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MEASURES, INCLUDING CONSIDERATION OF THEIR FEASIBILITY, PRACTICALITY AND COSTS, TO SUPPORT COMPLIANCE WITH PRIOR INFORMED CONSENT OF THE CONTRACTING PARTY PROVIDING GENETIC RESOURCES AND MUTUALLY AGREED TERMS ON WHICH ACCESS WAS GRANTED IN CONTRACTING PARTIES WITH USERS OF SUCH RESOURCES UNDER THEIR JURISDICTION

Disclosure of origin and prior informed consent for applications of intellectual property rights based on genetic resources: a technical study of implementation issues

Note by the Executive Secretary

1. The Executive Secretary is circulating herewith, for the information of participants in the second meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, a technical study commissioned by the Secretariat on the implementation issues related to disclosure of origin and prior informed consent for applications of intellectual property rights based on genetic resources. The study was prepared pursuant to the request of the Conference of the Parties in paragraphs 3 (c)-(f) of its decision VI/24 C and is intended to supplement the information contained on the subject in the note by the Executive Secretary on the role of intellectual property rights in access and benefit-sharing arrangements, including national and regional experiences (UNEP/CBD/WG-ABS/2/3).

2. The study is being circulated in the form and language in which it was received by the Secretariat.

* UNEP/CBD/WG-ABS/2/1.

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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

Prepared for the UNEP, Convention on Biological Diversity

Terms of Reference: COP Decision VI/24C, paragraph 3 (c) to (f)

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DISCLOSURE OF ORIGIN AND INFORMED CONSENT FOR APPLICATIONS OF INTELLECTUAL PROPERTY RIGHTS BASED ON GENETIC RESOURCES: A TECHNICAL STUDY OF IMPLEMENTATION ISSUES

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EXECUTIVE SUMMARY

This report is intended to provide an independent technical evaluation of the feasibility of implementing two additional disclosures to applications for intellectual property rights based upon genetic resources. In particular, this report considers the possible disclosure of (1) the country of origin of genetic resources (geographic origin) and (2) prior informed consent in obtaining the genetic resources (informed consent). The two requirements are discussed collectively as an "enhanced disclosure requirement," except when there are issues specific to the individual disclosures.

II. BACKGROUND

This report primarily addresses patent issues because patent rights provide the broadest protection and because patents based on unauthorized access to biological material have been a concern with regard to the aforementioned CBD goals. In addition, plant breeder rights (also sometimes referred to as PBR or plant variety rights) are also discussed.

There are three types of enhanced disclosure discussed in this report:

- ***optional*** requirement – pursuant to which noncompliance has no patent or other kind of impact because *no sanctions accrue*
- ***"mandatory"*** requirement – pursuant to which noncompliance has *no patent impact*, but may result in administrative, civil and/or criminal sanctions
- ***mandatory*** requirement – pursuant to which noncompliance results in a *loss of patent*

III. The INTERNATIONAL CONTEXT

Patent Rights

The most important agreements relating to patent rights are the TRIPS agreement, pursuant to the WTO, and the PCT agreement, under the auspices of WIPO.

TRIPS is of importance because it establishes minimum standards of intellectual property protection, such that any modification to intellectual property rights that arguably deviates from TRIPS could subject a WTO country to potential sanctions. A mandatory requirement (of an enhanced disclosure) for patentability would be most problematic because of its likely inconsistency with the minimum requirements for patentability under TRIPS. In addition, even an optional requirement might be problematic if it altered the examination of patents or resulted in discrimination as to field of technology. For completeness, this report also includes consideration of possible amendments to TRIPS, as well as a possible declaration/interpretation that might alleviate the inconsistency issue.

An enhanced disclosure requirement may also be inconsistent with the PCT. The PCT governs all international applications (in lieu of separate applications with each country in which a patent is desired) and requires that member states not make any modifications to the procedural requirements of international applications. Although the PCT governs the procedural requirements for these applications, it has no bearing on substantive patentability issues; national laws dictate substantive issues. Accordingly, a disclosure requirement that is considered a

procedural requirement for an application would be inconsistent with the PCT as it now stands. However, there is a proposed amendment to the PCT that may alleviate the inconsistency issue for optional enhanced disclosure requirements.

Plant Varieties

For plant varieties, the primary international agreement of relevance is UPOV. This agreement sets forth the criteria that all member states must use in issuing PBRs and also states that no additional requirements may be imposed. Therefore, a mandatory disclosure requirement would be in direct contravention with UPOV, while an optional requirement may be permissible.

IV. THE UTILITY OF ENHANCED DISCLOSURE FOR EXAMINATION OF IPR

One important initial issue for this discussion is that evidence of informed consent is unlikely to impact a substantive patent examination. In particular, the usual requirements that the invention constitute patentable subject matter, be new, contain an inventive step, and be useful are not directly related to whether information used in an invention was properly obtained. Although there may be additional laws that sanction improper access, the patentability analysis focuses solely on whether the invention claimed in the patent application – regardless of how it came into existence – satisfies the patent requirements.

An enhanced disclosure requirement would likely have the greatest impact in the patent examination process with respect to the patentability requirements of novelty and inventive step. These requirements, in turn, are based on national definitions of prior art. Prior art can be defined as pre-existing information that bars a patent, but is usually defined more narrowly to include only specific categories of information, such as patents, written publications, public use or sale. While the scope of prior art varies, no definition currently considers either component of the enhanced disclosure to be a specific type of prior art, although geographic origin may *lead to* prior art. In addition, in some countries, such as the U.S., prior art excludes the use of inventions outside the U.S., as well as oral information. So, to the extent that enhanced disclosure requirements would lead to such excluded information, there would still be no impact on the examination results.

Examiner capacity to consider additional information is also an important consideration in evaluating whether enhanced disclosure would facilitate examination. Patent applications are generally increasing, resulting in a heavy workload for examiners. In addition, some patent offices have taken steps to reduce the amount of examination time spent for each application. In light of these issues, it may be difficult for examiners to thoroughly consider/evaluate a new requirement for patentability. In addition, if examiners need to independently assess whether the disclosure is valid, that raises policy concerns that the patent office would be outside the scope of its competence. Moreover, such disclosures may be of limited utility to third parties in re-examination proceedings because the scope of such proceedings is limited.

Beyond the practical aspects of incorporating an enhanced disclosure requirement into patent laws, there are also some policy issues to consider. If enhanced disclosure requirements are considered to assist in the evaluation of whether applications satisfy the standards of novelty and inventive step, the requirement would seem consistent with policies for promoting innovation and increased knowledge, as well as for encouraging disclosure of relevant prior art information.

On the other hand, if examination of the disclosure requirement is considered to require an independent assessment of information outside the patent examiners' technical competency, there are policy issues that suggest the countries may be disinclined to adopt such a requirement. In addition, even if adopted, examiners may have difficulty evaluating a requirement perceived to be outside of the typical technical requirements of patentability.

V. FOSTERING ACCESS AND BENEFIT-SHARING THROUGH ENHANCED DISCLOSURE

The extent to which an enhanced disclosure requirement may foster access and benefit-sharing will necessarily depend on the parameters of the requirement. In general, a mandatory requirement (with corollary loss of patent rights) is probably of greatest utility. Only a mandatory requirement would seem to prevent the continued issuance of patents based on unauthorized access to genetic resources. However, one possible issue that may arise with the mandatory requirement is that potential patent applicants may elect to avoid the patent system altogether (and protect inventions through trade secrecy instead). In this case, patents would not issue, and the goals of access and benefit-sharing would not be fostered since inventions protected by trade secrecy are not available to the public.

An important consideration is that while enhanced disclosure may have the potential to improve benefit-sharing through some transparency, actual benefit-sharing is contingent on other factors. For example, a patent application does not guarantee commercial success. In addition, even if commercial success is attained, there may be multiple patents involved and additional negotiation will be required before any benefit-sharing results. A disclosure requirement might be considered more beneficial than no requirement at all for the negotiation process, although its actual utility is presently unknown.

The ability to facilitate access and benefit sharing may be limited by existing patent rules. Patent applications typically are not publicly accessible until eighteen months after filing, with additional information concerning the application (such as correspondence between the applicant and patent examiner) often not available until after the patent issues. In addition, the large volume of patent applications would make monitoring of these applications time-consuming. This is particularly true because every application (or patent) must be challenged individually throughout multiple countries and jurisdictions.

There are additional issues that exist for either geographic origin or informed consent. For example, an applicant may not be aware of the original geographic origin of biological material, thus potentially making it difficult to determine whether access was properly obtained. In addition, informed consent is presently a difficult requirement because many countries do not have systems for documenting or obtaining such consent; however, this issue is potentially addressed by the next section of the report which covers the possibility of an international certificate of origin system.

VI. THE FEASIBILITY OF AN INTERNATIONAL CERTIFICATE OF ORIGIN

An international certificate of origin is relevant to the extent that it may facilitate obtaining the requisite proof of origin or informed consent. There is no such present system in place. However, some models from the patent context, as well as permit systems outside the patent context, are evaluated. For example, patent analogs suggest either an amended form of existing

oath requirements for inventors to include an appropriate certification of origin and informed consent, or an independent international convention to specifically address the issue. The main difficulty with prior existing models of certificates of origin is that they all deal with tangible material to which a certificate or permit could constantly be accompanied. However, the nature of IPR involves intangibles. In addition, although IPR may be based on tangible genetic resources, not every genetic resource evolves into something that is protected by IPR, thus making a tracking system a difficult concept to implement.

VII. CONCLUSION

In addition to the foregoing issues mentioned, the report concludes with some additional issues to consider that may be relevant to the intended purpose of an enhanced disclosure requirement. In particular, expansion of both national and international definitions of prior art are raised as an additional method of enabling patent offices to consider information that might preclude the issuance of patents based on improper access to biological material. Also, an independent framework for requiring enhanced disclosure is raised as an issue to consider.

I. INTRODUCTION

1.0.1 This report is intended to provide an independent technical evaluation of the feasibility of implementing two additional disclosures to applications for intellectual property rights based upon genetic resources. In particular, this report considers the possible disclosure of (1) the country of origin of genetic resources (geographic origin) and (2) prior informed consent in obtaining the genetic resources (informed consent). Where appropriate, these two distinct types of disclosures will be discussed together as an "enhanced disclosure" requirement.

1.0.2 When considering the role of intellectual property rights in access and benefit-sharing arrangements, the Conference of the Parties in decision VI/24 "invites Parties and Governments to *encourage* the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources were granted." Furthermore, Decision VI/24C specifically requested that further work be undertaken to assess feasibility of disclosing both country of origin, as well as prior informed consent.

1.0.3 This report is part of such further study and in particular, provides an analysis of the following elements set out in decision VI/24C, paragraph 3, sub-paragraphs (c) to (f):

(c) The consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations

(d) Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications (including, but not limited to patents) and re-examination of intellectual property rights granted

(e) Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions (at the national level)

(f) Feasibility of an internationally recognized certificate of origin system as evidence of prior informed consent and mutually agreed terms.

1.0.4 To gather appropriate information upon which to base this report, official documents and reports from relevant international fora were considered.[1] In addition, reports and statements from non-governmental organizations,[2] industry groups,[3] and academics were also considered.

[1] Official reports, meeting minutes, and submissions from member countries within the context of the following international fora were considered: the Convention on Biological Diversity (CBD), the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the United Nations Conference on Trade and Development (UNCTAD), International Centre for Trade and Sustainable Development (ICTSD).

[2] For example, papers by the Center for International Environmental Law (CIEL) and the recently issued report of the Center for Intellectual Property Rights (CIPR) were reviewed. In addition, information was reviewed from Genetic Resources Action International (GRAIN), a non-governmental organization that "promotes the sustainable management and use of agricultural biodiversity based on people's control over genetic resources and

1.0.5 This report summarizes the information gathered and provides a technical analysis of each of the factors noted in Decision VI/24(C). To begin, Part II briefly sketches the rationale behind the origin of the enhanced disclosure requirement, including the relevant types of intellectual property rights indicated, as well as the possible parameters of an enhanced disclosure requirement. Part III then outlines the international framework that is implicated by the suggested disclosure and assesses whether such a disclosure would be consistent with international obligations. Part IV examines whether the suggested disclosure would assist in the examination of intellectual property rights on a national or regional level. Part V assesses whether the additional disclosure would effectively monitor compliance with the access provisions of the CBD. Part VI provides preliminary consideration of the feasibility of an international certificate of origin system as evidence of prior informed consent. Part VII concludes the report and provides additional issues for further consideration.

II. Background

2.1 A. Relevant Intellectual Property Rights

2.1.1 As necessary context to the discussion of a possible enhanced disclosure requirement, it is first important to consider the pertinent types of intellectual property rights. This report considers all applications for intellectual property rights based upon genetic resources.[4] The relevant intellectual property rights are patents,[5] as well as plant variety rights (sometimes referred to as plant breeder rights).[6]

2.1.2 Although patents, plant variety certificates, or both can protect genetic resources, patents generally provide more protection and are typically considered more commercially valuable.[7] In particular, patents typically provide their owners with near universal rights to exclude all others from the ability to make, use, sell, or import the patented invention. There is only a very narrow exception for experimental use. Plant variety rights, on the other hand, provide some limited exclusivity in the marketplace, but have explicit

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local knowledge." http://www.grain.org/about/index.cfm. In addition, the International Plant Genetic Resources Institute policy statements on intellectual property were considered.

[3] Representative industry group positions that were considered include: the International Chamber of Commerce (ICC), the International Association for the Protection of Intellectual Property (IAPPI), International Council of Chemical Associations (ICCA).

[4] The qualification that the project be limited to intellectual property rights requiring *applications* is an important one because not all such rights require applications. For example, applications are not required and in fact are contrary to the nature of trade secret protection.

[5] The term "patents" will be used in this report to refer to the most common type of patents, sometimes referred to as "utility" patents (as opposed to petty patents or design patents).

[6] The other two primary types of intellectual property – trademarks and copyrights – are not relevant to an enhanced disclosure requirement. Neither of these rights is typically linked to genetic resources. Copyrights involve protection of the expression of particular matter. Trademarks protect identifiers of goods or services used in commerce; unless genetic materials are sold in commerce under a specific name, trademarks would seem have to have any no relation to enhanced disclosure requirements.

[7] Patent applications typically exceed applications for plant variety protection. Mark Janis & Jay Kesan, *U.S. Plant Variety Protection: Sound and Fury . . . ?*, 39 HOUS. L. REV. 727 (2002) (providing history of the U.S. version of UPOV and noting that plant variety rights provided under this statute are economically insignificant); WIPO-UPOV Symposium on the Co-Existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developments, WIPO-UPOV /SYM/02/8 (Oct. 3, 2002).

exceptions that reduce the scope of protection. Moreover, plant variety protection by its very nature can only protect the plant varieties and not genetically engineered plants, or individual cells within genetically modified plants. Patents, on the other hand, can encompass almost any product that is humanly modified.

2.1.3 Because patents are the dominant type of intellectual property protection implicated by genetic resources, they will be given predominant weight in this report. Also, the patent systems of nations and regions with high volumes of patent applications will be given special attention, including the laws of the U.S., the EPC and Japan.

