

# From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent

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## I. INTRODUCTION

The introduction in patent statutes of a requirement to disclose the origin of genetic resources and prior informed consent of the use of traditional knowledge in claimed inventions (hereinafter “the Requirement”) has been at the center of an international debate for the last few years. Many developing, biodiversity-rich countries consider that the Requirement is an essential component of a broader approach to patent law, which should be informed by considerations of economic development.<sup>1</sup> At the other end of the spectrum, a few industrialized countries believe that the Requirement is not only incompatible with current international law, in particular the TRIPS Agreement,<sup>2</sup> but that it also undermines the value of patents as titles that secure private property rights because it unnecessarily

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1. See *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WIPO Doc. WO/GA/31/11 (Aug. 27, 2004). That proposal has received the support of the delegations of South Africa, Bolivia, Cuba, Ecuador, Iran, Kenya, Sierra Leone, Tanzania and Venezuela. See also *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WIPO Doc. WO/GA/31/13 (Sept. 27, 2004); *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WIPO Doc. WO/GA/31/14 (Sept. 28, 2004). All WIPO treaties and documents cited in this Article are available on the WIPO’s website, at <http://www.wipo.int>. See *infra* Part III.F for a brief report of ongoing multilateral discussions.

2. See *infra* notes 38 and 53 and accompanying text.

complicates the already complex patent procurement procedures and reduces legal certainty.<sup>3</sup>

Actually, the debate on the Requirement has caused international discussions on the advancement of standards of patentability to stall,<sup>4</sup>

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3. See *Working Group on Reform of the Patent Cooperation Treaty*, WIPO Doc. PCT/R/WG/6/12 (May 7, 2004). The United States delegation said that the Swiss proposal to include a provision in the PCT Regulations allowing PCT Parties to adopt the Requirement

would not achieve its stated goals of achieving timely solutions to access to genetic resources and traditional knowledge as well as the sharing of the benefits derived from such access. Rather, the proposal would sanction provisions in national laws to deny patent rights and challenge granted patents under prescribed circumstances, which would increase litigation, create a disincentive for innovation, and reduce any benefits that may be shared. The Delegation could thus not support the proposal . . . . The Delegation of the United States of America noted that Switzerland compared its proposal to disclosure requirements which were based upon fundamental principles of patent law or required as a practical matter to facilitate patent examination, but in the Delegation's view the disclosure requirement proposed by Switzerland was directed to matters falling outside patent laws such as access and benefit sharing. The Delegation expressed the view that patent laws were not the appropriate means for addressing matters of misappropriation of genetic resources and traditional knowledge, or other matters of general misconduct. Such thinking might lead States to attempt to advance other non-patent related goals, such as a tax reporting requirement, through the patent laws.

*Id.* at 17. Nevertheless, the United States has its own statutory provisions with a disclosure requirement that advances non-patent goals. In contrast with the Swiss proposal, however, the U.S. statutory provisions are consistent with international law because they are dictated by concerns over material (or proprietary) interests in the patents. See *infra* Part IV.D.

4.

Although the work of the SCP [WIPO Standing Committee on the Law of Patents] has produced some useful results, the lack of progress at recent SCP sessions clearly demonstrates that the current model for discussion is not workable. Indeed, discussions in the SCP have degenerated to the point that the SCP was unable to agree to a further work program at its most recent session of May 10–14, 2004. There are several reasons for this lack of progress . . . . Beyond this, the draft treaty documents contain several provisions that have been extremely controversial and of a high political sensitivity, leading to postponement of discussions on some provisions and protracted debates with little resulting progress on others.

*Proposal by the United States of America and Japan for Establishing a New Work Plan for the Standing Committee on the Law of Patents (SCP)*, WIPO Doc. WO/GA/31/10 (Aug. 27, 2004). That proposal was submitted to the WIPO 31st Ordinary (15th Extraordinary) General Assembly, of 2004. As described *infra*, in Part III.F, the United States and Japan have attempted to insulate the current work of the SCP on a draft Substantive Patent Law Treaty (SPLT) by separating topics that are of a more technical nature (such as novelty and inventiveness, or non-obviousness) from the debate of the adoption of the Requirement. That attempt, as noted *infra*, even if correct from a technical point of view, has not been successful in the SCP. The major concern of developing countries is, naturally, an eventual TRIPS

to the prejudice of the interests of inventors and the society at large in obtaining titles that are more secure and less prone to challenges, thus increasing legal security of intangible assets. An objective clarification of the legal aspects of the Requirement, therefore, has become a matter of urgency. That is what this Article intends to achieve. This Article has two main objectives: to explain that the Requirement, as a condition of patentability aimed at monitoring the implementation of the Convention of Biological Diversity (CBD),<sup>5</sup> is incompatible with current international law, including the CBD itself; and to discuss possible ways of adopting the Requirement that are compatible with international law.

Part II of this Article describes the main objectives that biodiversity-rich developing countries want to achieve by adopting the Requirement. It also explains the formal nature of the Requirement—several international treaties against which the Requirement is to be checked treat formal and substantive requirements differently.

Part III assesses the inconsistency of the Requirement vis-à-vis the relevant international instruments, namely the TRIPS Agreement,<sup>6</sup> the UPOV Convention(s),<sup>7</sup> the Patent Cooperation Treaty (PCT),<sup>8</sup> the

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inconsistency of the Requirement, for it might lead to disputes under the WTO Dispute Settlement Mechanism and, ultimately, the risk of commercial sanctions. Developing countries expect that, if they were able to include language in support of their view in the SPLT, they would be closer to a consensus on the adoption of the Requirement in the WTO framework.

5. The Convention on Biological Diversity, Dec. 29, 1993, *available at* <http://www.biodiv.org/convention/articles.asp> [hereinafter CBD]. Currently, the CBD has 188 parties. The text of the Treaty as well as an introductory guide to its provisions can be found on the CBD Secretariat's website, at <http://www.biodiv.org>.

6. Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization (WTO), Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter the TRIPS Agreement, or, simply TRIPS]. The text of the TRIPS Agreement as well as of the WTO documents cited in this Article are available on the WTO website, at <http://www.wto.org>.

7. "UPOV" is the acronym of the *Union pour la Protection des Obtentions Végétales*. Two different versions of the UPOV Convention of 1961 are in force: UPOV 1978 and UPOV 1991. The texts of the International Convention for the Protection of New Varieties of Plants, of December 2, 1961, as revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991 can be found on UPOV's website, at <http://www.upov.org>. The UPOV is not about patents for inventions, but about a sui generis regime for plant varieties. Because the main concern of this Article is patent law, references in this Article to UPOV are to be understood *mutatis mutandis*.

8. Patent Cooperation Treaty, June 19, 1970, *available at* <http://www.wipo.int/pct/en/>

Patent Law Treaty (PLT)<sup>9</sup> and the CBD. Part III also briefly reports on the current status of international negotiations on the Requirement in the different fora (such as the TRIPS Council and several bodies of WIPO).

Recognizing that an international solution for the gridlock is not in sight in the short- or mid-term, Part IV searches for possible ways to establish a Requirement consistent with TRIPS and other international instruments. Section (a) criticizes a solution that has already been proposed: to treat traditional knowledge holders who contribute genetic resources for inventions as inventors or co-inventors. Section (b) looks at a non-statutory solution, penalizing unjust enrichment from the concealment of valuable information. Even though this solution is available, it is not cast in stone, and courts have varied in dealing with differences in the level of information between contracting parties. Section (c) revisits a solution based on the unclean hands doctrine. Section (d) analyzes a solution adopted under U.S. law and which deals with government material interests in inventions funded with federal resources. Even if the situation and the consequences of that solution are different from the Requirement, nevertheless, the U.S. solution provides a useful hint that buttresses an additional solution, proposed in section (e): governments of biodiversity-rich countries would be entitled to claim ownership in the patents covering inventions derived from genetic resources extracted from their territory without permission. Following a parallel in the regime of employees' inventions as well as in the doctrines of conversion (or the right of accession in civil code countries), the unauthorized use by inventors of materials extracted from national territories would entitle those governments to have a material claim in the resulting title. This is, under a different dosage, the solution recognized by U.S. law for inventions funded by federal resources.

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texts/pdf/pct.pdf (entered into force on Jan. 24, 1978) [hereinafter PCT]. The PCT is administered by the International Bureau of WIPO.

9. Patent Law Treaty, *opened for signature* June 1, 2000, *available at* <http://www.wipo.int/clea/docs/en/wo/wo038en.html> [hereinafter PLT]. The PLT, once it enters into force, will be administered by the International Bureau of WIPO.

Notwithstanding the fact that Part IV may indicate valuable solutions for adopting a TRIPS-consistent Requirement without changing the text of the international agreement, Part V brings a word of caution. It may not be that valuable to tamper with already complex procedures for obtaining patent rights and add an extra argument for challenging them. Part V concludes that patents are not certificates of good behavior: they are certificates of inventive behavior. For the sake of a reasonably efficient international patent system, they should remain so.

## II. THE OBJECTIVE AND NATURE OF THE REQUIREMENT

### *A. The Objective of the Requirement*

In the last few years a number of developing, biodiversity-rich countries have insistently requested that international patent law be modified to permit national laws to require disclosure<sup>10</sup> of the origin of genetic resources and prior informed consent of the use of traditional knowledge in patent applications. The Requirement has a single objective: to help stakeholders monitor compliance with the legal or contractual obligation to share benefits derived from the commercial use of genetic resources and/or associated traditional knowledge, in the light of the recommendation contained in Articles 8 and 15.7 of the CBD.<sup>11</sup> Article 8 provides:

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10. Patent applicants have, primarily, the obligation of disclosing “the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.” TRIPS Agreement, *supra* note 6, art. 29.1. WTO Members, additionally, “may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.” *Id.*

11. A group of developing countries identified four objectives of the Requirement:

(a) reducing instances of bad patents; (b) enabling the patent office to ascertain more effectively the “inventive step” claimed in a particular patent application; (c) enhancing the ability of countries to track bad patents in the instances where they are granted and challenge the same; (d) improving compliance with their national laws on PIC [prior and informed consent] and fair and equitable benefit sharing prior to accessing a biological resource/associated traditional knowledge.

*The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, at 2–3, WTO Doc. IP/C/W/403 (June 24, 2003). The impact of the Requirement as a tool for assessing patentability (this is, in a nutshell, the objectives listed under (a), (b) and (c)) is significant only in those cases where patents have

Each Contracting Party shall, as far as possible and as appropriate:

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(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and *encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices*.<sup>12</sup>

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been applied for or obtained in regard to biological materials (plants, animals and micro-organisms). However, in most developing countries, only micro-organisms are patentable subject matter, as a result of implementing article 27.3(b). Other inventions concerning living organisms are not. So, the proposal of that group of developing countries could have a significant impact in developed countries rather than in their own territories. Moreover, never has a patent been granted in violation of rights and interests of traditional knowledge holders in developing countries. So far, the reports of "biosquatting" patents have only designated patents issued in the United States, Europe and Japan. It seems, therefore, that the problem of "bad patents" is exclusively one that respects developed countries. In this Article the word "biosquatting" will replace the term "biopiracy." Actually, the term "biosquatting" is more accurate than the word "biopiracy" for qualifying the appropriation (or misappropriation) of intangible components of genetic resources and/or of traditional knowledge that could be deemed in the public domain as well as the unauthorized claiming of traditional knowledge that is in control of Indigenous peoples and local communities. The reason is that the first modality is not necessarily illegal—in many cases, actually, private parties benefit from a loophole or a particular feature in the law, such as the one that only accepts written disclosure of prior art for the purposes of patent novelty assessment. Such claims, which impinge on knowledge that otherwise would be in the public domain are similar to settling "on public land in order to acquire title to the land," that is, squatting in the definition of the BLACK'S LAW DICTIONARY 1411 (7th ed. 1999). Squatting also means "entering upon lands, not claiming in good faith the right to do so by virtue of any title of his own or by virtue of some agreement with another who [one] believes to hold the title," *id.*, which corresponds to the misappropriation of TK that is in control of Indigenous and local communities. This second meaning would be closer to "piracy," but not the first one. Besides, under international intellectual property law, the word "piracy" is linked to some practices of copyright infringement. TRIPS Agreement, *supra* note 6, art. 51 n.14. Accordingly, the word "cybersquatting" has been used to designate those cases of misappropriation of third parties' names and brands as domain names over the Internet. The term "biosquatting" seems, therefore, more accurate to identify illegal or otherwise illegitimate intellectual property practices related to genetic resources and associated TK.

12. CBD, *supra* note 5, art. 8 (emphasis added).

Article 15.7 of the CBD provides:

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.<sup>13</sup>

Failure to comply with the Requirement may be sanctioned in different ways. For example, it can be stipulated that willingly omitting information on the origin of genetic resources in a patent application amounts to lack of candor in the context of relations between a private citizen and the public administration, a breach of a general duty of transparency punishable by a fine or a ban on entering into contracts with the government. But in the field of patents, the sanction that has been more frequently envisaged by governments is the rejection of the patent application or the revocation of the resulting patent, if granted.<sup>14</sup>

It is generally accepted that, once a piece of traditional knowledge (hereinafter “TK”)<sup>15</sup> has been instrumental for an inventor to reach a

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13. CBD, *supra* note 5, art. 15.7 (emphasis added).

14. This Article will focus on this last modality of sanctions, unless indicated otherwise.

15. The WIPO Secretariat has explained that the term “traditional knowledge” is, actually, a misnomer, for it comprises both technical ideas, that is, knowledge, and expressions of such knowledge, in the form of expressions of folklore (EOF) or traditional cultural expressions (TCEs) (the terms EOF and TCEs are interchangeable). In other words, the term TK has two different meanings. In a broader concept, it comprises both ideas and expressions. But, in a stricter sense, TK means technical ideas (technical solutions developed by traditional communities in fields such as medicine, agriculture, and environmental protection). Therefore, TK *lato sensu* corresponds to the traditional idea/expression dichotomy that buttresses the general framework of intellectual property. TK *lato sensu* comprises two different (but intertwined) fields: EOF or TCEs are closer to the copyright regime; TK *stricto sensu* has a close affinity with industrial property. See *Consolidated Survey of Intellectual Property Protection of Traditional Knowledge*, ¶¶ 8–9, WIPO Doc. WIPO/GRTKF/IC/5/7 (Apr. 4, 2003). It is in this narrow sense that the term TK is employed in this Article, and which has been defined by the WIPO Secretariat as:

ideas developed by traditional communities and Indigenous peoples, in a traditional and informal way, as a response to the needs imposed by their physical and cultural

new, creative and useful solution to a given technical problem, it is predictable that the same inventor will be able to put the invention on the market and extract revenues from it. Under Article 15.7 of the CBD and the legal or contractual instruments based thereon, the bioprospector or his/her successor is obligated to share those revenues with the TK holder. As a matter of law, that obligation arises from the TK-derived creation and the obtaining of benefits from it, not from the patent. In other words, the obligation remains regardless of whether the practical applications derived from the TK are submitted as patent applications or kept as trade secrets or simply disclosed into the public domain. A well-written TK licensing agreement will contain clauses providing for monitoring of unauthorized use of the TK, but a problem arises when there is no contractual relationship between the bioprospector and the TK supplier, and therefore the latter has no access to the former's accounting books or research records. Biosquatting then becomes a matter of breach of statutory measures (in those countries which have enacted measures on access to genetic resources and associated TK) or of breach of the law in general (as far as misappropriation of TK can be alleged).

The practical reason for some countries' insistence in keeping the Requirement is that without the voluntary<sup>16</sup> or mandatory disclosure it is extremely difficult, if not impossible, to assert with reasonable

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environments and that serve as means for their cultural identification; the technical scope of those ideas is therefore vast, and comprises all fields of technical application; those ideas contrast with the respective expressions, such as folk tales, poetry, and riddles, folk songs and instrumental music, dances, plays, etc.

*Id.* ¶ 8. The WIPO document explains further that handicrafts may be covered by either field of TK, or by both concomitantly, depending on their more or less utilitarian function. *Id.* ¶ 9.

16. Many patent applications do identify the origin of genetic resources used in making the invention, regardless of any legal constraint in that sense. See generally Asha Sukhwani, *PATENTES NATURISTAS* (Oficina Española de Patentes y Marcas, Madrid). See also *Patents Using Biological Sources Material (I) and Mention of the Country of Origin in Patents Using Biological Source Material (II)*, WIPO Doc. WIPO/GRTKF/IC/2/15 (Dec. 13, 2001). The U.S. delegation, in its response to the questionnaire that was used as the base for the WIPO technical study on the Requirement, said: "[B]ased on experience, the USPTO is aware that patent applicants, at times, provide information about the genetic resources used in their invention, including the source of origin, in order to meet the written description, enablement or best mode requirement." See *Draft Technical Study on Disclosure Requirement Related to Genetic Resources and Traditional Knowledge*, ¶ 60, WIPO Doc. WIPO/GRTKF/IC/5/10 (May 2, 2003) [hereinafter *Draft Study*].

certainty that a given invention has been made possible because of a certain hint given to the inventor on a certain use of a plant, animal or micro-organism. Where the invention consists of the very use of the plant (or of its active component) for a practical purpose,<sup>17</sup> the link between the invention and the TK is more visible—if they are not actually the same, as it turned out in the turmeric patent. In that hypothesis, the TK creator should be identified as co-inventor, because his contribution was one of clearly inventive nature. But in those many countries in which new uses of known substances are not patentable subject matter *per se*, situations like the turmeric patent would never arise.<sup>18</sup> In most cases TK is the hint that leads bioprospectors to select plants for collection and further analysis. In these cases there is no visible link between the final product and the initial lead. The invention consists of identifying the useful components and assessing their efficacy.<sup>19</sup> The TK holder who gave

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17. For example, U.S. Patent No. 5,401,504 was granted for the “Use of *turmeric* in wound healing” and it was thus summarized: “Method of promoting healing of a wound by administering *turmeric* to a patient afflicted with the wound” (hereinafter designated as “the turmeric patent”). The patent was re-examined and invalidated, on grounds of lack of novelty, upon request by the Indian Council of Scientific and Industrial Research (CSIR), a government agency linked to the Indian Ministry of Science and Technology. This was a clear-cut case in which a patent was granted for a traditional invention. The patent applicants had added nothing new or creative to what they had learned from ayurvedic traditional medicine. Nevertheless, if it were not for the lack of novelty, the people of Kerala might have been better off if the CSIR had requested the transfer of the title in the U.S. patent instead of pursuing its invalidation. Information on the CSIR can be obtained at <http://www.csir.res.in>.

18. See, e.g., Andean Community Decision No. 486 art. 21 (Sept. 14, 2000), available at <http://www.sice.org/trade/JUNAC/decisiones/DEC486e.asp>.

Article 21.—Products or processes already patented and included in the state of the art within the meaning of article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

Legislation and other documents of the Andean Community can be found on its website, at <http://www.comunidadandina.org>.

In the same sense, The Patents Act (1970) of India, provides:

The following are not inventions within the meaning of this Act . . .

(d) the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Indian statutes on industrial property can be found on the Indian patent office’s website, <http://www.patentoffice.nic.in>.

