing or by deposit without such information. The patent applicant may, for example, claim that he or she isolated or purified the genetic material, or identified a use for the material which was previously unknown. Or, the patent applicant may claim an invention derived from a material described as found in nature. In any of these cases, the work of the patent examiner may be facilitated by access to information regarding the source or origin of the materials. If the genetic materials are unique to a particular geographic location, the most likely prior art with respect to uses of or derivatives from that material may be found in sources from that geographic territory. A genetic material which is well-known in one geographic territory may be unknown in another. If a particular country or countries has chosen not to require disclosure of source or origin, this does not imply that other countries may not reasonably choose to do so within the meaning of the concepts of novelty and inventive step.

Article 27.1 of the TRIPS Agreement does not preclude WTO Members from requiring the disclosure of source and origin of genetic resources. Article 27.1 provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". A requirement to disclose the source or origin of genetic resources does not inhibit the grant of patents for biotechnological inventions. It is rather a requirement reasonably related to determinations of novelty and inventive step and, as discussed below, inventorship. The same article requires that patents should be available "without discrimination as to the place of invention". A requirement to disclose source and origin of genetic resources does not discriminate as to place of invention because, *inter alia*, the inventor is not prejudiced in any way by the disclosure. If in fact some WTO Members consider that a national obligation to disclose source and origin in a patent application is inconsistent with Article 27.1 of the TRIPS Agreement, this would be good grounds for seeking an amendment of the agreement.

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[34] *See* Beier, *supra*, and MPEP Rule 2141.

[35] *Accord*, Communication from the European Communities, IP/C/W/383, 17 Oct. 2002, at para. 47.

Article 29.1 of the TRIPS Agreement obligates Members to require sufficient enabling disclosure and Article 29.2 allows members to require information concerning foreign applications and grants. Article 62 of the TRIPS Agreement allows Members to impose reasonable procedures and formalities with respect to the grant and maintenance of intellectual property rights.[36] The provisions of these articles do not by their terms preclude Members from requiring the disclosure of information relevant to patentability and inventorship.

2. Inventorship

A strong argument in favor of an existing requirement to disclose the source or origin of genetic resources is the necessity to demonstrate ownership of the invention. Starting with the premise that each country owns the genetic resources located within its territory, the development of an invention by a third party based on the use of such resources would appear to presuppose a transfer of ownership or consent to use of such resources. Taking, for example, the oath or declaration required by the US PTO, the applicant must state that he or she is the true inventor. If the basis of the application is a genetic resource that the applicant was not lawfully entitled to use or own, it is difficult to see how that person can claim to be the true inventor asserting exclusive rights in it. An oath asserting ownership of the invention would effectively constitute a misrepresentation. The addition of a clarifying rule to existing patent office rules requiring applicants to demonstrate the means by which they acquired the right to own or use genetic resources, including by disclosure of source and origin of such resources, would appear to be consistent with existing patent office rules and procedures.

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[36] The TRIPS Agreement permits imposition of reasonable procedural requirements to further substantive compliance, and provides that procedures should not unreasonably interfere with grant of patents (art. 62.1-2). This would not preclude imposition of mandatory disclosure obligation for CBD compliance so long as an exceptionally cumbersome process is not put in place. Issues of effect of introducing mandatory disclosure requirements on administrative efficiencies should be addressed, but placing affirmative obligation on applicant is not inherently inefficient. Patent examiners do not typically verify accuracy of all information provided by patent applicants (e.g., patent examiners do not independently test whether invention is enabled by repeating invention in patent office). This is the role of third party opposition and litigation. The patent office is protected by rules precluding provision of misleading information and applicable penalties.

Article 62 provides:

> 1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, *compliance with reasonable procedures and formalities.* Such procedures and formalities shall be consistent with the provisions of this Agreement.
>
> 2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right *within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.*" [italics added]

The issue of inventorship is conceptually difficult in relation to protection of biodiverse resources, but this circumstance is brought about by the blurring of the distinction between discovery and invention consequent to industrial policy decisions to effectively offer patent protection for genetic resources in their natural state. As discussed earlier, the European Union and United States, among other countries, have decided to grant patents based on the isolation or purification of genetic resources. The patents granted on these inventions are generally not on the process of isolation or purification, the technologies (which may themselves be independently patented) are used in different subject matter applications (i.e., they are not specific to a particular genetic sequence or biological material). The patent is therefore granted on a genetic sequence or biological material isolated or purified through the use of a known process to yield a result which, in effect, is the genetic sequence or biological material itself. It is this artificial construct for invention (contrasted with discovery) that underlies the inventorship question. In this context, a failure to disclose the source or origin of a genetic resource amounts to a denial of the inventorship and ownership of the same invention by the country housing the genetic resource.

To illustrate, consider the situation in which a rival scientist breaks into a researcher's laboratory prior to the completion of an important experiment and steals the researcher's laboratory notebook. The rival completes the experiment successfully and makes a claim at the patent office. Is the rival is the first and true inventor? Compare the situation of a developing country housing a genetic resource stock. Consider the low invention threshold requirement of the EU Biotechnology Directive. Corporation A obtains genetic material from Country B without consent. It isolates part of the genetic material in Country C and files a patent application in that country. How does that differ from the misappropriation in the first scenario? Country B has provided all but the very final stage in the "inventive process". That final stage is likely to involve application of a known process to achieve a predictable result.