2.2 B. Rationale for An Enhanced Disclosure Requirement

2.2.1 A growing advocacy for an enhanced disclosure requirement appears tied to a number of factors including: (1) strengthening of intellectual property rights and patent rights in particular; (2) perception that patents based on biological material have been improperly issued, and (3) perception that countries and communities have been denied benefits that result from the use of their genetic resources and related knowledge in contravention of the CBD goals as well as general principles of equity.

Enhanced Intellectual Property Rights

2.2.2 On the international level, intellectual property rights have been undoubtedly strengthened by the landmark TRIPS agreement, which provides for minimum levels of intellectual property rights for all members of the WTO. The agreement is notable for requiring many countries to not only establish patent rights, but to also grant them to all subject matter (with limited exceptions), which in many cases is in contravention with historical norms.[8]

Improper Patents Based on Biological Material

2.2.3 In addition, the issuance of patents that are based on either indigenous knowledge or biological resources of diversity-rich countries – commonly referred to as "biopiracy"– has also fueled discussion for an enhanced disclosure requirement.

2.2.4 An example of how allegations of biopiracy arise is fairly easy to demonstrate. For example, consider a scientist from a multinational corporation who visits Country A where indigenous people tell him about a natural herb that has been used for centuries to promote healing. The scientist returns to his native country, which excludes entities found in nature from the definition of "new," but permits entities that are one-step removed from nature by a process of isolation or purification to constitute "new" compositions for patent purposes. The scientist purifies the herb and patents the super-concentrated herb with the same claimed utility that the indigenous people had informed him of, thereby essentially "pirating" the indigenous knowledge. This is in fact the situation that resulted in the Tumeric Patent – tumeric was widely known by indigenous

[8] *E.g.*, Carlos Correa, *Patent Rights*, IN INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENTS (Correa & Yusuf, eds. 1998).

communities in India for its wound healing properties, but nonetheless patented by the University of Mississippi Medical Center.[9]

2.2.5 Although some such patents have been successfully canceled, the enhanced disclosure requirement has been suggested as a method to limit the issuance of similar patents. For example, it has been suggested that disclosure of the country of origin could help patent examiners find relevant information to assist in determining whether patent requirements are satisfied.[10] In addition, certification of prior informed consent by those who provide genetic resources used in a patent application has also been suggested as helping to assist the determination of whether an invention deserves patent protection.[11]

Inequity

2.2.6 An enhanced disclosure requirement has also been suggested as a means to restore equity between those who provide biological resources and those who receive patents on either the identical resource, or something based upon the biological resource. The argument for equity is sometimes couched in terms of lack of informed consent by the country or people who provide the genetic resource. Alternatively, the equity argument is sometimes discussed in the context of the need to facilitate benefit sharing of resulting commercial rewards with the originators of the biological material.

2.3 C. Parameters of an Enhanced Disclosure Requirement

2.3.1 This section provides a brief overview of the possible implications of an enhanced disclosure requirement with respect to patentability to provide context for the technical feasibility issues that follow. This report will discuss three possible types of enhanced disclosure requirements (1) geographic origin only, (2) prior informed consent only, or (3) geographic origin and prior informed consent.[12]

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[9] U.S. Patent No. 5,401,504 (March 28, 1995). This patent was subsequently cancelled after the Indian government challenged the patent. However, it is notable that the patent was not cancelled based on the centuries of prior use in India. Rather, the challenge was successful on the more limited ground that there was a printed publication describing the traditional knowledge. The reason why prior use alone could not be a grounds for challenging the U.S. patent is further explained in Part IV of this report, in the context of explaining different national definitions of "prior art," as well as differing definitions of what is sufficiently "new" to merit patent protection.

[10] *See, e.g.*, The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403, Para. 4 (May 28, 2003) (noting that enhanced disclosure "would play a significant role in prevent biopiracy . . . and in some cases, prevent the issue of 'bad patents' awarded without due regard to the prior use and knowledge with regard to the resource"); Center for International Environmental Law, Comments on Improving Identification of Prior Art, p. 8 (Aug. 2, 1999) (advocating disclosure of country of origin as a means to help patent examiners find relevant prior art, including information that could establish 102(f) prior art).

[11] Center for International Environmental Law, Comments on Improving Identification of Prior Art, p. 9. Moreover, CIEL noted that the identification of those who gave prior informed consent could assist an examiner in obtaining further information, if necessary. *Id.*

[12] These are the types of disclosures covered by the terms of this report. However, some have advocated the additional requirement of proof of benefit-sharing. *E.g.*, The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, Communication from Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356 (June 24, 2002).

2.3.2 The relation between any new disclosure requirement and existing IP rights can be viewed according to the implications of noncompliance with the requirement. In particular, noncompliance can result in three basic possible outcomes: (1) no impact or penalty (optional disclosure), or (2) no impact on patent rights, but penalties through administrative, civil or criminal sanctions (required, but no patent impact), or (3) a total loss of patent rights (mandatory disclosure).

Optional Disclosure – no penalty

2.3.3 One possibility is for enhanced disclosure to be an option for the applicant. Essentially, the disclosure would be encouraged, but not required for patent rights.[13] This is most similar to the present situation since present patent laws permit an applicant to note the origin of genetic resources upon which the patent application is based, but there is no explicit requirement.[14]

2.3.4 The EU Directive on the Legal Protection of Biotechnological Inventions provides an example of an optional disclosure requirement.[15] In particular, recital 27 states that:

2.3.5 "if any invention is based on biological material of plant or animal origin, or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material if known; whereas this is *without prejudice to the processing of the patent applications or the validity of rights* arising from granted patents."[16]

"Mandatory," but no patent-related penalty

2.3.6 Another possibility is for the enhanced disclosure to be "mandatory" in the sense that it is required, but with no patent-based sanction for noncompliance. In this case, failure to comply with the enhanced disclosure would not bar patentability or enforceability of a patent. Rather, noncompliance would result in monetary fees, civil or administrative sanctions, or even criminal penalties.[17]

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[13] A recent WIPO report referred to this possibility as "in effect, a political exhortation" and suggested that the Bonn Guidelines actually fell within this category. Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, Document Prepared by the Secretariat, WIPO/GRTKF/IC/5/10, at 50 para. 131 (May 2, 2003).

[14] In fact, there are examples of cases where patent applicants have voluntarily disclosed the geographical origin of biological resources upon which the invention is based. Patents Using Biological Sources Material (I) and Mention of the Country of Origin in Patents Using Biological Source Material (II), Document submitted by the Delegation of Spain, WIPO/GRTKF/IC/2/15 (Dec. 13, 2001).

[15] Moreover, because EU directives are not directly binding on member states, there is flexibility in whether this encouragement must even be incorporated into national law. In particular, this recital has no equivalent among the affirmative articles of the Biotech Directive and there appears to be some disagreement as to whether the recitals must be incorporated into member states' laws. *See, e.g.*, Geertrui van Overwalle, *Belgium goes its Own Way on Biodiversity and Patents*, 2002 EIPR 233, 233 (noting that some believe recitals to be not legally binding on national authorities, whereas others believe that recitals are in fact binding unless there are valid overriding considerations recognized by EC law for non-implementation).

[16] Council Directive 98/44 on Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 [EU Biotech Directive].

[17] WIPO/CRTFK/IC/5/10, Annex I, pages 25-26, para. 70-71. Some countries consider this more

Mandatory for Patentability or enforceability

2.3.7 The final possibility is that noncompliance with an enhanced disclosure requirement would be directly linked to patent rights. In particular, failure to comply would result in a bar to patentability or a subsequent loss of patent rights.

2.3.8 First, the enhanced disclosure requirement could be an additional requirement for patentability, such that noncompliance would bar patent issuance. The requirement could be independently verified by examiners, such as current substantive requirement that a patent application adequately disclose the invention. Alternatively, the requirement could be a pre-requisite to patent examination, with applications being returned where there is noncompliance with the disclosure requirement.[18]

2.3.9 Second, the enhanced disclosure requirement could be an issue only when the patent is enforced. This would not impact current examination procedures. One commentator has suggested that this is a judicially equitable solution. [19] Although this proposal is based upon U.S. laws on inequitable conduct; no countries presently have laws that reflect this suggestion.[20]

2.3.10 A final option is that the enhanced disclosure requirement could be both a requirement for patentability, as well as an issue that could result in loss of patent rights during subsequent proceedings if noncompliance were later discovered. In this situation, the enhanced disclosure requirement would function like traditional elements of patentability (such as novelty or inventive step), which can bar a patent from issuing, or be utilized to cancel invalid patents. India's most recent amendment to its patent laws reflect this option by providing additional grounds for revocation, including the fact that an applicant did not disclose or wrongly disclosed the geographical origin of biological material used in the invention.[21]

2.3.11 Which type of disclosure, if any, a country elects is likely to be based upon a variety of factors, including consistency with international legal obligations, as well as national law and policy, both of which will be discussed in subsequent sections.

III. THE INTERNATIONAL CONTEXT FOR A POSSIBLE ENHANCED DISCLOSURE REQUIREMENT

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appropriate than making patentability contingent on disclosure because of a perceived weak link between the disclosure and the requisite elements of patentability. Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore: "A Concept Paper," Communication from the European Communities and Their Member States, IP/C/W/383, para. 55 (Oct. 17, 2002).

[18] Graham Dutfield, *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation*, at 25 (Oct. 2002), *available at* http://www.ictsd.org/iprsonline/unctadictsd/docs/Dutfield2002.pdf.

[19] 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, 394-96 (2000).

[20] *Id.* at 396-99.

[21] India Patent Act, section 25 (Second Amendment 2002).

3.0.1 International legal obligations provide an important context because nations that might consider enacting an enhanced disclosure requirement may nonetheless are bound by pre-existing international obligations.[22] This Part considers the international agreements relating to patents and plant variety protection -- the two primary methods of protecting intellectual property relevant to this report. Accordingly, it is necessary to determine whether a national enhanced disclosure requirement would conflict with any of these agreements.

3.1 A. Patents

3.1.1 Although patents are granted on a national basis, nations who are members of international agreements must align their national laws with these agreements. A table of membership in these respective agreements is provided as Appendix A.

3.1.2 This section first discusses international obligations that are relevant to national patent applications under TRIPS, followed by obligations relevant to procedures for filing "international" patent applications under the PCT.[23] Both international agreements need to be considered because patent applications can be filed through more than one method and either the PCT, TRIPS, or both may govern.[24] In addition, consistency with potential international requirements, including amendments to TRIPS and the PCT, as well as the possible enactment of the Substantive Patent Law Treaty (SPLT) will be discussed.

3.1.3 1. TRIPS

3.1.4 This section first highlights the relevant provisions of TRIPS, the core framework of present patentability and patent rights for all member states of the World Trade Organization (WTO), with a primary focus on the original TRIPS text.[25] After setting forth the basic framework, the relevant patent provisions will be further analyzed to determine consistency with an enhanced disclosure requirement.[26]

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[22] In addition, because there are several international agreements to which many member states are presently parties, an initial review of the international context provides a useful vehicle to consider the possibility of an enhanced disclosure requirement for all countries that subscribe to these international agreements.

[23] TRIPS is discussed first because it is presently the only international agreement that sets forth the minimum substantive criteria of patentability (together with some related procedural issues), whereas the PCT is solely limited to procedural issues involving the filing of international patent applications.

[24] A patent applicant may have multiple routes for filing a patent application, as explained in further detail in the next Part of this report. One method is to file directly with the national patent office of the country where a patent is sought. However, a popular alternative is to file an international patent application under the Patent Convention Treaty (PCT).

[25] The WTO currently comprises 146 member countries, including 139 countries who are also members of the CBD. The CBD actually has a wider/broader net of membership; there are presently 187 member countries. Current membership information on the WTO is available at www.wto.org/english/thewto_3/whatis_e/tif_e/org6_e.htm, whereas membership information for the CBD is available at www.biodiv.org/world/parties.asp.

[26] Where applicable, prior WTO panel decisions concerning relevant provisions of TRIPS will be incorporated into the analysis of TRIPS consistency. Technically, these panels can not change the scope of requirements under TRIPS. Understanding On Rules And Procedures Governing The Settlement Of Disputes, Annex 2 of the WTO Agreement, art. 3(2), *available at* http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm (noting that "[r]ecommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements [including TRIPS]"). However, when WTO panels interpret TRIPS provisions,

3.1.5 **a. Overview of Current TRIPS Requirements**

Any Invention May be Patentable – Nondiscrimination Requirement

3.1.6 The fundamental principle of the patent provisions under TRIPS is that patents are generally available for all *inventions*, without regard to the type of invention, or field of technology.[27] Although TRIPS does not define what an "invention" is – leaving that to national law – TRIPS clearly establishes that countries can not discriminate against the patentability of inventions in certain areas.[28]

Patentability Criteria and Patent Application Requirement

3.1.7 TRIPS also establishes patentability criteria for the invention, as well as criteria for the patent application. The substantive patentability criteria that an invention must satisfy are that they be "new, involve an inventive step and be capable of industrial application."[29] In addition, TRIPS establishes one criterion for patent applications – that the application "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[30]

Additional Permissible Criteria?

3.1.8 In addition to the foregoing explicit criteria, TRIPS permits nations to impose some additional requirements. In particular, article 62(1) allows member states to "require, as a condition of the acquisition or maintenance" of patent rights provided under TRIPS, "compliance with reasonable procedures and formalities." However, any such formalities must be consistent with the TRIPS agreement as a whole, which has been interpreted to require such formalities to be nondiscriminatory with respect to subject matter in accord with TRIPS article 27(1).

Summary of TRIPS Patent Provisions

3.1.9 A summary of the TRIPS provisions that are directly related to the acquisition of patent rights are included in the following table. The table uses the exact language from TRIPS – the starting place for any analysis of TRIPS compatibility – with highlights of some notable language:

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those interpretations are generally considered authoritative. *E.g.*, Raj Bhala, *The Myth About Stare Decisis and International Trade Law*, 14 AM. U. INT'L L. REV. 845 (1999) (noting that panel decisions effectively serve as precedent for further reports even though they technically only bind the actual parties to the dispute); Paul B. Stephan, *Sheriff or Prisoner? The United States and the World Trade Organization*, 1 CHI. J. INT'L L. 49 (2000) (noting that WTO decisions constitute legal authority).

[27] Although TRIPS does provide some limited exceptions, there is a general presumption of patent availability for inventions. TRIPS, art. 27.

[28] TRIPS, art. 27.

[29] TRIPS, art. 27.

[30] TRIPS, art. 29.

TRIPS Requirements Relevant to Patent Applications		
Art. 27(1)	Patentable Invention – substantive reqmts	[Subject to specific exceptions] "*Patents shall be available for any inventions*, . . that . . . are ***new, involve an inventive step and are capable of industrial application.***"
Art. 27(1)	Nondiscrimination Requirement	"*Patents shall be available for any inventions*, whether products or processes, in all fields of technology,, . . . "Patents shall be available . . . ***without discrimination as to . . . the field of technology***."
Art. 29(1)	Patent Application Requirements	"Members shall require that an applicant for a patent ***disclose the invention*** in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."
Art. 62	Additional Formalities	"Members **may** require, as a condition of the acquisition or maintenance of the intellectual property rights provided for . . . ***compliance with reasonable procedures and formalities***. Such procedures and formalities shall be ***consistent with the provisions of this Agreement***."
Art. 29(1)	***Optional*** Patent Application Requirements	"Members . . . **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." "Members **may** require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants."