19. Frequently the identified components are useful for purposes other than those known

the hint and eventually supplied the samples of the resources to the bioprospector can be deemed instrumental to the final output of the inventive activity, but he is not a co-inventor and possibly would have a hard time trying to identify his contribution in the claimed invention. The Requirement, accompanied with effective deterrent sanctions, becomes a crucial tool to obtain compensation from the unauthorized use of TK.

### *B. The Formal Nature of the Requirement*

The Requirement is a *formal* requirement, as opposed to a *substantive* one, and thus its place in the TRIPS Agreement, if ever adopted, should be Article 29, rather than Article 27.3(b). Substantive requirements are those that concern the nature of the invention itself. Substantive, therefore, are the elements of novelty, non-obviousness and utility. Those elements are not only substantive requirements but also substantive *conditions* of patentability, because the failure to meet them is sanctioned with either the rejection of the patent application or, if *a posteriori*, with the invalidity of the patent.<sup>20</sup>

In contrast, formal requirements are those that concern the form in which the invention is submitted to the patent office. The main formal requirement—failure to comply with it will cause the patent application to be denied—is disclosure of the invention, which must be enabling. This formal condition is actually a consequence of the substantive conditions of patentability: it is by reading specifications that disclose the invention in an enabling manner that patent examiners make decisions on whether they find the invention new, non-obvious, and useful.

Other formal requirements that may constitute conditions of patentability relate to evidence of ownership: a document assigning

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to the TK holder.

20. Another substantive requirement—which is not a substantive condition—is the unity of invention. In general, the failure to meet this requirement, if detected during the examination of the patent application, causes the patent application to be divided, but not rejected. If detected after the patent is granted, the patent is preserved. A fourth substantive condition of patentability—the condition of alternativeness of inventions—was identified by the United States Supreme Court in at least three cases. See Nuno Pires de Carvalho, *The Problem of Gene Patents*, 3 WASH. U. GLOBAL STUD. L. REV. 701, 725–34 (2004).

the right to apply for the patent to the inventor's employer, for example, or a statement that the applicant is the true inventor. This formal condition is explained by the fact that some patent laws retain the principle that patent rights are originally vested in the first and true inventors. Assignees are only entitled to acquire patent rights as a result of a transfer of original rights. Patent offices generally do not examine the issues of inventorship and ownership, because their role is more a technical one, but some evidence is generally required that identifies those upon whom the law vests the patent rights (or their legitimate expectations).<sup>21</sup>

A third category of formal requirements is evidence of the payment of fees to patent offices. There are two categories of fees: procurement fees, which patent applicants must pay to patent offices for services rendered, and maintenance fees. Procurement fees are not referred to either in the TRIPS Agreement or in the Paris Convention for the Protection of Industrial Property, but they stem from customary administrative practices and are set as an obligation by the PCT and its Regulations.<sup>22</sup> They are therefore authorized by Article 1.1 of the TRIPS Agreement. Maintenance fees, in contrast, are expressly mentioned by Article 5<sup>bis</sup> of the Paris Convention.<sup>23</sup> Article 5<sup>bis</sup>(2) authorizes Paris Union Members "to provide for the restoration of patents which have lapsed by reason of non-payment of fees"—which, *a contrario*, means that Paris Union Members (as well as WTO Members, in the light of Article 2.1 of the TRIPS Agreement) may provide for the lapse of patents on grounds of non-payment of maintenance fees.

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21. As explained below, the TRIPS Agreement does not contain any provisions on ownership of inventions. It is exclusively a matter for national laws to attribute property rights to inventors or to third parties that are legally entitled to succeed to inventors because of certain material interests in the inventions (such as employers, financial sponsors, etc). The only obligation of WTO Members in this regard is stated in article 4<sup>ter</sup> of the Paris Convention: to give inventors the right to be mentioned as such in the patent. Significantly, article 4<sup>ter</sup> of the Paris Convention does not say that the inventor has the right to be mentioned as *owner* in the patent, but only *as such*, that is, as the creator, the author of the invention.

22. PCT, *supra* note 8, arts. 3(4)(iv), 4(2), 39(1), Regs 14–16. The PCT and its Regulations are naturally concerned with fees due in the course of the international phase of patent applications. But article 39(1)(a) of the PCT makes explicit reference to national fees.

23. Mar. 20, 1883 (last amended in 1979) [hereinafter "Paris Convention"]. The text of the Paris Convention as well as of the other Treaties administered by the WIPO Secretariat can be found on WIPO's website, at <http://www.wipo.int>.

Evidence concerning the origin of genetic resources and prior informed consent of TK holders is a formal requirement in the sense that it does not concern the nature of the invention, but the manner in which the application is presented to the patent office. The Requirement may assume different forms according to the specific nature of the TK involved. When the knowledge about the origin of the genetic resource or the TK used in the invention is essential for understanding the working of the claimed invention, it becomes an element of the enabling disclosure. The Requirement, in such circumstances, is already imposed by current international and national patent law as a formal condition of patentability.<sup>24</sup> Governments' permission to access genetic resources and TK holders' authorization to use their knowledge, and/or genetic resources incorporating their knowledge, are not technical elements: they are exclusively legal elements. A patent application may, theoretically, describe a certain genetic resource or a piece of TK without the need for identifying its origin or its holder(s). But when TK is incorporated into the claimed invention as an inventive concept in its own right (such as in the turmeric patent), then the identification of the TK holder(s) and evidence of their prior informed consent become important elements for the attribution of inventorship and/or ownership. But the Requirement has already been set by current patent law, and does not generally present those characteristics; rather, this condition of patentability results from *sui generis* legislation that countries have gradually introduced.<sup>25</sup>

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24. Of course, this is true only as far as information concerning the genetic resource or associated TK is concerned. Evidence of prior informed consent is not relevant for enabling disclosure purposes.

25. The legal treatment of the Requirement by WTO Members can be categorized into four different groups: (a) countries that have established the Requirement as a condition of patentability (thus, failure to comply will cause the rejection of the patent application and the invalidity of the patent, if granted): in this category, we can identify the statutes of Brazil, Provisional Measure No. 2.186-16, of August 23, 2001, article 31, the Member States of the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela), Decision 391, of July 2, of 1996, articles 16, 26, 35 and second complementary provision and Decision 486, of September 14, 2000, articles 3 and 75, Costa Rica, Law No. 7.788, of 1998, article 81, Egypt, Law No. 82/2002, article 13, and India, The Patents Act, 1970, as amended by The Patents (Amendment) Act of June 25, 2002, Sections 10, 25 and 64; (b) countries that have accepted the Requirement but not as a formal condition for the grant and validity of patent rights: China, see *Information Provided by WIPO Member States Concerning Provisions to Ensure the Recording*

### III. THE REQUIREMENT AS A CONDITION OF VALIDITY OF INTELLECTUAL PROPERTY RIGHTS AND APPLICABLE INTERNATIONAL LAW<sup>26</sup>

#### A. *The TRIPS Agreement*

Three provisions in the TRIPS Agreement are relevant for assessing to what extent WTO Members may establish formal requirements (such as the Requirement) as a condition of patentability.<sup>27</sup> First, under Article 29.1, WTO Members are obliged to impose on patent applicants the duty to disclose the invention. Also, WTO Members may impose on patent applicants the duty to identify the best mode of carrying out the invention.

The second provision is Article 32. A question may be raised whether WTO Members may revoke patents for violating rules on access to genetic resources and/or failure to obtain informed authorization by TK holders. Even though Article 32 is silent on this

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*of Some Contributions to Inventions*, Addendum, at 1, WIPO Doc. WIPO/IP/GR/00/3/Rev.1 (Apr. 14, 2000) and the 25 Members of the European Community, Directive 98/44/EC of the European Parliament and the Council of July 6, 1998, on the protection of biotechnological inventions, Recital 27; on June 2003 Norway informed the TRIPS Council that a proposal in this same sense had been submitted to its Parliament, WTO Doc. IP/C/M/40 (Aug. 22, 2003), ¶¶ 87–88; (c) countries in which the Requirement only applies in the field of patents: Egypt and India; and (d) countries in which the Requirement extends to other fields of industrial property (such as breeders' rights and, eventually, utility models and industrial designs): Andean Community, Brazil and Costa Rica.

26. The following discussion does not analyze the disclosure related provisions of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, which was adopted by the FAO Conference on November 3, 2001. The reason is that the FAO Treaty does not provide for or even imply intellectual property protection, as the FAO representative stated at the second session of the WIPO Intergovernmental Committee. *See Report*, ¶ 15, WIPO Doc. WIPO/GRTKF/IC/2/16 (Dec. 14, 2001). One commentator suggests that the Material Transfer Agreement (MTA) that the FAO Treaty provides for is a sort of a transparency measure. Nevertheless, it is not an intellectual property measure nor is it patent-related. Martin A. Girsberger, *Transparency Measures under Patent Law Regarding Genetic Resources and Traditional Knowledge—Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing*, 7 J. WORLD INT. PROP. 451, 466 (2004). As of the date of this writing the FAO International Treaty has been signed by seventy-eight countries and accepted (or ratified, approved or acceded to) by fifty-four countries. The Treaty entered into force on June 29, 2004. The text of the Treaty is available at <http://www.fao.org/legal/treaties/treaty-e.htm>.

27. TRIPS Agreement, *supra* note 6, arts. 29.1, 32, 62.1. The TRIPS provisions on substantive conditions of patentability are articles 27.1 and 70.8(b).

issue, it seems that the general understanding of WTO Members, with the exception of India, is that they may not.<sup>28</sup>

The third provision is Article 62.1, which provides:

Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Section 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.<sup>29</sup>

Formal conditions that are not explicitly mentioned by Article 29 must be a) reasonable and b) consistent with the provisions of the TRIPS Agreement. The definition of “reasonableness” is not self-evident. Because the TRIPS Agreement “occupies a relatively self-contained, *sui generis* status in the WTO Agreement,” as the Panel in *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*<sup>30</sup> put it, that is, as the TRIPS Agreement deals with intellectual property in its trade-related aspects only, one might conclude that “reasonable” means those formal conditions that help patent offices assess whether the three substantive requirements of Article 27.1 have been met.

Reasonable also means the formal conditions that help patent offices and/or courts to identify the inventors and/or their successors in title. This issue comprises two different aspects: one has to do with the identification of the *inventor*; the other has to do with the identification of the *owner*.<sup>31</sup> It is generally understood that those

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28. See NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF PATENT RIGHTS*, at 373–75 (2d ed. 2005).

29. TRIPS Agreement, *supra* note 6, art. 62.1.

30. WTO Doc. WT/DS50/R (Sept. 5, 1997), Panel Report, as modified by the Appellate Body Report, adopted on January 16, 1998, ¶ 7.19.

31. Because there is a distinction between the owner and the inventor (although they may be the same person), article 4 of the PCT has two separate subsections concerning the identification of the applicant (article 4(1)(iii)) and the identification of the inventor (article 4(1)(v)) in the request. Subsection 1.4 states:

Failure to indicate in the request the name and other prescribed data concerning the inventor shall have no consequence in any designated State whose national law requires the furnishing of the said indications but allows that they be furnished at a time later than that of the filing of a national application. Failure to furnish the said indications in a separate notice shall have no consequence in any designated State

persons who contributed with their creative minds to the inventive solution of a given technical problem are entitled to the patent. The patent cannot be attributed to third persons if they do not receive it in a transfer of title. In the U.S., for example, a patent application shall be filed the inventor or by a person authorized by the inventor. Only under exceptional circumstances may the application be filed by someone other than the inventor.<sup>32</sup> In other countries, the application may be filed by a person other than the inventor (his/her employer, for example), provided that the applicant submits evidence of his/her legal right of succession (a labor contract, for example, or a statement by the inventor in that sense).<sup>33</sup> The inventor's right to the patent is both a material and a moral right, in the sense that the inventor has not only vested rights to acquire property in the fruit of his/her work, but also to be publicly acknowledged as such.<sup>34</sup>

The identification of the owner, in contrast with the identification of the inventor, is a necessary element for the many social purposes that stem from property, such as levying taxes, establishing rights to inheritance and providing collateral. Society at large must know what

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whose national law does not require the furnishing of the said indications.

PCT, *supra* note 8, art.4. Significantly, there is no parallel provision in the PCT regarding the applicant. This means that failure to indicate precise data on the applicant in the request does have consequences.

32. 35 U.S.C.A. §§ 111, 118 (2005).

33. *See, e.g.*, C.P.I. No. 9,279, art. 5.2 (Br.) Industrial Property Law 14/05 1996, No. 9,279, art. 6.2 (1996), which authorizes those who, by means of a labor contract or a services contract, acquired the rights from the inventor to file for patent applications on their own behalf. The English version of the Brazilian statute is available on the website of WIPO's Collection of Laws for Electronic Access, at <http://www.wipo.int/clea/en>.

34. For example, 35 U.S.C. § 111 deals with inventors' material rights. But where the Paris Convention says that "[t]he inventor shall have the right to be mentioned as such in the patent," it is recognizing inventors' moral rights. Paris Convention, *supra* note 23, art. 4<sup>ter</sup>. Article 9.1 of the TRIPS Agreement excludes protection of authors' moral rights from the scope of the Agreement—the reason being that moral rights are not trade-related. One might wonder then why the TRIPS Agreement does not have a similar provision concerning inventors' moral rights, because in its absence, and under article 2.1 of the TRIPS Agreement, WTO Members are obliged to comply with article 4<sup>ter</sup> of the Paris Convention. The reason is that, as already explained, patent law is not necessarily about protecting *inventors*, but about appropriating *inventions*. As Bodenhausen explains, because inventors have been accorded the right, and only the right, to be mentioned "as such" (that is, as inventors, not as owners) in the patent, national law may provide for their right to waive it. G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY AS REVISED AT STOCKHOLM IN 1967, at 64 (reprinted 1991). That possibility does not exist under article 6<sup>bis</sup> of the Berne Convention—hence the need for article 9.1 of the TRIPS Agreement.

technologies are available for use without authorization, so as to avoid infringement. In some cases, a patent may give rise to a public interest not only as far as government use is concerned, but also in regard to exceptions to rights conferred, such as compulsory licenses. Thus, the PCT establishes that the identification of the applicant is one of the mandatory elements of the patent request (Article 4.1(iii)). Likewise, the draft Standard Patent Law Treaty (SPLT), in Article 4, says that the right to a patent shall belong to the inventor or to the successor in title of the inventor.<sup>35</sup>

In view of the above, it can be submitted that requiring identification of not only the owner but also other persons that may have proprietary interests in the patent is within the scope of "reasonable procedures and formalities," under Article 62.1 of the TRIPS Agreement. This is an important aspect because it explains why the government funding disclosure clause under 35 U.S.C. § 202 (which requires contractors under government funding to mention in the patent application the fact that the invention was made under federal financial assistance) is TRIPS-consistent. As explained below, consistency arises from the fact that the government funding disclosure identifies proprietary interests in the claimed invention.<sup>36</sup>

The same applies to requirements of procurement or maintenance fees, provided these are consistent with the provisions of the TRIPS Agreement. As explained above, both procurement and maintenance fees are accepted by the TRIPS Agreement, either as elements of WTO Members' national legal systems and practices (Article 1.1) or as Paris Convention obligations (Article 2.1).<sup>37</sup>

In conclusion, formal conditions that (a) have nothing to do with helping patent examiners to assess novelty, inventiveness and susceptibility of industrial application, (b) have no connection with ownership, and (c) are not aimed at evidencing the payment of fees, are ultimately TRIPS-inconsistent.<sup>38</sup>

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35. The draft Substantive Patent Law Treaty (SPLT) is the subject matter of discussions in the WIPO Standing Committee on the Law of Patents.

36. See *infra* Part IV.D.

37. See *supra* text accompanying notes 24–25.

38. The conflict between the Requirement (as a condition of patentability) and the TRIPS Agreement was the subject of an exchange of views by WIPO Members at the third session of the WIPO Intergovernmental Committee. The United States expressed the view that such a

It is probably because of fear of violating TRIPS that biodiversity-rich developing countries have actively pursued in the WTO an amendment either to Article 27.3(b) or to Article 29, so as to explicitly allow for the Requirement to be included in national laws.<sup>39</sup> Actually, requiring information on the origin of materials or the consent of persons whose knowledge has been directly or indirectly used in the development of the invention would be TRIPS-consistent only if, besides being reasonable for the purposes of Article 62, it extended to all fields of technology. To confine the Requirement to the area of biotechnological inventions is an act of discrimination as to the field of technology, under Article 27.1.<sup>40</sup>

The need to implement Article 15 of the CBD is no excuse, because Article 27.1 admits no exceptions other than those it specifically identifies.<sup>41</sup> Moreover, the CBD not being a WTO Agreement, Article XX(d) of GATT 1994 would not justify the discrimination against a field of technology in violation of the provisions of an annex to the WTO Agreement. Actually, the WTO being an Agreement about customs barriers, the WTO has Members that are not Contracting Parties to the CBD. It would not be reasonable to impose on those Members an obligation they are not bound to observe.<sup>42</sup>

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Requirement does not keep with the TRIPS Agreement. *Report*, ¶ 71, WIPO Doc. WIPO/GRTKF/IC/3/17 (June 21, 2002). The Dominican Republic, *id.* ¶ 70, Sri Lanka, *id.* ¶ 75, Egypt and Sudan, *id.* ¶ 76, expressed an opposed understanding.

39. *See infra* Part III.F.

40. TRIPS Agreement, *supra* note 6, art. 27.1. It should be emphasized that the discriminatory nature would not be in requiring the identification of the origin of the genetic resources, but in doing so in respect of patent applications in the field of biotechnology only. Therefore, it would not be discriminatory to impose the Requirement in regard to all patent applications, regardless of their field of technology. Of course, one might allege that the Requirement would ultimately discriminate against other sorts of raw materials, such as minerals. But article 27.1 is clear in prohibiting discrimination as to the nature of the inventions, rather than to the type of raw materials. And, secondly, it is admitted that biological resources and tangible raw materials are different in nature because what matters in the former is the genetic and chemical information they contain. The Requirement, once it addresses genetic material, is therefore tolerated as a kind of differential treatment, as opposed to a discriminatory one. *See* CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS, *supra* note 28, at 168–70.

41. TRIPS Agreement, *supra* note 6, art. 27.1. As it will be explained below, actually it is CBD Contracting Parties that are under the obligation to respect international agreements on intellectual property, and not the other way around. *See infra* Part III.E.

42. One commentator has expressed his dissent with this view. Dutfield wrote:

In conclusion, WTO Members may adopt the Requirement as a mechanism for monitoring compliance with the CBD provisions on benefit sharing, but only if it does not constitute a condition for acquiring intellectual property rights which depend on registration, and provided that it is consistent with the provisions of the TRIPS Agreement, namely Articles 3, 4, and 27.1.<sup>43</sup>

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There is no compelling reason at all why the compulsory submission of a document, such as a certificate of origin, would impose another substantive condition as long as it is not linked to determining the patentability of the invention. After all examination and renewal fees have to be paid by patent applicants and owners, and TRIPS does not prevent them merely because they are not mentioned in the Agreement. Similarly, the submission of documentation attesting to the fact that the applicant had complied with the relevant ABS [access and benefit sharing] regulations, such as a certificate of origin, would be just another administrative requirement.