C. Historical Conflict

A potential conflict between the TRIPS Agreement and the Draft International Treaty on Plant Genetic Resources for Food and Agriculture was raised during the course of negotiations. Working drafts of the ITPGRFA provided for conditions on patented inventions derived from materials drawn from the Multilateral System, including payment of a royalty into a mechanism for distribution to be determined (draft Article 14.1). Certain countries objected to these conditions on the grounds that this would conflict with the nondiscrimination obligation of Article 27.1 of the TRIPS Agreement because certain biotechnological inventions would be treated differently than inventions in other fields of technology. While such an objection may not have been valid under the interpretation of the WTO panel in the *Canada-Generic Pharmaceuticals* case,[37] or of the Appellate Body in the later *EC-Enabling Clause* case,[38] the objection nonetheless had a chilling effect on the negotiators and led to the withdrawal of the conditions. Caution

[37] WT/DS114/R, 17 March 2000.
[38] European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries, AB-2004-1, WT/DS246/AB/R, April 7, 2004, *e.g.*, at paras. 173-74.

must therefore be exercised in evaluating the potential for conflict between the CBD and the TRIPS Agreement. In order to prevent disputes from arising regarding the proper interpretation of TRIPS Agreement rules, it may be necessary or appropriate to adopt a clarifying interpretation or amendment.

D. The Paris Convention

The Paris Convention does not expressly address disclosure requirements. Article 5 permits legislative measures to prevent abuses of patent rights, and provides that forfeiture should not be undertaken unless compulsory licensing has failed to prevent the abuse. This provision is only tangentially relevant to issues regarding mandatory disclosure of source or origin of genetic resources. National rules requiring disclosure of source and origin of genetic resources do not contravene the Paris Convention.

E. The Patent Cooperation Treaty and Patent Law Treaty

Switzerland in particular has identified certain provisions of the Patent Cooperation Treaty (PCT) and Patent Law Treaty (PLT) and related regulations which it has suggested create an impediment to the requirement of the disclosure of the source or origin of genetic resources in patent applications. As discussed below, it is not clear that the alleged impediment is as significant as Switzerland may have suggested because there is flexibility in the PCT and PLT systems that allow contracting states to require additional information from patent applicants. Even assuming that the PCT and PLT as currently drafted and implemented create the type of impediment suggested by Switzerland, the PCT and PLT are administrative treaties that are intended to give effect to the substantive requirements of the international patent system and should not be understood to stand as an impediment to changes in that system. Thus, to the extent that Switzerland has identified a real problem with these administrative treaties it may be necessary to amend them, but that should not imply that such amendment is a sufficient answer to the problem presented in respect to the relationship between the international patent system and the CBD.

As Switzerland has noted, Article 27.1 of the PCT provides that "No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations." However, Article 27.5-6 go on to provide:

> "5) *Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires*. In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior

art and other conditions of patentability *not constituting requirements as to the form and contents of applications*.

(6) *The national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law.* "[39] [Italics added]

If a country requires evidence from an applicant pursuant to Article 27.6 it necessarily must make provision in its patent office rules for obtaining it. A request might be framed as a regulatory requirement of evidence without specifically being part of an application form. Otherwise, there would be no way to give Article 27.6 effect in a manner consistent with Article 27.5, and we assume that Article 27.5 is not intended to render Article 27.6 *inutile.*

As Switzerland has also noted, Rule 4 contains mandatory and optional information that may be contained in a PCT application (or "request" in the terminology of the PCT). The optional information is intended to address matters which may be required by patent offices at the national stage. Rule 4.17 states:

"Declarations Relating to National Requirements Referred to in Rule 51bis.1(a)(i) to (v)

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:

(i) *a declaration as to the identity of the inventor*, as referred to in Rule 51bis.1(a)(i):
(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 51bis.1(a)(ii);
(iii) a *declaration of inventorship*, as referred to in Rule 51bis.1(a)(iv), which shall be signed as prescribed by the Administrative Instructions;
(iv) a declaration as to non-prejudicial disclosures or exceptions to lack of novelty, as referred to in Rule 51*bis*.1(a)(v)." [italics added]

Rule 51bis.1 is intended to give effect to Article 27 of the PCT, including its paragraphs 5 and 6. It provides:

"51bis.1 Certain National Requirements Allowed

[39] Switzerland has not referred to the permissive aspects of Article 27. *See* Communication from Switzerland, IP/C/W/400/Rev.1, 18 June 2003, at pgs. 19-20.

(a) Subject to Rule 51bis.2, the national law applicable by the designated Office may, in accordance with Article 27, require the applicant to furnish, in particular:

(i) any document relating to the identity of the inventor,

(ii) *any document relating to the applicant's entitlement to apply for or be granted a patent*,

(iii) …

(iv) …

(v) where the international application designates a State whose national law requires that national applications be filed by the inventor, any document containing *an oath or declaration of inventorship*,

(vi) …

(vii) the confirmation of the international application by the signature of any applicant for the designated State who has not signed the request;

(viii) any missing indication required under Rule 4.5(a)(ii) and (iii) in respect of any applicant for the designated State."

