

Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing The TRIPS Agreement: The Problem and The Solution

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I. INTRODUCTION

The purpose of this Article is to discuss how the requirement that the origin of genetic resources and prior informed consent be disclosed in patent applications (hereinafter “Requirement”) can be adopted by World Trade Organization (WTO) Members at the national, regional, or international levels without infringing the TRIPS Agreement.¹ This discussion arises in three different contexts. The first context is the implementation of the Convention on Biological Diversity by biodiversity-rich countries.² In doing so, these countries are seeking ways that enable article 15 of the Convention, and in particular its paragraphs 5 and 7,³ to acquire a

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1. Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, which concluded on Apr. 15, 1994, effective on Jan. 1, 1995.

2. Convention on Biological Diversity [hereinafter CBD], opened for signature on June 5, 1992, at the United Nations Conference on Environment and Development (the Rio “Earth Summit”). It became effective on Dec. 29, 1993.

3. CBD, *supra* note 2, art. 15.5, 15.7 (“Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.”). CBD, article 15.7 states:

Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 . . . 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

practical meaning. Some countries believe one possible way is to identify, through patent specifications, the commercial applications of inventions derived, directly or indirectly, from genetic resources extracted from their biodiversity. Ultimately, what is at stake is the possibility of detecting commercial gains from the use of genetic resources, so that countries supplying those resources can demand their share in the benefits. The second context is the review of article 27.3(b) of the TRIPS Agreement⁴ by the Council for TRIPS and the now suspended new round of multilateral negotiations in the WTO, which failed to begin in Seattle. In this context, a number of developing countries proposed to modify article 29 of the TRIPS Agreement, which establishes conditions on patent applicants. Finally, in the course of the discussions leading to the adoption of the Patent Law Treaty (PLT), under the auspices of the World Intellectual Property Organization (WIPO), Colombia proposed the inclusion of the Requirement in the Treaty.

This Article will show that the compatibility of such a requirement with the TRIPS Agreement will depend on the consequences arising from non-compliance. If the Requirement is introduced into national laws as a condition of patentability, either substantive or adjective, then there will be a conflict with the TRIPS Agreement. However, this does not mean that law may not establish the Requirement, but for that to happen, it will be necessary to modify the nature of the sanction. Instead of imposing the Requirement as a condition of patentability, which conflicts with the TRIPS Agreement, WTO Members should make the enforceability of patent rights dependent on compliance with the Requirement.

Party providing such resources. Such sharing shall be upon mutually agreed terms.

4. TRIPS Agreement, article 27.3(b):

Members may also exclude from patentability: . . . plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

TRIPS Agreement, *supra* note 1, art. 27.3(b). The TRIPS Council launched the review of article 27.3(b) at its meeting of Dec. 1-2, 1999. See Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, WTO Doc. IP/C/M/21, ¶¶ 110-18 (Jan. 22, 1999).

Part II of this Article describes the requirement that the origin of genetic resources and prior informed consent in patent applications, as proposed by different countries in at least two different international fora: in the WTO, before the Council for TRIPS and the General Council, and in the WIPO, before the Standing Committee on Patents. Part III shows why there is a problem of compatibility with the Requirement, as proposed, and the TRIPS Agreement. Finally, Part IV presents a solution to the problem by indicating how the Requirement should be incorporated into national, regional, or international law without infringing the TRIPS Agreement. This solution builds on the fraudulent procurement doctrine, as developed and established by United States courts.

However, before describing the proposed Requirement, one must understand that its relevance may be somewhat limited, depending on the adopted legal criteria. As a matter of fact, the Requirement would apply exclusively to the biotechnology field and only when natural genetic resources, conserved *in situ*, are employed. When the active components are isolated from those resources or even when they are synthesized, the link between the invention and the resources may become too weak to be of any significance.⁵ The same is true for *ex situ* conserved resources. Furthermore, the Requirement only applies in the context of patents and does not apply to trade secrets. It does not apply to certificates of plant varieties or plant patents obtained by breeding plant genetic resources.⁶ This limitation is a result of an

5. This point should be understood *cum granum salis*. Actually, the Requirement, if well worded, should include the genetic information contained in genetic resources and not be limited to the physical, tangible, and natural material. In addition, where the Requirement covers genetic resources, derived products, and substances as well, it follows that it reaches patents in the chemical field. Thus, it covers the whole spectrum of the biotechnology-based as well as the chemistry-based pharmaceutical industries, in addition to related industries such as cosmetics, dietary products, etc. For an example of provisions adopting the Requirement in that broad sense, see the text of the relevant Andean Decision No. 391 provisions *infra* note 17 and accompanying text.

6. It is assumed that the same exceptions to rights admitted by UPOV are also applicable in the context of plant patents. Actually, it is this assumption that explains the sort of farmers' exemption adopted by the European Directive on Biotechnology in the context of patents covering genetic plant material. The same reasoning, *mutatis mutandis*, could be invoked in order to extend the ten-year transitional period that applies to product patent protection in areas of technology more difficult to protect within the territory of Member developing countries (article 65.4 of the TRIPS Agreement) to *sui generis* plant variety protection. In this sense, the equivalence between patent and plant variety protection that article 27.3(b) established should

extensive application of article 15(1)(iii) of the 1991 Act of the Union for Protection of New Varieties of Plants (UPOV) Convention, which establishes that the breeder's right shall not extend to acts done for the purpose of breeding other varieties.⁷ Given that this exception applies to the results of human creative efforts in developing new uniform and stable plant varieties, it follows that the exception also applies to landraces (i.e., plant varieties which have not yet acquired stability) and natural genetic resources.

II. THE REQUIREMENT

The requirement that applicants for patents in the field of biotechnology disclose the source of the genetic resources eventually used as raw materials or tools in the inventive activity and, in addition, provide information (and evidence, if any, by means of contracts or licenses) on prior informed consent is not a new concept. It is a consequence of article 15 of the Convention on Biological Diversity (CBD), which deals with access to genetic resources.⁸ Paragraph four states that access, where granted by the country of origin, "shall be on mutually agreed terms and subject to provisions of this Article."⁹ Paragraph five adds that access "shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."¹⁰ In addition, paragraph seven establishes that the contracting parties shall take legislative action in order to ensure "sharing . . . the benefits arising

cut both ways.

Mathematically speaking, if $A = B$ (patent protection for plant varieties = *sui generis* protection for plant varieties) and $A = C$ (product patent protection = 10 years transitional period), it follows that $B = C$ (*sui generis* protection for plant varieties = 10 years transitional period). Recently, at a seminar on enforcement of intellectual property Rights (San José, Nov. 22-23, 1999), organized by the WIPO and the Government of Costa Rica, the President of the Parliamentary Commission on the Implementation of the TRIPS Agreement stated that Costa Rica was enjoying the 10 year period established by article 65.4 for the adoption of a *sui generis* plant variety protection statute. This discussion, however, is beyond the scope of this Article.

7. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, as revised in Geneva on Nov. 10, 1972, on Oct. 23, 1978, and on Mar. 10, 1991.

8. CBD, *supra* note 2, art. 15.

9. *Id.* at ¶ 4.

10. *Id.* at ¶ 5.

from the commercial and other utilization of genetic resources with the Contracting Party providing such resources.”¹¹ Article 8(j) of the CBD establishes that national legislation should “encourage the equitable sharing of the benefits arising from the utilization of knowledge, innovations, and practices of indigenous and local communities...relevant for the conservation and sustainable use of biological diversity.”¹²

The argument for the Requirement is that researchers and companies from developed countries are using genetic resources extracted from biodiversity-rich countries without appropriate authorization in order to obtain new technologies, inventions, techniques, and products. Furthermore, in many instances members of local, traditional communities, who cooperate with researchers to provide the lead for the identification and discovery of those genetic resources and their active principles, seldom receive payment. The press has described this frequently as “biopiracy” and this characterization has generated strong public indignation in developing countries.

In order to maintain a record of inventions that were developed with the use of genetic resources conserved *in situ* and/or traditional or indigenous knowledge,¹³ it has been proposed that patent applications disclose this information. In the absence of proper authorization, the countries of origin could then make the patent holders accountable for any infringement of the national laws implementing the mentioned CBD provisions. In other words, a specific provision of patent law would serve the implementation of an environmentally related treaty.¹⁴

So far, the Requirement has been incorporated into two statutes: Andean Decision No. 391 of August 16, 1996, which establishes a

11. *Id.* at ¶7.

12. *Id.* at art. 8, § j.

13. For a general discussion on indigenous knowledge and a suggestion on how to protect it by means of a *sui generis* data base mechanism, see Nuno Carvalho, *From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?*, 40, 41 REV. ABPI 3 (1999).

14. See Brendan Tobin, *Certificates of Origin, A Role for IPR regimes in Securing Prior Informed Consent*, paper presented at the Workshop on Regulating Access to Genetic Resources (organized by ACTS, ILS, IUCN, SPDA, WRI), Jakarta, Indonesia, Nov. 4-5, 1995.

Common Regime on Access to Genetic Resources;¹⁵ and the Biodiversity Law (No. 7788) of Costa Rica enacted May 27, 1998.¹⁶ Under both statutes patent applicants are obliged to provide patent offices with information concerning the origin of the genetic resource in question and some proof of prior informed consent from government authorities as well as traditional knowledge holders, whenever the resource will be obtained through their technical knowledge. As an intellectual property-related proposal, it could be expected that it would find its way to the two intergovernmental

15. Common Regime on Access to Genetic Resources, Andean Decision No. 391, Andean Community of Nations (July 2, 1996). Colombia informed the SCP, at its meeting of Sept. 6-14, 1999, that the Requirement would also be included in Decision 344 (Common Provisions on Industrial Property) by means of an amendment. Decision 344 is undergoing a complete revision in order to make it compatible with the TRIPS Agreement.

Two Supplementary Provisions of the Andean Decision No. 391 set up the Requirement in the following terms:

SECOND- The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.

Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.

THIRD- The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries.

The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.

English version available at <<http://www.comunidadandina.org>>, the official website of the Andean Community (Bolivia, Colombia, Ecuador, Peru, and Venezuela).

16. Article 81 of the Biodiversity Law of Costa Rica establishes that:

Both the National Seed Office and the Registers of Intellectual and Industrial Property shall consult with the Technical Office of CONAGEBIO before granting intellectual or industrial property protection to innovations involving elements of biodiversity. The certificate of origin issued by the Technical Office of the Commission and the prior informed consent shall be provided.

Justified opposition from the Technical Office will prohibit registration of a patent or protection for the innovation.”

organizations that cover patent matters: the WTO and the WIPO.¹⁷ Discussions on a proposed amendment to article 29 of the TRIPS Agreement will be discussed below.

At the meeting of the WIPO Standing Committee on the Law of Patents (SCP) on September 6-14, 1999, Colombia proposed the following language to be included in the proposed Patent Law Treaty (PLT):

1. All industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations¹⁸ that relate to elements of that heritage shall be subject to their having been acquired legally.
2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services¹⁹ for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.

Strictly speaking, the Requirement, to the extent it concerns information that does not relate directly to the activity of inventing,

17. It should be noted that, contrary to the common misunderstanding, it is not correct to say that the WTO and WIPO are two organizations with the goal of promoting respect for intellectual property rights. The WTO does not have such a goal. The purpose of the WTO is to promote free trade. Protection of intellectual property, under the WTO's perspective, is a valuable goal only to the extent that differences in national laws may lead to discrimination—and, therefore, constitute barriers to trade. If WTO Members decide that intellectual property may itself constitute a barrier against trade, they may seek lowering the levels of protection of authors and inventors. WTO Members have decided, for example, that the protection of moral rights is not a trade-related aspect, thus it has been excluded from the TRIPS Agreement. *See* TRIPS Agreement, Art. 9.1 (under which non-compliance with article 6bis of the Berne Convention may not be scrutinized by the dispute settlement mechanism).

The same could be said if WTO Members had accepted to include the issue of minimum labor standards in the agenda of negotiations of the suspended new round. The fact that the WTO might look into labor issues should not lead to the conclusion that the WTO and the International Labour Office (ILO) have similar goals.

18. Since the proposal was submitted to the SCP, one could expect it referred only to patents. But the fact that the proposals mentions "registrations" as well might lead to the conclusion that its subscribers would wish to have it extended to future discussions on plant variety protection—at a different forum: the UPOV.

19. Columbia has indicated that this text in English should read "products or processes."

does not characterize the invention itself. In this sense, it is not a “substantive” requirement. Unlike novelty, non-obviousness, utility, and unity—the four patentability requirements that concern the substance, i.e., the very essence of the inventive activity—the Requirement is an accessory, which relates to the invention colaterally. A parallel can be found in the requirement that the patent applicant, where the invention was invented as part of the work performed under a contract with the government, furnishes any document containing a statement which indicates any government licensing rights in the invention and identifies the government contract.²⁰ However, even though the Requirement is not a “substantive issue,” the fact that it has been proposed as a condition of patentability makes it an inappropriate matter for the Standing Committee to handle. The current scope of negotiations on a Patent Law Treaty (PLT) is limited to procedural matters not leading to patentability. Of course, the first part of the Colombian proposal makes the Requirement a condition of patentability. Although it received support from a number of developing countries, it is not a surprise that some developed country members of WIPO rejected the proposal on the grounds that it “was not appropriate for inclusion in the draft Treaty.”²¹ As a result of this discussion, WIPO has decided to convene a meeting on Intellectual Property and Genetic Resources in April 2000 to examine the issue (and other issues arising from the interface between the CBD and the TRIPS Agreement) in preparation

20. The United States has proposed that this requirement be included as an amendment to the Patent Cooperation Treaty Regulations. *See* Proposed item (vi) to Rule 51*bis* (Certain National Requirements Under Article 27 [of the PCT]), doc. WIPO PCT/A/28/2, of Jan. 28, 2000. Two main differences between the Disclosure Requirement and the U.S. proposal may be indicated. Firstly, the U.S. proposal is not a patentability condition. Article 27 of the PCT only addresses formal requirements. Paragraph 5 makes it clear that both the Treaty and the regulations are not 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.” Paragraph 6 adds that “The national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law.” Secondly, unlike the Colombian proposal, the U.S. proposal it is not mandatory. Countries that do not wish to adopt it may not do so.