Graham Dutfield, *Sharing the Benefits of Biodiversity—Is There a Role for the Patent System?*, 5 J. WORLD INT. PROP. 899, 921 (2002). This line of reasoning can be challenged on several grounds. Of course, there are some aspects of patent law that are not mentioned in the TRIPS Agreement. But one must distinguish between those aspects that are not mentioned because negotiators thought they were already implied, and those that negotiators did not mention because of their incompatibility with WTO principles and rules. As explained above, the requirement concerning evidence of the timely payment of fees is not similar to the Requirement because the obligation to pay procurement fees was already a legal practice in WTO Members before the entry of the TRIPS Agreement into force (namely, under PCT provisions), and therefore, it is adopted under article 1.1. Furthermore, payment of maintenance fees is subject to Paris Convention provisions, which have been incorporated by reference in the TRIPS Agreement. On the other hand, the Requirement is not a matter of “another substantive condition,” but rather a formal one, because it does not concern the invention itself. And, as far as formal conditions are concerned, the controlling provisions are articles 29 and 62. A formal condition is acceptable only when it is already covered by a provision of the Agreement (such as article 29) or when it is *reasonable*. That commentator does not explain why it would be reasonable to adopt a condition that aims at implementing a treaty that is not part of the WTO. Furthermore, as explained below, it is not reasonable to adopt a formal condition of patentability that creates tension with the TRIPS Agreement with the aim of implementing the CBD, when the CBD itself requires that all measures concerning benefit sharing must comply with international treaties on intellectual property (such as the UPOV Convention, the PCT and the TRIPS Agreement itself).

43. TRIPS Agreement, *supra* note 6, arts. 3.4, 27.1. Article 27.2 of the TRIPS Agreement seems to confine measures in the field of patents aimed at generating barriers to patentability to geographical borders. But in the case of the Requirement, neither article 27.2 nor the national treatment principle would necessarily stand in its way. The reasons are that (a) the Requirement does not give rise to an exclusion from patentability, but rather to some sanctions against illegal access (which may comprise, in some countries, patent invalidation); (b) the Requirement concerns resources that may serve as raw materials for inventions, not the nationality of patent applicants. Curiously, Bolivia has once attempted to justify the consistency of the Requirement as established in the statutes of the Andean Community (see *supra* note 25) to which it is bound by invoking Article 29.2 of the TRIPS Agreement. During the review of Bolivia's implementing legislation in the TRIPS Council, Japan asked the following question:

*B. The UPOV Convention(s)*

On the other hand, those WTO Members that are also Members of the UPOV may not revoke plant variety certificates on grounds of failure to inform the origin of genetic resources and prior informed consent. In fact, both UPOV 1978 and 1991<sup>44</sup> texts provide that plant varieties certificates may be annulled only when the varieties fail to meet the conditions of novelty and distinctness. Certificates may also be cancelled, but only when the varieties fail to meet the conditions of uniformity or stability as well as the following formal requirements: the breeder failed to provide the authority with the information, documents or materials deemed necessary for the maintenance of the variety (namely, its stability); the breeder failed to pay maintenance fees; the breeder did not propose a suitable denomination to replace the denomination previously submitted and which has been cancelled after the grant of the right.<sup>45</sup> More importantly, the grounds for annulling or canceling plant varieties certificates may not be expanded by UPOV Members.<sup>46</sup> This means that a breeder that develops a variety based upon a plant genetic resource unlawfully collected shall not have the respective certificate annulled or cancelled by any UPOV Member on the ground that

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Please explain the relationship between Article 29.1 of the TRIPS Agreement and Articles 26(h) and (I) of Decision 486 which oblige patent applicants to submit a copy of the contract for access to genetic resources and a copy of the documents certifying the authorization to use of traditional knowledge. Does your country consider the above-mentioned applicant's obligation as an enablement requirement which is clearly stipulated in Article 29.1 of the TRIPS Agreement, or as an additional requirement which is not stipulated in that Article?

Bolivia answered that Article 26(h) of Decision 486 "fit within [the] context" of Article 29.2 of the TRIPS Agreement (which authorizes WTO Members to require patent applicants to provide for information concerning the results of corresponding applications in other countries). TRIPS Article 29.2, *supra* note 6. But, in response to a follow-up question posed by Japan, Bolivia corrected its obviously mistaken answer and clarified that the Requirement was a matter of not allowing patents to be granted on inventions based on unlawfully obtained genetic resources. In other words, the Requirement had nothing to do with either paragraph 1 or 2 of Article 29. See *Review of Legislation (Bolivia)*, WTO Doc. IP/Q3/BOL/1 (Feb. 13, 2002), at 40–42.

44. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961 [hereinafter UPOV] (as revised on Oct. 23, 1978 and Mar. 19, 1991).

45. UPOV 1991, *supra* note 44, arts. 21–22; see also UPOV 1978 art. 10.

46. *Id.*

he/she has failed to comply with national laws concerning access to genetic resources. This view was affirmed by the UPOV Secretariat in a communication addressed to the TRIPS Council:

UPOV is not opposed to the disclosure, per se, of countries of origin or geographical origin of genetic resources in any way that will facilitate the examination mentioned above, but could not accept this as an additional condition of protection.

Thus, if a country decides, in the frame of its overall policy, to introduce a mechanism for the disclosure of countries of origin or geographical origin of genetic resources, such a mechanism should not be introduced in a narrow sense, as a condition for plant variety protection.<sup>47</sup>

In conclusion, UPOV members may adopt the Requirement, provided it does not constitute a condition for obtaining or maintaining plant breeders' rights.

### *C. The Patent Cooperation Treaty*

Parties to the PCT may not impose the Requirement, either as a condition of patentability or not, on international applications with the purpose of monitoring compliance with the CBD. Article 27.1 of the PCT (on "National requirements") provides that "[n]o national law shall require compliance with requirements relating to the form or contents of the international application *different from or additional to* those which are provided for in this Treaty and the Regulations."<sup>48</sup>

At the diplomatic conference of Washington, in 1970, there was a brief discussion about the meaning of the word "contents" in Article 27.1. A Canadian delegate asked whether the word "contents" (and its French version "contenu") was used with "the intent to cover

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47. *Review of the Provisions of Article 27.3(b), Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore, Information from Intergovernmental Organizations, Addendum, International Union for the Protection of New Varieties of Plants (UPOV)*, at 4, WTO Doc. IP/C/W/347/Add.3 (June 11, 2002).

48. PCT, *supra* note 8, art. 27.1 (emphasis added).

everything in the application from the point of view of substance, or simply to refer to matters that were, so to speak, treated in the application.”<sup>49</sup> The Secretary General of the Conference replied that the latter was intended.<sup>50</sup> Indeed, a footnote to the Final Text of Article 27.1 of the PCT explains that:

The requirements relating to form and contents are principally provided for in Articles 3 (The International Application), 4 (The Request), 5 (The Description), 6 (The Claims), 7 (The Drawings), and 8 (Claiming Priority), and the Rules pertaining to these Articles (mainly Rules 3 to 13). The words “form or contents” are used merely to emphasize something that could go without saying, namely, that requirements of substantive patent law (criteria of patentability, etc) are not meant.<sup>51</sup>

Article 27.5 of the PCT supports *a contrario* the understanding that no formal requirements other than those explicitly set out in the Treaty can be established on international applications.<sup>52</sup> The requirement to disclose the origin of genetic resources and to give evidence of prior informed consent, being a formal requirement, is therefore prohibited in the PCT context. Paragraph 8 of Article 27 contains exceptions to the provisions of paragraph 1,<sup>53</sup> but those do

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49. RECORDS OF THE WASHINGTON DIPLOMATIC CONFERENCE ON THE PATENT COOPERATION TREATY, 1970 at 553 (WIPO 1972).

50. *Id.*

51. *Id.* at 35.

52. PCT, *supra* note 8, art. 27.5. Article 27.5 of the PCT reads:

Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires. In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications.

53. PCT art. 27.8. reads:

Nothing in this Treaty and the Regulations is intended to be construed as limiting the freedom of any Contracting State to apply measures deemed necessary for the preservation of its national security or to limit, for the protection of the general economic interests of that State, the right of its own residents or nationals to file international applications.

not comprise the Requirement. Actually, Article 27.8 acknowledges some restrictions established by PCT Members (such as the United States) imposed on their own nationals in regard to the filing of patent applications in other countries, for reasons of national security or other reasons of national policy. Obviously, this is not a condition of patentability, but a matter of permitting the filing of patent applications. In conclusion, international patent applicants, under the PCT system, may not be required to add elements or documents to the patent applications that are designated to follow the so-called “PCT route” beyond those contained in the Treaty.<sup>54</sup>

In conclusion, the Requirement is not allowed under the PCT either as condition of patentability or as an additional requirement during the international phase. We will see below, however, that this rule applies in regard to the Requirement as an element for monitoring compliance with the CBD. But if the Requirement is adopted in the context of assessing proprietary interests, the PCT is no obstacle to its adoption in national laws. In that event, the Requirement ceases to be a formality aimed at assessing a certain type of disclosure—it is rather aimed at identifying the holder(s) of property rights and interests in the claimed inventions. Moreover, nothing in the PCT and its regulations stands in the way of PCT Members to adopt additional formal requirements once the application enters the national phase.<sup>55</sup>

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54. This same view was expressed by the delegation of Norway in the TRIPS Council:

The PCT explicitly prohibited any requirement which was different from or additional to the requirements provided for in the PCT or its Regulations. Thus, the PCT constituted an important obstacle to the introduction of a system where an international patent application covering biotechnological inventions should contain a reference to the source of origin.

*Minutes of Meeting*, ¶ 100, WTO Doc. IP/C/M/42 (Feb. 4, 2004).

55. See, for example, 35 U.S.C. § 371(c)(4) (2000), requesting an additional document containing an oath or declaration of the inventor (or other person authorized under chapter 11 of Title 35) complying with the requirements of section 115, once an international application enters the national phase in the United States.

*D. The Patent Law Treaty*

Article 10.1 of the PLT reads:

Non-compliance with one or more of the formal requirements referred to in Articles 6(1), (2), (4) and (5) and 8 (1) to (4), with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention.<sup>56</sup>

According to Article 6.1 of the PLT,

Except where otherwise provided for by [the PLT], no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty.<sup>57</sup>

In other words, formal conditions of patentability that are not provided either in the PCT or in the PLT itself are not allowed by the PLT. Given that the Requirement is, as shown, inconsistent with the PCT and that the PLT has no provision approving it,<sup>58</sup> the Requirement is also inconsistent with the PLT.

Finally, because the PLT is complementary to the PCT, in that it applies to national and regional patent applications permitted under the PCT,<sup>59</sup> the conclusion is that the Requirement is inconsistent with the PLT (as a condition of patentability or not) both at the international and the national phases.

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56. PLT, *supra* note 9, art. 10.1.

57. *Id.* art. 6.

58. Additional, formal conditions of patentability, under the PLT, are that the contents of an application "which correspond to the contents of the request of an international application under the Patent Cooperation Treaty be submitted under a special request form," the payment of fees, evidence of priority, and the form and means of transmittal of communications (concerning the patent application) to the Patent Offices. PLT, *supra* note 9, arts. 6, 8.

59. PLT, *supra* note 9, art. 3.1.

*E. The Convention on Biological Diversity (CBD)*

It is generally understood that the Requirement is necessary to help Contracting Parties to the CBD monitor compliance by bioprospectors and/or their successors with national legislation on access to genetic resources. It is also assumed that the Requirement stems logically from the provisions of Articles 8(j) and 15.7 of the CBD.<sup>60</sup> However, the Requirement, when adopted as a (formal) condition of patentability, is in violation of not only the TRIPS Agreement, the UPOV Convention, the PLT and, eventually, if adopted in the international phase, the PCT, but also the CBD itself.

Where Article 15.7 of the CBD suggests that Contracting Parties should take legislative measures with the aim of sharing benefits arising from the commercial exploitation of genetic resources, it says that they should do so “in accordance with Articles 16 and 19.”<sup>61</sup> The expression “in accordance with Article 16” means two things.

First, access to genetic resources in developing countries may require technology that is in the hands of private companies in developed countries. Therefore, in order to obtain technology that will create the means for accessing their genetic resources, developing countries shall observe Article 16, which provides for measures that “facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.”<sup>62</sup>

It has been suggested that the reference to Article 16 “expands the potential benefits [to be shared with suppliers of genetic resources] to include: access to and transfer of technology using the genetic resources.”<sup>63</sup> This aspect, however, is not clear. When Article 15.7 says that measures will be taken “in accordance with,” it seems that it

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60. *See supra* note 11.

61. CBD, *supra* note 5, art. 15.7. Interestingly, article 15.7 advises that benefits should be shared through the financial mechanism of articles 20 and 21, which dismisses the idea of an intellectual property contract approach (under which benefits could be extracted from royalties, for example).

62. *Id.* art. 16.1.

63. LYLE GLOWKA ET AL., A GUIDE TO THE CONVENTION ON BIOLOGICAL DIVERSITY 82 (1994).

is referring to procedural requirements that the measures must obey, and not to the scope of the benefits. If the intention were to expand the nature of benefits, the provision's language would be different. For example, the mention of the results of research and development and the benefits arising from the utilization of genetic resources could be followed by the expression "including the benefits referred to in Articles 16 and 19." This view is corroborated by the fact that Article 19 is not about concessions (access to biotechnology shall be on mutually agreed terms), but about procedures that must be respected in order to establish joint research ventures.

Second, the measures taken must be in accordance with paragraphs 2 and 3 of Article 16, which contain rules on technology transfer: "such access and transfer [and, under Article 15.7, all measures aiming at promoting benefit sharing] shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights" as well as "in accordance with international law."<sup>64</sup> In other words, all measures aimed at implementing Article 15.7, including measures to monitor compliance with the obligation of benefit sharing, must respect Contracting Parties' international obligations under intellectual property agreements—which, as shown above, do not permit the adoption of the Requirement as a condition for obtaining rights.<sup>65</sup> Therefore, any measures aimed at monitoring compliance with benefit sharing obligations that are inconsistent with international intellectual property treaties are also inconsistent with the CBD itself. It is true that Article 16.5, which invites Contracting Parties to make efforts to avoid infringing patent and other intellectual property rights, creates obstacles for the implementation of CBD objectives. However, those efforts shall be made "subject to national legislation

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64. CBD, *supra* note 5, arts. 15–16.

65. UPOV 1978 and the PCT were already in force when the CBD was negotiated and agreed, in 1992. UPOV 1991 and the TRIPS Agreement, which was signed in April 15, 1994, at Marrakesh, as an Annex of the Agreement Establishing the World Trade Organization (WTO), had their terms already negotiated. Between December 21, 1991, when the Director General of the GATT communicated the results of the Uruguay Round so far reached, and April 15, 1994, only a few minor aspects of the TRIPS Agreement were changed. But the TRIPS Agreement remained essentially the same, which means that the CBD Contracting Parties in 1992 were already aware of those obligations.

and international law.”<sup>66</sup> This means that, for Contracting Parties to be excused from observing current international obligations under intellectual property treaties, they must provide for the amendment of those treaties. But until that happens, they are obliged by the CBD itself to observe those treaties. The only conclusion possible is that countries that implement Article 15.7 through measures that are inconsistent with international treaties on intellectual property (such as adopting the Requirement as a condition of patentability) are in violation of the CBD itself. It could be argued, however, that Article 15.7 of the CBD applies to genetic resources only, in contrast with Article 8(j), which refers to knowledge, that is, to intangible assets, and which contains no parallel obligation to comply with Article 16.<sup>67</sup> In other words, one might argue that the CBD does not require measures aimed at monitoring compliance of contracts of TK licensing (either independently from access to genetic resources or in combination with it) with international treaties on intellectual property. But that argument would be wrong: the CBD is about tangible biological diversity and the intangible component is not defined as an integral part of genetic resources. TK, for the CBD, is complementary and accessory to genetic resources, and not an independent component, worthy of separate rules. In other words, measures taken under Article 8(j), because they are complementary and subordinated to those under Article 15.7, must likewise respect intellectual property-related international obligations.

Another argument that could be raised is that Article 15.5, which submits access to prior informed consent, makes no reference to international treaties on intellectual property. Compliance with the obligation of obtaining prior informed consent, therefore, could be monitored regardless of international obligations in the area of intellectual property. To that extent, prior informed consent would give rise to stand-alone obligations under the CBD. Such an argument, however, would be flawed. The reason is that Article 15.4 makes access subject to “the provisions of this Article,” which necessarily include those of paragraph 7.<sup>68</sup> In other words, measures

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66. CBD, *supra* note 5, art. 16.5.

67. *Id.* arts. 8, 15.

68. *Id.* art. 15.4.

aiming to implement the obligation of obtaining prior informed consent are, like those concerning benefit sharing, subject to paragraphs 2 and 3 of Article 16.

#### *F. Current Multilateral Negotiations*

There have been attempts to include the Requirement in international treaties. Those attempts have two different purposes. One, obviously, is to produce effects in territories other than those from which the genetic resources and TK were extracted. As a matter of fact, although genetic resources are raw materials for all sorts of inventions in all fields of technology, they are more important in the biotechnology field. And the main markets for biotechnology processes and products are in developed countries, where most patent applications in that area are filed. It follows that limiting the application of the Requirement to developing countries does not have practical consequences. With that in mind, during the discussions in the WIPO Standing Committee on the Law of Patents (SCP), in September of 1999, on the draft Treaty on the Law of Patents (PLT), Colombia proposed the addition of the following provision:

1. All industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations 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 services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.<sup>69</sup>

The SCP did not reach a consensus on this proposal,<sup>70</sup> and WIPO Member States subsequently revisited the issue no less than five

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69. *Protection of Biological and Genetic Resources*, WIPO Doc. SCP/3/10 (Sept. 8, 1999).

70. *See Report*, ¶¶ 202–09, WIPO Doc. SCP/3/11 (Sept. 14, 1999).

times. In November 1999, the WIPO Working Group on Biotechnology held informal discussions on Colombia's proposal and issued a questionnaire aimed at identifying the intentions of WIPO Member States as to the eventual adoption of the Requirement at the national or regional level.<sup>71</sup> The WIPO Meeting on Intellectual Property and Genetic Resources, held in Geneva in April 2000, discussed the responses to that questionnaire as well as other issues concerning TK, in preparation for the Diplomatic Conference for the adoption of the PLT. In that venue, Colombia softened its proposal: it no longer suggested that the provision had a mandatory nature, but rather that it merely permitted Parties to the future PLT to adopt the Requirement at the national level. Colombia's argument was that it was afraid that, without such permission, the Second Complementary Provision of Andean Community Decision No. 391<sup>72</sup> would be in conflict with the future Treaty. The new proposal read as follows: "When necessary, and if the invention has been obtained from genetic and/or biological resources, any Contracting Party may demand that a copy of the document issued by the competent national authority attesting the legality of access to those resources be submitted to the Office."<sup>73</sup> Subsequently, on the first day of the Diplomatic Conference, on May 11, 2000, WIPO Members held negotiations on Colombia's new proposal, the outcome of which was the grant of a mandate to WIPO's Director General to take the action necessary to establish a forum where Member States could exchange views on matters concerning protection of traditional knowledge, expressions of folklore and access to genetic resources. After intensive consultations, the Director General of WIPO proposed, and the Assemblies approved, in September 2000, the establishment of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (hereinafter

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71. See WIPO Doc. WIPO/IP/GR/00/3/Rev.1, *supra* note 25.