Since Article 27.6 of the PCT allows contracting states to request additional information concerning substantive conditions of patentability, and since the PCT and related rules allow a contracting state to confirm the entitlement of the inventor to claim ownership of the invention, it does not appear that the PCT or its implementing rules conflict with national requirements for disclosure of source or origin of genetic resources.

To the extent that Member states of the WTO were to adopt a mandatory requirement of disclosure of source or origin of genetic resources, this could be framed in the context of demonstrating the ownership or entitlement to the invention, or as a substantive condition of patentability, consistent with PCT rules. This is not to say, however, that useful changes might not be made to the PCT.

The reference by Switzerland to the PLT is also limited. As noted by Switzerland, the PLT in its Article 6.1 limits the information that can be required by a contracting state to that which is permitted under the PCT and otherwise by PLT regulations. However, Article 2.2 of the PLT provides:

"[*No Regulation of Substantive Patent Law*] Nothing in this Treaty or the Regulations is intended to be construed as prescribing anything that would limit the freedom of a Contracting Party to prescribe such requirements of the applicable substantive law relating to patents as it desires."

As discussed above, the PCT adopts and gives effect to this same principle. Therefore, it is not apparent why the PLT would act as a barrier to a requirement of the disclosure of the source or origin of genetic materials.

Switzerland also refers to Article 10.1 of the PLT as a limitation on remedies for failures of disclosure.[40] However, Article 10 .1 is expressly limited to failures of compliance with formal requirements and does not address failures to comply with substantive obligations. It is therefore not clear why Article 10.1 would act as a material constraint on the remedies that contracting states might impose, including forfeiture or revocation in appropriate cases.

V. Measures to Promote Complementarity between the CBD and the TRIPS Agreement

A. Foreseen Circumstance

When the Uruguay Round mandate was adopted by the GATT in 1986 genetic engineering was in its early stages of commercial application.[41] The CBD was adopted in late 1992 and the contentious TRIPS negotiations were brought to an end in late 1993. To a large extent the TRIPS negotiations put off important decisions about biotechnological inventions by adopting a vague formula in Article 27.3(b) that was based on a European Patent Convention provision that was sufficiently inadequate so as to necessitate adoption of the EU Biotechnology Directive, and by providing for review of that provision. Particularly in light of the express admonition in the TRIPS Agreement for review in this area it is appropriate that WTO Members give serious consideration to establishing a more complementary relationship between the CBD and the TRIPS Agreement in light of the wide adoption of both agreements by states comprising the international community.

B. The Existing Situation

As discussed above, the present situation under the TRIPS Agreement is that WTO Members may require the disclosure of the source or origin of genetic resources, but are not obligated to do so. This situation is unsatisfactory from the standpoint of countries housing substantial genetic resource stocks because the enforcement of CBD-based rights of these countries depends on third country cooperation and enforcement. An enterprise that bioprospects in a country without complying with that country's PIC requirements may not be able to patent an invention derived from the wrongfully acquired genetic resources in that country, or in other countries which require adequate disclosure for compliance purposes, but it may well be able to patent the invention in third countries (which may include the major markets for its product). So, for example, a bioprospecting enterprise which fails to comply with the Andean rules on PIC may elect not to seek a patent in the Andean Community, but it may seek patents in the United

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[40] Article 10 .1, PLT: "[*Validity of Patent Not Affected by Non-Compliance with Certain Formal Requirements*] Non-compliance with one or more of the formal requirements referred to in Articles 6(1), (2), (4) and (5) and 8(1) to (4) with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention."

[41] *See* review of recombinant DNA technology in Biogen v. Medeva, [1997] RPC 1 (UK House of Lords).

States, European Union, Japan and Switzerland without a disclosure that would aid in identifying its compliance failure.

In the absence of a multilaterally agreed requirement of disclosure or other means for encouraging compliance with obligations arising from the CBD and public international law, a country in which a patent application is filed may have no basis for determining whether the applicant has complied with obligations, and consequently whether the applicant is the legitimate owner of the claimed invention and whether the invention is novel or inventive.

B. Alternative Mechanisms

1. CBD-based enforcement

Parties to the CBD could adopt a supplemental agreement on enforcement obligating each state to take steps to investigate and pursue violations of CBD-based obligations. Such an agreement could impose an obligation to pursue enforcement measures against persons who obtain genetic resources within the territory of CBD member in the absence of PIC or an agreement on equitable benefit sharing. The steps to be taken could include intervention with respect to patent applicants and patent holders, including potentially de-recognition of patent rights or the grant of compulsory licenses to remedy compliance failures. One particular obstacle to effective implementation of such a supplemental CBD agreement is that the United States is not a party to the CBD. Therefore, one of the largest economic markets would be outside the territorial scope of the agreement.