3.1.10 **b. Consistency of Enhanced Disclosure with TRIPS**

3.1.11 An important initial note is that TRIPS compliance may be contingent on whether enhanced disclosure is mandatory for patentability. Because TRIPS is considered to be an absolute minimum below which member states can not fall, patents *must* issue if they satisfy the requirements of TRIPS (unless TRIPS specifically permits an exception).[31] Accordingly, if an enhanced disclosure requirement would bar the issuance of patents that presently satisfy the TRIPS criteria, there would seem to be an inconsistency.[32] If the disclosure requirement were *optional*, such that it did not impact patent examination, the inconsistency problem could be avoided. The remainder of this section analyzes TRIPS consistency, assuming that enhanced disclosure is *mandatory* for patentability.

3.1.12 **(i) Art. 29 -- Patent Application Disclosure Requirement**

3.1.13 Article 29 is pertinent to any requirement involving patent applications since this is the only provision of TRIPS that explicitly mentions requirements for patent applications. As noted earlier, article 29 only requires that the invention be sufficiently disclosed to be carried out by another person of "skill in the art."

[31] Nuno Pires de Carvalho, THE TRIPS REGIME OF PATENT RIGHTS, at 154 (2002) [hereinafter TRIPS REGIME OF PATENT RIGHTS] (noting that the "plain language" of TRIPS article 27(1) precludes member states from utilizing any substantive criteria for rejecting applications other than those provided in TRIPS).

[32] Dutfield, *supra* note 18, at 25.

3.1.14 Neither component of an enhanced disclosure requirement would typically be necessary to comply with article 29. For example, disclosure of geographic origin would not be necessary unless the only way to carry out a specific invention was to use a biological resource that is only available in a specific country.[33] The disclosure of prior informed consent is similarly not required to adequately describe the invention.[34]

3.1.15 Whether an enhanced disclosure requirement is consistent with article 29 depends primarily on whether article 29 permits requirements to applications other than those that are specified.[35] Article 29 specifically notes only two "optional" requirements that are considered permissible -- disclosure of best mode may be required, as well as priority for applications. This suggests that any other requirement not mentioned, such as an enhanced disclosure requirement, would not be permissible if it resulted in the denial of a patent application that complied with TRIPS requirements.[36]

3.1.16 **(ii) Art. 27 -- Patentability Requirement**

3.1.17 There is an argument that an enhanced disclosure requirement is inconsistent with TRIPS because it impacts the substantive criteria for examining patents and that because it is not a requirement currently specified under TRIPS articles 27, there is a clear inconsistency.[37]

3.1.18 **(iii) Art. 62(1) -- Reasonable Procedure and Formality**

3.1.19 Another relevant provision regarding TRIPS consistency is article 62(1), which allows some flexibility to member countries in requiring "reasonable procedures and

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[33] However, in many cases, including cases of patents based on unauthorized access to biological material, the new invention can be adequately explained in terms of its chemical composition, without reference to the original source. One example is the "Hoodia patent," so-called because the patent claims a process for obtaining the active ingredient of a hoodia patent, as well as its use in the manufacture of drugs having appetite suppressant activity. Pharmaceutical compositions having appetite suppressant activity, PCT International Publication No. WO/98/46243. The patent applicants learned about the hoodia plant through indigenous people in the Kalahari Desert who knew about the plant, as well as its natural ability to minimize hunger and thirst. The patent applicants utilized this knowledge to perform some research that resulted in the claimed patent.

[34] One commentator analogized the situation of patents based on unauthorized access to biological material to someone who steals a composition, reverse engineers it and further improves it to obtain a new and improved patent. Under this scenario, the new compound is probably patentable, but the inventor might violate criminal laws for stealing the original composition. TRIPS REGIME OF PATENT RIGHTS, *supra* note 31, at p. 159, para. 27.25.

[35] 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, Submission by the European Communities, WT/CTE/W/223, para. 46-48 (Feb. 14, 2003).

[36] *Id*.; Minutes of Meeting, Representative of Japan, IP/C/M/29, para. 155 (Mar. 6, 2001) ("…if the proposed requirement was not sought for the purpose of ensuring sufficient disclosure enabling a person skilled in the art to "carry out" the invention, it would be an additional requirement and go beyond the scope of Article 29.1").

[37] *See, e.g.,* Review of the Provisions of Article 27.3(b) – Japan's View, Communication from Japan, IP/C/W/236, pp. 7-8 (Dec. 11, 2000) (stating it is unclear how disclosure is related to optional exclusions from patentability under 27.3(b) and such an obligation goes beyond "the obligation of Members under the TRIPS Agreement"); Submission by the European Communities, WT/CTE/W/223, para. 55 (Feb. 14, 2003) (stating that a disclosure requirement should not act as a substantial patentability criterion or adversely affect the validity of a patent); Review of Article 27.3(b), Communication from Australia, IP/C/W/310, para. 10 (Oct. 2, 2002) (stating that Article 27 deals with thresholds for patentability and optional exclusions, an amendment would be more appropriate under Article 29).

formalities" attendant to the acquisition or maintenance of patent rights, provided that these procedures and formalities comply with the nondiscrimination requirement.

3.1.20 The first question is whether enhanced disclosure requirement could be considered a "reasonable procedure or formality." This term is not defined within TRIPS, but in the WTO panel decision Canada – Patent Term for Protection, the panel suggested that for procedures to be reasonable, they must be "*tied to valid reasons required to ensure a proper examination."*[38]

3.1.21 Accordingly, the next question is whether enhanced disclosure is sufficiently tied to proper patent examination, such that the requirement is "reasonable." It should be noted that information which does not assist patent examiners assess these criteria would be impermissible.[39] Whether geographic origin or informed consent assist examiners with these criteria is discussed in further detail in Part IV(A)(1).

3.1.22 A final issue is whether such a disclosure requirement would be discriminatory. Some commentators and countries have suggested that because an enhanced disclosure requirement is proposed only for inventions based upon biological resources, such a requirement would be discriminatory with respect to biological material.[40] Other countries have suggested that there is no discrimination unless the patentability criteria under article 27 (novelty, inventiveness and utility) are applied differently to different fields of technology.[41]

3.1.23 A useful source for interpreting the nondiscrimination requirement is the WTO panel decision in the case Canada-Patent Protection of Pharmaceutical Products,[42] which found no discrimination where the language of the contested statute was neutral, Canada asserted that it was not limited to one particular field of technology, and there was no systemic evidence regarding differential treatment among industries.[43] Despite the fact that there was some suggestion prior to enactment of the contested provision that the primary reason was to benefit the pharmaceutical sector, the Panel noted that "[s]o long as the broader application is not a sham, the legislation cannot be considered discriminatory."[44]

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[38] Canada – Term of Patent Protection, Report of the Panel, WT/DS170/R, at 6.115 (May 5, 2000) (emphasis added).

[39] TRIPS REGIME OF PATENT RIGHTS, *supra* note 31, at 155 para. 27.21.

[40] *See, e.g.*, TRIPS REGIME OF PATENT RIGHTS, *supra* note 31, at 155, para. 27.22 (noting that to limit a disclosure of origin requirement to "the area of biotechnological inventions is an act of discrimination as to the field of technology, under 27.1"); Minutes of Meeting, Representative of Japan, IP/C/M/29 (Mar. 6, 2001) (noting that an invention in the area of biological resource could be considered a specific type of technological field in contravention with the nondiscrimination requirement of article 27.1).

[41] The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403, para. 10 (June 24, 2003).

[42] Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R (March 17, 2000).

[43] WT/DS114/R, para 7.99-7.105 (finding no *de jure* or *de facto* discrimination).

[44] WT/DS114/R, para 7.104. An enhanced disclosure requirement could apply not only to genetic resources, but also to all technology that is derived or based upon resources or knowledge from another country. In fact, there have been proposals that the enhanced disclosure requirement should also cover use of traditional knowledge. *E.g.*, Proposal on Protection of the Intellectual Property Rights of the Traditional Knowledge of Local

3.1.24 **(iv) Articles 7 & 8**

3.1.25 Lastly, there is an argument that an enhanced disclosure requirement is supported by TRIPS articles 7 and 8.[45] The Doha Public Health Declaration recently noted that all TRIPS requirements should be read "in light of" articles 7 and 8.[46] Some countries have specifically cited article 7 in support of an enhanced disclosure requirement, based on the argument that such a requirement would assist in ensuring that IPR "should contribute to . . . social and economic welfare."[47] In addition, an enhanced disclosure requirement could also be consistent with article 8 because article 8(1) notes that members may "adopt measures . . . to promote the public interest in sectors of vital importance" as well as to "prevent the abuse of intellectual property rights."[48]

3.1.26 **c. Consistency of Enhanced Disclosure with Proposed Amendments**

3.1.27 **(i) TRIPS**

3.1.28 There are a number of amendments that have been formally proposed to the TRIPS Council relating to an enhanced disclosure requirement. This section both outlines the details of the proposals, as well as the likelihood of an actual amendment. In addition, this section considers whether some action short of an actual TRIPS amendment would be useful in clarifying the consistency of an enhanced disclosure requirement with TRIPS.

Proposed Amendments

3.1.29 Specific amendments to TRIPS have been suggested with respect to two different articles. The first suggestions to amend TRIPS to include an enhanced disclosure requirement targeted article 27(3), in the context of a review of article 27(3).[49] More

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and Indigenous Communities, Communication from Cuba, Honduras, Paraguay and Venezuela, IP/C/W/166 (Nov. 5, 1999).

[45] The argument that the enhanced disclosure requirement is *consistent* with these provisions should not be confused with the fact that these provisions *alone* would provide inadequate support since no WTO panel has ever found these provisions to constitute free-standing exceptions to TRIPS requirements.

[46] Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001, WT/MIN(01)/Dec/2, para. 5(a) (Nov. 20, 2001). There is an issue as to the precise legal status of this declaration. *E.g.*, James Thuo Gatthi, *The Legal Status of the Doha Declaration on TRIPS and Public Health*, 15 HARV. J.L. & TECH. 291 (2002); Paul Vandoren, *Clarification of the Relationship between TRIPS and Public Health Resulting from the Doha Ministerial Declaration*, 5 J. WORLD. INTELL. PROP. 5 (2002) (suggesting that Doha declaration can be used as "evidence" in interpreting TRIPS).

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

[48] TRIPS REGIME OF PATENT RIGHTS, *supra* note 31, at 159, n. 445 (noting that implementing the CBD constitutes a type of public interest consistent with TRIPS article 8 and that enforcing patent rights that are based on unauthorized genetic resources can be considered abusive).

[49] Review of Article 27.3(b), Communication from Brazil, IP/C/W/228, para. 25, 27 (Nov. 24, 2000); Preparations for the 1999 Ministerial Conference, Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda, WT/GC/W/355, para. 28 (Oct. 11, 1999). The TRIPS agreement provides that article 27(3)(b) -- the provision regarding the permissible exclusion of plants and animals other than micro-organisms, as well as the mandatory protection of plant varieties,

recently proposals have been based on article 29.[50] The following table summarizes the proposed amendments, together with their supporters:

Summary of Amendments to Specific TRIPS Provisions		
Proposed Amendment	Supporters	Relevant Docs
Amend article 27(3) to "include the possibility of members requiring, *where appropriate*, as condition to patentability: (a) the identity of the source of the genetic material; (b) the related traditional knowledge used to obtain the material, (c) evidence of fair and equitable benefit sharing; and (d) evidence of prior informed consent … for the exploitation of the subject matter of the patent.[51]	Brazil	IP/C/W/228, (11/24/00)
Amend Article 27(3)(b) "in light of provisions of the CBD"	Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka, Uganda	WT/GC/W/355 (10/11/99)
Amend article 29 to mandate "clear mention of biological source material and the country of origin"	India African Group Norway	IP/C/W/195 7/12/00 IP/C/W/404 (06/26/03) IP/C/M/39 (03/21/03)

3.1.30 In addition, some suggestions to amend TRIPS are not stated as concrete proposals of actual TRIPS text. For example, some proposals only broadly suggest the idea of an amendment to TRIPS to prevent the granting of patents "incompatible with CBD," but without specifying an article of TRIPS that would be amended.[52] Other proposals suggest

albeit not necessarily under patent protection -- would be reviewed "four years after the date of entry into force of the WTO Agreement." TRIPS art. 27(3)(b).

[50] Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, Joint Communication from the African Group, IP/C/W/404 (June 26, 2003); Minutes of Meeting, Representative from Norway, IPC/M/39 (March 21, 2003). In addition, India initially suggested a similar article. Communication from India, IP/C/W/195, para. 16 (July 12, 2000).

[51] In addition, GRAIN provides a complete chart of country positions and proposals on TRIPS Article 27.3(b), that includes suggested amendments to TRIPS, as well as oppositions to any changes. *See* Official Country Positions and Proposals on TRIPS Article 27.3(b), *available at* www.grain.org/publications/trips-article-273b-en.cfm (Updated June 2003).

[52] Communication From India, IP/C/W/195 (July 12, 2000) (stating that TRIPS is incompatible with CBD and that a provision is needed to ensure that patents inconsistent with CBD art. 15 are not granted); The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, Communication from Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356 (June 24, 2002) (stating that TRIPS and CBD should be mutually supportive and that a modification to TRIPS is necessary to ensure this); The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, IP/C/W/356/Add.1 (11/01/02) (requesting that Peru be added to list of sponsors of IP/C/W/356).

some type of multilateral rules to protect rights to traditional knowledge, without further specification.[53]

Likelihood of an Actual TRIPS Amendment

3.1.31 A formal amendment to TRIPS to clarify that an enhanced disclosure requirement is TRIPS compatible is possible, but depends on the voting requirements for formal amendments.[54] In addition, the likely success of an amendment may be contingent on the provision of TRIPS under which amendment is sought. Some countries have been strongly opposed to an amendment of article 27 to include an enhanced disclosure requirement on the ground that the requirement is not and should not be a condition of patentability.[55] Similarly, some countries are opposed to amending article 27(3) to include an enhanced disclosure requirement on the grounds that review of this provision of TRIPS does not include enhanced disclosure.[56]

Amendment Alternative: A Disclosure Declaration

3.1.32 An alternative to a formal amendment is some type of declaration that an enhanced disclosure requirement is consistent with TRIPS. The Doha Public Health Declaration provides a recent model of a declaration to clarify that national action to address epidemic health crises would be considered consistent with a compulsory licensing exception to patent rights under TRIPS.[57] In fact, one group of countries has suggested some type of WTO decision to clarify TRIPS compatibility for an enhanced disclosure requirement.[58] In addition, the TRIPS Council has been specifically mandated to consider the general compatibility of the CBD and TRIPS.[59]

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[53] Review of the Implementation of the Agreement Under Article 71.1, Communication from Cuba, Honduras, Paraguay and Venezuela, IP/C/W/166 (Nov. 5, 1999) (suggesting negotiations to "establish multilateral rules to accord effective moral and economic intellectual property rights to traditional knowledge, medicinal practices and expressions of folklore and take into account the social and collective nature of these rights" and to incorporate such rules into TRIPS by 2004).