21. Standing Committee on the Law of Patents, 3d Sess. WIPO Doc. SCP/3/11, ¶ 205. The countries that supported the proposal were Bolivia, Paraguay, China, Namibia, Cameroon, Mexico, South Africa, Chile, Cuba, India, Kenya, Costa Rica, and Barbados. The countries that disagreed were Germany, the United States, Japan, France, the Republic of Korea, Romania, and Finland (speaking on behalf of the European Communities and their Member States).

for the Diplomatic Conference that will negotiate the adoption of the PLT in May 2000.

III. THE PROBLEM

The issue is whether the Requirement described above complies with the standards concerning the availability of patent rights established by the TRIPS Agreement. In this framework, the relevant provisions of the Agreement are: article 27.1 on patentable subject-matter; article 29 on conditions on patent applicants; article 62 on acquisition and maintenance of intellectual property rights and related *inter partes* procedures; and article 32 on revocation and forfeiture of patents.

Article 27.1 lists the substantive conditions of patentability: “[P]atents shall be available for any inventions . . . provided they are new, involve an inventive step and are capable of industrial application.” A footnote to this article explains that the terms “inventive step” and “capable of industrial application” may be deemed by a member state to be synonymous with the terms “non-obvious” and “useful,” respectively, which are commonly employed in U.S. legal practice.²² These are substantive conditions in the sense that they refer to the invention *per se*, because they result from the technical characteristics of the invention.

The Requirement quite obviously is not compatible with article 27.1. The manner of obtaining genetic resources used in the development of inventions is an external condition. The outcome of the inventive activity is indeed independent of the ways and means employed to reach it. The situation that arises from an invention

22. A footnote was added as a manner of accommodating the differences in language between the negotiating proposals presented by the European Communities and the United States. However, the first report presented by the Chairman to the Negotiating Group opted for combining the two proposals into a single provision:

Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.

Text that has not been agreed to appears inside the brackets. The Brussels draft adopted the current language of the first part of article 27.1, including the footnote, GATT Doc. MTN.TNC/W/35/Rev.1 (Dec. 3, 1990).

derived from the use of genetic resources that have been illegally extracted from their *in situ* environment is similar to the situation of an invention that has been developed with the assistance of a stolen microscope. This event would infringe the common law but not patent law under article 27.1 of the TRIPS Agreement. In both situations inventors would still be entitled to the patent, provided the conditions of patentability were met. Nonetheless they would be subject to criminal and civil liability for stealing (both the genetic resources, depending on the existence of appropriate legislation, and the microscope) in the country from which the resources had been taken.

Article 29 of the TRIPS Agreement contains disclosure conditions. Disclosure of the invention must be in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. An optional condition WTO members are free to adopt is the disclosure of the best mode for carrying out the invention. Another optional condition is the requirement that an applicant for a patent provide information concerning the applicant's corresponding foreign applications and grants (as well as rejections). This last condition is aimed at assisting the examination of patent applications in developing countries where insufficient human and technical resources jeopardize the adequate assessment of the substantive conditions of patentability. However, it may not impair the principle of independence of patents, as established by the Paris Convention²³ and incorporated by the TRIPS Agreement.²⁴

As a matter of course, the present language of article 29 is not an appropriate framework for the Requirement. The indication of the origin of the genetic resources and of other circumstances related to their acquisition is not generally necessary for the invention to be carried out by a person skilled in the art. Where the biotechnological invention does require the use of the natural resource to be carried out, the knowledge of where to obtain the resource may be relevant

23. Paris Convention for the Protection of Industrial Property, art. 4bis(1) (1967):

Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.

24. See TRIPS Agreement art. 2.

for the practical exploitation of the invention. In this context, the United States' statement at the November 24-25, 1997 meeting of the WTO Committee on Trade and Environment applies: where the source of the resource is unique, it must be disclosed under article 29.²⁵ There is no need for additional language to be included in the Agreement. However, sometimes the source of the material may be relevant, even though it may not be of essence. In that case the information may even constitute a trade secret. For instance, a natural extract obtained in some particular geographical area may be more effective than a similar extract obtained somewhere else. However, the scope of article 29 does not reach beyond the obligation to explain how the invention works. Therefore, the agreement does not require disclosure of the material's source where knowledge of that source is not essential to reduce the invention into practice.

A third provision of the TRIPS Agreement deals with the conditions that patent applicants may be required to meet by the law of WTO Members. This provision is article 62, which constitutes the entire part IV of the Agreement on acquisition and maintenance of the intellectual property rights provided for under sections 2 through 6 of part II.²⁶ Article 62 authorizes members to require compliance with reasonable procedures as a condition of the acquisition or maintenance of patents.²⁷ The Agreement provides a few elements that may help clarify what a reasonable procedure is but does not define it.

First, article 62.1 establishes that such procedures and formalities shall be consistent with the provisions of the Agreement. In other words, they shall comply not only with the basic principles of the Agreement, including the national treatment and the most-favored-

25. See *infra* note 49, and accompanying text.

26. Sections 1 and 7 of part II are not included because neither copyright nor trade secrets are subject to formalities. This does not mean that those categories of intellectual property rights are completely strange to formalities. Fixation of works upon which the protection of copyright may depend is undoubtedly a sort of formality, though not an administrative one. The same goes for the need of trade secret holders to prove that they have taken reasonable steps under the circumstances to keep the information secret. See TRIPS art. 39(2)(c).

27. Article 62 applies to other types of intellectual property rights the acquisition of which depends on administrative procedures, such as trademarks, geographical indications, industrial designs and layout-designs of integrated circuits. This Article, however, is exclusively concerned with patents.

nation treatment principles but also with specific relevant provisions.²⁸ This means that a link exists between the reasonable procedures admitted by article 62 and the conditions of patentability established in section 5 of part II, namely article 27.1 and article 29.²⁹ Second, article 62.2 clarifies that the procedures, subject to compliance with the substantive conditions for acquisition of the right established by article 27.1, should permit the granting of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

Therefore, it appears that reasonable procedures are those that assist patent administrations to assess whether the substantive conditions, such as novelty, inventive step, and industrial applicability have been met by the invention the patentability of which is under examination. In addition, moderate fees are admitted. This understanding results not only from the reading of the text of the TRIPS Agreement, but also from the history of the negotiations. During the negotiations members never proposed that conditions that did not relate to the characteristics of the invention or the fees to be charged by patent offices would be admitted.