2. International patent system requirements

a. Disclosure of source or origin

Patent-system based measures could be adopted as a means to promote compliance with CBD-based obligations. A requirement to disclose the source and/or origin of genetic resources in the context of the patent application process would serve several purposes. First, it would aid in providing patent applicants with effective notice of their obligation to comply with national legal requirements with respect to PIC. Patent attorneys and agents preparing patent applications would be aware of the legal basis for the requested information and would communicate this information to their clients. Second, when patent applications are published notice would be provided to countries where genetic resources were obtained of the claims to inventions based on such resources allowing them to intervene in the application process by providing third-party information. Third, a disclosure requirement would provide an independent basis for action by the patent office or third party with respect to the patent applicant. The nature of such action could vary depending on the nature of the compliance deficiency, for example, it might vary depending on the state of knowledge of the applicant or the economic consequences of the deficiency.

Existing international patent rules require a country seeking to enforce rights acknowledged under the CBD to initiate claims either before the patent office or the courts in each country where a patent is sought or has been granted to a third party. The pursuit of such claims in this way is inefficient, costly and time-consuming. It places an enormous burden on the limited resources of developing countries. A multilaterally agreed requirement to disclose source and origin would not remedy this situation on its own. However, to the extent it reduced the frequency with which problematic patents are granted it would reduce the burden on these countries.

There are technical issues with respect to identifying the "source" or "origin" of genetic resources. Generally speaking, a patent applicant will be aware of the person from whom a genetic resource was obtained. Therefore, the last person in the "chain of custody" of the genetic resource should generally be identifiable by the patent applicant without substantial effort. It is, of course, possible that one or more intermediaries might be involved in a chain that moves from securing the genetic resource from a particular geographic location to the patent applicant. Therefore, a disclosure obligation limited to the person from whom a genetic resource was directly obtained may be too narrow to provide a CBD party with an adequate basis for intervening to protect its rights. It may therefore be necessary to impose on the patent applicant an obligation to identify the originating source of the genetic resource, which in turn would require those supplying such materials to maintain adequate records of the chain of custody. Alternatively, as has been suggested, some form of "certificate of provenance" could be introduced as a means for identifying the source of genetic resources, without which a patent applicant would not be entitled to pursue its application.

A patent applicant may not be able to identify the "origin" of a genetic resource with assurance from a technical standpoint. A plant genetic resource may reflect hundreds of thousands of years of evolution across a wide geographic expanse. The country from which the genetic resource is obtained may not be the true or only "country of origin" of the resource from an evolutionary perspective. Cases may arise in which state parties to the CBD dispute the origin of a genetic resource. Therefore, a requirement to disclose the origin of the genetic resource may involve a best effort on the part of the patent applicant.

A combination of obligations to disclose source “and” origin of the genetic resources in a patent application would appear preferable to an obligation to disclose either source “or” origin because this would provide alternative routes for tracing the sovereign owner of the resources. It may be that no single CBD contracting state is able to claim ownership of a genetic resource, but it may be possible to identify a group of countries that share ownership. In such cases, equitable benefit sharing may involve distribution to more than one country.

In addition, there is a technical issue regarding the relationship between genetic resources in their natural state and inventions "derived from" such genetic resources. A patent applicant may have obtained a genetic resource within a national territory and have used that resource as the basis for experimentation which ultimately yielded a product

substantially different from the genetic resource. In such case, the CBD would have required that the patent applicant obtain PIC with respect to the basis for the research, and requiring disclosure of the source and origin of the genetic resource upon which experimentation was based would remain useful for promoting compliance with the CBD. There are likely to be cases in which an invention is sufficiently remote from the genetic resource, and the inventor (and patent applicant) is sufficiently remote from the person who obtained the genetic resource, that it may be unreasonable to hold the patent applicant (who acted in good faith without notice) responsible for disclosure as to the source or origin of the resource.

C. Disclosure of PIC or Equitable Benefit Sharing

In addition to disclosure of the source and origin of genetic resources, it has been suggested that patent applicants might also be required to disclose compliance with PIC and equitable benefit sharing.[42] The disclosure of compliance with CBD PIC requirements would involve certification of compliance with national laws implementing such requirements.[43] Such requirements will vary from country to country.[44] Some countries might have a procedure pursuant to which a certificate of compliance is issued by the regulatory authorities. A certified contract between the patent applicant and the national authorities might be submitted.

The proposal to extend the disclosure requirement to certification of compliance with PIC and equitable benefit sharing appears to be based on recognition that disclosure of source and origin, standing alone, will not prevent the grant of patents when genetic resources have been taken and used without the consent of the host country. Action by

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[42] *See* Submissions from Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela, IP/C/W/438, 10 Dec. 2004 and IP/C/W/429/Rev.1, 27 Sept. 2004.