[54] WTO agreement art. X (requiring two-thirds vote to amend TRIPS provisions).

[55] *E.g.*, Communication From the European Communities and Their Member States, Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore: "A Concept Paper," IP/C/W/383, para. 48, (Oct. 17, 2002) (stating that the making patentability subject to a disclosure requirement "constitutes a clear step beyond the current provisions of the TRIPS Agreement"); Minutes of Meeting, Representative of Canada, IP/C/M/37/Add.1, para. 232 (Nov. 8, 2002).

[56] *E.g.*, Communication from Australia, Review of Article 27.3(b), IP/C/W/310 (Oct. 2, 2001) (noting reservations about any proposed amendment to article 27.3(b), and further noting that if an amendment were made, article 29, rather than article 27 would be appropriate); Minutes of Meeting, Representative of Switzerland, IP/C/M/29, para. 178 (Mar. 6, 2001) (noting that any issues other than the ones explicitly stated within TRIPS article 27.3(b) were necessarily beyond review).

[57] Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001, WT/MIN (01)/DEC/2, pmbl (Nov. 20, 2001); Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, Ministerial Declaration on the TRIPS Agreement and Public Health, IP/C/W/312 WT/GC/W/450 (Oct. 4, 2001).

[58] Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, Joint Commission from the African Group, IP/C/W/404 (Annex) (June 26, 2003) (containing a draft decision on traditional knowledge). However, this draft decision goes beyond the scope of this report in arguing that any patents inconsistent with the CBD, including patents based on traditional knowledge should be invalid.

[59] Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001,

3.1.33 **(ii) SPLT**

3.1.34 The Substantive Patent Law Treaty (SPLT) is presently under negotiation and discussion under the auspices of WIPO. If this draft treaty is concluded, it could pre-empt TRIPS as an agreement that specifies substantive criteria of patentability because TRIPS does not inherently define the scope of the substantive criteria it requires. SPLT is aimed at establishing uniform standards on the criteria of substantive patentability, sufficient disclosure, grounds for refusal of an application, and revocation or invalidation of a patent.[60]

3.1.35 The SPLT, if enacted, could be consistent with an enhanced disclosure requirement. In fact, recent negotiations on the SPLT have included discussion of a specific SPLT provision to clarify that national laws requiring enhanced disclosure would be permissible under the SPLT. In particular, a November 2002 proposal notes: "A contracting party *may* also *require compliance with the applicable law on* public health, nutrition, ethics in scientific research, environment, ***access to genetic resources***, protection of traditional knowledge and other areas of public interest in sectors of vital importance for their social, economic and technological development."[61]

3.1.36 **2. PCT/PLT: International Applications**

3.1.37 Although TRIPS sets forth important standards with respect to substantive patent law, the Patent Cooperation Treaty (PCT) is also relevant in the international context. In particular, the PCT provides a popular streamlined procedure for applicants who wish to file a single "international" patent application with PCT member states, in lieu of filing applications with each national patent office.[62] The Patent Law Treaty (PLT), adopted by the WIPO, but not yet in force, also applies to international applications and is intended to complement the PCT.[63]

3.1.38 **a. Current Requirements under the PCT**

3.1.39 PCT and the PLT provide the framework for procedural requirements with respect to international applications. The PCT sets forth all the components of a complete international application, which are primarily requirements of form, but also require a

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WT/MIN (01)/DEC/1, para. 19 (Nov. 20, 2001) (instructing the TRIPS Council to consider the relationship between TRIPS and the CBD for the protection of traditional knowledge and folklore and other relevant new developments raised by members pursuant to the review of Article 27.3(b), as well as article 71.1).

[60] *E.g.*, Study on the Interface between the SPLT, the PLT and the PCT, WIPO, SCP/6/5 paras. 13 (Sept. 24, 2001); Draft Substantive Patent Law Treaty, prepared by the International Bureau, WIPO, SCP/9/2 articles 3-14 (Mar. 3, 2003).

[61] Draft Substantive Patent Law Treaty, prepared by the International Bureau, WIPO, SCP/9/2 article 13(2); 14(2) (Mar. 3, 2003) (grounds for refusal or invalidation of a patent) (emphasis added); *see also id.* art. 2(2)-(3) (providing proposed general exceptions to the SCP agreement). However, further substantive discussion of this language is postponed as of March, 2003. *Id.*

[62] The international application is considered to have the same effect as if it had been filed with the national office of each country *See* PCT art. 3(1) (noting that "applications for the protection of inventions in any of the Contracting States may be filed as international applications under this Treaty.").

[63] Diplomatic Conference for the Adoption of the Patent Law Treaty, Final Act, PT/DC/46 (June 1, 2000). The PLT will officially become effective once ten instruments of ratification are deposited. PCT art. 21.

description of the invention that mirrors the TRIPS substantive requirement for applications.[64]

PCT Exclusively Governs Procedures for International Applications

3.1.40 Of particular relevance to the issue of whether an enhanced disclosure requirement would be consistent with the PCT is the fact that PCT article 27(1) mandates that no requirements relating to the "form and contents" of international applications, other than those explicitly set forth under the PCT can be established. Although the phrase "form and contents" is not explicitly defined within the PCT, it is generally understood to refer to procedural requirements, rather than substantive criteria for patentability.[65] In addition, PLT article 6(1) states that contracting parties are forbidden from requiring compliance with the form and contents of international applications that conflict with the PCT.[66]

National Law Governs Substantive Patentability Requirements

3.1.41 For substantive criteria of patentability, PCT explicitly notes that member states are free to establish their own patentability requirements.[67] The PLT similarly affirms that it does not govern any substantive requirements of patentability.[68]

PCT Consistency – Is Enhanced Disclosure Procedure or Substance?

3.1.42 The issue of whether an enhanced disclosure requirement is permissible for international applications depends on whether the requirement is a "substantive condition of patentability" or relates to the "form and contents" of the international application. If the enhanced disclosure requirement relates to the "form and contents," the PCT, as well as the PLT seem to preclude such a requirement.[69] The following table highlights the provisions most pertinent to this distinction:

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[64] PCT art. 3(2); PCT art. 5 (noting that description shall disclose invention….).

[65] Prior negotiations indicate that the terms were "used merely to emphasize something that could go without saying, namely, that requirements of substantive patent law (criteria of patentability, etc) are not meant." TRIPS REGIME OF PATENT RIGHTS, *supra* note 31, para 27.23 (citing the Records of the Washington Diplomatic Conference on the Patent Cooperation Treaty, 1970, at 553 (WIPO, 1972). Moreover, existing provisions of the PCT clarify the distinction between "form and contents" versus substantive requirements. In particular, article 27(5) explicitly clarifies that each contracting state is entitled to establish its own *substantive conditions of patentability*, including its own definition of prior art, as well as other conditions of patentability that do not constitute the "form and contents" of the application.

[66] PLT art. 6(1).

[67] PCT art. 27(5).

[68] In particular, article 2 of the PLT states that "[n]othing in the Treaty or in the Regulations is intended to be construed as prescribing anything that would limit the freedom of a contracting state ... to prescribe such requirements of the applicable substantive law relating to patents as it desires." PLT art. 2(2).

[69] Nuno Pires de Carvalho, *From Shaman's Hut to the Patent Office: In Search of Effective Protection for Traditional Knowledge*, paper presented at Washington University School of Law, Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge, at pp. 45-47 (April 4-6, 2003) (concluding that enhanced disclosure requirement is not permissible during international phase of the PCT), *available at* http://law.wustl.edu/centeris/Conf/papers/; Article 27.3(b), The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge, Communication from Switzerland, IP/C/W/400 (May 28, 2003).

art.	**PCT Text Distinguishing "Form" of Applications from Substantive Patentability**
art. 27(1)	"***No national law shall require compliance with requirements relating to the form or contents of the international application*** *different from or additional to those which are provided for in this Treaty and Regulations*."
Art. 27(5)	"Nothing in this Treaty and the Regulations is intended to . . . limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires. . . . ***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***.

National Requirements Permitted in International Applications

3.1.43 Although the PCT doesn't govern substantive requirements, it does permit applicants to include information in the international application to comply with substantive national law, or to provide additional supporting material once the application is examined by national patent offices.[70] For example, although the PCT rules do not request the identification of an inventor,[71] the PCT regulations explicitly note that the application *may* contain declarations that establish the inventor's identity, as well as any document that relates to the applicant's entitlement to apply for a patent.[72] A summary of the requirements of international applications in comparison to the possible additional documents that may be submitted in conjunction with the application to comply with national law are shown in the following table:

Requirements of Int'l Applications		**Permissible Compliance with National Law**	
art. 3(2)	An international application **shall** contain . . . a request, a description, one or more claims, one or more drawings (where required), and an abstract	reg. 4.17	**May** contain declarations re: (i) identity of inventor (iv) declaration of inventor
art. 5	"The description **shall** disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."		

[70] PCT art. 27(2) permits national patent offices to require additional documentation of information first asserted in the international application during the national phase of examination. *See* TRIPS REGIME OF PATENT RIGHTS, *supra* note 31, at 157 (noting that "nothing in the PCT stands in the way of requirements being imposed after the applications enter their national phases – hence, after they cease to be a PCT issue). At least one country has proposed explicitly amending the PCT to clarify that nations may require enhanced disclosure for applications when they enter the national stage of examination. Article 27.3(b), The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge, Communication from Switzerland, IP/C/W/400/Rev.1, pp. 1-2 (June 18, 2003).

[71] PCT art. 3(2).

[72] PCT art. 27(2) (The provisions of paragraph (1) neither affect the application of the provisions of Article 7(2) nor preclude any national law from requiring once the processing of the international application has started in the designated office, the furnishing . . . (ii) of documents not part of the international application but which constitute proof of allegations or statements made in the application.").

Art. 27(6)	"The national law **may** require that the applicant furnish *evidence in respect of any* ***substantive condition of patentability*** prescribed by such law."	reg. 51bis	National law **may** require applicant furnish: (i) any document regarding identity of inventor (ii) any document re: applicant entitlement to apply for or be granted a patent (iii) any document with oath or declaration of inventorship.

3.1.44 **b. Proposed Amendments to PCT**

3.1.45 Switzerland has made specific suggestions to amend PCT rules to allow for an enhanced disclosure requirement, as summarized in the following table.[73]

Rule	Amend	Proposed Text
4.17	New *vi*	"a declaration as to the source of a specific genetic resource . . . relevant for the conservation and sustainable use of biological diversity, as referred to in Rule 51bis.1(g)."
51bis.1	New (g)	The national law applicable by the designated Office **may,** in accordance with Article 27, require the applicant: (i) to declare the *source of a specific genetic resource* to which the inventor has had access, if an invention is *directly based on* such a resource; if such source is unknown, this shall be declared accordingly; . . . ."

3.2 **B. Plant Varieties**

3.2.1 Although plant variety protection is much less extensive than patent protection and potentially less of an issue for inventions based upon biological material, the relevant international agreements are nonetheless considered for completeness. This section follows the same basic format as the patent section by first examining consistency with TRIPS, followed by a separate international convention.

3.2.2 **1. TRIPS**

3.2.3 TRIPS does not provide details for the protection of plant varieties, although it does mandate that plant varieties be given intellectual property protection. In particular, Article 27(3)(b) states that members "*shall* provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof."

3.2.4 To the extent that member states utilize patents to protect plant varieties, the previous analysis of TRIPS consistency for patents applies, as noted in paras. 3.1.10-3.132.

[73] Article 27.3(b), The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge, Communication from Switzerland, IP/C/W/400 (May 28, 2003).

3.2.5 To the extent that member states decide to *exclude* plant varieties from patent protection, a different analysis is applicable. TRIPS requires that some "effective" system of sui generis protection must be established, but does not provide specific guidelines.[74] Accordingly, one could argue that because TRIPS does not set forth specific criteria for the standards of issuing plant variety protection, TRIPS is silent on this issue and enhanced disclosure could not conflict with a silent provision. However, if failure to comply with a mandatory enhanced disclosure requirement for plant variety protection would effectively result in denial of such protection, that raises the perception that the sui generis system is not "effective" because it is not providing the same level of protection that the patent system would under TRIPS.[75]

3.2.6 **2. UPOV**

3.2.7 Another important international convention for plant varieties is the Union for the Protection of New Varieties of Plants (UPOV), the only international convention that specifically addresses plant varieties. In addition, some have assumed that compliance with UPOV would likely satisfy the TRIPS requirement for providing an "effective sui generis system."[76]

3.2.8 UPOV is an intergovernmental agency that establishes the framework for which member countries provide rights to the developers of new plant varieties. Although there are multiple versions of UPOV to which countries are members (as noted in Appendix A), they are essentially identical with respect to the technical requirements that must be satisfied for issuance of a plant variety certificate. All require a certificate to issue if the UPOV requirements are satisfied – that the new variety be novel, distinct, uniform and stable.[77] In addition, the certificate can only be annulled on the same grounds.[78]

3.2.9 The most important provisions of UPOV for the issue of enhanced disclosure relate to explicit statements that the requirements for issuing or canceling plant variety certificates may *not* deviate from those specified under UPOV. UPOV explicitly provides that the breeder's right may not be subject to any additional conditions.[79] Similarly, UPOV specifically states that the grounds for canceling plant variety certificates may *not* be

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[74] TRIPS, art. 27(3).

[75] There is a suggestion that "effectiveness" of a sui generis system can be based on the scope of protection available; in particular, one report suggests that a framework that provides protection for the largest range of plant varieties. Biswajit Dhar, Sui Generis Systems for Plant Variety Protection: Options Under Trips, para. 2.1.3 (April 2002), at www.quno.org (click on Geneva pages).

[76] *See, e.g.*, Daniel Gervais, THE TRIPS AGREEMENT, at 151 (1998) (noting that [p]resumably, in the case of a sui generis system, what is contemplated is a UPOV-type protection."); George Tansey, Trade, IP, Food and Biodiversity, 22.3 (1999); Biswajit Dhar, Sui Generis Systems for Plant Variety Protection: Options Under Trips, para. 2.1.2 (April 2002), *available at* www.quno.org (click on Geneva pages).

[77] 1978 UPOV art. 6 (noting that [t]he breeder *shall* benefit from the protection provided for in this Convention" when the requirements of novelty, distinctiveness, uniformity and stability are satisfied); 1991 UPOV art. 5 (noting that "[t]he breeder's right *shall* be granted where the variety is new, distinct, uniform and stable").

[78] 1978 UPOV, art. 10(1)-(2); 1991 UPOV, art. 21.