72. See *supra* note 25.

73. WIPO Doc. WIPO/GR/00/4 (Apr. 14, 2000) (document on file with the WIPO Secretariat). Two elements in this proposal made it optional for PLT Contracting Parties: first, it could be adopted only when Members thought it was necessary (for example, necessary for implementing the CBD); and, second, the word "may" expresses an authorization, not a mandatory action.

designated as the “Intergovernmental Committee”).<sup>74</sup> The Requirement was again discussed in WIPO after a request from the Secretariat of the CBD, conveying to the Intergovernmental Committee the invitation by the Conference of the Parties that the WIPO Secretariat prepare a study

on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*: (a) Genetic resources utilized in the development of the claimed inventions; (b) The country of origin of genetic resources utilized in the claimed inventions; (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions; (d) The source of associated traditional knowledge, innovations and practices; and (e) Evidence of prior informed consent.<sup>75</sup>

The resulting WIPO study scrutinizes the Requirement and its possible technical and legal implications in a very thorough and consistent fashion, but, as a matter of course, it does not state an opinion on its compatibility with international treaties or propose new, alternative solutions.<sup>76</sup> The WIPO Secretariat has not such a mandate.

More recently, and again in the SCP, which is currently having discussions on a Draft Substantive Patent Law Treaty,<sup>77</sup> the

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74. See *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO Doc. WO/GA/26/6 (Aug. 7, 2000); *Report of the Twenty-Sixth (12th Extraordinary) session of the WIPO General Assembly*, WIPO Doc. WO/GA/26/10 (Oct. 3, 2000).

75. See WIPO Doc. WIPO/GRTKF/IC/5/10, *supra* note 16, Annex, at 3.

76. See *supra* note 16.

77. See *Draft Substantive Patent Law Treaty*, WIPO Doc. SCP/8/2 (Oct. 16, 2002); *Practice Guidelines Under the Substantive Patent Law Treaty*, WIPO Doc. SCP/8/4 (Oct. 16, 2002). The draft SPLT contrasts with the PLT in the sense that it goes beyond merely procedural provisions, and contains substantive rules of patent law, namely rules on conditions of patentability and on revocation. However, if we take the word “substantive” with its narrow meaning of standards of rights granted and protected (in other words, the standards concerning the scope of patent rights)—as the TRIPS Agreement does in section 5 of part II—then the SPLT, which is mostly concerned with the harmonization of conditions of patentability, does not cover actual substantive law. It is true that conditions of patentability do have an impact on the definition of standards of rights protected, but they are not substantive standards themselves. The only substantive provision that the current draft of the SPLT contains is article 4, on

Dominican Republic, on behalf of a group of countries,<sup>78</sup> proposed to amend paragraph 2 of draft Article 2 (on “General Principles”), which, after the change, would read:

Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to take any action it deems necessary for the preservation of essential security interests or to comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment.

Brazil has also suggested an amendment to Article 13 (on “Grounds for Refusal of a Claimed Invention”)<sup>79</sup> of the draft SPLT, which would read: “[Compliance with Applicable Law on Other Matters] A Contracting Party may also require compliance with the applicable law on access to genetic resources, protection of traditional knowledge . . . .”<sup>80</sup> These two proposals aim at avoiding the same conflict that exists under the PCT and the PLT. In an explanatory note, however, the Dominican Republic justifies its proposal with the need to fulfill international commitments under the CBD. To that extent, therefore, the argument becomes circular: as explained above, in order to comply with the CBD, countries must comply with international agreements on intellectual property; the violation of the latter leads to the violation of the CBD itself. Therefore, in order to comply with the CBD, it is necessary to include the Requirement in intellectual property treaties. However, because the Requirement is not established in the CBD—on the contrary, unless intellectual property treaties are modified, the CBD prohibits

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inventorship/ownership—the language of which, incidentally, has been borrowed from the draft Treaty Supplementing the Paris Convention as far as Patents Are Concerned, article 9. The Diplomatic Conference convened (at The Hague, on June 3 to 28, 1991) to adopt this draft Treaty failed to reach a conclusion. Nevertheless, some of its provisions were later incorporated into section 5, part II, of the TRIPS Agreement.

78. The countries are: Chile, Colombia, Cuba, The Dominican Republic, Ecuador, Honduras, Nicaragua, Peru and Venezuela.

79. The Brazilian proposal also impacts article 14 of the SPLT, which deals with revocation of patents.

80. *See Proposals by the Delegations of the Dominican Republic and Brazil Concerning Articles 2, 13 and 14 of the Draft Substantive Patent Law Treaty*, WIPO Doc. SCP/8/5 (Nov. 5, 2002), Annexes I and II.

it—it makes no sense to amend the draft SPLT (or, for that matter, any treaty in force) to permit Contracting Parties to enact measures “in order to comply with international obligations” (as proposed by the Dominican Republic) or to impose “the applicable law on . . . access to genetic resources” (as proposed by Brazil).<sup>81</sup> The two proposals are, in fact, circular. Because those obligations are not explicitly stated in the CBD, they cannot be assumed. For the proposals to make sense it would be better to adopt the language proposed by Colombia during the negotiations that led to the adoption of the PLT. Or, as it will be explained below, countries can adopt the Requirement, although not as a condition of patentability with the goal of implementing the CBD, but rather as a measure for establishing proprietary interests derived from the material contributions to the inventive output. Anyway, the two proposals have already been the subject matter of discussions in the SCP,<sup>82</sup> but in view of the different opinions as to whether the SCP is the appropriate forum to address the issue, it was decided to include the two proposals in the text of the draft SPLT in square brackets, accompanied by the following note: “The SCP agreed at its eighth session to include the paragraphs in square brackets, but to postpone substantive discussions on these provisions.”<sup>83</sup>

More recently, Switzerland proposed to include the Requirement in the Regulations under the PCT.<sup>84</sup> According to the Swiss proposal,

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81. *Id.*

82. *See Report, Eighth Session of the SCP*, ¶¶ 37–49, WIPO Doc. SCP/8/9 (Dec. 18, 2002).

83. *Id.* ¶ 49; *see also Summary by the Chair*, ¶ 11, WIPO Doc. SCP/8/8 (Nov. 29, 2002) 11. At the tenth session of the SCP, the United States, Japan and the European Patent Office proposed to focus discussions on a “first package of provisions,” comprising the definition of prior art, the grace period, novelty and non-obviousness. *See Proposal from the United States of America, Japan, and the European Patent Office Regarding the Substantive Patent Law Treaty (SPLT)*, at 2, WIPO Doc. SCP/10/9 (Apr. 22, 2004), Annex. The SCP has not reached consensus on that proposal. *See Summary by the Chair*, ¶ 67, WIPO Doc. SCP/10/10 (May 14, 2004).

84. Switzerland proposed to amend Rules 51*bis*.1 (by introducing a new subparagraph (g)) and 4.17 (by introducing a new subparagraph (vi)). The Swiss proposal and its justification were submitted to the Fourth Session of the Working Group on Reform of the Patent Cooperation Treaty (PCT) held on May 19 to 23, 2003. *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO Doc. PCT/R/WG/4/13 (May 5, 2003). The proposal was discussed by the Working Group at that same session as well as the session it held from November 17 to 21,

the Requirement could be imposed by national laws in the national phase of international applications. The participants of the Working Group on Reform of the PCT have not reached an agreement. Some delegations would accept the proposal not only because they saw it as “constructive and pragmatic,” but also because the PCT was a good starting point for changing international law because the proposal would have an impact on national patent applications.<sup>85</sup> Other delegations, however, said that the WIPO Intergovernmental Committee is a more adequate forum to discuss the proposal.<sup>86</sup> Other delegations were not convinced that the patent system was the proper context in which to address concerns of benefit sharing because implementing measures whereby patents might be invalidated for failure to comply with the requirements of disclosure of source would reduce certainty in patent rights, increase litigation, and reduce patent filings.<sup>87</sup> The topic continues under discussion in the Working Group.<sup>88</sup>

Some WTO Members have addressed the Requirement several times in discussions in the TRIPS Council—the idea would be to amend the TRIPS Agreement so as to establish the Requirement as an additional formal condition of patentability. That discussion was inaugurated by India in 1997, with a document submitted to the Committee on Trade and Environment,<sup>89</sup> but was soon transferred to

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2003. See *Summary of the Session by the Chair*, WIPO Doc. PCT/R/WG/4/14 (May 23, 2003), and PCT/R/WG/5/13 (Nov. 21, 2003)—at this session the Swiss proposal was re-submitted as WIPO Doc. PCT/R/WG/5/11 Rev. (Nov. 19, 2003). See also *Additional Comments by Switzerland on its Proposal Regarding the Declaration of Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO Doc. PCT/R/WG/6/11 (Apr. 21, 2004). The United States delegation has stated that it could not support the Swiss proposal. See *supra* note 3. For a detailed discussion of the Swiss proposal and the current status of multilateral negotiations, see generally Martin A. Girsberger, *Transparency Measures*, *supra* note 26.

85. See *Summary of the Session*, ¶ 133, WIPO Doc. PCT/R/WG/5/13 (Nov. 21, 2003).

86. *Id.* ¶¶ 131, 134.

87. *Id.* ¶ 135.

88. *Id.* ¶ 144; see also *Summary of the Session*, ¶¶ 82–104, WIPO Doc. PCT/R/WG/6/12 (May 7, 2004).

89. For an overview of the debates on the Requirement and other TK-related issues in the WTO, see *The Relationship Between the TRIPS Agreement and The Convention on Biological Diversity—Summary of Issues and Points Made*, WTO Doc. IP/C/W/368 (Aug. 8, 2002); *Review of the Provisions of Article 27.3(b)—Summary of Issues Raised and Points Made*, WTO Doc. IP/C/W/369 (Aug. 8, 2002), and *The Protection of Traditional Knowledge and Folklore—Summary of Issues Raised and Points Made, Note by the Secretariat*, WTO Doc. IP/C/W/370

the TRIPS Council in the context of the review of Article 27.3(b) of the TRIPS Agreement. Subsequently, in the preparations for the fourth session of the WTO Ministerial Conference in Doha, several WTO Members raised the issue again.<sup>90</sup> The Ministerial Declaration, approved in Doha, included the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore as topics of the work program to be pursued by the Council for TRIPS under the review of Article 27.3(b).<sup>91</sup> But the debate has not made substantive progress since Doha. Papers were submitted by the European Communities,<sup>92</sup> a group of developing countries,<sup>93</sup> Switzerland<sup>94</sup> and the African Group.<sup>95</sup> The papers by the group of developing countries and the African Group sought the possible incorporation of the Requirement into the TRIPS Agreement. Switzerland communicated its proposal concerning the amendment of the Regulations under the PCT. And the European Communities reiterate their view that the Requirement “should not act, *de facto* or *de jure*, as an additional formal or substantial patentability criterion. Legal consequences of the non-respect of the requirement should lie outside the ambit of patent law.”<sup>96</sup> With the purpose of giving focus

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(Aug. 8, 2002).

90. See, e.g., *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, WTO Doc. IP/C/W/356 (June 24, 2002), (proposal by Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe).

91. *Ministerial Declaration*, ¶ 19, WTO Doc. WT/MIN(01)/DEC/1 (Nov. 20, 2001). It should be noted that, according to ¶ 52 of the *Ministerial Declaration*, the work program does not necessarily entail negotiations on new standards. The TRIPS Council may, therefore (and it probably will), keep its focus on TK (and, particularly, on *stricto sensu* TK) at the level of discussions and exchange of views.

92. *Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore—A Concept Paper*, WTO Doc. IP/C/W/383 (Oct. 17, 2002).

93. *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, WTO Doc. IP/C/W/403 (June 24, 2003) (submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela).

94. *Article 27.3(b), the Relationship Between the TRIPS Agreement and the Convention of Biological Diversity, and the Protection of Traditional Knowledge*, WTO Doc. IP/C/W/400/Rev.1 (June 18, 2003).

95. See *Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*, WTO Doc. IP/C/W/404 (June 26, 2003).

96. *Ministerial Declaration*, *supra* note 91, at 2. Norway expressed the same view in the

to the debate, a group of developing countries submitted a checklist of issues to the TRIPS Council, containing three groups of questions (in a total of fourteen questions) on the meaning and scope of the Requirement.<sup>97</sup> That proposal has been rejected by the delegations of the United States and Japan.<sup>98</sup> That same group of developing countries detailed its proposal in two subsequent papers.<sup>99</sup> The United States expressed their views on the inconvenience of the Requirement and proposed alternative solutions to the problem of erroneously granted patents.<sup>100</sup>

#### IV. IN SEARCH OF A SOLUTION FOR ADOPTING THE REQUIREMENT WITHOUT UNDULY BURDENING THE PATENT SYSTEM AND/OR INFRINGING INTERNATIONAL LAW

##### A. *The TK Holder: A Co-Inventor?*

It has already been proposed that the best manner to address the issue of misappropriation of traditional knowledge and unauthorized access to genetic resources is to consider traditional knowledge

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TRIPS Council. See WTO Doc. IP/C/M/39 (Mar. 21, 2003), ¶ 120.

97. See *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD)—Checklist of Issues*, WTO Doc. IP/C/W/420 (Mar. 2, 2004) (submission from Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela). Subsequently, Bolivia joined the group. See *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge—Addendum*, WTO Doc. IP/C/W/420/Add.1 (Mar. 5, 2004).

98. See TRIPS Council Zooms in on Disclosure Requirements, Bridges Trade BioRes, vol. 4 n.17 (Sept. 23, 2004), at <http://www.ictsd.org/biores/04-09-23/story1.htm>.

99. See *Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention*, WTO Doc. IP/C/W/429/Rev.1 (Sept. 27, 2004) (submission by Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand, and Venezuela). Subsequently, Bolivia and Colombia requested to be added to the list of sponsors. WTO Docs. IP/C/W/429/Rev.1/Add.1 (Oct. 14, 2004), and Add.2 (Jan. 20, 2005). See *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge—Elements of the Obligation to Disclose Evidence of Prior Informed Consent Under the Relevant National Regime*, WTO Doc. IP/C/W/438 (Dec. 10, 2004).

100. See Article 27.3(b), *Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, WTO Doc. IP/C/W/434 (Nov. 26, 2004). In a nutshell, the United States reaffirmed that the Requirement would not be cost-effective, for it would be too cumbersome and would not accomplish its purpose. *Id.* at 2–7. The United States proposed that erroneous patents could be avoided by resorting to prior art databases, the inequitable conduct doctrine and post-grant opposition or re-examination. *Id.* at 7–8.

holders as co-authors of inventions derived from genetic resources and/or associated traditional knowledge.<sup>101</sup> Of course, when traditional knowledge holders inform bioprospectors of the results of their own inventive activity and those results are later claimed in a patent application, there is no doubt that the original inventors are entitled to be recognized as co-owners of the resulting patents (provided that the conditions of patentability are met). As one commentator explains:

Patents for plant-derived drugs may be of three kinds: patents on the structure of the compound, patents on the process of isolation, and patents on specific uses of the drug. The contribution of indigenous knowledge may differ for each of these. For example, indigenous knowledge will have little contribution to patents on the structure of a compound, and, in many cases, patents on the process of isolation. Nevertheless, since the compound may very likely never have been isolated without knowledge of the existence of a particular plant and its importance in indigenous medicine, indigenous knowledge is still of critical importance in the identification and development of the drug. Where the use of the isolated drug is the same as, or very similar to, that of the source plant, it is clear that the contribution of indigenous knowledge has been essential to the development of the drug. On the other hand, where the use of the isolated compound as a drug diverges

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101. Michael J. Huft, Comment, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U. L. REV. 1678 (1995), says that “[i]t seems clear that there will be little difficulty in establishing the requisite level of collaboration to maintain joint inventorship in the development of plant-derived drugs using indigenous knowledge.” *Id.* at 1722; see also Anil K. Gupta, *Rewarding Creativity for Conserving Diversity in [the] Third World: Can IPR Regimes Serve the Needs of Contemporary and Traditional Knowledge Experts in [the] Third World?*, available at <http://www.sristi.org/pub/html> (last visited Nov. 5, 2004).

Given the high hit rate in formal research around locally identified uses of plants and other kinds of biodiversity, transaction costs of formal R and D systems in private and public systems are reduced considerably. They should in turn share the benefits that may accrue from commercialization of so protected products. In some cases local communities or individuals as the case may be should be considered co-inventors of the new value added products.

*Id.* at 4.

considerably from the use of the source plant in indigenous medicine, the contribution of indigenous knowledge is minimal at best.<sup>102</sup>

The contribution of TK holders to patented inventions, therefore, takes two possible forms: they inform bioprospectors of the possible use of genetic resources (thus leading to the identification of useful bioactive components) and they supply samples of the genetic resources in question.

Traditional knowledge holders are inventors of the uses of those bioactive components (even if they ignore their specific composition), where uses are sufficiently inventive.<sup>103</sup> As inventors

102. Huft, *supra* note 101, at 1724 (note omitted).

103. An interesting discussion about the patentability of traditional uses of genetic resources can be found in *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co. Ltd.*, [1996] R.P.C. 76:

The Amazonian Indians have known for centuries that cinchona bark can be used to treat malarial and other fevers. They used it in the form of powdered bark. In 1820, French scientists discovered that the active ingredient, an alkaloid called quinine, could be extracted and used more effectively in the form of sulfate of quinine. In 1944, the structure of the alkaloid molecule (C<sub>20</sub>H<sub>24</sub>N<sub>2</sub>O<sub>2</sub>) was discovered. This meant that the substance could be synthesized.

Imagine a scientist telling an Amazonian Indian about the discoveries of 1820 and 1944. He says: "We have found that the reason why the bark is good for fevers is that it contains an alkaloid with a rather complicated chemical structure which reacts with the red corpuscles in the bloodstream. It is called quinine" The Indian replies: "That is very interesting. In my tribe, we call it the magic spirit of the bark." Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever and that is one description of quinine.

On the other hand, in a different context, the Amazonian Indian would not know about quinine. If shown pills of quinine sulphate, he would not associate them with the cinchona bark. He does not know quinine under the description of a substance in the form of pills, and he certainly would not know about the artificially synthesised alkaloid . . . .

The quinine example shows that there are descriptions under which something may in a relevant sense be known without anyone being aware of its chemical composition or even that it has an identifiable molecular structure. This proposition is unaffected by whether the substance is natural or artificial. So far I have been considering what it means to know about something in ordinary everyday life. Do the same principles apply in the law of patents? Or does patent law have a specialised epistemology of its own?