[43] IP/C/W/438 specifically proposes:

> "10. To fulfil the requirement of furnishing evidence of prior informed consent, the applicant will have a positive obligation and would therefore have to discharge a positive burden in this regard. This means that the applicant will have to provide evidence that he or she accessed the genetic resources and/or traditional knowledge used in the invention for which a patent is sought through approval or consent of the national authorities of the country of origin and/or the local or indigenous community, as applicable.
> 11. It is foreseen that the applicant will be deemed to comply with the requirement of furnishing evidence of prior informed consent if the patent application contains and/or is accompanied by a declaration, in the prescribed form, indicating that prior informed consent was obtained from the relevant national authorities (and local and indigenous communities, where applicable). Further, the declaration would be accompanied, where relevant, by the actual evidence of prior informed consent, for example, in the form of a certificate or duly certified contract between the applicant and the national authorities of the country of origin. In this regard, it should be noted that it may be possible that a single declaration with the necessary evidence could be furnished to cover the requirements on disclosure of source and country of origin, evidence of prior informed consent as well as evidence of equitable benefit-sharing. …"

[44] The Bonn Guidelines suggest general principles for implementing PIC and equitable benefit sharing requirements, but these are not binding obligations.

the host country to prevent the issuance of the patent or to seek its revocation would be required.[45] The additional certification requirements would elevate the burden of proof on the patent applicant and, theoretically, provide an unambiguous signal of compliance with CBD obligations to the patent office. The patent examiner could delay processing the application until the necessary certification and evidence is provided.

A new system requiring certification of compliance with PIC and equitable benefit sharing would be substantially more complex than a system requiring disclosure of source and origin of genetic materials. The patent examiner would need to be familiar with the basic requirements of each of the country in order to determine whether the certification was adequate. For example, the patent examiner will need to know whether the host country made provision for a certificate issued by the national authorities, and whether any comparable certificates might or could be issued by subnational authorities.[46] With respect to countries for which no certification procedures were in effect, the patent examiner would be relying on self certification by the patent applicant that or she had complied with foreign law.

An action could presumably be brought by the host country subsequent to the issuance of the patent alleging false or misleading certification of compliance, or failure to certify compliance. This may ultimately lead to the question whether the patent applicant had complied with PIC and equitable benefit sharing rules of the foreign host country. This would raise the issue of how a court or administrative body in the country where the patent was granted should evaluate questions of compliance with foreign law. On one hand, representations by the foreign host government could be given automatic effect, in essence constituting "acts of state" not reviewable by the country where the patent is granted. On the other hand, the court or administrative body in the country where the patent is granted could make an independent determination regarding compliance with foreign law. Both possibilities raise significant policy and legal issues. Because of the industrial policy sensitivity of patents (as reflected in the Paris Convention rule of independence) it is doubtful that courts or administrative bodies in the country where the patent is granted would automatically accept a ruling by the foreign host country. An independent determination of the merits appears more likely.

The difficulties of evaluating foreign legal claims of misappropriation or misuse of biodiverse resources will be present whether or not a certification scheme is adopted. In other words, in the absence of such a scheme, court or administrative bodies in countries where patents are sought will be asked to invalidate, revoke or otherwise intervene in the patents based on failure to comply with foreign and international law. The question at this stage is whether the gains from adding a certification system of compliance with PIC and equitable benefit sharing would outweigh the administrative difficulties and uncertainty that may arise.

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[45] Such as by submitting evidence that materials were acquired without PIC, or by submitting evidence of anticipation and lack of inventive step, during the examination phase. Alternatively, ex post facto proceedings for revocation or invalidation of the patent would be necessary.

[46] In theory, this could be dealt with by referring the patent application to a foreign authority, although this might be cumbersome.

The benefit of such a system would be notice to the patent applicant of the requirements imposed by the CBD and national implementing legislation. Implementation of the certification requirement by national and regional patent offices would presumably cut down on the frequency with which "bad" applications are filed and "bad" patents granted. The drawback would be added complexity in the application review process based on the need for patent examiners to be familiar with the implementation systems in place in foreign countries. In addition, patent applicants may be reluctant to self-certify compliance with foreign law if the requirements of foreign law are not clearly spelled out (and in situations in which subfederal bodies have the power under national law to grant or deny PIC). Finally, courts and administrative bodies will need to work through questions of evaluating foreign legal compliance.

The adoption of a system of certification of compliance with PIC and equitable benefit sharing would require substantial working through of details. It can be argued that more experience in the implementation of national legislation on PIC and equitable benefit sharing would be useful before attempting to introduce a certification requirement into the international patent system. An internationally-adopted system of certification might be a useful adjunct to the CBD. Such a system might reduce potential conflicts involving evaluations of foreign law. On the other hand, it can be argued that a system relying solely on disclosure of source and origin will not be adequate to remedy the problem of misappropriation or misuse of genetic resources. Moreover, the adoption of an international framework for certification is far in the future and not a practical solution for present purposes. Finally, even though legal questions will arise if a certification system is adopted without further international agreement, courts and administrative bodies are capable of working through such questions.

This study does not propose at this stage the adoption of a system for certification of compliance with PIC and equitable benefit sharing because of uncertainties regarding how such a system would operate in practice. However, if the logistical issues are adequately addressed, such a system might be a reasonable adjunct to mandatory disclosure of source and origin of genetic resources.