[79] 1978 UPOV art. 6 ("the grant of protection may not be made subject to conditions other than those set forth" other than compliance with national formalities and fees); 1991 UPOV art. 5 ("the grant of the breeder's right shall not be subject to any further or different conditions" other than complying with national formalities and requisite fees).

altered by member countries.[80] The UPOV Secretariat has noted that while UPOV was not fundamentally opposed to disclosure that would facilitate examination, UPOV could *"not accept this as an additional condition of protection."*[81]

IV. EVALUATION OF THE UTILITY OF ENHANCED DISCLOSURE FOR EXAMINATION OF IPR

4.0.1 The specific focus of this section, in accordance with the COP 6/Decision VI/24(C) terms of reference, is on whether an enhanced disclosure requirement would *assist the examination*, or re-examination of intellectual property applications, with a primary focus on patent applications.[82] This Part begins with an overview of patent examination process, as well as patentability criteria to provide relevant context for the utility of an enhanced disclosure requirement. Section B then considers the practical implications of an enhanced disclosure requirement for actual examination of applications. Section C considers some additional practical and policy issues raised by a possible enhanced disclosure requirement.

4.1 A. The Patent Examination

4.1.1 1. Criteria for Patentability

4.1.2 The basic criteria for patentability for most nations are those required by TRIPS – that there be an "invention" considered to be patentable subject matter, and that the invention satisfy the requirements of novelty, inventive step and utility; in addition, as noted before, the patent application must provide a complete description of the invention. However, TRIPS does not define the individual criteria of patentability and unless another international agreement (such as the SPLT under current negotiation) provides uniform definitions that nations must comply with, there will be variation in the meaning of these terms.[83] Accordingly, this section goes beyond the TRIPS framework to highlight the national definition of the patentability criteria most relevant to an enhanced disclosure requirement.[84]

4.1.3 a. Patentable Subject Matter

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[80] 1978 UPOV, art. 10(4); UPOV 91, art. 21(2)(nullity); art. 22(2)(cancellation).

[81] 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), IP/C/W/347/Add.3, at 4 (June 11, 2002).

[82] Although decision VI/24(C) does not define either "examination" or "re-examination," the terms will be given a broad scope in this report for maximum utility. In particular, "examination" is understood to refer to the traditional examination of an original patent application, whereas re-examination will be considered to include all other situations where an examined application or issued patent will be re-evaluated to determine if it is valid. For example, proceedings in which the validity of patents may be re-examined include opposition proceedings, re-examination or revocation proceedings, and litigation.

[83] In addition, even if SPLT specifies uniform definitions, neither the SPLT, nor WIPO, the auspices under which SPLT was negotiated, provide for any enforcement system akin to the WTO dispute settlement system.

[84] For example, although utility is a requirement, that is not an issue that arises in the context of patents that are based on unauthorized access to biological material and typically is also easy to satisfy. In addition, although the invention disclosure requirement is sometimes discussed with respect to an enhanced disclosure requirement, this was previously discussed in the section of international consistency, at paras. 3.1.13-3.1.14 and incorporated herein.

4.1.4 There are two types of (TRIPS permissible) exclusions from patentable subject matter that are important to distinguish for the enhanced disclosure requirement – categorical exclusions and exclusions based on possible violation of *ordre public* or morality.[85] Presently, none of the categorical exclusions from patentability encompass situations based on unauthorized access of biological material; rather, the exclusions disallow patenting of surgical methods and plants and animals in their entirety.[86]

4.1.5 The exclusion based on *ordre public* or morality, however, has been suggested as a possible basis to exclude subject matter not otherwise excluded under TRIPS. In particular, there is an argument that a patent application could be excluded for lack of patentable subject matter in a country that both has an exclusion based on *ordre public* or morality *and* interprets such an exclusion to include a situation where an application fails to disclose the geographic origin or prior informed consent. Although no country presently meets both conditions, Belgium has proposed amendments to its patent laws that do so, as will be later discussed.

4.1.6 **b. Novelty**

Basic Novelty Definition

4.1.7 The basic requirement of novelty is that a patent can not issue if the identical invention already exists in the prior art, however prior art is defined in the relevant jurisdiction. The rationale for the novelty requirement is that the patent system should not remove things from the existing public domain. If the invention is not identical to anything disclosed in the prior art and the application was promptly filed,[87] it passes the novelty threshold, although it may ultimately still be barred by the inventive step requirement.

Prior Art

4.1.8 An important initial step to determining whether an application discloses an invention that is novel is to determine the scope of the prior art because the examination process compares the (claimed) invention with pre-existing subject matter, referenced as "prior art."[88] Individual countries have different definitions of what constitutes prior art.[89] The varying definitions of prior art may result in a patent issuing in one country, but not another, even though the invention disclosed is identical.

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[85] TRIPS art. 27(2)-(3).

[86] TRIPS art. 27(2)-(3).

[87] Some countries have a grace period during which an invention may be disclosed without impacting patentability, while other countries have a very limited grace period.

[88] As explained in a report by the WIPO Standing Committee on the Law of Patents, "prior art is generally understood to constitute the body of knowledge which was available to the public before the filing date, or, if priority is claimed, before the priority date, of a patent application." SCP/4/2, para. 11 (Sept. 25, 2000). In addition, the definition of prior art, as well as novelty, are also important after a patent is issued because they can be utilized to challenge the validity of the patent.

[89] There are additional variations on the definition of prior art of less importance for this report. For example, some countries have specific rules on the extent of the disclosure in the prior art that is necessary.

4.1.9 Some countries and regions, such as the EPC, take a broad view of what can constitute prior art, sometimes referred to as an "absolute novelty" regime. Under such a system, an invention is not novel if it was known in any way, in *any* country, prior to the date of the patent application, or the priority date.[90] Prior art can include printed or oral material describing the invention, as well as use or sale of the invention.

4.1.10 Other countries utilize a "relative novelty" regime in which certain types of information is not considered to constitute prior art, depending on how the information is available to the public. For example, oral information is not recognized as prior art by either the U.S. or by the PCT international search. Similarly, while many countries will consider any prior use of an invention to constitute prior art, some countries, such as the U.S., exclude prior use in *other countries* from the scope of prior art. The basic rationale for the relative novelty approach is that only printed material is readily accessible, whereas use of an invention or oral information is difficult to ascertain.[91]

4.1.11 The following table summarizes what type of information is considered prior art by individual countries or conventions. As this table shows, printed publications – whether articles, patents or patent applications – constitute prior art everywhere. However, there is more variability for non-printed prior art, such as oral information, public use, and sales.

Comparative Definitions of Prior Art

Prior Art?	EPC	PCT	U.S.	Japan
Patents	Y	Y	Y	Y
Printed Pubn.	Y	Y	Y	Y
Public Use – in nation	Y	___	Y	Y
Public Use Anywhere	Y	____	___	Y
Oral information	Y	----	—	---

Novelty of Biological Inventions

4.1.12 The most significant variation in national definitions of novelty exists with regard to the area of biological inventions. In particular, some nations, such as the United States and the EU consider that biological material that is isolated (and or purified) from naturally existing substances *can* be considered sufficiently novel because the isolated substance does not exist in nature in the exact form.[92] However, other countries consider such substances to lack novelty.[93]

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[90] Most countries will compare prior art not just to the date of the patent application, but to the earliest date claimed the patent application, sometimes referred to as a "priority date."

[91] *Gayler v. Wilder*, 51 U.S. 477, 497 (1850). However, in recent years, especially in light of the internet, the rationale for the relative novelty approach has been questioned. Margo Bagley, *Patently Unconstitutional: The Geographical Limitation on prior Art in a Small World*, 87 MINN. L. REV. 679 (2003); Leanne M. Fecteau, *The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Patent Policy*, 21 B.C. THIRD WORLD L.J. 69, 70 (2001).

[92] *E.g.*, Dutfield, *supra* note 18, at 20-21 (noting that in Europe and North America, there has never

4.1.13 The differing novelty definition is particularly important in cases where inventions are "based on" genetic resources or traditional knowledge of another country. For example, someone who illegally accesses genetic material from another country can chemically manipulate the resource in a way that satisfies the novelty requirement for jurisdictions that recognize isolated material as novel.[94]

4.1.14 **c. Inventive Step (Non-Obviousness)**

4.1.15 Inventive step (referred to as non-obviousness in some countries) is another important criteria for patentability. To meet the inventive step criteria, prior art is once again important. In particular, if an invention, when compared to the appropriate prior art, would be obvious to a person skilled in the art, the inventive step is not satisfied, and a patent is not proper. This inquiry is determined based on what would have been obvious at the time of filing, or any earlier date to which the applicant is entitled.[95]

4.1.16 **1. The Examination Process**

4.1.17 This section is intended to provide an overview of the basic process of examining an application. The first part of this section discusses original examinations, whereas the second section discusses "re-examinations," which include any type of examination applicable to patents that have been examined once by the relevant patent office. In addition, it should be noted that although this section focuses on national examinations, the same basic framework applies to applications to regional offices (such as the EPC).

4.1.18 **a. Original National Examination**

4.1.19 The first step of a patent examination process requires the applicant to submit an application.[96] In particular, the application must include a specification that contains a description of the invention and one or more claims. The claims are a critical part of the

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been a categorical exclusion of inventions based on natural substances); PHILIPPE G. DUCOR, PATENTING THE RECOMBINANT PRODUCTS OF BIOTECHNOLOGY AND OTHER MOLECULES 6 (1998) (noting that isolation or purification of naturally occurring products are generally considered patentable subject matter under U.S. precedent).

[93] Review of the Provisions of Article 27.3(b), Communication from Mauritius on behalf of the African Group, IP/C/W/206, para. 2 (Sept. 20, 2000); Review of Article 27.3(b), Communication from Brazil, IP/C/W/228, para. 5-6 (Nov. 24, 2000).

[94] Of course, novelty is only one component of patentability. A patent could still be denied for lack of inventive step. In addition, if the chemically different compound does not have a clear utility or industrial application, a patent could still be denied.

[95] In addition to different definitions of prior art, nations may also arrive at different results with respect to the inventive step inquiry. For example, there are different definitions of what a person "skilled in the art" means, as well as differing views with respect to when specific items of prior art may be combined for the inventive step inquiry. E.g., Standing Committee on the Law of Patents, Suggestions for the Further Development of International Patent Law, SCP/4/2 (Sept. 25, 2000).

[96] There are some elements of a complete application that although required as a matter of procedure, are not necessary to begin the examination process. For example, in the U.S., a patent applicant must provide a fee for examination, as well as an oath by the inventor(s), stating that they believe that they are the first and true inventors of the invention in the application. 35 U.S.C. 111.

application because they determine both whether the invention is patentable, as well as the scope of any issued patent.

4.1.20 The first substantive action the patent office (PTO)[97] undertakes is a search for relevant prior art, based primarily on databases of patents and published patent applications. The PTO has a limited archive of printed publications, but generally relies on the electronically searchable databases.[98] In addition, although some patent offices have explicit authorization to request additional information for the patent examination process, this power is not typically utilized.[99]

4.1.21 The applicant is often expected to assist the PTO by providing the most relevant prior art known to the applicant.[100] Failure to provide complete disclosure of relevant prior art, or other misrepresentations during the application process can lead to revocation of a patent, monetary sanctions or criminal penalties.[101]

4.1.22 The examiner then compares the application with the prior art[102] to determine whether a patent should issue. If the examiner determines that any element of patentability – patentable subject matter, novelty, inventive step, utility, or adequate disclosure – is not satisfied, the examiner will reject the application.[103] If the examiner initially rejects the application, the applicant is provided an opportunity to explain why a patent should be granted.[104]

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[97] The abbreviated title for most countries patent offices is typically some variation of PTO. For example, the U.S. is U.S.PTO, while the patent office for an EPC application is the EPO and the patent office for Japanese Patent office is JPO. PTO is used here to refer to refer to any such office.

[98] U.S.PTO, 2002 Performance and Accountability Report, p. 17, *available at* http://www.uspto.gov/web/offices/com/annual/2002/lowres/1-58.pdf (noting continued efforts by the U.S.PTO to "remove the examiner paper search files, relying instead on the automated database….").

[99] *E.g.*, John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 749-50 (2002); *see also* MPEP 2005 (8th ed. 2001) (permitting U.S. patent examiners to request information from patent applicants that is considered "necessary," to examination, even if not material to patentability).

[100] *See, e.g.*, PCT Rule 5.1(a)(ii) (requiring disclosure of background art); 37 C.F.R. 1.56 (noting an affirmative duty of "good faith and disclosure" for each individual associated with filing and prosecution of a United States patent application, that requires disclosure of "all information known ... to be material to patentability ...."); Australia Patent Law 101D (noting that applicant must inform the patent office of the results of any documentary searches); Japan Patent Law 36(4)(ii). In addition, in response to a recent WIPO request, other countries that indicated such a reporting requirement included Mexico, Spain, and Uruguay. *See, e.g.*, Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, Document prepared by the Secretariat, WIPO/GRTKF/IC/5/10, at 43 (May 2, 2003). In addition, although the EPC does not presently impose such an obligation, it may. EPO Diplomatic Conference 2000 Act Revising the Convention on the Grant of European Patents, Article 124, *available at* http://www.european-patent-office.org/epo/dipl_conf/pdf/em00003a.pdf.

[101] For example, according to a recent WIPO report, several countries allow the provision of false information to provide the basis for patent revocation, including New Zealand, Australia and Italy. In addition, Italy provides for monetary sanctions in addition to loss of patent rights. Canada's patent legislation imposes criminal penalties for some acts relating to falsification or provision of false information. WIPO/GRTFK/IC/5/10, at 25 (para. 70) (May 2, 2003).

[102] The prior art that the examiner relies on may include both prior art that was independently uncovered by the examiner, as well as prior art submitted by the applicant.

[103] The office action explains the bases for the examiner's rejection and the office action becomes an official part of the record of the patent examination (sometimes referred to as the "file wrapper" or "prosecution history").

[104] Sometimes the applicant will narrow the claims in response to the examiner's objections

4.1.23 **b. Re-examination**

4.1.24 There are several types of procedures that fall under the general heading of re-examination. Basically, the procedures can be categorized into two types: procedures within the patent office, and procedures within the judicial system.

4.1.25 A common type of patent office proceeding after the initial examination of an application is an "opposition proceeding." The EPO and Japan explicitly permit such a system, which allows parties to challenge a patent within a limited period after the patent (or patent grant) has been published.[105] The U.S. does not provide for an opposition proceeding, but has a re-examination proceeding, during which a more limited sub-set of information can be used to challenge the patent; however, the time-period to utilize this proceeding is not limited in duration.[106]

4.1.26 The validity of a patent may also be examined during a judicial proceeding. Typically, allegations of patent invalidity are raised as defenses to a claim of patent infringement. All of the substantive criteria of patentability may typically be raised at this time, although the burden of proof may be difficult to satisfy, as will be specifically addressed in the next section.

4.2 **B. Application of Enhanced Disclosure to Patent Examination**

4.2.1 This section will consider whether adding an enhanced disclosure requirement will impact patent examinations based upon general patentability requirements and examinations, as discussed in the prior section. Some nations and regions currently require some type of an enhanced disclosure requirement, such as India,[107] Costa Rica,[108] and the Andean Community.[109] However, the actual utility of such a requirement is difficult to determine because of the lack of publicly available sources.

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concerning prior art . In addition, this process (office action, followed by response) may be repeated, but ultimately will result in a final rejection, or allowance of the application to issue as a patent.

