

*Patents, Biotechnology and Human
Rights: The Preservation of Biodiverse
Resources for Future Generations*

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1. INTRODUCTION

THE PATENTING OF biotechnological inventions potentially affects human rights in a number of ways. Human rights to identity and the practice of religion may be affected by the availability of patents on genetically modified human beings (or elements of the human body). Patents as mechanisms for market exclusion affect access to new medicines, including those based on biotechnological innovation. Access to medicines and health care are part of the panoply of human rights.

During the past decade, the international community has focused significant attention on the protection of biological diversity and the potential impact of patents and other intellectual property rights on that protection. All of mankind benefits from the preservation of biological diversity. Genetic resource stocks likely will be the source of future agricultural, medicinal and other innovations. The preservation of plant and animal species is important to the functioning and continuing evolution of the Earth's ecosystem, and therefore to the preservation of human life. While the maintenance of biological diversity is not part of the traditional catalogue of protectable human rights, a generalised human interest in the preservation of such diversity might be considered part of the common human interest in the wellbeing of future generations.

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Differentiated biological resources are concentrated in a group of megadiverse countries, almost all of which are developing countries. The geographic territories in which such resources are located are often populated by poor indigenous peoples. The exploitation of biological resources from territories inhabited by these individuals has the potential substantially to affect their economic wellbeing. The maintenance of basic human rights, including rights to security, food and shelter, are dependent on a minimum level of economic welfare. The Convention on Biological Diversity (CBD) recognises sovereign rights over biological resources located within national territories, in part with a view towards assuring that individuals benefit financially from biotechnological inventions derived from such resources.

The potential for conflict between the objectives and terms of the CBD and the rules governing the international patent system has been debated since the conclusion of negotiations on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in late 1993. In 2006 this subject is on the active agenda of the WTO TRIPS Council, and it is being considered at the World Intellectual Property Organisation (WIPO).¹ This chapter analyses the relationship between the CBD and the rules governing the international patent system with a view to making a recommendation regarding whether a multilaterally agreed mandatory requirement for disclosure of the source and origin of genetic resources in patent applications would aid in achieving greater complementarity. The chapter concludes that adoption of such a requirement would be useful.

This chapter does not expressly address information referred to as 'traditional knowledge' except to the extent that such information is relevant to evaluating applications for patents on inventions under the generally applied criteria of patentability. Traditional knowledge may itself be protected as intellectual property distinct from patentable invention.²

¹ See, eg, 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'. See WIPO Secretariat, Patent Disclosure Requirements Relating to Genetic Resources and Traditional Knowledge: Update, WIPO/GRTKF/IC/7/10, at para 11. The subject matter also is also discussed in the context of negotiations on a substantive patent law treaty.

² See, eg, T Cottier and M Pannizon, 'Legal Perspectives on Traditional Knowledge: the Case for Intellectual Property Protection' in K Mascus and J Reichman (eds), *International Public Goods and Transfer of Technology* (Cambridge, Cambridge University Press, 2005).

2. DEFINING THE INTERESTS AT STAKE

2.1. The Convention on Biological Diversity

The CBD has the primary objective of preserving diversity of genetic resources found in nature, including in animals and plants.³ 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.

The second objective of the CBD is to recognise 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 secondly, to enhance economic welfare in countries that house existing stocks of genetic resources by assuring compensation for genetic assets.

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.⁴ 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.⁵

³ See, eg, Secretariat of Convention on Biological Diversity, 'Sustaining life on Earth', Apr 2000 ('CBD Secretariat Summary').

⁴ See, eg, T Cottier, 'The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law' (1998) 1 *Journal of International Economic Law* 555 and JP Rosenthal, Fogarty International Center, National Institutes of Health, USA, 'A Benefit-sharing Case Study for the Conference of Parties to Convention on Biological Diversity' The International Cooperative Biodiversity Groups Program (ICBG).