For example, during the first part of the unsuccessful negotiations that led to the Montreal mid-term conference in 1988, some parties to the GATT had already presented their views on what they understood to be the main trade problems connected to intellectual property rights. The European Communities complained that procedural differences and complexities in some contexts made it more difficult for Community firms to obtain protection outside the Community than their competitors within the Community. The Nordic countries, Finland, Iceland, Norway, and Sweden, stated the similar view that a

28. See TRIPS Agreement art. 3 and 4.

29. See DANIEL GERVAIS, *THE TRIPS AGREEMENT—DRAFTING HISTORY AND ANALYSIS* 239 (1998):

As regards other intellectual property rights [other than copyright and undisclosed information], the rules set out in Article 62 apply where reasonable procedures and formalities are required as a condition for the acquisition or maintenance of such rights. The general provisions and principles of the TRIPS Agreement apply. For instance, as regards conditions of disclosure of the invention in a patent application, *Article 29 applies and is not superseded by other acquisition rules.*

Id. (emphasis added).

potential trade problem in the field of national procedures to protect intellectual property rights was related to the complexity of the procedures as such. Switzerland expressed the concern that complicated, costly, and lengthy national procedures made it difficult for small or medium-sized undertakings to gain access to the markets of other countries. Canada also expressed its view that discriminatory and non-transparent procedures increased uncertainty in international trade of goods and services. In a nutshell, even before concrete proposals on the would-be TRIPS Agreement were put on the table, parties to the GATT had already made it clear that there was the need for procedures that were simple, short, and cheap so that certainty as to the grant and enforcement of patent rights were increased, and at the same time the length and the burden of administrative procurement were reduced.

These points have been taken into account by the different proposals presented to the GATT. The first proposal, submitted by the European Communities, contained the text that was incorporated entirely into the final language of the TRIPS Agreement with minor changes.³⁰

30. The negotiations in the Uruguay Round on TRIPS started really after the European Communities tabled their proposal. See GATT, *Draft Agreement on Trade-Related Aspects of IPRs, Communication from the European Communities*, GATT Doc. MTN.GNG/NG11/W/68 (Mar. 29, 1990). Proposals from the United States, Japan, a group of developing countries, and Switzerland followed this proposal. Australia submitted a proposal on geographical indications.

European Communities proposal	TRIPS Agreement
Part 4: Acquisition on Intellectual Property Rights and Related Inter-Partes Procedures	Part IV – Acquisition and Maintenance of Intellectual Property Rights and Related <i>Inter Partes</i> Procedures
	<p>Article 62</p> <p>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.</p>
<p><u>Article 1</u></p> <p>Where the acquisition of an intellectual property right covered by this Annex is subject to the intellectual property right being granted or registered, contracting parties shall provide for procedures which permit, subject to the substantive conditions for acquiring the intellectual property right being fulfilled, the granting or registration of the right within a reasonable period of time so as to avoid that the period of protection is unduly curtailed.</p>	<p>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 the grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right with a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.</p>

	<p>3. Article 4 of the Paris Convention (1967) shall apply <i>mutatis mutandis</i> to service marks.</p>
<p><u>Article 2</u> Procedures concerning the acquisition or renewal of such intellectual property rights shall be governed by the general principles set out in Part 3, Section 1, articles 2 and 3.</p>	<p>4. Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and <i>inter partes</i> procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of article 41.</p>
<p><u>Article 3</u> Where the national law provides for opposition, revocation, cancellation or similar inter-partes procedures, they shall be expeditious, effective, fair and equitable.</p>	
<p><u>Article 4</u> Final administrative decisions concerning the acquisition of an intellectual property right or any other matter subject to an inter-partes procedure referred to in article 3 above, shall be subject to the right of appeal in a court of law or quasi-judicial body.</p>	<p>5. Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.</p>

In the debate that followed the submission of the proposal by the European Communities, it is worth noting that no party rejected the principles on which the proposed concept of reasonable procedures had been based. For example, a participant stated that the TRIPS Agreement should not deal with procedural matters. Another participant stated a preference for less broadly drafted provisions. Another delegate wondered why article 3 of the proposal did not contain the same reference to the general principles on enforcement like article 2. However, no delegation present expressed outright rejection of the proposal at that particular meeting of the negotiating group.

In the Chairman's report to the negotiating group, dated July 23, 1990, the proposed requirements of patentability were the following:

Requirements such as filing of an adequate disclosure in patent application and payment of reasonable fees shall not be considered inconsistent with the obligation to provide patent protection;³¹

The owner of the patent shall have the obligation to disclose prior to grant the invention in a clear and complete manner to permit a person versed in the technical field to put the invention into practice [and in particular to indicate the best mode for carrying out the invention];³²

The European Community proposal was incorporated *ipsis verbis*.³³

These precedents appear to indicate that the TRIPS Agreement only admits three substantive requirements of patentability: novelty, inventiveness, and industrial applicability. Requirements are strictly limited to the need to inform the patent offices about the meeting of these three requirements. The same reasoning applies to the other two conditions allowed (not imposed) by article 29: the best mode requirement is obviously not strange to the industrial applicability

31. This language was extracted from the US proposal of a draft Treaty.

32. This requirement was explicitly connected to the previous one by means of a cross-reference.

33. See GATT Doc. MTN.GNG/NG11/W/76 (July 23, 1990).

condition; and the information concerning foreign applications and grants (and denials) helps verify the findings on novelty and inventiveness as established by patent offices in other countries. In addition to these conditions, WTO Members may impose reasonable procedures under article 62.1. The measure of reasonableness, as it results from the history of negotiations, is assessed according to the direct relationship of the procedures with the substantive requirements established by article 27.1 and the conditions defined by article 29. Other than the payment of reasonable fees, no procedures may be imposed that are strange to the identification and/or assessment of the three substantive conditions of patentability.

This rule can already be found in the first draft of the Patent Law Treaty (PLT) (i.e., the substantive one, titled “Treaty Supplementing the Paris Convention for the Protection of Industrial Property as far as Patents are Concerned”), in which the TRIPS Agreement has deep roots.³⁴ Article 3 of the PLT had rules on disclosure and description of the inventions. Paragraph 1(a) of article 3 established that: “The application shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.” More importantly, paragraph 3 of article 3 established that, “in respect of the disclosure or the description, no requirement additional to or different from those provided for in this article and in the relevant provisions of the Regulations may be imposed.”