*Id.* at 88 (*per* Lord Hoffman). This text was quoted in *Defensive Protection Measures Relating*

(or co-inventors), and in accordance with internationally accepted principles of patent law, traditional knowledge holders could claim co-ownership in patents granted in any country that covered inventions derived from their inventive contributions.<sup>104</sup> In other words, those who omit information on the inventive contribution of traditional knowledge holders in patent applications are in violation of patent law. There is no need for an additional requirement: the requirement already exists in Article 4<sup>ter</sup> of the Paris Convention.

However, shamans who supply relevant, if not crucial, genetic material may provide important support for the activities of research and development of pharmaceutical and biotechnology companies, but they are not co-inventors of the products and processes obtained as ultimate derivatives of those genetic resources. This issue was already addressed by U.S. courts in at least two cases: *Moore v. Regents of the University of California*<sup>105</sup> and *Regents of the University of California v. Synbiotics Corp.*<sup>106</sup>

In *Moore*, the Supreme Court of California held that the plaintiff, from whom the spleen had been extracted and the respective cells been used for medical research, which led to a patented cell line,<sup>107</sup> had a cause of action against the five defendants (the physician, the owners and operators of the University's hospital, a researcher, a biotechnology institute and a pharmaceutical company) for breach of

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*to Intellectual Property, Genetic Resources and Traditional Knowledge: An Update*, at 7–8, WIPO Doc. WIPO/GRTKF/IC/6/8 (Dec. 15, 2003). The judge, however, framed his argument as an element of novelty rather than of patentable subject matter. Actually, if a patent were granted for the use of chinchona bark (or quinine, for that matter) to treat malaria and other fevers, there would be no doubt that the Peruvian communities should be designated the rightful inventors. See generally MARK HONIGSBAUM, *THE FEVER TRAIL—IN SEARCH OF THE CURE FOR MALARIA* (Pan Books, 2002), which contains a very detailed and vivid account of how chinchona bark became a staple medicine in Europe. The book also tells about the adventures of European explorers in Peru and Bolivia who, in spite of local laws banning the unauthorized exportation of chinchona bark (in order to avoid the total depletion of the chinchona trees), took enormous risks to find and collect the precious natural medicine.

104. In many countries, uses (and in particular second uses of known substances) are not patentable subject matter if they do not consist of new, inventive and useful processes formed by a series of steps. See CARVALHO, *THE TRIPS REGIME OF PATENT RIGHTS*, *supra* note 28, at 188–90.

105. 793 P.2d 479 (Cal. 1990).

106. 849 F. Supp. 740 (S.D. Cal. 1994).

107. *Moore*, 729 P.2d at 480–81.

the physician's disclosure obligations, but not for conversion.<sup>108</sup> One of the reasons that led the Court to refuse the allegation of conversion was that

the subject matter of the Regent's patent—the patented cell line and the products derived from it—cannot be Moore's property. This is because the patented cell line is both factually and legally distinct from the cells taken from Moore's body. Federal law permits the patenting of organisms that represent the product of "human ingenuity," but not naturally occurring organisms. Human cell lines are patentable because "[l]ong-term adaptation and growth of human tissues and cells in culture is difficult—often considered an art" . . . and the probability of success is low. It is this *inventive effort* that patent law rewards, not the discovery of naturally occurring raw materials.<sup>109</sup>

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108. *Id.* at 497. Conversion, is "under tort and criminal law, the wrongful possession or disposition of another's property as if it were one's own; an act . . . of willful interference, without lawful justification, with any chattel in a manner inconsistent with another's right, whereby that other person is deprived of the use of possession of the chattel." BLACK'S LAW DICTIONARY 333 (7th ed. 1999).

109. *Moore*, 729 P.2d at 492–93 (citations omitted). In his dissent, Judge Mosk acknowledged that, as a matter of law, suppliers of materials cannot be seen as joint inventors because of the particular nature of their contributions. *Id.* at 512 (Mosk, J., dissenting). He suggested, however, that as an analogy, the plaintiff could be entitled to claim inventorship. "A patent is not a license to defraud," he said. *Id.* (Mosk, J., dissenting).

I am aware that "patients and research subjects who contribute cells to research will not be considered inventors." Nor is such a person, strictly speaking, a "joint inventor" within the meaning of the term in federal law. But he does fall within the spirit of the law . . . . Although a patient who donates cells does not fit squarely within the definition of a joint inventor, the policy reasons that inform joint inventor patents should apply to cell donors.

*Id.* (Mosk, J., dissenting) (citations omitted). The problem with Judge Mosk's analogy is that patents are not certificates of fraud-free conduct. Patents have not been devised to certify that the inventor has a *good* character. They have been devised as certificates that someone with an *inventive* character (or with luck) has reached an *inventive* outcome. Furthermore, Judge Mosk's analogy would create serious problems of proportionality: what proportion of the patent rights should go to those who contributed with the materials? If it is accepted that without them the invention would not have arisen, then they might be entitled to the whole patent (the understanding being that the uniqueness of the invention lied in the uniqueness of the material—therefore, any other scientist might very well, if in possession of the same material, develop a similar invention). Judge Mosk, ultimately, was proposing a complete reformulation of the patent system, so that all sorts of contributions, in addition to the inventive contributions,

In *Synbiotics*, the owner of several cats that were showing some particular symptoms, took them, along with her written observations on the cats' symptoms, to be blood tested.<sup>110</sup> From the blood samples, scientists were able to isolate the virus (similar to the human AIDS virus), and subsequently filed for and obtained two patents.<sup>111</sup> The district judge refused to see an inventive nature in the act of bringing the cats and calling the scientists' attention to the cats' symptoms.<sup>112</sup> Because gene- and chemical-related inventions are conceived only when the inventor "has reduced the invention to practice through a successful experiment," the cats' owner could not be seen as an inventor.<sup>113</sup> "As a matter of law," the court said, "only those persons who contributed to the acts and events that resulted in the conception and reduction to practice are properly considered the inventors of the patents."<sup>114</sup> And because the cats' owner had neither been present, nor participated in any way in the events of identifying and isolating the virus, she was not a co-inventor.<sup>115</sup>

The same reasoning can be applied to most (but not to all) TK holders' contributions to patented inventions. Their contributions generally consist of indicating a specific use of a specific resource, or of samples of the material. Based on that information, researchers will be able: to identify the bioactive ingredient that causes the positive action identified by the TK holder; to assess and describe the properties of that ingredient; to isolate and to purify that ingredient (and, eventually to synthesize it); and to transform it into a final

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are recognized. Stretching his reasoning, where an inventor failed to pay the rent of the premises where he did his research, the landlord might as well ask for a share in the ownership of the invention. The only manner to overcome that uncertainty would be to follow the example of some provisions that deal with employees' inventions, which attribute a pre-determined, arbitrary proportion of proprietary interests to employers when inventions are made by employees not hired to invent and who used the employers' data, experience, and resources. See *infra* Part IV.E. However, contrary to Judge Mosk's view, this solution is not about *inventorship* but rather about *ownership*. Purely material contributions can never give rise to claims of inventorship.

110. *Synbiotics*, 849 F. Supp. at 742.

111. *Id.* at 741.

112. *Id.* at 742.

113. *Id.*

114. *Id.*

115. *Id.* Because she was not a co-inventor, she had no vested rights in the patent title, and therefore, she had no standing for licensing the patents to a third party—which was actually a patent infringer, not a patent licensee.

product. Obviously, the TK holder has not participated in any of these activities. Therefore, he is not one of the inventors.<sup>116</sup> The provision of resources, as crucial as they may be for the inventive output, is not inventive *per se*.

Therefore, where the TK holder's contribution consisted in handing over genetic resources and/or indicating their utility, the Requirement is not relevant for detecting inventorship of claims that are not limited to uses. It seeks only to establish a contractual interest in the commercial gains of an invention derived from genetic resources, in the event these resources have been extracted from a territory where there is a duty to obtain formal consent in order to have legitimate access. The Requirement, under those circumstances, is not ancillary to patent law—it is ancillary to administrative and/or contract law.

*B. Non-Statutory Standards and the Duty of Disclosure: Unjust Enrichment and Uninformed Consent*

Because inventions derived from traditional knowledge do rely on contributions from TK holders, either in the form of knowledge or in the form of materials, or both, one could allege that the patent applicants are, directly or indirectly, benefiting from those contributions; therefore, they are being unjustly enriched if no recognition is given to the contributors. However, under current standards of international law, knowledge that is not claimed in the form of a patent application becomes a matter of public domain, and, in the absence of effective measures aimed at keeping it secret, no claim can be made as to ownership. Unpatented and disclosed ideas are free to circulate and be used without any restriction—this is the core of the patent and trade secret systems. Thus, in the absence of a

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116. But, on the other hand, based on that same information, researchers may have tested and confirmed that the resource (or a bioactive ingredient in the resource) had effective results when used in the manner indicated by the TK holder (such as the use of a plant as an antibiotic). If a patent is applied for the *use* of that ingredient, the TK holder may rightfully claim that he is indeed an inventor (or a joint inventor, if the researchers have generated some additional concept to the TK holder's original invention), because in this event he was indeed the person who conceived the technical solution for the problem. But when the TK holder is the true inventor, he should be identified as such under current patent law. The Requirement, therefore, does not create a new obligation in this narrow sense.

special statutory provision obliging patent applicants to inform patent offices of the use of traditional knowledge either as a lead or as a component of the claimed invention, courts may hesitate to recognize traditional knowledge holders' legal standing to claim compensation for misappropriation of or unjust enrichment from their unpatented and disclosed knowledge. Let us take the following hypothetical example: a bioprospector obtains information from a shaman on the medicinal use of a given genetic resource; the bioprospector may then buy some samples of that resource from the shaman or may receive them as a gift, and, back in a developed country, sells the information and the collected samples to a pharmaceutical company. Guided by such information, the company identifies a bioactive component in the resource, discovers its useful properties and develops such information into a final product several years later. Eventually, the company obtains a patent on the isolated and purified bioactive component as well as on its use. The company also obtains marketing approval from the health authorities and starts commercializing the drug.

As discussed above, we have here two different situations: when the patent is obtained on the isolated and purified component, the shaman has supplied information and samples of the genetic resources, and in exchange he has received no remuneration at all or, at most, a very small amount of money, which eventually (and frequently) is not proportionate to the potential economic value of the information and materials provided; but when the patent is obtained on the use of a bioactive component, the shaman is indeed an inventor or co-inventor, because he (or one of his ancestors) was the person who created the mental concept of the solution for the technical problem (the problem was a certain illness and the solution was the use of the bioactive compound to combat the illness or its symptoms). This second situation is already dealt with by patent law, and the following discussion will not cover it. The difficulty lies in the first situation (in the absence, of course, and as noted, of a special statute). As seen before,<sup>117</sup> the shaman cannot be deemed a co-inventor, regardless of the importance of the raw material to the final

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117. See *supra* Part IV.A.

inventive output. His contribution concerned raw material in which no inventive concept was embodied—or, if it was (for example, the breeding work that made it possible for the genetic material to acquire (or enhance) the properties in question), it did not have any influence whatsoever on the inventive work of isolating and purifying the compound. The shaman's contribution to the invention, therefore, was not of an intellectual nature.

The problem is whether the shaman can allege that the bioprospector had failed to disclose to him the potential or actual value of the genetic resource (and the associated element of traditional knowledge, which consists of the discovery of the resource's bioactive properties). Otherwise he would have requested an increased payment (or, eventually, a share in the commercial gains derived from the final output). Is the bioprospector, and his/her successors (eventually, the pharmaceutical company), liable for fraudulent concealment? Does the bioprospector (or the company) have a duty to disclose information to the shaman on the effective or potential value of his TK? Is the bioprospector, therefore, liable in the event that he/she fails to do so? If the answer is yes, traditional knowledge holders may have standing to ask U.S. courts to make biosquatters accountable for concealment.

The controlling case is *Laidlaw v. Organ*,<sup>118</sup> where the Supreme Court held that the buyer did not have the duty of disclosing to the seller of tobacco the news that a treaty of peace had been signed at Ghent between England and the United States, which caused the value of tobacco to rise “from 30 to 50 percent.”<sup>119</sup> Justice Marshall wrote:

The question in this case is, whether the intelligence of extrinsic circumstances, which might influence the price of the commodity, and which was exclusively within the knowledge of the vendee, ought to have been communicated by him to the vendor? The court is of opinion that he was not bound to communicate it. It would be difficult to circumscribe the contrary doctrine within proper limits, where the means of

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118. 15 U.S. 178 (1817).

119. *Id.* at 183.

intelligence are equally accessible to both parties. But at the same time, each party must take care not to say or do any thing tending to impose upon the other.<sup>120</sup>

If we extrapolate this holding into the contractual relationship between the bioprospector and the shaman, we will notice that: (1) most probably the bioprospector is not aware of the real value of the genetic resource; the information he/she controls is that eventually the genetic resource shown to him/her by the shaman has potential pharmacological value, but ultimately such a value will be assessed several years later, after much research and testing; anyway, that is already a piece of information that the shaman did not know; therefore, that is not a situation “where the means of intelligence are equally accessible to both parties,” in the words of Justice Marshall; (2) the increased value of the genetic resource (as compared to the value the shaman thinks it has) is both *intrinsic* and *extrinsic* to it—it is intrinsic to the extent that it is a medicinal bioactive component of the resource that adds value to it; and it is extrinsic to the extent that the firm’s activities of screening, researching, isolating, purifying and testing the pharmaceutical product, not to mention the FDA’s administrative act of granting marketing approval, are the factors that increase the resource’s commercial value; (3) the bioprospector’s failure in disclosing to the shaman what he already knows about the resource’s potential value can be deemed a misrepresentation by silence<sup>121</sup> and the failure in informing the shaman of the increased value as a result of the downstream activities carried out by the pharmaceutical firm could eventually be seen as continuing misrepresentation.<sup>122</sup>

Keeton explains that the law after *Laidlaw* was expanded and that the buyer has no duty to disclose to the vendor circumstances that make the property much more valuable, “and this is true regardless of whether the fact concealed is extrinsic or intrinsic.”<sup>123</sup>

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120. *Id.* at 195.

121. See W. Page Keeton, *Fraud—Concealment and Non-Disclosure*, 15 TEX. L. REV. 1, 1 (1937).

122. *Id.* at 6.

123. *Id.* at 21. Keeton exemplifies with several cases holding that a purchaser of real estate who is aware of the existence of valuable mineral ores underlying the property has not the duty

One might argue that this is an unfair rule, to the extent that it preserves a situation of unequal information and power between the contracting parties. But, as Keeton suggests, “the law cannot hope to put all parties to every contract on an equality as to knowledge, experience, skill and shrewdness; even if it could, would such be a just and equitable law?”<sup>124</sup> The point is that there is no economic efficiency in promoting negligence and laziness, and, on the contrary, there is economic efficiency in rewarding those who diligently pursue information and knowledge. “It is pointed out,” Keeton said, “that [the duty to disclose information to an indolent vendor] is neither just to the individual nor is it a wise social policy to follow because it tends to discourage industry and training.”<sup>125</sup>

Based on this argument, Kronman crafted the theory that where the individual obtains information as a result of deliberate efforts, such information should be considered the subject matter of property rights.<sup>126</sup> Therefore, and whereas “[t]he only feasible way of assigning property rights in short-lived market information is to permit those with such information to contract freely without disclosing what they know,”<sup>127</sup> the bioprospector should be allowed to conceal the information about the intrinsic value of the genetic resource and associated TK from the shaman. The reason for distinguishing between knowledge that has been deliberately acquired by the bioprospector (or his/her employer—the pharmaceutical company) and knowledge that has been acquired casually is that denying protection to the latter “will have no significant effect on his future behavior. Since one who casually acquires information makes no investment in its acquisition, subjecting him to a duty to disclose is not likely to reduce the amount of socially useful information which he actually generates.”<sup>128</sup>

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to disclose such information to the seller, even when he is aware that the seller is not in possession of such information. *Id.* at 22.

124. *Id.* at 22–23.

125. *Id.* at 23.

126. Anthony T. Kronman, *Mistake, Disclosure, Information, and the Law of Contracts*, 7 J. LEGAL STUD. 1, 14 (1978).

127. *Id.* at 15.

128. *Id.* at 15–16.

Under Kronman's approach, therefore, the duty to disclose information on the value of the genetic resource would take place only where genetic resource collection is random or ethnobotanical,<sup>129</sup> and when the bioprospector is actually in possession of such information, which most frequently he is not. In contrast, taxonomic collection would never be subject to the duty of disclosure, because taxonomic collection is deliberate and targeted, which leads to the presumption that knowledge about the value of the collected genetic resources has been previously acquired.

Another commentator, with the same purpose of fostering acquisition of socially useful information, stretched Kronman's idea and proposed that doctors and biotechnology firms should be allowed to lie to patients who contribute with materials extracted from their own bodies.<sup>130</sup> Accordingly, bioprospectors should not only be allowed to conceal information for taxonomic collection of genetic resources: they should also be allowed to lie, if asked by the shaman about their intentions as to the utilization of the resources.

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129. James Miller says that there exist three strategies for collecting plants for screening programs: random, taxonomic and ethnobotanical. See James S. Miller & Stephen J. Brewer, *The Discovery of Medicines and Forest Conservation*, in CONSERVATION OF PLANT GENES 122 (Acad. Press, 1992). "Random collecting is an attempt to sample as much taxonomic diversity as possible." *Id.* One limitation of random collecting "is that it often yields samples that are often taxonomically biased by the geographical restriction of collecting." *Id.* "Taxonomic collecting is based on the general tendency . . . for related taxa to contain related compounds." *Id.* at 123. And ethnobotanical collecting consists of selecting the plants to be collected based on their use by traditional medicine. *Id.* The use of ethnobotanical data may be applied in the study of the use of plants in traditional medicine, followed by a testing of their effectiveness. It also may be used for random screening of plants "used in traditional medicine on the assumption that they have a higher probability of yielding bioactive compounds." *Id.*

130. See Robert Heidt, *Maintaining Incentives for Bioprospecting: The Occasional Need for a Right to Lie*, 13 BERKELEY TECH. L.J. 667, 667-720 (1998). Bioprospecting, in Heidt's comment, means "the search for valuable cells." *Id.* at 667. Heidt addresses a single situation: a doctor extracts some material from the body of one of his patients, and he/she finds some interesting and potentially valuable properties in some cells. But because the cells did not resist the tests and perished, the doctor needs to obtain additional material. Heidt suggests that the doctor should not only be entitled to omit that information to the patient (which would have Kronman's assent), but also, if asked by the patient, he should also be allowed to lie about the real value of the cells. *Id.* at 670. For a general discussion about how patent law applies to collection of human genetic material, see generally Cynthia M. Ho, *Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patient-Based Discoveries*, HOUS. J. HEALTH L. & POL'Y 107 (2002).