⁵ See G Dutfield, 'Legal and Economic Aspects of Traditional Knowledge' in Mascus and Reichman (eds), n 2 above, at 495, 504-5, for references to literature with economic estimates.

Developing countries are the preponderant owners of diverse genetic resources.⁶ The special interest of the international community in encouraging development—evidenced, inter alia, in the Preamble to the WTO Agreement and in the United Nations Millennium Development Goals—suggests that a presumption in favour of recognising rights in genetic resources on the part of developing countries is appropriate. In other words, to the extent that developing countries are able effectively to exploit economic interests in genetic resources it is in the interests of the wider international community to support this.

2.2. The International Patent System

The objectives of the international patent system derive from the basic objectives of the patent which are:

1. To encourage innovation;
2. To encourage investment in the commercialisation of innovation, and
3. To promote the dissemination of technical knowledge.⁷

Multilateralisation of the international patent system effectively commenced with conclusion of the Paris Convention for the Protection of Industrial Property in 1883. That Convention adopted the principles of national treatment, right of priority and independence of patents. The disparate interests of developed and developing countries were not given special attention in the Paris Convention.⁸ However, the TRIPS Agreement was adopted in 1994. It significantly expanded the scope of multilateral rules applicable to patenting, and expressly acknowledged developmental objectives, for example, in its preamble which '[r]ecogni[ses] the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives', and in Article 7, which provides:

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and

⁶ See FIC—Economic Development and Biodiversity, Table—Economic Development and Biodiversity, available at www.fic.nih.gov/programs/countries.html and UN list of Megadiverse countries.

⁷ See F Machlup, *An Economic Review of the Patent System*, Subcomm. on Patents, Trademarks and Copyrights, of the Committee on the Judiciary, 85th Congress, 2nd Sess. (excerpts reprinted in F Abbott, T Cottier and F Gurry, *The International Intellectual Property System: Commentary and Materials* (The Hague/London/Boston, Kluwer Law International, 1999), 224–46. Another school of thought considers patents to protect a human right in a person's creative efforts.

⁸ See ET Penrose, *The Economics of the International Patent System*, (Baltimore, Mid Johns Hopkins University Press, 1951), chap XI.

dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Furthermore, the objectives of the TRIPS Agreement must be understood in the context of the WTO Agreement, the Preamble to which includes the objectives of:

allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development . . .'

The objectives of the international patent system which is grounded in the Paris Convention and the TRIPS Agreement should therefore be considered to include not only the three basic objectives of the patent, but also the objectives of promoting economic development, social welfare and environmental sustainability.

2.3. Mechanisms for Achieving Objectives

The CBD accomplishes its objectives by (i) broadly recognising sovereignty over genetic resources,⁹ (ii) requiring prior informed consent (PIC) of the host country as a condition of access to genetic resources,¹⁰ and (iii) providing for the equitable sharing of benefits from the exploitation of such resources.¹¹ Methods for implementation of PIC and equitable ben-

⁹ The CBD provides:

'Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.'

Because some countries are not parties to the CBD, and, particularly from an economic standpoint, the US 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. The US has in multilateral fora acknowledged its acceptance of this principle. 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.

¹⁰ 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.'

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

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.¹² In addition, a number of countries through regulatory guidance offer some form of protection for genetic resources.

The international patent system accomplishes its objectives by prescribing in the TRIPS Agreement a set of rights in favour of patentees to exclude third parties from the market when their claimed inventions have met four criteria: (1) novelty, (2) inventive step, (3) capability of industrial application, and; (4) enabling disclosure. The international patent system is not a unitary mechanism. Patents are granted and enforced by national and regional authorities. The granting of patents in multiple jurisdictions is facilitated by multilateral agreements, including the Paris Convention, Patent Co-operation Treaty and Patent Law Treaty administered by WIPO, and the TRIPS Agreement.

2.4. Complementarity and its Limits

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 legally to protect their recognised interests in genetic resources, including inventions derived from genetic resources, including through commercialisation.