As previously mentioned, there is another provision in section 5 of part II of the TRIPS Agreement that is relevant to this issue. Article 32 provides that when revoking or forfeiting a patent, WTO Members must give patent holders the opportunity to ask for a judicial review

34. Although the TRIPS Agreement added a new dimension to intellectual property—the trade-related dimension—it is undeniable that the failure of the negotiations of the original PLT convinced some parties to the GATT to include intellectual property in the ministerial declaration of Punta del Este in 1986. It is worth noting, the mandate concerning the adoption of substantive standards of intellectual property protection was merely exploratory, in a sharp contrast with the mandate for the negotiating groups to adopt rules to prevent the trade of illegitimate goods, which became the rules on enforcement, including the special requirements related to border measures. On the other hand, it is undeniable that the language of the proposed PLT strongly influenced the text of section 5 of part II (on Patents) of the TRIPS Agreement. For example, article 28 of the TRIPS Agreement clearly draws inspiration from article 19, alternative B of the PLT (Rights Conferred by the Patent), and article 34 of the TRIPS Agreement is based on article 24, alternative B, of the PLT (Reversal of the Burden of Proof).

of that decision. The extent to which national laws are free to adopt grounds for revocation has been subject to discussions in the TRIPS Council. This matter is relevant in the sense that both the Colombian proposal (in the SCP as well as the Andean Decision No. 391) and the Biodiversity Law of Costa Rica make the validity of the patent dependent on the fulfillment of the Requirement. If a patent has been granted without meeting the Requirement, arguably the invalidation (or revocation) of the patent would follow. Then the question is whether article 32 of the TRIPS Agreement allows the revocation of patents on that specific ground. It appears that the answer is no.

The history of the negotiations shows that the United States delegation was particularly worried about the revocation of patents. In effect, it proposed specific language to be included in the Agreement that would clearly establish that patents could be revoked only for failing to meet the requirements of novelty, usefulness, and nonobviousness.

The TRIPS Council later discussed the issue of revocation. In the Committee on Trade and Environment, India's representative commented that the TRIPS Agreement did not preclude a member from revoking a patent in order to serve general societal goals, such as promoting technology transfer for environmentally sound technologies. In reaction, the United States representative, at the TRIPS Council meeting of July 22 to 25, 1996, said that, as a result of the conjunction of articles 27, 29 and 33 of the TRIPS Agreement, patents could not be revoked by members except on grounds that would have justified denial of the grant of the patent on the underlying application. Furthermore, article 32 only made review procedures available and did not represent a substantive standard. Subsequently, the United States elaborated on these arguments in a paper, *Remarks on revocation of patents and the TRIPS Agreement*, circulated to WTO Members.³⁵

At the following meeting of the TRIPS Council, the view of the United States received support from Japan, Switzerland, Norway, Canada, the European Communities, and New Zealand. No other

35. See Council for Trade Related Aspects of Intellectual Property Rights, *Remarks on Revocation of Patents and the TRIPS Agreement by the United States of America*, WTO Doc. IP/C/W/32 (Aug. 6, 1996).

WTO Member supported India's view. India continued to hold that article 32 gave some leeway for members to dictate the grounds for revocation of patents, referring to article 5 of the Paris Convention as the applicable framework. In other words, when it referred to the possibility of revoking patents on grounds other than the absence of patentability requirements, India admitted that revocation was possible only when the grant of compulsory licenses would not prevent the abuses resulting from the exercise of the exclusive rights conferred by the patent.³⁶ The Japanese delegation explicitly noted this aspect.³⁷ It is worth noting that the current negotiations by the PLT on procedural matters contains similar restrictions on the possibility of revoking or invalidating patents.³⁸

The problem is that to require that patent applicants identify the source of genetic resources and give evidence of prior informed consent as conditions of patentability conflicts with the TRIPS Agreement. First, in the Agreement the conditions of patentability are limited to novelty, inventiveness, and industrial applicability. Second, the disclosure requirements are limited to the obligations established by article 29. Third, it is not reasonable under article 62 to impose the Requirement. Finally, the patent may not be revoked on the grounds that the Requirement has not been met.

IV. THE SOLUTION

A. A possible but improbable (at least in the short term) solution: to incorporate the Requirement into the TRIPS Agreement

Since a problem of compatibility exists between the national or

36. For example, failure to work. See Paris Convention, art. 5(A)(1)-(3).

37. See Council for Trade Related Aspects of Intellectual Property Rights, *Remarks on Revocation of Patents and the TRIPS Agreement by the United States of America*, WTO Doc. IP/C/M/9 Item F (Oct. 30, 1996).

38. See article 10 of the Basic Proposal for the Patent Law Treaty, submitted by the Director General of WIPO to the Diplomatic Conference for the Adoption of the Patent Law Treaty, WIPO doc. PT/DC/3 (Nov. 11, 1999) stating: once granted, a patent may not be revoked on the ground of non-compliance with one or more of the formal requirements, "except where the non-compliance with the formal requirement occurred as a result of fraudulent intention." Those requirements refer to the form or contents of the application and the communication of addresses.

regional laws that adopt the Requirement and the TRIPS Agreement, the most obvious solution might be to amend the TRIPS Agreement.³⁹ In the WTO India mentioned the Requirement for the first time within the Committee on Trade and Environment (CTE).⁴⁰ In a communication on item 8 of the CTE, India noted that “the fair and equitable sharing of benefits arising out of the patenting and commercial exploitation of genetic resources is not dealt with at all in the TRIPS Agreement.”⁴¹ The two Agreements represent:

two significantly separate multilateral approaches to the utilization of living resources. While TRIPS seeks to promote and foster technological innovation by ensuring the certainty of intellectual property protection and of world markets for at least some biotechnological inventions, its provisions are silent on how this protection can achieve the objective of sustainable development, especially in developing countries.⁴²

The Indian delegation added that the TRIPS Agreement and the CBD presented two main contradictions. The first was the lack of any conditions on patent applications to mention the origin of biological or genetic resources and indigenous or traditional knowledge used in the biotechnological field. The present mandatory conditions were confined to disclosure of the invention. The second contradiction was

39. Another obvious solution might be to modify the requirement so as not to constitute a condition of patentability. In that event, non-compliance might be punished by different mechanisms, like administrative sanctions (a raise in maintenance fees, for example, provided that they should be kept at reasonable levels, according to article 62 of the TRIPS Agreement). In preparation for the WIPO meeting on Intellectual Property and Genetic Resources, which will take place in April 2000, see *supra* note 21 and accompanying text, two countries have informed that they do require patent applicants to disclose the origin of genetic resources used in developing inventions. The sanctions, however, are merely of an administrative nature. Those countries are China and Denmark. The problem with this solution, at least for developing, biodiversity-rich countries might be its ineffectiveness in obliging importers of biological resources to comply with laws or contracts on access. Those importers might prefer to face the administrative sanctions rather than admitting the failure to disclose the origin of the resources in order to avoid the payment of royalties or other contract obligations.

40. The CTE was established by the WTO General Council following a Decision taken by the Ministers in Marrakech, on Apr. 15, 1994.