[105] Under the EPC, the time period is nine months from publication of the patent grant, whereas under the Japanese Patent Law, the time period is six months from publication of the patent. EPC article 97; Japan section 66.

[106] 35 U.S.C. 311 (noting that re-examination can be done at "any time").

[107] Indian Patent Act (Second Amendment 2002), section 10 requires disclosure of geographic origin of any biological material deposited in lieu of a description. In addition, failure to disclose or disclosure of the incorrect geographic origin of biological material used for the invention is a new ground for opposition of a patent under section 25.

[108] The 1998 Biodiversity Law of Costa Rica requires certificate of origin to accompany applications for intellectual property rights pursuant to articles 77-85.

[109] There are two decisions relevant to enhanced disclosure. First, the Community Decision 391 (1996) requires consent for actual and potential use of a resource pursuant to article 22. The decision broadly covers genetic resources, as well as *derivatives* of genetic resources under article 3. Moreover, the decision states that intellectual property rights for genetic resources obtained without compliance with the decision shall not be recognized by member states. Decision 486, article 26(h) further specifies that patent applications must contain a copy of a contract for access if the invention is obtained or developed from genetic resources originating in one of the member countries. Furthermore, article 26(i) requires that a patent application be filed together with certification of license to use traditional knowledge.

4.2.2 This section first provides some initial consideration of the role informed consent may play for all phases of patent examination. Then, the section considers the potential implication of a disclosure of origin requirement on a patent application, based upon the same criteria of patentability. Lastly, the section examines the potential implications for re-examinations of applications, whether within the patent system, or within the judicial system.

4.2.3 **1. Initial Consideration -- Informed Consent**

4.2.4 Although most of this report has utilized the term "enhanced disclosure requirement" to refer to two different types of potential disclosures, this section will separate out the disclosures because they have distinct differences with respect to patent examination. For example, the source and origin of biological material used for an invention *may* be relevant in determining the patentability, but evidence of prior informed consent does not seem linked to the traditional patentability requirements.[110] The illegality of something that an invention is based on is not considered in a traditional analysis of patentable subject matter; rather, the focus is on whether the claimed invention alone (without regard to the method by which it came into existence) meets the requirements.[111] Informed consent will not govern whether the invention is new or has an inventive step because those inquiries are based upon what exists in the prior art and not whether prior art was appropriately accessed under non-patent rules. Similarly, as previously discussed in Part III, disclosure of informed consent is typically not necessary to satisfy the requirement of adequate disclosure of the invention.[112] There might be an argument that it would be necessary to perform the best mode if the best mode required a single type of genetic resource that could not otherwise be obtained.[113] Accordingly, none of the requirements of patentability are assisted by the addition of prior informed consent and the remainder of this section will only discuss the possible utility of a disclosure of the geographic origin of the relevant biological material.

4.2.5 **2. Original Examinations**

4.2.6 **a. Patentable Subject Matter**

4.2.7 An enhanced disclosure requirement could potentially impact the examination of whether an application contains patentable subject matter, depending on whether a national law permits exclusion of inventions that violate *ordre public* or morality. As noted above, TRIPS article 27 allows member countries to include such an exclusion.[114]

4.2.8 Belgium has proposed an enhanced disclosure requirement that would limit the scope of patentable subject matter. Proposed Article 15(1) of the Belgium Patent Act specifically adds a new requirement that patent applications contain the geographic origin of the plant

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110 Dutfield, *supra* note 18, at 25.

111 TRIPS REGIME OF PATENT RIGHTS, *supra* note 31.

112 *See* TRIPS REGIME OF PATENT RIGHTS, *supra* note 34 and accompanying text.

113 Dutfield, *supra* note 18, at 25.

114 TRIPS, art. 27(2). One example is EPC article 53(a), which has provided a long-standing exception to patentability.

or animal material that formed the basis for the development of the invention.[115] In addition, proposed article 4(4) of the Belgium Patent Act provides that exploitation of an invention is contrary to *ordre public* and morality when the invention is developed on the basis of biological material that was collected or exported in breach of Articles 3, 8(j), 15 and 16 of the CBD.[116] However, as of the writing of this report, the proposed law does not appear to have been enacted.[117]

4.2.9 One commentator has suggested that the proposal is inconsistent with existing case law concerning *ordre public*. In particular, she suggested that Belgian civil law concerning the definition of *ordre public* and morality is typically very narrow and conceived of as a breach of the "utter limits of what present-day society tolerates," further opining that the failure to indicate geographic origin to satisfy this standard seems "hard to imagine."[118]

4.2.10 **b. Novelty and Inventive Step**

4.2.11 Disclosure of the origin may have an impact on the novelty determination, but only in some instances. First, geographic origin is not – at least not alone – a type of prior art that is recognized. Rather, disclosure of geographic origin might suggest that the invention is based on a natural resource. Natural resources can not be patented because they are not new. However, as explained before, depending on a country's definition of novelty, variations and derivations of naturally occurring products may be considered patentable.

Not Actual Inventor

4.2.12 An enhanced disclosure requirement might be relevant to a determination of whether a patent applicant is the true inventor of the claimed invention, such that a patent should be issue. For example, the United States patent laws allow rejection of an application on the grounds that the inventor did not actually invent the claimed subject matter.[119] Some have suggested that this law can be useful in establishing that patents and applications based on improperly accessed biological material are invalid.[120] However, this is rarely invoked in practice because the provision has been interpreted to require proof that the applicant *derived* the invention from another.[121] In the absence of an actual publication authored by

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115 van Overwalle, *supra* note 15 at 234.

116 *Id.*

117 Personal Communication from Stefanie Missotten. The proposal itself is available at www.dekamer.be (in French and Dutch).

118 van Overwalle, *supra* note 15 at 234-35.

119 35 U.S.C. 102(f) (noting that one of conditions that bars patentability is that the applicant "did not himself invent the subject matter sought to be patented"). In addition, applicants are often required to identify the inventor, but this issue is traditionally not one that patent offices try to independently verify. 37 C.F.R. 1.63; MPEP 602. Similarly, EPC article 81 provides that "[t]he European patent application shall designate the inventor." In addition, the EPO Guidelines for examination also note that the EPO does not verify the accuracy of this information. EPO Guidelines 5.2; Rule 17(2). Similarly, PCT article 4(1)(v) requires the "name of and other prescribed data concerning the inventor where the national law of at least one of the designated States requires . . . ."

120 *E.g.*, CIEL Comments on Improving Identification of Prior Art (1999).

121 MPEP 2137 (8th ed. 2001) (citing *Ex Parte Kusko*, 215 USPQ 972, 974 (Bd. App. 1981) ("most, if not all, determinations under section 102(f) involve the question of whether one party derived an invention from another"). Moreover, even if an examiner were to suspect that an invention was unpatentable based upon this

the person from whom the applicant derived the invention, there appears to be no basis for an examiner to doubt the veracity of an applicant's allegation of inventorship.[122]

4.2.13 **3. Re-examination**

4.2.14 The utility of an enhanced disclosure requirement for re-examination proceedings is likely similar to the utility of the requirement for original examination because the two examinations consider similar information. For example, both types of examination will consider whether the invention is novel and involves an inventive step; in addition, improper inventorship is also a basis for re-examination in some countries.[123] Accordingly, the utility of an enhanced disclosure requirement discussed with respect to original examination in paras. 4.2.5-4.2.12 is incorporated.

4.2.15 One distinction in the utility of an enhanced disclosure requirement at the re-examination stage is that the involvement of a third party may alter the consideration of relevant prior art. Unlike an original examination, which typically only involves the applicant and the patent office, a re-examination is often initiated by an interested third party.[124] In addition, a third party may have more incentive to utilize the enhanced disclosure to uncover prior art than the PTO if the third party has a specific interest in whether the patent is invalidated. Some patents based on unauthorized access to biological material have been cancelled as a result of the efforts of third parties.[125]

4.2.16 However, the procedural rules governing re-examination may be challenging for interested third parties. For example, in some cases, the re-examination proceedings consider a narrower scope of information than in the original examination. For example, for re-examinations in the U.S., only prior art publications not previously considered by the patent office may be considered; previously uncovered prior art public uses or sales are not considered.[126] In addition, although judicial proceedings may permit a broader scope of grounds to invalidate a patent, it is more difficult to establish the invalidity of an issued patent.[127]

4.2.17 **4. Limits of Examiner Capacity**

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ground, the applicant can easily rebut a rejection by providing an "unequivocal statement" by way of affidavit. MPEP 716.10 (8th ed. 2001).

[122] The only examples provided in the U.S. PTO's patent examination guidelines where an applicant's declaration was discounted all involved cases where there was an actual article, patent or published application in existence. MPEP 716.10 (8th ed. 2001).

[123] Australian Patents Act 138(3) (1990) (noting that a patent may be revoked if the patentee is "not entitled to the patent," or if the "patent was obtained by fraud, false suggestion or misrepresentation," among other grounds).

[124] Most such proceedings allow "any person" to challenge a patent, including individuals, as well as corporate competitors. *E.g.*, 35 U.S.C. 302; EPC art. 99; Japan Patent Act 113.

[125] For example, in addition to the cancelled patent on tumeric discussed in footnote 9, the ayahuasca (vine) plant patent was also revoked during re-examination proceedings. *See, e.g.*, Wiser, PTO Rejection of the 'Ayahuasca' Patent Claim: Background and Analysis (CIEL, Nov. 1999); EPO Press Release, Neem tree oil case: European patent No. 0436 257 revoked, www.european-patent-office.org/news/pressrel/2000_05_11_3.ehtm (noting the EPO's revocation of a patent based on the neem tree in light of prior use in India).

[126] 35 U.S.C. 301 (only permitting patents and printed publications).

[127] For example, in the U.S., a patent is given a presumption of validity that must be disproved with clear and convincing evidence 35 U.S.C. 282 (presumption of validity).

4.2.18 An important final consideration is the actual time that examiners have to consider information. The current and future workload of patent examiners may not realistically be able to handle additional information.[128] As noted by one commentator, the increased volume of patent applications, [129] together with the questionable ability of patent offices to competently process them, has become "an ever more acute concern."[130] Commentators have repeatedly criticized patent examination systems for issuing invalid patents.[131] Additionally, some countries have suggested that invalid patents are especially prevalent in cases of patents based on unauthorized access to biological material.[132]

4.2.19 In response to the aforementioned volume problems, patent offices have been known to take steps to limit the amount of time spent on each application as a method to reduce the total workload. For example, in the U.S., the performance of examiners is contingent on the number of total applications reviewed.[133] In addition, the European Patent Office (EPO) has begun to issue preliminary rejections of applications, based solely on automated search results, where a search was already done pursuant to the PCT.[134]

4.2.20 An enhanced disclosure requirement's burden on examiners will likely depend on the exact parameters of the requirements. For example, if independent verification of each component were required, the time requirement could be substantial. Arguably, the additional burden could be minimized if an enhanced disclosure requirement were only

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[128] As noted by Professor John Thomas, "[i]mposing a requirement for information can be time-consuming for an examiner. ... The benefits . . . seem to be slight from an examiner's perspective. Any received information would like negatively impact the application and prolong the prosecution,. . . . ." John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 749-50 (2002).

[129] For example, the most recent annual report from the U.S.PTO noted that there were 333,688 applications and that there was a continued increase in patent applications. U.S.PTO, 2002 Performance and Accountability Report, at 22 *available at* http://www.uspto.gov/web/offices/com/annual/2002/lowres/1-58.pdf.

[130] Dutfield, *supra* note 18 at 21. The inadequate number of examiners handling a large number of applications do not have the necessary resources to allow for careful review. *Id.* at 23. In addition, this commentator cites the U.S. as a particular problem, referring to the U.S.PTO examination as a "quasi-registration" scheme. *Id.* at 22.

[131] *See, e.g.*, Mark Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495 (2001); Thomas, *supra* note 128.

[132] The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the protection of Traditional Knowledge, Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela , IP/C/W/403, para. 4-9 (June 24, 2003); Protection of Biodiversity and Traditional Knowledge – The Indian Experience, Submission by India, IP/C/W/198 para. 8-11 (July 14, 2000) (citing "…several cases of bio-piracy of TK from India"); Review of Article 27.3(b), Communication from Brazil, IP/C/W/228, para. 21-24 (Nov. 24, 2000) (discussing exploitation and bio-piracy of genetic resources through patents).

[133] *E.g.*, James Ruland, *Chapter 2100 of the Manual of Patent Examining Procedure – A Means for Persuasion*, 6 TEX. INTELL. PROP. L.J. 49, 50 (1997) (noting that examiner performance and compensation is tied to the volume of cases they handle in a given period, with bonuses awarded for examiners that exceed their quota); Quentin Hardy, *Search 500,000 Documents, Review 160,000 Pages in 20 Hours, and then Do it All Over Again*, Forbes.com (June 24, 2002) (noting an average review time of twenty hours per patent application).

[134] Notice of the President of the European Patent Office (November 2, 2001) *available at*http://www.european-patent-office.org/epo/president/e/2001_11_13_e.htm; *see also* JC Boff, PCT-Lite (*available at* http://www.cipa.org.uk/info_ip_pros/document/pct-lite.pdf).

applied in some cases, rather than uniformly across all applications.[135] However, the PTO would still need to decide in *every* case whether to impose such a requirement.

4.2.21 The actual or perceived difficulty of a new requirement for examiners is important because history suggests that patent offices are reluctant to consider additional issues that are difficult to examine; moreover, they seem more willing to grant patents and defer to courts to later invalidate patents if there are problems on these issues. For example, although the U.S. regulations provide that patents are not to be granted where applicants violate the duty to disclose relevant prior art,[136] the patent office does not investigate this issue. Rather, the guidelines for the patent examiners note that the office is "not the best forum" to determine this information and instead suggest that courts are in a more appropriate position to make such determinations *after* a patent is issued, despite a noted policy of issuing valid patents.[137]

4.3 C. Patent Policies

4.3.1 While the previous section focused on the practical aspects of incorporating an enhanced disclosure requirement into the examination procedure, this section will focus more on the possible inter-relation of existing patent policies and an enhanced disclosure requirement. This section begins with a discussion of policy underlying the patent system, as well as the patent examination process. Then, policy considerations underlying an extension of the scope of patent examination to a new area are considered.

4.3.2 1. Traditional Patent Policies

Policy of Innovation and Increased Knowledge

4.3.3 The policy for granting patents is often tied to the promotion of innovation and increased knowledge in the public domain.[138] Patents are often justified as a tool to fostering

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[135] Review of Article 27.3(b), Communication from Brazil, IP/C/W/228 (Nov. 24, 2000) (arguing that an enhanced disclosure requirement would be no more burdensome than existing requirements, especially if only imposed where there are reasonable grounds to suspect that national biodiversity provisions have been violated; in response to U.S. assertions that the disclosure requirement would be a "legal and administrative nightmare"). In addition, differential treatment raises an issue of the TRIPS obligation of nondiscrimination.

[136] 37 C.F.R. 1.56 (stating that "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.").