Keeton, however, notes that courts tend to include non-economic factors in their analysis of contractual relationships where differences in knowledge may lead to misinformed consent, or mistakes:

In the present stage of the law, the decisions show a drawing away from this idea [that law is concerned with freedom of contract, not with morals], and there can be seen an attempt by many courts to reach a just result in so far as possible, but yet maintaining the degree of certainty which the law must have. The statement must often be found that if either party to a contract of sale conceals or suppresses a material fact which he is in good faith bound to disclose then his silence is fraudulent.

[I]t would seem that the object of the law in these cases should be to impose on parties to the transaction a duty to speak whenever justice, equity, and fair dealing demand it. This statement is made only with reference to instances where the party to be charged is an actor in the transaction. This duty to speak does not result from an implied representation by silence, but exists because a refusal to speak constitutes unfair conduct.<sup>131</sup>

It is possible that a shaman may persuade a U.S. court to determine that a biosquatter and/or his successors must compensate the shaman for the omission in informing him of the real or potential value of a genetic resource and/or associated TK, so as to enable the shaman to request a review of the amounts paid (and eventually,

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131. Keeton, *supra* note 121, at 31 (citations omitted). Given that this issue involves fairness, and in the absence of a rule of mathematical precision to dispose of all situations, Keeton lists nine items to be checked so as to assess whether there is or is not a duty to disclose, such as the difference in degree of intelligence of the parties to the transaction, the manner in which the information is acquired, the general class to which the person who conceals the information belongs, the materiality of the fact not disclosed and the conduct of the person with knowledge of the non disclosed fact. *Id.* at 33–37. In the light of some of those items, the bioprospector would not be blamed for concealing information from the TK holder. But other items, in Keeton's view, would clearly speak in favor of the TK holder and against the bioprospector and his successors. It should be noted that Keeton's reasoning may also apply to differences in levels of information between a prospector and a government that supplies a certain genetic resource. However, in this case, the issue at stake would not be one of difference in knowledge, for the genetic resource is not knowledge in itself, but one of prospective or actual gains derived from a material contribution by the government.

where it may make economic sense, a rescission of the contract).<sup>132</sup> This has nothing to do, however, with patent law. What the shaman may complain about is the lack of transparency or candor by the bioprospector. The fact that a patent application does not disclose any element that may help the shaman assess the real value of the information he had provided may simply constitute an additional element for persuading the judge that the bioprospector has acted in bad faith. But the breach of the shaman's right to be informed and the act of misappropriation and fraudulent concealment took place at the moment the bioprospector received the material (and/or the information on its traditional use) from the TK holder.

### *C. Revisiting the Unclean Hands Doctrine*

When traditional knowledge is used, directly or indirectly, as a basis for creating inventive uses for genetic resources to which they are associated, and where those inventions become the subject matter of patents, society has two ways to deal with the need for ensuring the sharing of eventual benefits arising from those inventions with TK holders: one is to adopt the Requirement as a condition of patentability; the other is to adopt the unclean hands doctrine.

I have proposed elsewhere that governments could resort to the unclean hands doctrine as an alternative to adopting the Requirement as a condition of patentability:

[C]ourts 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

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132. Actually, some transfers of genetic material do require a continued supply. This is particularly true in the cosmetics and perfume industry, where synthetic materials are never as efficient as the natural ones. But in the pharmaceutical sector the same circumstances may also arise. For example, it has been reported that efforts to successfully synthesize taxol are still undergoing. The use of the bark of the Pacific yew to produce the anti-cancer drug has put serious strain in the tree's population. See *Pacific Yew: The Taxol Story*, Canadian Forest Service, at [http://www.pfc.forestry.ca/ecology/yew/taxol\\_e.html](http://www.pfc.forestry.ca/ecology/yew/taxol_e.html) (last visited Nov. 5, 2004).

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, it can be imposed that one must have clean hands to obtain relief from an equity court. Only after a patentee abandons its unlawful practice and the effects of the misuse are completely dissipated may it sue infringers. 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.

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 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.<sup>133</sup>

The use of the unclean hands doctrine would have advantages over the patentability condition approach:

(1) first, as a rule of enforcement, it would be compatible with the different international treaties mentioned above (namely the TRIPS Agreement, the UPOV Convention, the PCT and the PLT); several of the arguments listed in paragraph 29.74 *supra* indicate that such a rule would be fair for the purposes of Article 41.2 of the TRIPS Agreement;

(2) second, it would not affect the patentability of an invention. Actually, the idea proposed does not resort to the inequitable conduct rule, because inequitable conduct can only be alleged when the patent applicant fails to disclose to the patent office some material fact that may be (or probably is) material to the patentability; therefore, inequitable conduct, like the Requirement, is linked to the conditions of patentability. The inequitable conduct may also lead to the partial or total unenforceability of the patent, but, unlike the unclean hands doctrine, it cannot be purged.<sup>134</sup> To this extent, the idea of permitting the biosquatter to clean his/her hands is a mitigated inequitable conduct approach. However, when the claims contain matter that is

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133. See Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement*, 2 WASH. U. J.L. & POL'Y 371, 399–400 (2000) (footnotes omitted).

134. For an overview of recent cases on the inequitable conduct doctrine, see Lisa A. Dolak, *The Inequitable Conduct Doctrine: Lessons from Recent Cases*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 719, 723–40 (2002). As noted above, the inequitable conduct doctrine has been identified by the United States as an alternative solution to prevent the granting of patents that claim previously disclosed TK. See *supra* note 100.

traditional knowledge (such as the turmeric patent<sup>135</sup>), the obligation to disclose it is already clearly established by patent law. Likewise, when the origin of a genetic resource is relevant for enabling an appropriate description of the invention, applicants are already under the obligation to disclose it in the specifications.<sup>136</sup> In those two circumstances, failure to inform the patent examiner about those facts amounts to concealing elements of material importance for the assessment of the patentability. Those would be grounds for a finding of irremediable inequitable conduct.

(3) third, the unclean hands doctrine does indeed promote benefit sharing because it surprises the patent owner at the moment he/she is using the court authority to collect revenue from an infringer (in the form of damages) and/or to impose his/her exclusive rights (and maintain his/her position as exclusive user of the invention in the market by means of an injunction). Because the court will refuse to do so until the patent owner cleans his/her hands, the patent owner has no solution other than seeking a settlement with both the supplier of the genetic resources and the licensor of the associated TK.

One commentator has already discussed this point in relation to the collection of human material from patients. Commenting on Judge Mosk's dissent in *Moore*, she wrote:

[I]n the case of failing to disclose patient contributions, unless the law changes with respect to whether patients can jointly conceive of an invention, failure to disclose the identity of patients, or even their contributions, would not rise to the level of material information for patentability purposes. Although patients believe that but for their actions, no patentable invention would have been conceived in the first instance, this information is not material to whether the ultimate invention is patentable. In addition, allowing information that is not material to the patentability analysis to be the basis for inequitable conduct runs counter to the traditional basis for such unenforceability . . . .

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135. See *supra* note 17.

136. Several countries, in their responses to the WIPO questionnaire on the Requirement, have noted that aspect. See *Draft Study*, *supra* note 16, ¶¶ 57–64.

In addition, even if the patent laws were amended to make patents unenforceable if patient contributions were not properly disclosed to the patent office, it is unclear whether this would be an optimal approach. In particular, for patients who want to share of patent profits, creating a new rule for unenforceability would negate any such hope of profits. Nonetheless, if patients cannot be considered joint inventors, an unenforceability rule might provide a helpful bargaining platform for some patients. Accordingly, perhaps patients should advocate a new patent rule requiring all patent applicants to disclose the extent of patient contributions to the invention, as well as what compensation, if any, has been provided for such contributions.<sup>137</sup>

The inequitable conduct, like the Requirement (if adopted as a condition of patentability), seriously reduces the possibility of the TK holder to share benefits. Of course, it is not because the patent will become unenforceable that the inventor will completely cease to obtain gains from its exploitation. A patent is not a *sine qua non* of commercial success. Nor does the inventor cease commercially exploiting it once it is lost or expired. We can think of a very long list of inventions that continued being profitably exploited by their inventors after the expiration of the respective patents. Besides, as explained above, the obligation to share benefits under Article 15.7 does not necessarily stem from their commercial utilization. Their use for scientific or technological purposes is already sufficient ground to trigger benefit sharing—even though, in the absence of commercial gains, it may become very difficult to evaluate those benefits. Nonetheless, the expiration of the patent (or the lapse of the rights to enforce it) reduces the patentee's capacity of reaping the fruit of a commercially successful invention because nothing will prevent others from doing the same—and consequently it undermines the patentee's financial capacity of sharing benefits.

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137. Cynthia Ho, *supra* note 130, at 155–56. The commentator describes a situation that is almost exclusive to U.S. law. In most countries patents cannot be granted on cells, cell lines, genes, or gene sequences, if of human origin. See *Review of the Provisions of Article 27.3(b)—Illustrative List of Questions*, WTO Doc. IP/C/W/273/Rev.1 (Feb. 18, 2003).

The unclean hands doctrine approach has the advantage that it does not affect the enforceability of the patent—it just suspends it until the patent owner cleans his/her hands.<sup>138</sup>

*D. The Duty to Disclose Relevant Material Interests in Patent Applications; The Example of the Government Funding Disclosure Clause of 35 U.S.C. § 202.*

In 1999, the WIPO Secretariat included the following question in a questionnaire on WIPO Member States' practices related to the protection of biotechnological inventions:

Does your legislation include any special provisions to ensure the recording of contributions to inventions (such as the source of government funding, the source of genetic resources that originate or are employed in biotechnological inventions, the grant of prior informed consent to have access to those resources)?<sup>139</sup>

The question was deliberately drafted so as to imply that the requirement to identify the origin of genetic resources, then adopted only by Costa Rica and the Andean Community, and the obligation to inform about the use of government funding, as imposed by the United States Code, are similar. Indeed, they are similar to the extent that both are formal requirements because they concern the manner in

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138. See MANUEL RUIZ, SOUTH CENTRE, THE INTERNATIONAL DEBATE ON TRADITIONAL KNOWLEDGE AS PRIOR ART IN THE PATENT SYSTEM (Oct. 2002), available at [www.southcentre.org/publications/occasional/paper09/traditionalknowledge.pdf](http://www.southcentre.org/publications/occasional/paper09/traditionalknowledge.pdf); COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 86–87 (Sept. 2002), available at [http://www.iprcommission.org/papers/pdfs/final\\_report/ciprfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf).

139. Actually this question was originated by the debate in the SCP on the Colombian proposal. Because of that proposal, Colombia was invited to attend the meeting of the WIPO Working Group on Biotechnology, in November 1999. See *Issues for Proposed Work Program on Biotechnology*, WIPO Doc. WIPO/BIOT/WG/99/1 (Oct. 28, 1999) (on file with the WIPO Secretariat). The responses to the questionnaire were collected and circulated and submitted to the WIPO Meeting on Intellectual Property and Genetic Resources of April 17 and 18, 2000 (*Information Provided by WIPO Member States Concerning Special Provisions to Ensure the Recording of Some Contributions to Inventions*, WIPO Doc. WIPO/IP/GR/00/3 Rev.1 (Apr. 14, 2000))—the meeting that was the precursor of the Intergovernmental Committee. The same responses can also be found in WIPO Doc. WIPO/GRTKF/IC/1/6 (Apr. 6, 2000), submitted to the first session of the Committee, from April 30 to May 3, 2001.

which the claimed invention is described, and thus they do not regard the nature of the invention. Both requirements are, therefore, *extrinsic* to the invention. But the similarity stops there. As it will be shown, unlike the Requirement, the U.S. requirement that contractors inform about government funding is consistent with international obligations, including those of the TRIPS Agreement.

Contractors, under 35 U.S.C. § 202,<sup>140</sup> have actually two disclosure obligations: they must disclose the very existence of the

140. The relevant provisions of Chapter 18 (“Patent Rights in Inventions Made with Federal Assistance”), 35 U.S.C. § 202 *et seq.* read:

35 U.S.C. § 202 Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention . . . The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter . . . .

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to a contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time . . . .

(4) With respect to any invention in which the contractor elects rights, the federal agency shall have a nonexclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for on or behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights; including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency . . . .

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention . . . .

35 U.S.C. § 203 March-in rights

(1) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor, an assignee, or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself . . . .

35 U.S.C. § 206 Uniform clauses and regulations

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The Secretary of Commerce may issue regulations which may be made applicable to federal agencies implementing the provisions of sections 202 through 204 of this chapter . . . .

Those regulations can be found in 37 C.F.R. § 401 (2004), and in particular in the following rules:

§ 401.3 Use of standard clauses at § 401.14.

(a) Each funding agreement awarded to a small business firm or nonprofit organization . . . shall contain the clause found in § 401.14(a) . . . .

§ 401.14 Standard patent rights clauses.

(a) The following is the standard patent rights clause to be used as specified in § 401.3(a).

Patent rights (Small Business Firms and Nonprofit Organizations) . . .

(b) Allocation of Principal Rights

The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. § 203. With respect to any subject invention in which the Contractor retains title, the Federal government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for on or behalf of the United States the subject invention throughout the world.

(c) Invention Disclosure, Election of Title and Filing of Patent Application by Contractor

(1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters . . . .

(2) The *contractor* will elect in writing whether or not to retain title to any such invention by notifying the *Federal Agency* . . . .

(d) Conditions When the Government May Obtain Title

The *contractor* will convey to the *Federal Agency*, upon written request, title to any subject invention —

(1) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in (c) above, or elects not to retain title; provided that the *agency* may only request title within 60 days after learning of the failure of the *contractor* to disclose or elect with the specified times . . . .

(f) *Contractor* Action to Protect the Government's Interest . . . .

(4) The *contractor* agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the *contract*) awarded by (identify the Federal agency). The government has certain rights in the invention."

The provisions of 35 U.S.C. § 202 *et seq.* apply to all firms regardless of their size, in accordance with Presidential Executive Order 12,591. It should be noted that, because the march-in rights, under 35 U.S.C. § 203, amount to a compulsory license, they are subject to the

subject inventions to the funding agency; and they must inform that the subject invention was made under a funding agreement in the patent application.<sup>141</sup> If the contractor fails to disclose the invention to the funding Agency, the Government may acquire title to the invention. Such an acquisition, however, is not automatic—"the agency may only request title within 60 days of learning of the failure to disclose or elect within the specified times."<sup>142</sup> And because the provision says that the Government *may* request title, it follows that such a request depends on the discretionary authority of the governmental agency.

The purpose of the government funding requirement (hereinafter designated as "the U.S. requirement") is two-fold. On the one hand, it is aimed at informing the government itself about the existence of the invention, because the fact that the invention was publicly funded gives the government some rights in the invention, namely the right to a nonexclusive, nontransferable, irrevocable and paid-up license.<sup>143</sup> On the other hand, the requirement provides information to the public at large, because, if some circumstances of public interest arise, the government has march-in rights in the invention, which means that interested third parties may eventually obtain the right to use the patented invention.<sup>144</sup> However, the notice on the patent letter that the invention was made with Federal financial assistance is "neutral" in the sense that the actual rights that the government may have reserved are not specified thereon.<sup>145</sup>

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provisions of article 31 of the TRIPS Agreement. Therefore, the possibility for the U.S. government to grant "partially exclusive, or exclusive" compulsory licenses is inconsistent with article 31(d) of the TRIPS Agreement, which provides that compulsory licenses "shall be non-exclusive." TRIPS Agreement, *supra* note 6, art. 31.

141. Section 302(c)(6) states that the funding agreement shall contain the obligation "on the part of the contractor . . . to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support." Evidently, the second aspect of this provision is beyond the contractor's control. Only the United States Patent and Trademark Office (USPTO) can implement the obligation of including a certain language in the patent. The only thing the patent applicant can do is to inform the USPTO of the interests of the federal government in a given patent application and to request a correction if the patent is issued without such a note.

142. 37 CFR § 401.14(a)(d)(1) (2004)

143. 35 U.S.C.S. § 202(c)(4) (2004); Exec. Order No. 12, 591, 52 Fed. Reg. 13,414 (1987).

144. 35 U.S.C.S. § 203 (2004).

145. "The only concrete evidence Duke cites is the statement on each of the patents noting that the government has rights in the patents. This, however, is insufficient because these short

Secondly, § 202 *et seq.* do not provide for any mandatory action to be taken by Federal agencies. They contain no standards for courts to use to examine legality.<sup>146</sup>

Another important aspect of Chapter 18 is that its provisions do not set a clear entitlement to patent rights. “Though the indication is strong,” said the Court of Appeals for the Eleventh Circuit in *Southern Research Institute v. Griffin Corp.*,<sup>147</sup> “that the government should ordinarily grant such [patent] rights, the statute admits of no considerations by which we could fairly gauge the propriety of a refusal to so grant such rights.”<sup>148</sup> In a footnote the court noted that commentators had suggested that the Bayh-Dole Act<sup>149</sup> created a presumption in favor of researchers working with a government funding grant. The court, however, repeated: “[w]hile we may not disagree with this view, we note that the Act leaves us without sufficient judicial standards by which to evaluate a *refusal* to give away patent rights.”<sup>150</sup>

What is then the consequence of failure to comply with the government funding disclosure requirement—or more specifically, what happens if the contractor fails to acknowledge in the patent application that the invention was made with public financial assistance? It seems that, according to courts, the consequence ultimately lies in the discretionary authority of the government, provided the deadlines established by 37 C.F.R. § 401.14 are

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notations on the patents do not define the scope of the government's rights.” *Madey v. Duke Univ.*, 307 F.3d 1351, 1364 (Fed. Cir. 2002).

146. “The court held that Vartanian’s complaint must be dismissed because (1) § 202 did not provide, either explicitly or implicitly, a private right of action regarding the ownership of inventions; (2) judicial review of the agency’s purported refusal to grant ownership rights was unavailable . . . because the underlying statute, § 202, does not provide any standards for meaningful review of the agency’s actions . . . . We also agree with the court that judicial review is not available because the underlying statute, § 202, provides no standards for judging the propriety of the agency’s action.” *See Vartanian v. Gen. Elec. Co.*, No. 99-1404, 2000 U.S. App. LEXIS 6327, at \*2–\*3, \*6 (Fed. Cir. Apr. 6, 2000) (*per curiam*).

147. 938 F.2d 1249 (11th Cir. 1991). The plaintiff alleged that the government was under a statutory duty to assign the rights stemming from a patent covering an invention to which SRI’s employees had contributed under a federal grant.

148. *Id.* at 1254.

149. Bayh-Dole Act, 35 U.S.C.S. §§ 200–11 (2004).

150. 938 F.2d at 1254 n.10. 35 U.S.C. § 202 *et seq.* were introduced in the Patents Act (Title 35) by the Bayh-Dole Act.

complied with. In *Gen-Probe Inc. v. Center for Neurologic Study*,<sup>151</sup> the District Court for the Southern District of California held that section 202 provides for no private right of action.<sup>152</sup> The court added that, unlike sections 281 and 141–45 of the Patent Act, section 202 contains no mechanism for private enforcement.<sup>153</sup>

Moreover, the transfer of title does not occur automatically where the contractor failed to disclose the invention to the Federal agency or to the USPTO office. In *Jewish Hospital of St. Louis v. Idexx Laboratories*,<sup>154</sup> the District Court of Maine construed section 202 in the following manner:

[n]either the statute nor the regulation results in the automatic transfer of title IDEXX asserts. The statute requires funding agreements to provide that the Government ‘may receive title’ under certain circumstances . . . . Rather than automatically transferring title to the invention upon late disclosure, the

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151. 853 F. Supp. 1215 (S.D. Cal. 1993).