41. Item 8 of the CTE's agenda is The Relationship Between the TRIPS Agreement and the Convention on Biodiversity.

42. See *The Relationship Between the TRIPS Agreement and the Convention on Biodiversity*, WTO Doc. WT/CTE/W/65 ¶¶ 7, 12-14 and 16 (Sept. 29, 1997) (communication from Indian delegation).

the lack of provisions in the TRIPS Agreement concerning prior informed consent of the country of origin and the knowledge-holder of the biological raw material meant for usage in a patentable invention. This needs to be reconciled with article 15.5 of the CBD.

In view of these two contradictions, India proposed that the TRIPS Agreement incorporate an obligation on patent owners to execute Transfer of Information Agreements for any traditional or indigenous knowledge already in the public domain or a part of the recorded or otherwise publicly accessible knowledge. This would give a concrete shape to the laudable objective of benefit sharing incorporated in the CBD.⁴³

This proposal triggered different reactions at the CTE meeting of September 22-24, 1997.⁴⁴ Colombia, who made reference to Andean Decision No. 391,⁴⁵ and Malaysia, on behalf of the ASEAN, affirmed their support. The United States initially reacted negatively.

Later at the CTE's meeting of November 24-25, 1997, the United States delegation produced extensive comments rebutting the Indian proposal. On the one hand, access to genetic resources should be governed by sets of laws other than intellectual property laws, such as contracts, conservation, export controls, etc. On the other hand, countries providing genetic resources must keep track of their use, not the patent offices of other countries. Moreover,

[i]f the source of biological/genetic resource was unique, an applicant would have to identify it so that a person skilled in the art would be able to carry out the invention Requiring additional disclosure would increase the costs of research because of the record keeping required, thereby reducing research and increasing the costs of products.

In conclusion, the purpose of the TRIPS Agreement was "to establish minimum levels of IPR protection, not to specify contractual obligations governments were to impose regarding access to genetic

43. *Id.*

44. See *Committee on Trade and Environment, Report of Meeting Held on 22-24 September 1997*, WTO Doc. WTE/CTE/M/15 (Nov. 20, 1997).

45. For a discussion of the Andean decision see *supra* Part 2.

materials in other countries' territory."⁴⁶

The United States delegation made four basic arguments:

- a) to amend article 29 of the TRIPS Agreement would fail to address the many situations where the genetic resources have been used to create non-patentable technology;
- b) given that patent rights are eminently territorial, compliance with the CBD could not be monitored and enforced where the patents were obtained in countries other than the one from which the genetic resources were originated;
- c) in many cases the inventor does not know the origin of the genetic resources; and
- d) the introduction of a new condition on patent applications would burden and slow down the administrative procedures leading to the grants.

Two years later in the TRIPS Council, India used the opportunity given by the review of article 27.3(b) of the TRIPS Agreement to repeat its proposal.⁴⁷ At the TRIPS Council meeting on July 7-8, 1999, the India delegation proposed that the objective of harmonising the approaches to the utilisation of living resources in the CBD and in the TRIPS Agreement "could be operationalized if an obligation was imposed in the TRIPS Agreement to share benefits through material transfer agreements and transfer of information agreements Such an obligation could be incorporated through inclusion of provisions in article 29 of the TRIPS Agreement, which dealt with conditions on patent applicants, requiring a clear mention of the biological source of the material and the country of origin."⁴⁸

The TRIPS Council did not examine this proposal at that meeting,

46. See WTO Doc. WT/CTE/M/16 ¶ 89-92 (Dec. 19, 1997).

47. See *supra* note 4.

48. WTO Doc. IP/C/M/24 ¶ 81 (Aug. 17, 1999). Actually, if the Indian proposal had been taken up, there might be a problem concerning the scope of the Council's mandate. Indeed, it is article 27.3(b), which is included in the built-in agenda of the WTO, not article 29. The mandate of the TRIPS Council probably would not cover an eventual review of article 29. The solution might be to leave article 29 as the framework for establishing general conditions on patent applications and adopt article 27.3(b) with special conditions as applied especially to patents for biotechnology inventions.

although several WTO members stated interest in discussing the links between the CBD and the TRIPS Agreement. In preparation of the subsequent meeting of the TRIPS Council, the United States submitted a paper with comments on the Indian proposal.⁴⁹ The paper suggests that the best mode to put the CBD in practice, with respect to genetic resources, would be to require that parties seeking access to genetic resources or traditional knowledge enter into a contract with the sovereign entity grant that access. The paper states the Requirement would be:

an extremely ineffective way for countries that are the source of genetic resources or traditional knowledge. Monitoring copies of publications from patent offices around the world in search of notices of genetic resources or traditional knowledge would [be] an onerous task. If the secrecy of results of research using particular resources or knowledge can be maintained while those results are commercialised, parties might be encouraged to protect their rights through trade secrets rather than patents, in which case, no information would be available at all. In addition, imposing additional requirements on all patent applicants only increases the cost of obtaining patents that would have a greater adverse effect on individual inventors, non-profit entities, and small and medium sized businesses, including those in developing countries.⁵⁰

These differences remained unsolved at the TRIPS Council meeting on November 20-22, 1999.⁵¹ However, the link between article 29 of the TRIPS Agreement and article 15 of the CBD did not receive attention from many WTO members at that meeting. The European Communities supported the view of the United States. Kenya, South Africa, and Pakistan agreed with India. Norway recommended that the Indian proposal should be seriously considered. It appears that the perspective of the imminent Ministerial Conference in Seattle prejudiced the whole debate in October. WTO members, particularly developing country members

49. See WTO Doc. IP/C/W/162 (Oct. 29, 1999).

50. See *id.* at 5-6.

51. See Bridges, Oct.-Nov. 1999 Issue, page 10.

appeared to believe that negotiations on access to genetic resources and the protection of traditional knowledge could move forward in a new multilateral round. This may have diminished their interest in the debate at the TRIPS Council.

Parallel to this discussion, several WTO members proposed to the General Council, in the course of the preparations for the Third Ministerial Conference in Seattle, that the next round of negotiations should encompass the adoption of the Requirement by the TRIPS Agreement.⁵² Given the failure in launching the round, it is improbable that the issue is subject to developments in the WTO soon, either as a component of the built-in agenda or as an element of new negotiations. Therefore, the adoption of the Requirement by the TRIPS Agreement is not a solution in the near future.⁵³

B. A feasible solution: compliance with the Requirement as a condition of enforcement of the rights, rather than as a condition of patentability, under the fraudulent procurement doctrine

To make patentability of inventions derived directly or indirectly from natural genetic resources dependent on the indication of their

52. Those countries are: India, Zambia, Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda, and Venezuela. See *Preparations for the 1999 Ministerial Conference*, WTO Doc. WT/GC/W/282 (Aug. 6, 1999) (communication from Venezuela delegation); *Preparations for the 1999 Ministerial Conference*, WTO Doc. WT/GC/W/225 (July 2, 1999) (communication from Indian delegation); *Preparations for the 1999 Ministerial Conference—Proposals on IPR Issues*, WTO Doc. WT/GC/W/147 (Feb. 18, 1999) (communication from Indian delegation).