[137] MPEP 2010 (8th ed. 2001). Similarly, although U.S. patent law states that every application must disclose a best mode, the patent office does not make an independent inquiry of this issue. The manual for examination explains that courts are in a better position to evaluate the evidence necessary to determine whether a best mode exists and whether it was concealed. MPEP 2165.03 (8th ed. 2001) (noting that the necessary information to form basis for rejection based on failure to set forth best mode is "rarely accessible to the examiner, but is generally uncovered during discovery procedures" during litigation, or other inter partes proceedings). A patent may be invalidated for failure to comply with the best mode if through litigation it is discovered that there was in fact a better mode that was concealed. 35 U.S.C. 112; MPEP 2165.03 (8th ed. 2001).

[138] In fact, some courts and commentators have described patents as a type of social contract between an inventor and society that encourages innovation and promotes increased knowledge in the public domain. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146-49 (1988) (noting that the federal patent system reflects a "carefully crafted bargain" and that the system is intended to encourage innovation); *see also* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512 (Fed. Cir. 1995) (Newman, J., concurring), *aff'd*, 520 U.S. 17 (1997) ("patent law is directed to the public purposes of fostering technological progress, investment in research and

innovation by providing either an incentive or reward for discovery of useful inventions. In addition, patents have been known to promote innovation on a broad level by increasing publicly available information concerning inventions (because patents are public and patent requirements mandate that the patent disclosure adequately inform others how to replicate the invention).[139] In this way, patents can simultaneously increase knowledge in the public domain, as well as encourage further innovation.

4.3.4 There is an issue of whether an enhanced disclosure requirement can be considered consistent with the policy of promoting innovation and increased knowledge. In particular, some have suggested that an enhanced disclosure requirement is necessary to prevent patent issuance for inventions derived from genetic resources or traditional knowledge.[140] However, others have suggested that an enhanced disclosure requirement is inconsistent with the patent policy goal of promoting innovation because the disclosure requirement is primarily designed to track appropriate access to and use of genetic resources.[141]

Policy of Full Disclosure

4.3.5 The patent examination system also has traditionally recognized a policy of encouraging and even requiring full disclosure of inventions, as well as related prior art. For example, the U.S. guidelines for patent examiners explicitly recognize that patents are "affected with a public interest" and that public interest is best served when the examination is based on a comprehensive scope of prior art.[142] Other countries also support a policy of full disclosure of prior art by imposing similar requirements. In addition, the policy of full disclosure seems to be reinforced by recent U.S. legislation that allows examiners to request applicants to provide even more information than what is included within the traditional definition of prior art.[143] For example, patent examiners may request the identification of information used in the invention process, although that would traditionally not constitute prior art.[144] In addition, although not an absolute requirement, most patent applications tend to disclose background information to the invention, which would seem consistent with the principle of full disclosure.

4.3.6 An enhanced disclosure requirement could be considered consistent with the policy of

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development, capital formation, entrepreneurship, innovation, national strength, and international competitiveness . . . .").

[139] The patent policy is sometimes contrasted to that of trade secrets since most inventions that are patentable, could also be protected by trade secrets. By definition, trade secrets last as long as the information is kept reasonably secret from public knowledge. Because of this definition, public knowledge can not be furthered when inventions are protected by trade secrecy, rather than patenting.

[140] CIEL Comments on Improving Identification of Prior Art (Aug. 2, 1999).

[141] For example, the EU recently noted that the intellectual property system is not the appropriate instrument for regulating access to genetic resources, or commercialization of intellectual property protected goods. *See* Minutes of Meeting, Representative of European Communities, IP/C/M/32, para. 120 (Aug. 23, 2001); Review of the Provisions of Article 27.3(b) of the TRIPS Agreement, Communication from the European Communities and their member States, IP/C/W/254 (June 13, 2001).

[142] 37 C.F.R. 1.56(a) ("The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability...").

[143] 37 C.F.R. 1.105.

[144] 37 C.F.R. 1.105(a)(1)(v).

full disclosure because it may possibly provide information relevant to prior art. In addition, because there seems to be some policy for expanding disclosure requirements beyond the current definitions of prior art, an enhanced disclosure could be consistent with this. Of course, for those who believe that enhanced disclosure has no bearing on determination of novelty or obviousness, the policy of full disclosure would likely be less persuasive.

Policy of Tying Patent Requirements to Patent Concepts

4.3.7 Patent requirements seem to be based on a policy that requirements reflect patent concepts. This principle is exemplified in substantive patentability criteria. So, to the extent that enhanced disclosure is characterized as related to substantive patentability, such as novelty determinations, there may be support for imposing an enhanced disclosure requirement. In addition, there seems to be a policy for allowing patent application requirements that are not related to substantive patent requirements, but are nonetheless related to ownership of any resulting patents. In particular, applicants to the U.S. PTO are required to indicate any government funding received.[145] The government funding situation might be considered distinct because it directly implicates ownership of the patent. On the other hand, enhanced disclosure is still tied to proper ownership of patents and perhaps closely tied to the innovation concept because it could indicate that an application fails to disclose adequate innovation to justify a patent.[146]

Policy of Issuing Valid Patents

4.3.8 Another issue is whether there is a policy of issuing valid patents that could be promoted by an enhanced disclosure requirement. In particular, if enhanced disclosure is perceived as possibly assisting in the process of discovering prior art and properly applying that art to the claimed invention, that could be consistent with a policy of issuing valid patents. However, most patent systems seem to recognize that there will be cases where the PTO grants invalid patents by allowing for re-examination procedures. In addition, recent scholarship suggests that it is more practical to allow the patent offices to quickly examine patents and have validity be determined later -- if and when interested parties contest the patent.[147]

4.3.9 **2. Policy Considerations for Non-traditional Patent Examination**

4.3.10 This section further examines policy considerations that are applicable to non-traditional patent requirements.

4.3.11 **a. Dangers**

4.3.12 There are dangers in requiring patent examiners to undertake duties beyond their technical competency. If an enhanced disclosure were a condition of patentability, the

[145] An applicant is expected to provide the name of any U.S. government agency and government contract number applicable if the invention was made by or under contract with an agency of the U.S. government. 37 CFR 1.51(c)(1); 35 U.S.C. 202.

[146] CIEL Comments on Improving Identification of Prior Art (Aug. 2, 1999).

[147] Lemley, *Rational Ignorance at the Patent Office,* 95 NORTHWESTERN U. L. REV. 1495 (2002).

patent office might be required to make its own independent assessment of whether the disclosed information was correct. This could not only be difficult, but beyond the scope of examiners' traditional expertise in technical subject matter, as well as the substantive criteria of patentability.

4.3.13 Imposing obligations on the patent office that are not directly tied to the technical elements of patentability should be given serious consideration since history suggests that patent offices historically have difficulty doing so. Of particular relevance to this issue is the exception from patentability in some patent laws based on possible violation of *ordre public* or morality.[148]

4.3.14 The EPO has been reluctant to deny patents based on this ground and repeatedly noted that patent examiners are not qualified to determine whether inventions violate *ordre public* since patent examiners are hired on the basis of technical expertise, not ethical or philosophical competence.[149] In addition, EPO courts have noted that they were uncomfortable deciding whether an invention violated *ordre* public because relevant information for this decision was often not available either in the patent application, or anywhere at the time of examination. Similarly, the traditional resources of a PTO would not include information that could independently verify an enhanced disclosure.

4.3.15 In addition, based on prior instances of public discord of patent office expertise, countries may be disinclined to adopt policies which might subject its patents to greater scrutiny and controversy. For example, the *ordre public* exception has been used as a ground to protest issued EPO patents.[150] Similarly, after the U.S. recently began to issue patents on so-called business methods, the patent office was criticized for issuing bad patents and of having a suspect examination process.[151]

4.3.16 **b. Possible Limits**

4.3.17 To some extent, the danger of over-extending patent examiners beyond their traditional competence may be minimized, depending on the type of enhanced disclosure that is adopted.

4.3.18 One possibility is if the PTO was not required to independently verify the accuracy of the enhanced disclosure. This would be consistent with procedural requirements because

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[148] TRIPS, art. 27(2); EPC. art. 53(a).

[149] PGS at 620-21; Relaxin, 1995 OJEPO at 403; *see* also Cynthia M. Ho, *Splicing Morality And Patent Law: Issues Arising From Mixing Mice And Men*, 2 WASH. U. J.L. & POL'Y 247, 279-80 (2000) (noting that "EPO courts have repeatedly emphasized that the function of the patent offices is to grant patents, rather than to regulate technology").

[150] *See, e.g.*, Philip Shishkin, *Greenpeace Protests Europe's Gene Study Patent*, WALL ST. J., Feb. 23, 2000 (noting that the EPO Munich headquarters came under siege); *Greenpeace Paralyzes Patent Office In Genetic Engineering Protest*, Agence France Presse, Feb. 22, 2000, available in Lexis, Nexis library, News File (noting that Greenpeace activists shut down the EPO by bricking up the entrance and provided a written statement declaring that "[w]e shut down the EPO to prevent it from granting patents on living organisms as long as possible" and criticizing the EPO for its practice of patenting "living beings").

[151] Part of the problem in this case is directly analogous to an issue common to biopiracy patents – relevant prior art typically did/does not exist in the form of printed publications and accordingly was not accessible to the patent office. For an example of criticism of the U.S. PTO during this time, see James Gleick, *Patently Absurd*, NY TIMES MAG., Mar. 12, 2000, at 44-49.

such requirements typically are not subject to independent verification.[152]

4.3.19 In addition, even if enhanced disclosure were considered a substantive requirement for patentability, there is some basis for arguing that the PTO need not verify the information. For example, although the U.S. requires a patent application to describe the "best mode," of utilizing the invention, the patent office does not make an actual assessment of this requirement.[153]

4.3.20 The business method patent controversy can also be instructive with respect to how to limit over-extension, as well as how to improve public confidence in the patent system. In particular, the U.S.PTO has hired some examiners with business background – not a traditional background of examiners.[154] In addition, the U.S.PTO created an extra layer of examination for applications filed within this particular class of subject matter.[155]

V. FOSTERING ACCESS & BENEFIT SHARING THROUGH ENHANCED DISCLOSURE

5.0.1 This part of the report returns to some of the initial underlying policies animating an enhanced disclosure requirement. In particular, this part considers whether such a requirement (assuming consistency with international obligations, as outlined in Part III), would foster the access and benefit sharing goals of the CBD.

5.0.2 This part begins by outlining the CBD provisions relevant to the issue of enhanced disclosure to provide relevant context. Then, the details of whether an enhanced disclosure requirement would actually foster the relevant CBD provisions are discussed. Part B discusses issues that apply to both disclosure of geographic origin, as well as informed consent. Part C then discusses issues that are specific to the individual types of disclosure.

5.1 A. CBD Requirements

5.1.1 The CBD contains a number of provisions relating to the ability to monitor proper access to genetic resources, as well as benefit-sharing. To begin with, one of the three primary objectives of the CBD is to promote "fair and equitable sharing of benefits" that arise from the "utilization of genetic resources."[156] Articles 15-16 then articulate in more detail how such benefits may arise from utilization of genetic resources. The specific CBD

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[152] For example, every patent application must be accompanied by an oath of all the listed inventors, stating that they are the true inventors. However, the examiner does not independently verify this information.

[153] MPEP 2165.03 (8th ed. 2001) (noting that the examiner should *assume* that the best mode is disclosed . . . unless evidence is presented that is inconsistent with that assumption).

[154] *See* Business Methods Still Experiencing Substantial Growth - Report of Fiscal year 2001 Statistics, *available at* http://www.uspto.gov/web/menu/pbmethod/fy2001strport.html (noting that as of 2001, a number of examiners were hired with business industry work experience, as well as examiners with graduate degrees in business to properly examine the increased number of business method patent applications).

[155] U.S.PTO, Business Method Action Plan, *available at* http://www.uspto.gov/web/offices/com/sol/actionplan.html; Press release – under Secretary of Commerce for Intellectual Property Dickinson Unveils New Initiative Focusing on Business Method Patents (March 30, 2000), *avaialable at* http://www.uspto.gov/web/offices/com/speeches/00-22.htm; U.S.PTO, Patent Quality Improvement: Expansion of the Second Pair of Eyes (last modified April 4, 2003), *available at* http://www.uspto.gov/web/offices/com/strat21/action/q3p17a.htm.

[156] CBD article 1.

provisions relating to this report are as follows:

- access to genetic resources – if granted – is to be on mutually agreeable terms (Article 15(4))

- access is to be subject to prior informed consent of member providing resources (Art. 15(5))

- members are to take action necessary towards the "aim of sharing in a fair and equitable way the results of R&D and the benefits arising from the commercial and other utilization of genetic resources" with the member providing the resources (also on mutually agreed terms) (Article 15(7))

5.2 **B. Envisioned Benefits and Possible Limitations**

5.2.1 **1. The Impact of Disclosure Parameters**

5.2.2 An important initial caveat to the discussion of the utility of enhanced disclosure for monitoring access is that the utility will likely depend on the exact parameters of enhanced disclosure that is adopted. However, because an enhanced disclosure requirement is a new proposal for most countries, there is little evidence about how this proposal would directly impact CBD goals. This section will outline some broad themes that exist with regard to the types of enhanced disclosure discussed in this report.

5.2.3 While enhanced disclosure alone may not guarantee equitable sharing of benefits, such disclosure is suggested as a means to provide more opportunity for transparency and benefit sharing than the current situation. Although not every patent application results in a commercial success, for applications that do have such results, the enhanced disclosure requirement could serve as a step in determining who might deserve to share in the commercial benefits.[157] A disclosure could provide countries or communities with something tangible to bring to the bargaining table if a patent results in commercial benefits. Of course, allocation of benefits may be difficult to determine and negotiate because commercial products are often the result of multiple patents. Nonetheless, a disclosure requirement has the possibility of improving the enhancement of access and benefit-sharing, although the level of such enhancement is contingent on additional factors that are currently unknown.

Mandatory Requirement for Patentability

5.2.4 Although there is no direct evidence on the possible impact of an enhanced disclosure requirement, some insight into possible outcomes can be gleaned from existing proposals. In particular, those who advocate an enhanced disclosure requirement typically support a mandatory requirement, rather than an optional requirement.[158] Many note that the present

[157] The ultimate result of any such negotiation is not guaranteed. Where genetic resources, perhaps together with indigenous knowledge concerning the use of naturally occurring substances, are used as a starting point for creating a synthetic compound, there is likely controversy concerning what benefit, if any, should inure to the country that provided the resources since the patent technically does not cover the natural resources themselves.