152. *Id.* at 1217 (citing with approval *Platz v. Sloan-Kettering Inst.*, 787 F. Supp. 360 (S.D.N.Y. 1992)).

153.

This conclusion [that under section 202 no private right of action exists] is supported by the fact that elsewhere in the patent statutes, Congress did explicitly grant private causes of action. *See, e.g.*, 35 U.S.C. § 281 (1988) (“a patentee shall have remedy by civil action for infringement of his patent”); 35 U.S.C. §§ 141–145 (1988) (applicant whose patent is rejected by the Patent Office on appeal may pursue his claim in the federal courts). The fact that elsewhere in the patent statutes private rights were expressly provided indicates that “when Congress wished to provide a private damage remedy, it knew how to do so and did so expressly.” Likewise, that such a right was not created under § 202(c)(7)(B) suggests that no right was intended.

*Id.* at 1218 (citation omitted). This is debatable, however. True inventors are entitled to claim and enforce in courts inventorship and ownership of the patent, and yet the Patent Statute contains no provision explicitly recognizing such a right. That right stems from the principle that patents should be granted for those whom the law qualifies as the rightful patent letter addressees.

154. 973 F. Supp. 24 (D. Me. 1997). Idexx had moved to file a third amended answer and counterclaim to assert three affirmative defenses to patent infringement: (1) lack of standing or failure to join an indispensable party (the Federal government); (2) patent misuse and unclean hands; and (3) inequitable conduct. Order on Idexx’s Motion to File Third Amended Answer and Counterclaim (Docket Item 202) 1, *Jewish Hosp. v. Idexx Labs.*, 973 F. Supp. 24 (D. Me. 1997) (Civ. No. 95-290-P-H) [hereinafter Order]. The argument of Idexx was that, because Jewish Hospital had neglected to promptly communicate to the NIH the making of the patented invention under a NIH funding agreement (the communication was made after the patent was issued), the government had automatically acquired title and therefore the Jewish Hospital had no standing for enforcing rights in that patent.

Secretary has provided in regulation 401.14(d)(1) that grant recipients like Jewish Hospital retain title to the invention unless and until the Federal agency meets two requirements. First, the Federal agency must make a “written request.” 37 C.F.R. §401.14(d). Second, the Federal agency must make this request “within 60 days after learning of the failure of the [grant recipient] to disclose.” 37 C.F.R. § 401.14(d)(1).<sup>155</sup>

The result that title does not transfer automatically to the Government under section 202 is even clearer when its language is compared to the language of the Federal Nonnuclear Energy Research and Development Act (FNERDA). “Unlike the permissive and conditional language of the statute and regulation here [section 202 and 401.14], FNERDA clearly provides that ‘title to any invention made or conceived under a FNERDA contract *shall vest* in the United States.’”<sup>156</sup>

Disputes involving title to the invention between the Federal agency and the funded inventor may not benefit third parties. The court said:

Simply put, I fail to see how the allegations of improper delay, even if true, are at all material to this patent infringement case. These allegations concern the Jewish Hospital-NIH funding contract and its procurement. But whether Jewish Hospital mislead the NIH has no bearing on any legitimate issues in IDEXX’s answer or counterclaims. IDEXX cannot benefit from potential disputes between Jewish Hospital and the NIH arising under the contract and procurement process.<sup>157</sup>

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155. Order, *supra* note 154, at 4. The court noted: “Indeed, the very title of regulation 401.14(d) is ‘*Conditions When the Government May Obtain Title.*’ 37 C.F.R. § 401.14(d).”

156. *Id.* at 4 n.3 (citation omitted).

157. *Id.* at 5. These aspects of Chapter 18 represent a departure from pre-existing law. In a case involving the alleged infringement of a patented invention made under a 1974 grant from the Public Health Service (invention which was communicated to the funding agency nearly eighteen years after the grant expired), *VDI Technologies, Inc. v. Price*, Civil No. 90-341-M, Order of August 31, 1994 (D.N.H. 1994), the District Court of New Hampshire said that “[w]hile the regulations and reporting requirements did not automatically vest title to grant-related inventions in the United States, they did automatically vest in the government the exclusive right to determine who could obtain and exercise ownership rights and on what terms.” *Id.* at 8. “For purposes of the present declaratory judgment action, Sudbury’s ownership

Actually, if it is not possible to identify here a case of inequitable conduct, because the funding contract is not material to the issue of patentability, the failure to timely disclose the invention to the government and to society at large (through the notice on the patent letter) may raise a question of unclean hands—which apparently the district judge’s order failed to address. The question is that the notice on the patent informs the public that the government—and, consequently, tax-payers—has interests in the patented invention, which may include the royalty-free use of the invention by the government itself, or, if some circumstances of public interest arise, march-in rights claims.<sup>158</sup> Even though it seems that the government, and the NIH in particular, will be parsimonious in resorting to the extreme solution of marching in private patent rights,<sup>159</sup> the possibility exists nonetheless. Failure to communicate to the USPTO that ownership of a certain invention made under federal funding is limited by Federal statutes and regulations may be seen as a serious omission of facts relevant to public policy; therefore, any attempt to enforce rights thus acquired might be deemed abusive.

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of the ‘854’ patent is not established, rendering the purported case and controversy between these parties unripe, at least as to the patent related claims.” *Id.* at 9. “Moreover, what Sudbury knew, or should have known, of the reporting requirements would be critical to an assessment of whether Sudbury was guilty of inequitable conduct before the Patent and Trademark Office (‘PTO’). If Sudbury did know of the restrictions on patentability and deliberately withheld that information, then the ‘854’ patent would most probably be unenforceable.” *Id.* at 10 (citation omitted). “At this juncture, until the government exercises its right to determine ownership of the invention, and, the scope of those ownership rights are determined if they are awarded to Sudbury, the regulations operate to preclude its claim to record ownership of the patent and preclude its current claim of infringement.” *Id.* at 11.

158. 35 U.S.C. § 206 (2000).

159. See *Determination In the Case of Petition of Cell Pro*, National Institutes of Health, Office of the Director, of August 1, 1997, available at [www.nih.gov/news/pr/aug97/nihb\\_01.htm](http://www.nih.gov/news/pr/aug97/nihb_01.htm). The Director said that the NIH is

wary . . . of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies’ and investors’ future willingness to invest in federally funded medical technologies. . . . In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.

*Id.* at 8.

On its face, the U.S. requirement is substantially distinct from the Requirement because it does not establish a condition of patentability. In other words, the Patent Office will neither reject a patent application because the applicant failed to inform about the fact that the claimed invention was made under a Federal grant, nor will a court invalidate or refuse to enforce patent rights on that ground. However, that is not the point, because, as seen above, the Requirement is not always imposed as a condition of patentability. Furthermore, even when it is not a formal condition of patentability, the Requirement is in violation of those WIPO treaties that deal with formal requirements (which are not necessarily patentability conditions), such as the PCT and the PLT. Therefore, even if it is not a formal condition of patentability, the U.S. requirement could be in violation of the United States' international obligations under the PCT and the PLT. But it is not. The government funding disclosure requirement helps the funding agency and tax payers to assess matters of attribution of rights in the invention, i.e., ownership. Patent laws in general designate inventors as the original owners of patented inventions. But ownership may as well stem from contractual arrangements between inventors and their employers<sup>160</sup> or funding providers.

Worried that entities benefiting from federal grants were not adequately reporting inventions made in compliance with a statutory mandate,<sup>161</sup> two federal agencies have already inspected the levels of actual implementation of 35 U.S.C. § 202. The first report was elaborated by the Office of Inspector General of the Department of Health and Human Services, in 1994. It specifically checked the reported disclosure of inventions made under NIH grants at the Scripps Research Institute and concluded that they were underreported.<sup>162</sup> The Inspector General recommended a review of patents obtained by NIH grantees (to the argument that such a review would cause too much work, the Inspector suggested that the NIH

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160. See *U.S. v. Dubilier Condenser Corp.*, 289 U.S. 178 (1933).

161. See 35 U.S.C. § 202(b)(3) (2000).

162. See DEP'T OF HEALTH HUM. SERVS., *Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute* (June 1994), available at <http://www.oig.hhs.gov/oas/reports/phs/c9300029.pdf>.

take a “risk-based approach that would ensure that those grantees most likely to have inventions and file for patents are reviewed”).<sup>163</sup>

The second report was issued by the United States General Accounting Office (GAO), in August 1999.<sup>164</sup> This second Report also concluded that there was not enough information on patent documents on government interests in inventions made under federal grants. Based on that conclusion, the GAO recommended Congress to consider amending the Bayh-Dole Act “to standardize, improve, and streamline the reporting process for inventions subject to both the Act and Executive Order 12591.”<sup>165</sup> In order to achieve that, the GAO recommended:

[t]he Congress could consider (1) requiring the Secretary of Commerce to develop standardized disclosure forms and utilization reports for federally funded inventions, (2) making the patent the primary control mechanism for reporting and documenting the government’s rights and the only written instrument for confirming the government’s royalty-free license, and (3) requiring the Patent and Trademark Office to provide information to the funding agencies to assist them in monitoring compliance.<sup>166</sup>

GAO’s argument was that the

patent database is a better source than the Government Register for determining the government’s rights to federally sponsored inventions. It is more accessible than the Government Register in that the official patent records are available for inspection and a user can obtain from PTO’s Internet Web site the full text of patents issued since 1976.<sup>167</sup>

Among the measures aiming to streamline the reporting process, the GAO had suggested a requirement that the notice on the patent application include “the name of each specific agency that funded

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163. *Id.* at 9–10.

164. U.S. G.A.O. OFFICE, REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION (1999).

165. *Id.* at 19.

166. *Id.*

167. *Id.* at 14–15.

research, the contract or grant number(s) under which the invention was created, and a provision stipulating that the government has a nonexclusive, paid-up, royalty-free right to the use of the invention.”<sup>168</sup> The GAO also proposed that the USPTO should keep the funding agency informed of events that might affect the government's rights during the application's prosecution (so that the funding agency could take preventive measures to protect its interests in the invention) and that the Patent Gazette include a notice on the government's interest on patents issued.<sup>169</sup> The GAO also proposed that the USPTO could charge applicants a fee for applications that contained a government interest notice.<sup>170</sup>

The USPTO agreed that the requirement, if adopted in GAO's terms, would be in compliance with the draft of the Patent Law Treaty that was then being negotiated. What the USPTO did not agree with was the increased burden on patent applicants.<sup>171</sup>

The GAO's recommendations were not implemented and thus the USPTO has no obligation to seek information on the nature or origin of the funds used by inventors for making claimed inventions. Interestingly, many of the proposals made by the GAO could have been subscribed to by environmental agencies of biodiversity-rich countries seeking ways and means to monitor compliance with contracts on access to genetic resources (likewise, the GAO was seeking a practical means to monitor, through patent documents, compliance with contracts of access to government funds). To the allegation that using the patent system to monitor the use of genetic resources is not efficient because it would not cover inventions kept undisclosed, the GAO would answer that that is not a problem because section 202 actually requires a patent to be filed. Therefore, in principle, all inventions made with government funding that are patentable subject matter will find their way to the USPTO. But that is not the issue, of course. The issue is that it would be wrong (however not offensive to international legislation) to use patents to verify whether contractors have complied with their contractual

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168. *Id.* at 32.

169. *Id.*

170. *Id.*

171. *Id.* at 20.

obligations. The idea that patents are not certificates of good behavior does not apply to bioprospecting only, it also applies to government funding.

Anyway, the government funding disclosure requirement is consistent with the obligations of the United States under the four international agreements mentioned above.

First, it is compatible with the TRIPS Agreement, and not only because it is not a formal condition of patentability. Actually, if the US requirement were a (formal) condition of patentability, it would be nonetheless compatible with Article 62 of the TRIPS Agreement. And the reason was given above: it is indeed *reasonable* to impose any conditions necessary to identify the right to ownership of the invention. In contrast with the Requirement, as explained, under which suppliers of genetic resources or of associated TK do not have a claim of inventorship, the funding Federal agency may indeed claim property rights in the invention, in the event that the contractor fails to do so within the established period. Moreover, there are public interests involved in the notice concerning public funding because, in view of the public nature of the funding, march-in rights may be invoked by the government as per interested third parties' request. The notice on the patent, therefore, operates as a notice to society at large that the rights deriving from that particular patent are subject to some considerations and actions that may be dictated by public policy.<sup>172</sup> In contrast, the Requirement has the single purpose of informing stakeholders of an eventual interest in the results of the research or of the commercial exploitation of the claimed invention—results to which the patent does not contribute. If the claimed invention consists of a cloned animal cell line, for example, the

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172. As the Office of Inspector General of the Department of Health and Human Services said: “[w]hen the Government is not aware of a grantee’s invention, it is not able to exercise its rights and to protect the taxpayers’ interest.” See DEP’T OF HEALTH HUM. SERVS., *supra* note 160, at 7. The GAO also took note of the rationale set out by Federal Regulations:

It is important that the Government and the contractor know and exercise their rights in inventions conceived or first actually reduced to practice in the course of or under Government contracts in order to ensure their expeditions available to the public and to enable the Government, the contractor, and the public to avoid unnecessary payment of royalties and to defend themselves against claims and suits for patent infringement.

48 C.F.R. § 27.305-1(a) (2004).

original material of which was the product of bioprospection, the fact that the Patent Office may be informed of the circumstances in which the raw material was obtained will have no consequences at all if in the country in question cloning technology may not be commercially exploited (in many countries it cannot be patented either).

The UPOV Convention is not affected by the U.S. requirement, which applies to patents only (including, eventually, plant patents). However, if the U.S. requirement were applicable to plant variety protection, again, unlike the Requirement, it would be UPOV 1991 consistent. The reason is that Article 1 of UPOV 1991 defines "breeder" as

—the person who bred, or discovered and developed, a variety,

—the person who is the employer of the aforementioned person or who has commissioned the latter's work, where the laws of the relevant Contracting Party so provide, or

—the successor in title of the first or second aforementioned person, as the case may be.<sup>173</sup>

As a supplier of financial resources to the breeder, the Federal agency would acquire title, if the U.S. Plant Variety Act so established, provided the breeder failed to claim the right or disclose the origin of the funding, as a commissioner of the breeder's work. And since the basic obligation of the Contracting Parties to the UPOV Convention is to "grant and protect breeders' rights,"<sup>174</sup> it follows that Congress may impose an obligation on the precise identification of the breeder (including its employers and commissioners) within the application for a variety certificate.

The U.S. requirement is not only compatible with PCT provisions, but it is also expressly permitted by the Treaty.<sup>175</sup> Actually, among

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173. UPOV 1991, *supra* note 44, art. 1.

174. *Id.* art. 2.

175. Actually, the United States government itself may have thought, at some point, that the U.S. requirement could be in conflict with the PCT because it has proposed to add a new subparagraph to Rule 51*bis*.1 of the PCT Regulations (on "Certain National Requirements Allowed") as follows: "where the invention was invented as part of the work performed under a contract with the government of the designated State, any document containing a statement

the formal requirements the PCT refers to, there is a mention of the identification of “the name and other data concerning the inventor where the national law of at least one of the designated States requires that these indications be furnished at the time of filing a national application.”<sup>176</sup> The U.S. requirement, which applies to United States patent applications only,<sup>177</sup> concerns the identification of the inventor—concept which comprises the funding Federal agency which, under the circumstances established in Chapter 18, may acquire the rights which originally belong to the inventor, thus becoming “the inventor” for all legal purposes.

Because the U.S. requirement has the purpose of clarifying issues of ownership, and because ownership is crucial to the patent system, the U.S. requirement is consistent with PLT provisions (which, as explained, incorporates the conditions of patentability established by the PCT) and with the draft SPLT provisions (which permits Contracting Parties to define the conditions under which third parties may succeed the inventor in his/her rights in the invention).<sup>178</sup>

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which indicates any government license rights in the invention and identifies the government contract.” *See Proposed Amendments of the PCT Regulations and Modifications of the PCT Administrative Instructions, Relating to the Draft Patent Law Treaty*, at 12, WIPO Doc. PCT/A/28/2 (Jan. 28, 2000), Annex I. Later the U.S. Delegation withdrew this proposal,

in light of having undertaken a review of the controlling statutory provision. That review revealed that the controlling statutory provision only imposed an obligation on a contractor-applicant to include in the application a statement as referred to in proposed (vi); it did not provide any authority for the United States Patent and Trademark Office to require such statement.

*See Report*, ¶ 11, WIPO Doc. PCT/A/28/5 (Mar. 17, 2000). Actually, the U.S. delegation was correct in concluding that there was no need for the proposed amendment, but the real reason, as explained above, is not that the USPTO has no authority to verify compliance with the statutory requirement. Actually, the PCT is not about the authority of patent offices to impose formal requirements: it is indeed about the possibility of Contracting Parties to impose those requirements, either through statutes or patent offices’ administrative practices. If the PTO argument prevailed, countries could establish the Requirement as a condition of validity of patents, provided patent offices did not have the task of verifying compliance (which would be left to courts). To this extent, the U.S. requirement may indeed be scrutinized in the light of the PCT. But the reason is different: actually, the PCT allows for the U.S. requirement because it relates to the identification of third parties’ ownership interests in the claimed invention.

176. PCT, *supra* note 8, art. 4.

177. 35 U.S.C. § 202(c)(6) (2000).

178. PCT, *supra* note 8, art. 4.2.

In conclusion, the U.S. requirement not only makes good sense in view of the public policy considerations that buttress it, but it is also entirely consistent with U.S. international obligations.

*E. Another Possible Solution Under Current National and International Patent Law: Material Contributions to the Inventive Activity May Generate Material Interests in the Patent*

Several developing countries have shown reluctance to adopt a disclosure requirement that is less than a condition of patentability—even though, as we have seen, it may be inconsistent with several international agreements, including the TRIPS Agreement. The reason is one of efficiency, for illegal bioprospecting might not be deterred unless a stronger remedy is available. The question, then, is whether it is possible to impose the Requirement as a significant and effective measure—that is, with an impact at least as strong as if it were a condition of patentability—without infringing current international patent law (and without the need for amending the TRIPS Agreement, which, anyway, seems a very unlikely exercise in the short or medium term). The answer is yes, provided some fundamental aspects are taken into consideration.

Under the national law of some WTO Members, when an employee who has not been hired to invent makes an invention using resources (including raw materials) and data that belong to his/her employer, the latter is entitled to a material claim in the invention, and, consequently, in the patent. In the United States, such claim means the royalty-free right of using the invention.<sup>179</sup> In Brazil, the employer is entitled to ownership of half of the proprietary patent rights (that is, the employer becomes a co-owner) and to a paid, exclusive license of the other half.<sup>180</sup> In France, the employer may claim full ownership of the invention or an exclusive license.<sup>181</sup> In all cases, the employer's claim stems from its material contribution to

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179. See Mark B. Baker & Andre J. Brunel, *Restructuring the Judicial Evaluation of Employed Inventors' Rights*, 35 ST. LOUIS U. L.J. 399 (1991).