53. The TRIPS Agreement will be reviewed in 2000, under article 71.1. However, this provision does not call for the Agreement to be amended necessarily, as it refers to a simple review of its implementation. At most, the review might require a mere fine tuning of those provisions the implementation of which would have shown to be practically unfeasible. Two further points should be taken into account. First, the Council for TRIPS will spend the next two years reviewing the implementing legislation of developing countries (24 countries in the course of 2000, the remainder in 2001). Therefore, it is unlikely that an effective and useful review under article 71.1 may start before completion of that exercise. Second, the TRIPS Council deals with intellectual property rights only; it does not provide a multilateral set where different trade interests could be bargained; as in the General Council. In other words, in the TRIPS Council, WTO Members can negotiate around intellectual property standards only. They cannot bargain tariffs in agriculture or textiles in exchange of concessions in the intellectual property area. This reason explains why the TRIPS Council has been unable to conclude the built-in agenda (which covers three items: geographical indications, under article 24.2, patent protection, under article 27.3(b), and the application of non-violation complaints in the context of intellectual property rights, under article 64.3).

origin and/or the evidence of prior informed consent infringes articles 27, 29, 62, and 32 of the TRIPS Agreement. However, this does not mean that the TRIPS Agreement prohibits WTO members from adopting patent law provisions intended to secure compliance with the provisions of the Convention on Biodiversity. The Agreement does prohibit provisions that leads to the rejection of patent applications or the revocation of patents.

It is a matter of course that the legal system of a party to the Biodiversity Convention should be able to secure that compliance. Various statutes that are not limited to biodiversity law or contract law may have a bearing on access to genetic resources and economic gains resulting from their utilization. Statutes should include patent law to the extent it may contribute to induce benefit sharing. Therefore, patent applicants should be required in those countries that have adopted rules on access to genetic resources to indicate their origin, if it is known or can be determined by reasonable means. On the other hand, it seems reasonable and appropriate that the acquisition and enforcement of rights in inventions knowingly derived directly or indirectly from an illegal act, such as the unauthorized acquisition of genetic resources, be deemed abusive.

The legal framework for this understanding has been established by article 8 of the TRIPS Agreement. Paragraph 1 authorizes WTO members to adopt measures necessary to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided such measures are consistent with the provisions of the Agreement. As a result of this language, if the implementation of benefit sharing under the CBD framework is a matter of vital importance both from an economic and a technological perspective, then biodiversity and the knowledge of its use in a sustainable manner are the comparative advantage of developing countries in international trade and the Requirement may be adopted by national patent laws.⁵⁴ Its consistency with the other provisions of the TRIPS Agreement is indisputable, provided the grant or the

54. See *Protection of Traditional Knowledge: A Global Intellectual Property Issue*, WIPO Doc. WIPO/RT/LDC/14 (Sept. 30, 1999), prepared by the International Bureau of WIPO and distributed at the High-Level Interregional Roundtable on Intellectual Property for the Least Developed Countries (LDCs).

validity of the patent does not depend on applicants meeting the Requirement—otherwise it would be deemed unreasonable under article 62.

In addition, paragraph 2 of article 8 authorizes WTO members to adopt appropriate measures to prevent the abuse of intellectual property rights.⁵⁵ Therefore, WTO members are authorized to establish legal sanctions to patent owners that fail to meet the Requirement. However, those sanctions may not include the revocation of the patent, but nothing prevents them to deem the enforcement of patent rights illegitimately obtained as abusive. Therefore, the fraudulent procurement doctrine may be applied as developed by U.S. common law in the context of the Requirement.

The United States Supreme Court in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.* set out the fraudulent procurement doctrine.⁵⁶ In *Walker Process* the patent owner sued Walker Process Equipment for patent infringement.⁵⁷ The defendant alleged that Food Machinery obtained its patent in bad faith knowing it had no basis for a patent.⁵⁸ The patent applicant fraudulently swore that he neither knew nor believed that the invention had been in public use more than one year before filing the application.⁵⁹ However, the patent owner himself publicly used the invention prior to the bar date. The Court said given that the dispute involved fraudulent procurement “the action does not directly seek the patent’s annulment.”⁶⁰ The Court accepted that an attempt to enforce patent rights obtained by fraudulent means might constitute an antitrust violation under section 2 of the Sherman Act.⁶¹

55. Article 8 of the TRIPS Agreement, therefore, is the provision that allows the link between international intellectual property standards and the implementation of the CBD in the context of article 16 of the CBD (Access to and Transfer of technology). CBD article 16 refers to consistency with the adequate and effective protection of intellectual property rights as well as accordance with international law, which includes the TRIPS Agreement. The ongoing debate on the compatibility between the TRIPS Agreement and the CBD is moot. The Agreements are, per definition, compatible. What may be (but should not be) incompatible is the respective implementation.

56. 382 U.S. 172 (1965).

57. *Id.* at 173.

58. *Id.* at 173-74

59. *Id.* at 174.

60. *Id.* at 176.

61. 382 U.S. at 178. For a discussion on fraudulent patent procurement as an antitrust

Subsequently, lower courts refined the doctrine of fraudulent procurement. These courts qualified it as a consequence of the duty of patent applicants to provide patent examiners with complete information in order to allow a thorough examination of the substantive conditions of patentability. If patent applicants fail to be candid on matters that may have an impact on the final decision on patentability, such as novelty or inventiveness, then the patent may be invalidated. When the lack of candor regards matters that are not essential to the grant or rejection of the patent, then fraudulent procurement is sanctioned by non-enforceability.⁶² Enforceability is restored when the patent owner corrects the misrepresentations or other inequitable conducts—in other words, when *he cleans his hands*.

For example, in *SCM Corp. v. Radio Corp. of America*, SCM sought a judgment declaring, among other things, that one of defendant's patents had been fraudulently obtained and thus, in asserting rights under the patent, the defendant had violated section 2 of the Sherman Act.⁶³ Judge McLean concluded that SCM had not passed the "but for" test in the sense that it had not proved that, in the absence of the misrepresentation, the patent would not have been granted.⁶⁴ However, this conclusion did not dispose of the matter; "We still have to deal with the doctrine of '*unclean hands*,'" the judge wrote.⁶⁵ However, the line between fraud, which invalidates a patent, and unclean hands, which bars its enforcement, was a shadowy one.⁶⁶ The court cited several decisions requiring complete candor and full disclosure of a patent applicant in his dealings with the Patent Office.⁶⁷ Therefore, the court concluded it was not required

violation, see L.A. SULLIVAN, ANTITRUST 512-14 (1977); and H. HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 291-93 (1994).

62. The duty of candor has been linked by some courts to the *ex parte* nature of procedures. It should not be so. Even in countries that adopt *inter partes* procedures, the difficulty of patent examiners to accurately assess the novelty and inventiveness of inventions, particularly when absolute standards are adopted, is likewise extremely high. Patent examiners, therefore, must rely always on the candor of applicants, regardless of the nature of the applicable procedure.