However, to recognise 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

¹¹ The CBD provides:

'Article 15. Access to Genetic Resources

"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."

¹² See WIPO database of CBD implementing legislation, available at www.wipo.int. See also references in Cottier and Pannizon, n 2 above at 575–76.

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.

3. TOWARDS ACHIEVING COMPLEMENTARITY

3.1. The Patent Problem

3.1.1. *Inventorship*

Patents on inventions derived from genetic resources present some unique issues. Under the jurisprudence of the US Court of Appeals for the Federal Circuit (CAFC),¹³ and pursuant to the EU Biotechnology Directive,¹⁴ a biotechnological invention may consist of a purified or isolated form of genetic material as found in nature. Traditionally, patent law has distinguished between discoveries of natural phenomena, on one hand, and inventions which solve a technical problem, on the other. Discoveries are not patentable. Inventions are. The decision by the CAFC and EU to allow patenting of purified or isolated genetic material is an industrial policy decision which effectively modifies traditional patent law and policy.

¹³ See, eg, *Amgen v Chugai Pharmaceutical*, 927 F 2d 1200 (CAFC 1991).

¹⁴ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions provides:

'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.' [Emphasis added]

A patent is granted only to the true 'inventor' of a product or process. The various patent treaties, regional and national patent laws, require an oath of ownership of the invention by the person claiming it. Normally, this will be the individual(s) who first conceived of the invention (and reduced it to practice).¹⁵ But, who is the 'inventor' when the claimed invention is a product of nature, or so closely related to a product of nature as to be essentially indistinguishable? The CBD recognises national sovereignty over genetic resources. If a business bioprospects within a national territory and files a patent application claiming as invention an isolated form of a genetic resource obtained from that territory, who is the owner of the invention? Does a CBD state lose its rights in the genetic resource because the bioprospector took it home and isolated it? Such a result might seem to defeat the purpose of recognising sovereign rights in genetic resources. In light of this, information concerning the source and origin of genetic resources may be directly relevant to determining ownership of the invention, or 'inventorship'.

3.1.2. *Criteria of Patentability*

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).¹⁶

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 anticipated by the prior art requires identifying the inventions in their natural state; that

¹⁵ European law allows a corporate entity to claim inventorship. Under US law, only natural persons may be inventors, although natural persons may assign their rights in patents to corporate persons.

¹⁶ MPEP Rule 2112.01.

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.¹⁷ 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 with respect to both 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.¹⁸ 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

¹⁷ See F-K Beier, 'The European Patent System' (1981) 14 *Vanderbilt Journal of Transnational Law* 1 and MPEP Rule 2141.

¹⁸ See also the Communication from the European Communities, IP/C/W/383, 17 Oct 2002, at para 47.

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.

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.¹⁹ The provisions of these Articles do not by their terms preclude Members from requiring the disclosure of information relevant to patentability and inventorship.

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

3.2.1. 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

¹⁹ 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 was not put in place. Issues of the effect of introducing mandatory disclosure requirements on administrative efficiencies should be addressed, but placing affirmative obligation on an applicant is not inherently inefficient. Patent examiners do not typically verify the accuracy of all information provided by patent applicants (eg, patent examiners do not independently test whether the 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*. [Emphasis]

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 members 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 licences 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.

3.2.2. Need for a Multilateral Solution

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 co-operation 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 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.

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 that it reduced the frequency with which problematic patents are granted it would reduce the burden on these countries.

3.2.3. Mandatory disclosure of source and 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. Secondly, patent examiners would be directed to prior art from those countries most likely to have information relevant to the issues of novelty and inventive step. Thirdly, 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. Fourthly, 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.

Also, a strong argument in favour 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. 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.

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.²⁰ It

²⁰ There are technical issues with respect to identifying the 'source' or 'origin' of genetic resources. 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 states 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.

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.