180. See Brazilian Law No. 9279 of May 14, 1996, art. 91.

181. CODE DE LA PROPRIETE INTELLECTUELLE, art. L611-7, ¶ 2. The French Intellectual Property Code is available (in a searchable form), at <http://legifrance.gouv.fr> (last visited Jan. 4, 2005).

the final inventive result, and not from an inventive contribution. As the district court held in *Synbiotics*,<sup>182</sup> there is an essential difference between material contributions and inventive contributions. The latter leads to a share in the invention as co-inventorship, which was not the case at bar in *Synbiotics*. Nevertheless, material contributions may lead to a share in the patent, as compensation for the value of the contribution. This is an issue of civil law that is well settled in Civil Codes, under the term “right of specification”<sup>183</sup> or “right of accession.”<sup>184</sup> The general rule is that when a new material is obtained from the application of an intellectual contribution to a raw material in a manner that transforms it, the new material belongs to the person who made the modification. But when the raw material (or the original material) is acquired in bad faith, the property in the resulting material goes to the owner of the raw material. A general exception occurs when the value of the labor (or the intellectual contribution) is disproportionately higher than the value of the raw material—in this case the property right belongs to the person who made the modification, but the owner of the raw material is in any event entitled to compensation. Examples of labor that are assumed as having a disproportionately high value are painting, sculpture and writing (for example, the Brazilian and the Spanish Civil Codes) and

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182. See *supra* note 106 and accompanying text.

183. See, e.g., Civil Code of Brazil, Law No. 10.406, of January 10, 2002, arts. 1269–71. In Brazil, the right of specification is different from the right of accession in the sense that the latter does not apply to chattels. Other than that difference in terminology, Brazilian law follows the general principles adopted in European continental countries. The text of the new Brazilian Civil Code is available at <http://www.planalto.gov.br>.

184. See, e.g., Civil Code of France, as amended, arts. 565–74, available at <http://legifrance.gouv.fr>. The parallel of “right of accession” in common law is conversion. See *supra* note 107 and accompanying text. In *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990), the acquisition of rights in the invention through conversion was rejected because of the difference of nature between the act of supplying raw material and the act of inventing. See *supra* note 107 and accompanying text. Indeed, nothing justifies converting the act of supplying raw materials (even if accompanied with information based on observation) into an act of inventing. The right of accession is based on a different rationale—the rationale that, since it is impossible for the unauthorized user of the raw material to reduce it back to its natural state, compensation for the loss of property in the raw materials is paid in the form of attribution of property rights in the invention. Neither the provisions on employees’ inventions nor the Civil Codes attempt to substitute invention for supply of raw materials—to this extent, that rationale is the same rationale that the Supreme Court of California used in *Moore*.

artisanship (French Civil Code).<sup>185</sup> Of course, the law can stipulate otherwise, as in the case of the Brazilian Industrial Property Law (which assigns to the employer half of ownership of the patent, regardless of the value of both the materials used by the employee and the final value of the invention). The invention's final value has an impact only on the compensation to be paid for the exclusive license. Anyway, the controlling concept is intention. Was the bioprospector acting in good or bad faith? When national law contains rules on access to genetic resources, and the bioprospector willingly fails to notify the competent authorities of some collection made, bad faith may be presumed.

Likewise, national law can stipulate that where genetic resources have been incorporated into inventive outputs, the country that has provided the resources, and in the absence of a contract establishing otherwise (such as a contract of access to genetic resources), the invention is deemed to belong (partly or totally) to the national authority in charge of managing biodiversity resources. The rationale underlying such a provision would not be different from the rationale that underlies those provisions on employees' inventions mentioned above—or, for that matter, the provisions on the U.S. disclosure requirement concerning financial contributions by federal authorities.

Eventually, the person who, or entity which, by law, acquires a material interest in the invention (and, consequently, in the resulting patent rights), is entitled to renounce his/her rights and, consequently, seek the rejection of the claim or the invalidation of the patent granted. The point here is not one of opposing a patent application on grounds of failure to comply with a formal requirement: it is indeed a matter of *abandoning* a claim of proprietary rights and letting the subject matter of the claim fall into the public domain.

Would resorting to the doctrine of specification or of accession, under civil law, either in order to transfer title in inventions developed from genetic resources (and associated TK), or to seek the rejection of patent claims or the invalidation of patents, be acceptable

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185. See Civil Code of Brazil, art. 1270, § 2; French Civil Code, arts. 570–71, as amended by Law No. 60-464, of May 17, 1960; Spanish Civil Code, art. 377. The complete text of the Spanish Civil Code is available at <http://todoelderecho.com/SeccionInternacional/codigosjuridicos2.htm> (last visited Jan. 4, 2005).

under the TRIPS Agreement? The answer can only be yes, on three grounds.

First, the issue now being considered is not one of implementing the CBD—which, as explained above, is outside the scope of the TRIPS Agreement—but one of affirming proprietary rights in the output of the inventive use of genetic resources. As explained above, international treaties, implicitly or explicitly, do permit (if they do not require) the national laws to clarify proprietary interests in inventions. To some extent, that is not only a matter of tolerance, but also a crucial issue that speaks to legal security and predictability.

Second, the TRIPS Agreement does not stand in the way of WTO Members' rights of addressing proprietary interests of suppliers of material contributions and assessing their importance so as to evaluate the final stake of those suppliers in the final inventive output. Of course, no one could say that the U.S., the Brazilian, and the French provisions that give employers a material interest in inventions made by employees not hired to invent are TRIPS-inconsistent. Nor, for that matter, could one say that the rules on specification or accession of the Brazilian and French Civil Codes are TRIPS-inconsistent. Attributing proprietary rights or interests in the result of inventive uses of genetic resources is a matter of national law, and the TRIPS Agreement does not establish that only inventors are entitled to the patents. As explained before, the TRIPS Agreement is not about protecting *inventors*, but about protecting *investors*. Like the U.S. government, which contributes with financial resources, and employers, who contribute with materials and data (including raw materials), governments that contribute with genetic resources may have assigned to them by law proprietary interests in the inventions.

Obviously, the matter here is not contribution of the plants or animals or micro-organisms to the inventive output, but contribution of the genetic and biological information contained therein. It is that information that has been transformed or assimilated by the inventive contribution of the inventor. In this sense, given the unique value of such information, one should not take lightly that the economic value of genetic resources is minimal as compared to the final value of the invention—particularly when the invention does nothing else other than identifying pre-existing valuable properties or uses of the genetic resources.

Third, even where the contributor of genetic resources retains the right to oppose the grant of the patent or to obtain its invalidation, and thus the proprietary interest generates an issue of patentability as a supplementary aspect of the assignment of title, that is a reasonable formal requirement in the light of Article 62.1 of the TRIPS Agreement to the extent it stems from proprietary interests in the invention. Several national laws, indeed, contain provisions making it possible to invalidate a patent when the applicant had no just title to claim property rights.<sup>186</sup> The Requirement, under this new approach, is not different.<sup>187</sup>

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186. Several countries, in their responses to the WIPO questionnaire on the Requirement, have noted that aspect. See *Draft Study, supra* note 16, ¶¶ 70–71. If a country acquires, under this approach, a proprietary interest in the patent, would it be interested in promoting its invalidation? Probably not, in general. Actually, it may be the case under certain exceptional circumstances, such as when the patent claims properties of genetic resources and/or associated TK that present particular cultural or religious relevance to traditional communities. In that case, the government may prefer to let the invention fall into the public domain.

187. As noted above, both the UPOV Convention (in both versions) and the PCT would accept new requirements established on grounds of proprietary interests. That issue in the context of the PCT has been thus scrutinized by the WIPO Secretariat:

The PCT does not have a mechanism for a distinct declaration concerning source of GR/TK as a separate element of the form or content of an international application, or as an additional national requirement relating to the form or content of an international application. The PCT stipulates that it is 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.” This clearly applies to patentability of the invention as such. However, as has been noted several times above, the entitlement of the applicant to apply for and be granted a patent is also a matter of substantive law, distinct from the technical patentability of the invention as such, but potentially at least as important in terms of the ultimate ownership and exercise of the patent.

WIPO Doc. WO/GA/30/7/Add.1, ¶ 179. Of course, the provisions on the entitlement to apply for a patent cannot be found in article 27 of the PCT, because they are formal requirements (as explained above, they do not concern the invention itself). The provision in the PCT that allows countries to take measures concerning the identification of those who are entitled to apply for a patent (either because they are the inventors or because they are contractual or legal assignees of the right to apply for the patent) is article 9 (“The Applicant”). The result, nevertheless, is the same: the PCT does not stand in the way of national laws establishing the Requirement as a manner of identifying the person or entity legally entitled to apply for a patent on an invention directly or indirectly derived from genetic resources (or, for that matter, an invention funded with governmental resources). As far as the UPOV 1991 Convention is concerned, the permission for Contracting Parties to impose requirements concerning proprietary interests arises from the third indent of small roman (iv) of article 1 (on “Definitions”), which refers to the successor in title of the breeder or his/her employer. It is a matter for national law, therefore, to establish the conditions and terms under which succession in title occurs.

It goes without saying that, even where the Requirement is adopted as a condition of patentability in the context of the attribution of proprietary interests, its inconvenience may be the same as adopting it as a means of monitoring CBD compliance. The reason is that a shift in the purpose and the scope of the Requirement does not eliminate the complexity of proving use of a legitimately accessed genetic resource. The fact that the Requirement, if adopted as a means of establishing proprietary interests in patents and plant variety certificates, may be TRIPS-compliant, does not eliminate the problems of legal insecurity and unpredictability to which it gives rise.

#### V. A WORD OF CAUTION: THE LIMITED VALUE OF THE REQUIREMENT

It is not certain that the costs generated by the implementation of the Requirement correspond to the benefits society is able to extract therefrom.<sup>188</sup> Actually, not all costs arising from the implementation of the CBD can be internalized by society if they are not kept at a reasonable level.<sup>189</sup> On the one hand, when biosquatting is the result of the claim of private property rights in knowledge that is in the public domain (as in the turmeric patent) in foreign countries (which may have legislation that is more open to patentability in the biotechnology field), the losers of unwarranted claims are not the TK holders, but the granting countries' society at large. As a matter of law, TK in the public domain can be used by anyone for free. The misappropriation of TK permits biosquatters to put a higher price on

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188. To my best knowledge, the Requirement has never been applied in practice, that is, no patent application has been rejected and no patent has been invalidated because of failure to comply with the Requirement. However, where the Requirement is a condition of validity of patent rights, a situation of legal insecurity stems from its imposition because it may be alleged by third parties or the patent office *ex officio* at any time after the grant. Legal insecurity increases transaction costs and thus reduces the aggregated value of the output of enforcing and using patent rights.

189. See Rick Cannell, *Biodiversity's Incalculable Value*, FIN. TIMES, at 14 (July 21, 1998):

Bioprospecting is not always quite as immediately lucrative as some have been led to believe and nations (such as the Philippines) that are imposing strict costs and conditions on those who wish to carry out bioprospecting may be rendering their biodiversity too expensive to be of any use.

products and services that otherwise would be sold for less. Moreover, unduly patented traditional knowledge cannot be incorporated into products and services of squatters' competitors, thus blocking the development of competing derivatives. But squatting of traditional knowledge does not prevent its holders to continue using it in their daily life. When the preparation of traditional knowledge databases has no other purpose than opposing patent and trademark claims, and considering the high costs that such preparation entails, it may well represent a waste of resources. On the other hand, when biosquatters claim property rights in traditional knowledge which remains under the private control of indigenous peoples and traditional communities, the enactment of measures of positive protection, such as a *sui generis* regime, may be much more effective tools to correct and repress situations of misappropriation. In that event, traditional knowledge holders will be in a position of enforcing their rights—rights which are recognized, if not formalized, by law. Enforcement of intellectual property rights may not be a very simple and cost-free issue, but it is always more effective than challenging the validity of patents based on traditions (which are frequently undocumented) and customary law.

Moreover, an undue burden imposed on patent applications may create serious difficulties to the management of national and international patent systems and deviate the focus of the whole patent system from contributing to the progress of useful arts to the acknowledgement of third parties' stakes in claimed inventions. The transaction costs arising from uncertainties as to ownership of traditional knowledge, in the absence of an international system of its registration, would be enormous.<sup>190</sup>

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190. This same point was noted by the representative of a group of users in the Working Group on Reform of the PCT:

One representative of users stated that an essential feature of any national law requiring proof of having obtained prior informed consent would be a centralized procedure for showing that the requirement had been met. Without this, an alleged failure to obtain permission for use would become a standard attack in any country with such a provision. An applicant may have received consent from one source, but be attacked on the grounds that he should have sought permission from a different source. The consequence would be that fewer patent applications would be filed in these countries, resulting in there being no benefits for the applicant to share at all. Even if such systems were set up in countries with this type of legislation, it was

## VI. CONCLUSION: PATENTS ARE CERTIFICATES OF INVENTIVE BEHAVIOR, NOT GOOD BEHAVIOR

This Article has shown that the requirement to disclose the origin of genetic resources and prior informed consent in patent applications, as a formal condition of patentability aimed at monitoring compliance with the CBD, is not consistent with international obligations, in particular the TRIPS Agreement and the CBD itself. Because the debate on its adoption at the international level has led to the blockage of negotiations that might lead to increasing security in international patent protection, it has become a matter of urgency to identify mechanisms that permit biodiversity-rich countries to adopt the Requirement without infringing their international obligations, which could give rise to trade-related tensions, and yet keep the resulting encumbrances on patent procurement procedures at a reasonable level.

The Article has explained that a possible solution may lie in linking the granting of patents on inventions directly or indirectly derived from genetic resources with proprietary interests in the raw materials supplied—the so-called “right of accession” of civil law. That solution has two parallels in patent law: one is the possibility of employers to claim proprietary interests in the inventive output of employees (not hired to invent) where the latter have used data and materials that belong to the former; the other is the legal mechanism that ensures material interests of the U.S. government in inventions made with federal funding. The U.S. government is not necessarily entitled to property rights in the inventions in question, but it is nevertheless entitled to non-paid use and third parties may request compulsory licenses of those inventions. Under some special circumstances—both claims are, if not proprietary claims, at least material claims in property rights.

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pointed out that this would not help the case of inventions where the information was gained from a different country.

*See Summary of the Session, WIPO Doc. PCT/R/WG/5/13 (Nov. 21, 2003), ¶ 140; Cynthia M. Ho, Disclosure of Origin and Prior Informed Consent for Applications of Intellectual Property Rights Based on Genetic Resources: A Technical Study of Implementation Issues, Final report, July 2003, study commissioned by the Secretariat of the CBD, and distributed in document UNEP/CBD/WG-ABS/2/INF/2 of September 29, 2003 (available on the CBD website).*

Nevertheless, establishing the Requirement as a material claim by governments of countries from the territory of which genetic resources have been subtracted without permission is an issue of civil law, which does not change the essential thrust of the patent system: to attribute property rights in inventions (no matter who the owner is). The Requirement thus can be introduced so as to identify who that owner is—so that the patent is granted to whom the law indicates is the legitimate owner.<sup>191</sup>

Notwithstanding its eventual compliance with international obligations, the Requirement, if adopted as a condition of patentability, undermines the value of patents as effective means of securing property rights in inventions. The possibility of attacking the validity of those rights because of factors concerning conditions that are intrinsic to raw materials used, and extrinsic to the invention itself or to inventorship, would create unpredictability. Patents would lose much of their accuracy as reliable tools for measuring the invention's value, in particular in the biotechnology field, as their validity could depend on elements that have nothing to do with the invention. As said above, patents are certificates of *inventive* behavior, and is in that capacity that they perform their social function. If transformed into certificates of *good* behavior, patents cease being patents as such and become certificates of the origin of genetic materials. Incidentally, the validity of patents could also be scrutinized vis-à-vis the acquisition of other raw materials and research tools, and their purpose of securing intangible assets would necessarily become meaningless. Moreover, the Requirement, if established as a condition of patentability, does not promote benefit sharing: it simply generates information about the use of genetic resources and associated TK in the making of claimed inventions. Most patents fail to generate any economic revenue, particularly in the pharmaceutical industry, where patent applications are filed very early in the research process, and patent applicants are far away from obtaining a positive

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191. As explained above, in a very limited number of cases, governments (in principle eventually entitled to succeed a biosquatter in title) may prefer to invalidate the patents where the public outrage against some practices of biosquatting disallows maintaining them, even if the title is transferred to the rightful owners. Likewise, patent laws of several countries allow for the invalidation of patents when they are not granted to those legally entitled to apply, such as the true, first inventor. *See supra* note 185 and accompanying text.

commercial outcome. Thus, as a monitoring tool, the Requirement would give TK holders information about the existence of a patented invention only. It would not inform them about the commercial exploitation of that invention, let alone the financial gains of the patent owner. Moreover, one should not underestimate the difficulties of patent applicants in identifying the origin of genetic resources, the properties of which might have found their way into a claimed invention. The Requirement might prove impossible to meet in many instances, and therefore, it would only add to the already existing complexities of the patent system.

Patents are the recognition of an inventive activity, and not of the manner in which that activity has been pursued. So, if an inventor has access to a genetic resource in a way that contradicts the legislation and the national policy of a given country, sanctions may be imposed upon the inventor. But the new and useful result of his mental activity of inventing, although resulting from the use of that genetic resource, should nonetheless entitle him to the patent. To this extent, it can be said that patents are certificates of *inventive* behavior; patents are not certificates of *good* behavior.<sup>192</sup> For this reason, patents should not be used to assess the legitimacy of access to genetic resources or the fairness of the treatment of traditional knowledge holders by bioprospectors. That is not the function of the patent system.

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192. The representative of the United States said in the TRIPS Council that

with regard to the relationship between the TRIPS Agreement and the CBD, he said that the agreements could be implemented in a mutually supportive manner and that no conflict existed between them. Although he supported the objectives of the CBD, he did not favour using the patent system as a means to seek compliance with the CBD's provisions on prior-informed consent and benefit-sharing. It was the view of the United States that national systems outside patent laws were the most effective way to achieve these objectives. These regimes could have many components, including the use of permits, contractual obligations, and civil and/or criminal penalties. Patent laws were simply not intended, nor were they appropriate, to regulate misconduct, as they provided exclusive rights for a limited time in exchange for disclosures in order to further innovation. Misconduct, such as misappropriation of genetic resources, required direct regulations with enforcement by criminal or civil penalties.

*See Council Trade Related Aspects of Intellectual Property Rights—Minutes of Meeting—Held in Centre William Rappard on 18 November 2003*, ¶ 19, WTO Doc. IP/C/M/42 (Feb. 4, 2004), ¶ 109. The United States expressed the same view in the WIPO Working Group on the PCT Reform, *Summary of the Session*, ¶ 95, WIPO Doc. PCT/R/WG/6/12 (May 7, 2004).