63. 318 F. Supp. 433 (S.D.N.Y. 1970).

64. *Id.* at 449.

65. *Id.* (emphasis added).

66. *Id.*

67. *Id.*

that the inequitable conduct has a but for effect on the granting of the patent as a prerequisite to a court's refusal to enforce it.⁶⁸ Agreeing to Judge Wright's opinion in *Corning Glass Works v. Anchor Hocking Glass Corp.*,⁶⁹ Judge McLean recognized that no one could tell with certainty what would have happened if the patent applicant had behaved with candor.⁷⁰ Since a patent affects the public interest and considering the patent owner withheld relevant facts from the Patent Office, the only rule that could adequately discourage conduct of that sort was to conclude "that this court should not enforce a patent obtained under these circumstances."⁷¹

The solution to the problem of requiring that patent applicants disclose the origin of genetic resources and prior informed consent can be obtained from that rationale. Considering that patents affect a public interest, biodiversity-rich countries may affect patents granted for chemical or biotechnological product inventions directly or indirectly derived from genetic resources based on the CBD's objective of promoting benefit sharing. In this manner patents become consistent, not in conflict, with public policies adopted in response to environmental concerns. As the Supreme Court stated in one of its most quoted statements, the public policy which places inventors' rights within a constitutional frame⁷² "forbids the use of the patent to secure an exclusive right or limited monopoly not granted by the Patent Office and which it is contrary to public policy to grant."⁷³ The Supreme Court has consistently held that inventors'

68. *Id.*

69. 253 F. Supp. 461, 470 (D.Del. 1961).

Even though the misrepresentations made to the Patent Office are not legally material to the issuance of a patent, nevertheless, this Court, being a court of equity, can and should refuse to enforce the patent if the Court finds the patentee made intentional misrepresentations to the patent examiner, i.e., if the patentee came into court with unclean hands.

Id.

70. 318 F. Supp. at 449.

71. *Id.* at 449-450.

72. U.S. CONST. art. I, § 8, cl. 8:

The Congress shall have the power . . . to promote the progress of . . . useful arts, by securing for limited times to . . . inventors the exclusive rights to their respective . . . discoveries.

73. *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 492 (1942).

rights are subject to the convenience of public policy.⁷⁴ The language of paragraph 1 of article 8 of the TRIPS Agreement does not read otherwise.

To make the granting and validity of those patents dependent on the meeting of the Requirement conflicts with the obligations imposed on WTO members by the TRIPS Agreement. Nevertheless, courts should be able to sanction the lack of candor of patent applicants who knowingly failed to disclose the source in a manner that would facilitate benefit sharing, as established by article 15 of the CBD. Actually, the determination that the concealment of information might lead to the implementation of public policies concerning benefit sharing is fraudulent is a matter of law. Consequently, any attempt to enforce patent rights thus obtained would be an abuse of rights. In compliance with paragraph 2 of article 8 of the TRIPS Agreement and given that infringement both direct and contributory is a tort,⁷⁵ it can be imposed that one must have clean hands to obtain relief from an equity court.⁷⁶ Only after a patentee abandons its unlawful practice and the effects of the misuse are completely dissipated may it sue infringers.⁷⁷ In the case of the Requirement, this implies that patent owners would have to disclose the origin and obtain the appropriate authorizations from the appropriate stakeholders (governments, local authorities, and traditional knowledge holders) before the patent rights could be enforced against infringers.

74. See, e.g., *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330-31 (1945) (stating that “the primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences”); *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942) (stating that “The promotion of the progress of science and the useful arts is the ‘main object’; reward of inventors is secondary and merely a means to that end”); *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 492 (1942) (stating that “the grant to the inventor of the special privilege of a patent monopoly carries out a public policy adopted by the Constitution and laws of the United States, ‘to promote the Progress of Science and useful Arts’ . . .”); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) (stating “[T]his court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is ‘to promote the progress of science and useful arts’”).

75. See, e.g., *Carbice Corp. of Am. v. American Patents Dev.. Corp.*, 283 U.S. 27, 33 (1931).

76. See, e.g., *Carter-Wallace, Inc. v. United States*, 449 F.2d 1374, 1377 (Ct. Cl. 1971).

77. See, e.g., *B.B. Chemical C. v. Ellis*, 314 U.S. 495, 498 (1942).

In sum, the national or regional laws of WTO members that restrict access to the genetic resources found in their territory may require that patent applicants indicate, if known, the source of genetic resources directly or indirectly used in obtaining the invention. The lack of that indication by a patent applicant who knew or had reason to know constitutes fraud. Therefore, the enforcement of the resulting patent therefore, may be deemed an abuse of rights.

In the same vein, if one obtains the genetic resource directly or indirectly used in making a patented invention in a country that has adopted legislation requiring prior informed consent, the failure to obtain that consent constitutes fraud and, therefore, an attempt to enforce that patent may be deemed an abuse of rights. In both cases the patentee's cleaning his hands by providing the missing information and/or obtaining the required prior consent, would purge the abuse of rights.

Importantly, this proposal would not raise transaction costs to an unacceptable level, making patents cost ineffective. The sort of care required from patent applicants would be reasonable under the circumstances. They would be required to indicate the origin of the resources that they knew or that they had a reason to know; this is a reasonable care standard. In many cases, mere evidence of compliance with the national laws of the countries providing the genetic resources would suffice, without imposing on the patent applicants the burden of engaging in complicated and costly investigative efforts. On the other hand, infringers would not be able to get away with illegal practices because the burden of proving the failure by the patent owner to meet the reasonable care standard would fall upon them. If they provided no evidence, no defense would exist against the patent owner. Nevertheless, as explained before, that standard would not be impossible to meet particularly where the countries of origin had enacted laws on access to genetic resources. In these cases, assessing whether the patent owner met the standard would be almost a matter of objective fact finding.

One should bear in mind, however, that the real economic dimension of the Requirement is closely linked to the filing of patents for inventions derived from the utilization of genetic resources—inventions in the fields of chemistry and biotechnology which find their main markets in developed countries. Therefore, to enact laws

imposing the Requirement in developing, biodiversity-rich countries may not be economically significant if the same conditions do not apply in developed countries. The ultimate goal of developing biodiversity-rich countries, therefore, should be to establish the Requirement as a condition of enforceability of patent rights at a multilateral level, preferably in the framework of WIPO, which is the most appropriate international forum for the discussion and negotiation of new intellectual property concepts.⁷⁸ As a second step, and in order for biodiversity-rich countries to have access to the WTO dispute settlement mechanism, the concept developed in WIPO could then be incorporated into the TRIPS Agreement as a result of multilateral trade-related negotiations.

78. See Convention Establishing the World Intellectual Property Organization, July 14, 1967, as amended on Sept. 28, 1979, articles 3 and 4. The application of the fraudulent procurement doctrine in the context of access to genetic resources is a new concept indeed.