3.2.4. Disclosure of PIC and 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.²¹ The disclosure of compliance with CBD PIC requirements would involve certification of compliance with national laws implementing such requirements.²² Such

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 may be involved in a chain that moves from securing the genetic resource from a particular geographic location to the patent applicant. 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.

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.

²¹ 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.

²² 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

requirements will vary from country to country.²³ Some countries may 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 the host country to prevent the issue of the patent or to seek its revocation would be required.²⁴ 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 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

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. . . .'

²³ The Bonn Guidelines suggest general principles for implementing PIC and equitable benefit sharing requirements, but these are not binding obligations.

²⁴ 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.

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.

3.2.5. Remedies for Non-compliance

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 may take with regard to non-compliance 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.²⁵ 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 (ie, 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 very broadly the information as to which a duty, of disclosure is owed. This includes, for example, information regarding 'prior invention by another, inventorship conflicts, and the like'.²⁶ The US PTO recommends that patent attorneys ask inventors whom they represent questions about 'the origin of the invention and the point of departure from what was previously known and in the prior art'.²⁷

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.²⁸ 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 as a criteria for patentability but rather is a judicial application of the doctrine of unclean

²⁵ Chapter 2000, Duty of Disclosure, Manual of Patenting Examining Procedure, 8th Edition, Aug 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 s 2, 3, 131, and 132), which are further elaborated in the Code of Federal Regulations, at 37 CFR s 1.56.

²⁶ MPEP, Rule 2001.04.

²⁷ Ibid, at Rule 2004.

²⁸ Ibid, at Rule 2016. See, eg, *Bristol-Myers v Rhone-Poulenc*, 2003 US App LEXIS 7103 (CAFC 2003).

hands. . .²⁹ An applicant who by inadvertent error files an incomplete application is generally permitted to correct that application.³⁰ Similarly, if an error is discovered subsequent to the grant of the patent, the patent holder may request correction and reissuance of the patent.³¹ 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.³² The patent office does not consider itself equipped to evaluate evidence as to intent.

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.³³ Also, the patent holder may be required to license its invention to third parties as is sometimes the remedy in competition cases. Remedies may 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.

The international patent system does not recognise the concept of a 'central attack' on a patent. The principle of independence of patents recognised 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 cognisant 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.

²⁹ *Ibid*, at Rule 2010.

³⁰ *Ibid*, at Rule 2004, para 11.

³¹ *Ibid*, at Rules 2012 and 2022.05. The use Rules are based on 35 USC §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...' [emphasis added]

³² *Ibid*, at Rules 2010, 2012, 2013, 2014 and 2022.05.

³³ *Ibid*, eg, Communication from the European Communities, IP/C/W/383, 17 Oct 2002, at para 55.

3.2.6. *Locus of Amendment*

The international patent system is effectively regulated by two multilateral institutions—the WTO and WIPO—with complementary and overlapping rules and institutional mechanisms.³⁴ 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 Patent Co-operation Treaty and the Patent Law Treaty. Finally, such a requirement should be reflected in the draft text of the Substantive Patent Law Treaty.

4. THE CBD, THE INTERNATIONAL PATENT SYSTEM AND HUMAN RIGHTS

The objective of the CBD is to preserve biodiversity and the global genetic heritage. If preservation of biodiversity is necessary or important to the future wellbeing of the human race, it is reasonable to include its preservation as part of the broad panoply of human rights. The CBD has recognised sovereign rights in genetic resources in part with a view to assuring the equitable distribution of benefits from the exploitation of those resources. If such distribution aids individuals in developing countries to obtain the necessities of food, shelter and health care, it too is important to the promotion of human rights.

The international patent system can and should be consciously aligned with the CBD to promote the preservation of biodiversity. The adoption of a modest change to the international patent system to incorporate a disclosure rule would be a good step in this direction.

³⁴ See FM Abbott, 'Distributed Governance at the WTO-WIPO: An Evolving Model for Open-architecture Integrated Governance' (2000) 3 *Journal of International Economic Law* 63.