As noted at the outset of this section, a system which permits but does not mandate disclosure of source and origin of genetic resources raises significant problems for countries which house genetic resource stocks. The fact that a developing country may take measures within its own territory may have a very limited economic effect if the primary markets for the sale of products based on genetic resource stocks are in the developed countries. It does not therefore appear that a modification to the international patent system that merely confirms the right of countries to regulate patent applications within their own territories would further the objectives of the CBD in a meaningful way. If the interests of countries housing genetic resource stocks are to be protected consistent with the rules and objectives of the CBD, a principal means for accomplishing this would be to adopt and implement some form of mandatory requirement within the international patent system.

D. Effects of Noncompliance

The objective of the disclosure system would be to assure compliance with the basic objectives of the CBD. There are several different approaches that states might take with regard to noncompliance with mandatory requirements to disclose the source and origin of genetic resources in patent applications.

Patent offices typically impose on applicants a duty to deal with the office in good faith. The United States Patent and Trademark Office ("US PTO"), by way of illustration, maintains in its Manual of Patenting Examining Procedure ("MPEP") a fairly extensive set of rules regarding the "Duty of Disclosure" on the part of patent applicants.[47] The Rules of the US PTO (based on the Patent Act and from the Code of Federal Regulations) state:

> "A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section."[48]

Since the source and origin of genetic resources are relevant to determinations of novelty and inventive step, as well as to the question of patentable subject matter (*i.e.*, discovery or invention), it would be consistent with existing Rules of the US PTO to require applicants to disclose the source and origin of such resources.

US PTO Rules describe the information as to which a duty of disclosure is owed very broadly. This includes, for example, information regarding "prior invention by another, inventorship conflicts, and the like".[49] The US PTO recommends that patent attorneys ask inventors who they represent questions about "the origin of the invention and the point of departure from what was previously known and in the prior art".[50]

The remedy for fraud, inequitable conduct and/or a violation of the duty of disclosure is to render all of the claims by the inventor unpatentable or invalid.[51] A determination of inequitable conduct involves an evaluation of the "intent" of the patent applicant. The applicant must have intended to mislead the patent office through its action or omission. As the US PTO Rules note, "inequitable conduct is not set by statute

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[47] Chapter 2000, Duty of Disclosure, Manual of Patenting Examining Procedure, Eighth Edition, August 2001, Latest Revision, May 2004. The Chapter 2000 Rules of the US PTO are based on several sections of the Patent Act prescribing the duties of the Director of the Patent Office (35 USC sections 2, 3, 131, and 132), which are further elaborated in the Code of Federal Regulations, at 37 CFR section 1.56.
[48] 37 CFR section 1.56(a).
[49] MPEP, Rule 2001.04.
[50] *Id.* at Rule 2004.
[51] *Id.* at Rule 2016. *See, e.g.,* Bristol-Myers v. Rhone-Poulenc, 2003 U.S. App. LEXIS 7103 (CAFC 2003)

as a criteria for patentability but rather is a judicial application of the doctrine of unclean hands …"[52] An applicant who by inadvertent error files an incomplete application is generally permitted to correct that application.[53] Similarly, if an error is discovered subsequent to the grant of the patent, the patent holder may request correction and reissuance of the patent.[54] As a general rule, claims with respect to fraud, inequitable conduct and/or a violation of the duty of disclosure must be determined by the federal courts and not by the US PTO.[55] The patent office does not consider itself equipped to evaluate evidence as to intent.

Because a finding of patent invalidity has serious economic consequences for the patent holder, it is reasonable to require that the patent applicant acted with intent to mislead as a precondition of such remedy. However, such an intent standard should not allow an applicant to hide behind a shield of willful ignorance. First, it is reasonable to anticipate that persons with sufficient knowledge and resources to file a patent application with respect to genetic resources would be aware of the requirement to disclose source and origin. As the US PTO has recommended, patent attorneys and agents would generally be expected to request such information from their clients. Second, if the disclosure requirement were incorporated expressly in the PCT and PLT forms, this would provide notice of the requirement to the applicant. The kinds of errors which might be anticipated as "unintentional" may be those in which an applicant in good faith is unable to precisely determine the information needed to make a complete disclosure or in which the applicant in good faith relies on a third party or certification for information which is later determined to be inaccurate.

A finding of invalidity and/or revocation of a patent is not the only potential remedy even in cases of intentional misconduct. Conceptually remedies may be fashioned that would provide equitable benefit sharing to countries from which genetic resources were obtained in the form of royalties.[56] Also, the patent holder might be required to license its invention to third parties as is sometimes the remedy in competition cases. Remedies might well be fashioned to address the specific circumstances of cases. The key point, however, is that a system of purely voluntary compliance is unlikely to have any real effect on market participants. There must be some material risk to patent applicants for failure to comply with their obligations.

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[52] *Id.* at Rule 2010.
[53] *Id*. at Rule 2004, para. 11.
[54] *Id.* at Rules 2012 & 2022.05. The use Rules are based on 35 U.S.C. §251 which provides:

> "Whenever a patent is, through error *without any deceptive intention*, deemed wholly or partly inoperative or invalid, by reason of a deceptive specification or drawing, or by reason of the patentee claiming more or less than 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…" (italics added)

[55] *Id*. at Rules 2010, 2012, 2013, 2014 and 2022.05.
[56] *See, e.g.,* Communication from the European Communities, IP/C/W/383, 17 Oct. 2002, at para. 55.

The international patent system does not recognize the concept of a "central attack" on a patent. The principle of independence of patents recognized in the Paris Convention establishes that a determination of patent invalidity or the revocation of a patent in one member state does not affect the validity of parallel patents in other member states. Judges in patent cases may be cognizant of findings of foreign judges and take them into account as evidence, but are not bound by such findings. Therefore, a requirement to disclose source and origin of genetic resources combined with a potential remedy of invalidity or revocation will still require action in more than one forum by a country from which genetic resources have been improperly appropriated. Nonetheless, if the patent holder is subject to legal proceedings in the major market countries this is likely to have a significant compliance and deterrence effect.

The recommended mandatory nature of a disclosure requirement should therefore be combined with a minimum requirement that states permit claims for providing misleading information to the patent office, including by failure to disclose, with remedies sufficiently serious to deter abuse.

A counterargument to provision for serious remedy is that this will introduce insecurity into the patent system that will deter investment in invention.[57] It is important to recognize that patents are inherently insecure. A substantial proportion of patents subject to third party legal challenge are found to be invalid or unenforceable.[58] Patent holders are already held to a duty of good faith in making disclosure in the application process. It is not recommended here that patent holders be subject to severe sanction for inadvertent errors or minor mistakes. Just as in other circumstances affecting patentability, patent holders should be held accountable for attempts to mislead the patent office in respect to the source or origin of genetic resources.

VI. Review of Proposals

The proposals submitted to date by WTO Members to the TRIPS Council reflect a division along North-South lines. That division also largely (but not wholly) reflects a division between countries with advanced technological capacity and the megadiverse countries. The United States is a megadiverse Northern-tier country with advanced technological capacity.

A group of developing countries (Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela) advocates mandatory disclosure of the source and origin of genetic resources, as well as mandatory certification of compliance with PIC and equitable benefit sharing requirements, in patent applications.[59] This group of developing countries has noted that the absence of enforceable rights in developed country markets

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[57] *See*, *e.g.*, Communication from the United States, IP/C/W/434, 26 Nov. 2004, at para. 3.
[58] In the United States, about 30-35% of patents brought to trial are found invalid or unenforceable. Kimberly A. Moore, *Judges, Juries, and Patent Cases - An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 392 (2002).
[59] *See recently* Submissions from Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela, IP/C/W/438, 10 Dec. 2004 and IP/C/W/429/Rev.1, 27 Sept. 2004.

diminishes the value of rights arising in developing countries. It proposes that failure to comply with the disclosure requirements would lead to invalidity or revocation of the patent where (a) the information which should have been provided would have resulted in denial of a patent *ab initio* or (b) the applicant acted with bad intent.

The European Union does not perceive a conflict between the TRIPS Agreement and the CBD, but suggests that measures might be considered to promote the objectives of the CBD. The EU supports some form of requirement for the disclosure of source and origin of genetic resources in the patent application process which it considers would promote transparency and compliance with the CBD. It expresses strong opposition to patent-based remedies, but suggests that alternative remedies, "such as for example in civil law (claim for compensation) or in administrative law (fee for refusal to submit information to the authorities or for submitting wrong information)", might be used.

As noted earlier, Switzerland has proposed amendments to the PCT and PLT to enable state parties to require the disclosure of the source of genetic resources.[60] Switzerland has recently clarified that it does not propose a mandatory disclosure requirement for all parties to the agreements or Members of the WTO, but rather proposes that countries be allowed to optionally require such disclosure.[61] Switzerland also indicates that failure to disclose should not be grounds for rendering a patent invalid or unenforceable, except in cases of intentional fraud on the patent office.[62]

The United States does not support the introduction of mandatory disclosure of source and origin of genetic resources. Its objections are that such information is not relevant to patentability or inventorship, that a disclosure requirement would introduce insecurity into the patent system, that new administrative burdens would be introduced and that the requirement would not promote the objectives of the CBD. The objections based on relevance to patentability and inventorship are so far stated only in a conclusory way.[63] While asserting that the disclosure requirement would not aid in determining

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[60] *See* Communications from Switzerland, IP/C/W/400/Rev.1, 18 June 2003, IP/C/W/423, 14 June 2004 and IP/C/W/433, 25 Nov. 2004.

[61] IP/C/W/433, at para. 9.

[62] IP/C/W/423, 14 June 2004, stating:

> "Furthermore, if it is discovered after the granting of a patent that the applicant failed to disclose the source or submitted false information, such failure to comply with the disclosure requirement may not be a ground for revocation or invalidation of the granted patent, except in the case of fraudulent intention (Article 10 PLT). However, other sanctions provided for in national law, including criminal sanctions such as fines, may be imposed." At para. 26.

[63] Communication from the United States, IP/C/W/434, 26 Nov. 2004, stating:

> "First, none of the suggested new patent disclosure requirements aim to ensure compliance with patentability requirements such as proper inventorship, novelty or inventive step. Second, disclosure of source and/or origin can be expressed in wide variety of ways. Information indicating country of origin, *ex situ* collection sites, etc., would do little to ensure ascertainment of appropriate inventorship, novelty or inventive

inventorship, the United States nonetheless observes that its patent law requires good faith disclosure relevant to inventorship and patentability and suggests that other WTO Members follow its model:

> "Furthermore, Members way wish to consider a requirement such as that used in the United States for patent applicants to disclose any information known by the applicant to be material to patentability.[64] If the objectives are to truly to [sic] determine prior art, to ascertain inventorship and to prevent mistakenly granted patents, this type of requirement is directly related to achieving these goals, to the extent that the applicant may have such information. Inventorship is included here because US law clearly requires that inventorship be a requirement for entitlement to a patent.[65] This type of information is directly related to the questions of patentability and can aid examination of patent applications in a manner that disclosure of source and/or origin of genetic resources or traditional knowledge cannot." At pages 7-8 [footnotes renumbered from original]

It appears somewhat paradoxical that the United States emphasizes disclosure for determining proper inventorship, yet dismisses the requirement of disclosure of source and origin of genetic resources on grounds this is not related to patentability. US PTO Rules specifically state that a patent should not be awarded to a party who comes to the patent office with "unclean hands", a doctrine derived from equity. If an inventor files a patent application without disclosing that he or she has obtained the materials constituting or underlying the claimed invention in contravention of foreign law, this would appear to bring the doctrine of unclean hands into play. Moreover, the United States seems to acknowledge that the source or origin of genetic materials might be relevant to a determination of prior art. It is hard to quarrel with the proposition that, in general, the mere submission to the patent office of genetic materials taken from nature would not be novel in a patent law sense, and thus that source and origin is not irrelevant.

As a megadiverse country with advanced technological capacity, the United States more than any other country may be in a position to take economic advantage of the genetic resources located within its own territory. At the same time, the United States is so far most resistant to securing its apparent economic interests. It should not come as a surprise if after further review of this situation the United States decides to change both its internal and external policies in this area.[66]

> step, because such information does not generally address the considerations underlying these requirements, such as acts of invention or the state of the relevant art." At page 4.

[64] "37 CFR 1.56(a): Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [United States Patent and Trademark] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. "

[65] "See 35 USC 102(f): 'A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented."

[66] The United States has made two submissions with respect to internal policies recognizing rights in genetic resources; those of the National Institutes of Health and the US Park Service, IP/C/W/341 and IP/C/W/393. The documents reflect episodic policy development by particular federal agencies. The United States has been slow to consider a national policy with respect to genetic resources.

VII. Recommendations

The proposal of this report is to institute a mandatory requirement of disclosure of source and origin of genetic resources in the TRIPS Agreement and the WIPO administrative treaties. Failure to comply with such a requirement should allow a third party to seek revocation or declaration of invalidity of the patent when the applicant has intentionally sought to mislead the patent office by act or omission, whether or not the patent would have been validly issued had proper disclosure been made. If a third party is able to demonstrate to a court or administrative body that a patent should not have been granted *ab initio*, whether or not there is an intentional failure to disclose, this should ordinarily lead to a declaration of invalidity. In that regard, if the third party is able to demonstrate that the invention is not novel or inventive, or that the patent applicant is not the inventor, this should allow the court or administrative body to act. This should not require a change in international patent law, which already contemplates such determinations. An unintentional failure to make proper disclosure which is not the basis for a determination of invalidity may provide the basis for correcting the patent and/or the prosecution history.

At the present time, this study does not recommend the adoption of a system of certification to the patent office of compliance with PIC and equitable benefit sharing requirements. However, proposals may be further elaborated which will recommend such a system in the future.

If a mandatory international patent system requirement to disclose source and origin of genetic resources is to be adopted, it will be necessary to reach agreement on the specific terms of the requirement. There is scope regarding the extent to which such a requirement may apply to "derived from" inventions, what duty of inquiry will apply to the patent applicant and the extent to which parties may wish to define the nature of enforcement obligations.[67]

The international patent system is effectively regulated by two multilateral institutions - the WTO and WIPO - with complementary and overlapping rules and institutional mechanisms.[68] As a consequence of this relatively unique multilateral institutional framework, rules to implement a mandatory multilateral disclosure requirement with respect to source and origin of genetic resources will be needed in each forum. Therefore, an amendment to the TRIPS Agreement, presumably situated at Article 29, will be required. Also, rule changes reflecting the mandatory nature and the disclosure obligation will be required for the PCT and PLT. Finally, such a requirement should be reflected in the draft text of the Substantive Patent Law Treaty.

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[67] Regarding administrative efficiencies, *see, e.g.,* Queen Mary Intellectual Property Research Institute, Report on Disclosure of Origin in Patent Applications, For the European Commission, DG-Trade, October 2004.

[68] See Frederick M. Abbott, *Distributed Governance at the WTO-WIPO: An Evolving Model for Open-Architecture Integrated Governa and of a nce*, 3 J. INT'L ECON. L. 63 (2000).