[158] E.g., Minutes of Meeting, Representative of India, IP/C/M/39, para. 122 (Mar. 21, 2003) ("…for

situation of patents improperly issuing that are based on biological material is an imperative for enacting an enhanced disclosure requirement. Some countries note that because there is a patent-based problem, a patent-based solution is required.[159] Moreover, some countries have indicated that their preference is not only a mandatory requirement in national laws, but also a mandatory requirement within TRIPS to ensure uniform compliance, as well as an effective enforcement mechanism.[160]

5.2.5 All the foregoing rationale for an enhanced disclosure requirement seem to be inconsistent with a requirement that has no patent consequences, or only possible civil, administrative or criminal penalties. For example, if the consequences of noncompliance are minor administrative fees, that would seem to provide little incentive to patent applicants to disclose information that could negatively impact patentability and/or gain the attention of third parties who might challenge the issued patents. Moreover, the fact that the commercial value of a patent may well exceed any administrative fees is an additional reason why compliance might be difficult. Additionally, criminal penalties on the basis of fraud seem remote since only a few countries have noted that any such penalties exist.[161]

5.2.6 One additional consideration is that there are additional access problems that may persist even if a mandatory patent-precluding disclosure is adopted. In particular, such a requirement could result in some inventions being protected outside the patent system through trade secrecy.[162] Because trade secrets need not be applied for, the use of any genetic resources or traditional knowledge as a trade secret would have even less transparency and the possibility for benefit sharing would be reduced to nothing. Alternatively, even if the patent system is still utilized, some prospective patent applicants may decline to seek patents from nations or regions that require the disclosure. Accordingly, such applicants may choose to forego obtaining biological material from biodiverse areas.

5.2.7 **2. Patent System Limitations**

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the purpose of determining the prior art it should be mandatory for the patent applicant to disclose necessary information on the geographical source"); Representative of Norway, IP/C/M/39, para. 120 (supporting a provision to "either require or enable Members to oblige patent applicants to disclose the source of origin"); Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, Communication from the African Group, IP/C/W/404 (June 26, 2003) (stating that every Member should require disclosure in order to prevent misappropriation of genetic resources); Review of Article 27.3(b), Communication from Brazil, IP/C/W/228, para. 47 (Nov. 24, 2000) (amend 27.3(b) to include requirements of enhanced disclosure).

[159] The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the protection of Traditional Knowledge, Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela, IP/C/W/403, para. 4-9 (June 24, 2003).

[160] E.g., Communication from African Group, IP/C/W/404 (noting the need to amend TRIPS article 29 in light of the "failure of certain domestic systems to prevent patents that constituted a misappropriation of genetic resources"); Communication from Brazil, IP/C/W/228, para. 25, 27, (Nov. 24, 2000) (stating that TRIPS Article 27.3(b) should be amended to include an enhanced disclosure requirement and that TRIPS "would provide the adequate enforcement of such requirements through its dispute settlement mechanism").

[161] According to a recent WIPO report, Canada permits criminal penalties under its patent legislation for certain acts of falsification of information, while Switzerland and Spain have general criminal sanctions that may apply. WIPO/GRTFKF/IC/5/10, Annex I, at 25, para. 70 (May 2, 2003).

[162] Review of the Provisions of Article 27.3(b), Communication from the United States, IP/C/W/162, at 6 (Oct. 29, 1999) (noting that disclosure of origin might result in trade secrecy, rather than patents with additional information).

5.2.8 The ability to monitor access and benefit-sharing for any type of enhanced disclosure in patent applications will be limited by existing patent rules concerning access to patent applications. Most countries do not allow initial public access to patent applications. Rather, countries publish the patent application about eighteen months after filing, at the earliest.[163] In addition, although some have proposed that the enhanced disclosure information should be immediately available,[164] some countries have objected that this would be administratively burdensome.[165] Also, additional written documentation of correspondence between the applicant and examiner (file wrapper) is typically not available to the public before an application is filed and sometimes not until an actual patent is granted.[166]

5.2.9 In addition, there is still a necessary investment of administrative resources to monitor and challenge patent applications. Considering the volume of patent applications that are filed, this could be an onerous task.[167] There has been at least one proposal that the burden should fall on existing patent offices to notify relevant countries when there is a patent application that may be relevant.[168] This could minimize the administrative burden of monitoring patent applications. However, even after such discovery, problematic patents would still need to be challenged on an individual basis.

5.3 C. Specific Issues for Elements of Enhanced Disclosure

5.3.1 1. Geographic Origin

5.3.2 There are some practical issues that may arise with respect to identification of the geographic origin of biological material. For example, if an applicant does not know the exact source of the genetic material, the transparency function of the enhanced disclosure will be unattainable.[169]

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[163] EPC art. 93 (noting that European patent application shall be published "as soon as possible after the expiry of a period of eighteen months" from the date of filing or of priority); Japanese Patent Law 64(1) (publication "one year and six months from the filing date"); 35 U.S.C. 122(b)(1)(A) (noting that U.S. patent applications will generally be published "promptly" after a period of 18 months from the earliest filing date, unless an applicant requests an earlier date, or unless an exception to publication applies); PCT art. 21(2) (noting that in general the international application will be published "promptly after the expiration of 18 months from the priority date of the application").

[164] Communication from India, IP/C/W/195 (July 12, 2000) (suggesting that the enhanced disclosure portion could be open to the public upon filing to give sufficient time to allow oppositions to be filed).

[165] Minutes of Meeting, Representative of the United States, IP/C/M/39, para. 128 (March 21, 2003) (suggesting that such a disclosure would discourage patent applications and result in a disincentive to innovate).

[166] EPC art. 128(4) (allowing inspection of files of European application); PCT Rule 94.1(b); Japan Art. 66.

[167] Review of the Provisions of Article 27.3(b), Communication from the United States, IP/C/W/162, at 6 (Oct. 29, 1999).

[168] Article 27.3(b), The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge, Communication from Switzerland, IP/C/W/400/Rev.1 (June 18, 2003).

[169] Additional problems exist if patent applicants are not entirely truthful in their disclosure. For example, what is to prevent an applicant from indicating a geographic origin that is not true? Similarly, if biological material *could* be obtained from multiple sources, what would prevent an applicant from listing an "incorrect" source?

5.3.3 There are also some issues unique to disclosure of geographic origin for plant varieties. Some commentators have noted that for plant varieties, genetic material may be obtained from a number of sources and that it is not common practice to take note of each source in the process of creating a plant variety.[170] Moreover, one commentator suggested that such a requirement may actually have perverse results with respect to overall CBD goals because it might encourage use of only existing collections, resulting in greater genetic uniformity, rather than the biodiversity intended to be fostered by the CBD.[171]

5.3.4 **2. Prior Informed Consent**

5.3.5 Disclosure of prior informed consent raises some additional issues beyond the ones already discussed for disclosure of geographic origin.

5.3.6 A number of countries and commentators have already noted that many countries do not have existing systems for obtaining informed consent.[172] If national laws do not specify requirements or methods for obtaining prior informed consent, an additional requirement in patent applications would have little to enforce. The lack of national infrastructure to provide prior informed consent might be addressed by providing an international framework for issuing such consent; however, as will be noted in the next section, this is still an idea in very formative stages.

VI. THE FEASIBILITY OF AN INTERNATIONAL CERTIFICATE OF ORIGIN SYSTEM

6.0.1 This section outlines some potential models that may be considered in discussions of a potential certificate of origin requirement. Additionally, despite the continued relevance of the international and national patent issues previously discussed, the following analysis is presented independently.

6.1 A. The Need For An International Framework

6.1.1 Before discussing potential models of an international certificate of origin system as evidence of prior informed consent, it is useful to first consider the relevant context. The suggestion for an international system is related to criticisms that an enhanced disclosure requirement would be of limited utility because most nations do not presently have a system for obtaining access and informed consent.[173] However, an international certificate of origin would directly address this criticism.

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[170] Dutfield, *supra* note 18, at 26.

[171] *Id.*

[172] Communication from Switzerland, IP/C/W/400/Rev.1 (June 18, 2003); Communication from Norway, IP/C/W/293, at 3 (June 29, 2001); ICC, 2002, Policy Statement, *Should Patent Applicants disclose the Origin of Biological Materials on which they File Patents? Should they demonstrate Prior Informed Consent (PIC) for their Use?* available at http://www.iccwbo.org/home/statements_rules/statements/2002/whoooould_patent_applicants.asp; Graham Dutfield, *Sharing the Benefits of Biodiversity: Is there a Role for the Patent System?*, 6 J. W. INTELL. PROP., 924 (2002) (noting that even if patent laws require a certificate of origin, there may be no authority to provide such a certificate).

[173] *E.g.*, Review of the Provisions of Article 27.3(b) of the TRIPS Agreement, Communication from the European Communities and their member States, IP/C/W/254 (June 13, 2001) (noting that few countries can presently certify informed consent).

6.1.2 There are presently a few countries that have used some type of certification of prior informed consent as a link to patent issuance.[174] However, these existing certification schemes are difficult to utilize as models for an international scheme, which has inherent additional complexities based on its scale, as well as an increased number of different viewpoints.

6.1.3 Nonetheless, there are some potential models for effectuating a similar purpose within the intellectual property system. Accordingly, this section first considers potential models within the intellectual property scheme, then considers certificates of origin in other areas.

6.2 B. Existing Models – Intellectual Property Scheme

6.2.1 1. Inventor Oath

6.2.2 The closest certification of origin in the intellectual property context that comes to mind is an inventor's oath that he is in fact the inventor and knows of no reason why an invention should be barred. Some countries, such as the U.S. require such an oath and the PCT also permits such an oath to be filed with an international application.[175] However, further consideration of whether an amended oath would be consistent with international obligations should be considered.

6.2.3 2. Independent International Convention

6.2.4 Another possible route would be an independent international convention that might use certificates or some other method to provide certification of prior informed consent. The patent context actually has several models by which some requirements are complied with on an international scale, including the PCT, as well as the Budapest Treaty.

6.2.5 One possibility is for an international convention to dictate the form of a certificate of origin that could be used by all member countries and be universally accepted as adequate. Such a system could be based upon the PCT, which, as previously discussed, has served as a basis for subsequent international agreements, such as the PLT and SPLT. If the PCT were amended to clearly permit enhanced disclosure requirements, additional PCT rules or regulations governing the form of a certificate of origin would seem appropriate. Alternatively, the PCT could be used solely as a model for establishing a free-standing international agreement to establish uniform certification of prior informed consent.

6.2.6 Another patent-related analog for a certificate of origin is the Budapest Treaty, an international convention that allows applicants from member states to deposit biological

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[174] It is notable that existing certification schemes are not incorporated within patent laws, but rather, under biodiversity laws. *E.g.*, Costa Rica Biodiversity Law. On the other hand, India enacted amendments to its patent laws, but does not require certification of informed consent and accordingly has no need for such a requirement in its patent laws.

[175] 35 U.S.C. 115; 35 C.F.R. 1.63(a)(4).

material that is the subject of a patent application in satisfaction of the patent disclosure requirement.[176] Not all applicants of inventions involving biological materials need to make a physical deposit pursuant to the Budapest Treaty. However, the Budapest Treaty provides an *option* and is usually used when a description in words alone would not suffice. In particular, the Budapest Treaty was created, in part, to provide an officially recognized deposit system that patent offices could rely upon and that would enable applicants to more easily "describe" a microorganism.

6.2.7 If an enhanced disclosure requirement were included as a mandatory part of patent applications via an amendment to TRIPS article 29, something akin to the Budapest Treaty might be a reasonable model. However, it should be noted that consensus to establish the Budapest treaty arose from the fact that the treaty was directly related to existing practices. In particular, deposits of microorganisms in culture collections for patent purposes was common by the early 70s, although there was no internationally recognized procedure.[177] The need for an international system was recognized by countries and supported by a WIPO Committee of Experts.[178]

6.3 C. Other Existing Models

6.3.1 Certificates of origin have been utilized for tangible items that are transported and in particular, in connection with trade agreements. For example, certificates of origin appear to be commonly used among NAFTA participants/members to ensure that goods are produced only in qualifying regions.[179]

6.3.2 The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) could be a preliminary model to consider in formulating an international certificate of origin system.[180] However, the permit system under CITES relates to trading in endangered species, which are tangible objects to which a permit may constantly accompany. On the other hand, intellectual property rights may protect tangible objects, but often not from their inception. In fact, by definition, intellectual property rights protect *intangibles*. The genetic resources upon which intellectual property rights may be based are tangible. However, because an application for intellectual property rights may still be several steps removed from the original (tangible) genetic resource, it may still be difficult to obtain a certificate that gives adequate consent for all possible uses of the genetic material. This is especially true because at the time the

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[176] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241, 1861 U.N.T.S. 361.

[177] Applicants often needed to make multiple deposits of the identical item as a requirement for complying with the patent disclosure requirement. Intellectual Property Rights and Transfer of Technologies Which Make Use of Genetic Resources, Note by the Secretariat, UNEP/CBD/COP/2/17, para. 15 (Oct. 6, 1995).

[178] Guide to the Deposit of Microorganisms under the Budapest Treaty, at 2, para. 4 (April 2000), *available at* http://www.wipo.org/about-ip/en/budapest/guide/pdf/guide.pdf.

[179] U.S. Customs Serv., Dept of Homeland Security, Form 434, NAFTA Certificate of Origin (1997), *available at* http://www.customs.ustreas.gov/xp/cogv/toolbox/forms/; or at http://www.ups.com/using/services/intlforms/help/us_eng_expdoc_certorig_help.html. For another example of the use of certificates for tangible goods, see Tracey Michelle Price, *The Kimberley Process: Conflict Diamonds, WTO Obligations and the Universality Debate*, 12 MINN. J. GLOBAL TRADE 1 (2003).

[180] Convention on International Trade in Endangered Species of Wild Fauna and Flora, Mar. 3, 1973, 27 U.S.T. 1087, 993 U.N.T.S. 243.

certificate is given, all possible uses of the genetic material may not yet be known and a patent application may not even be contemplated.

VII. CONCLUSION

7.0.1 This report should highlight some major feasibility issues involved with the possible disclosure requirement to help determine the next steps for additional study and continuing consideration of implementation issues. For example, international consistency with any such requirement is a complex issue that hinges upon many factors. This report also notes practical barriers to the effective utilization of any such requirement by patent examiners because of current prior art definitions, as well as the fact that patent examiners have limited time to evaluate information. In addition, although this report discusses the possible impact of such a requirement on CBD goals, these impacts are admittedly speculative given the fact that the requirement is still under consideration for most countries. Also, whether CBD goals will be promoted is in part based upon whether a practical system to certify informed consent on an international level is possible. Some preliminary possibilities are outlined here, but further consideration and evaluation would likely be most helpful in making an overall assessment of the feasibility of such a requirement.[181]

7.0.2 This report also raises additional issues that might be considered in achieving the underlying CBD goals. In particular, to minimize patents based on improper access to genetic resources, amendments to national and international definitions of prior art could be helpful. As noted in this report, some controversial patents have issued because of limited definitions of prior art that do not consider use of inventions outside of the patent-issuing country. A broader definition of prior art to allow any use, no matter where such use occurred, as well as oral information, would necessarily provide more information that patent examiners could readily apply as prior art. Altering the scope of prior art, together with further strengthening the database of available traditional knowledge available to patent examiners seems to support the same goals as enhanced disclosure requirement and possibly have even more potential.

7.0.3 Another possibility is to consider an independent framework to achieve the goals of an enhanced disclosure requirement. In particular, some of the issues raised by including an enhanced disclosure requirement into the existing national and international framework for patents may suggest that a new framework would be useful or even preferable.

[181] A number of countries have noted that further discussion of an enhanced disclosure requirement is necessary. E.g., Minutes of Meeting, Representative of Australia, IP/C/M/38 (Feb. 5, 2003) (generally supporting a disclosure requirement, but suggesting that specific legal consequences need further investigation); Minutes of Meeting, Representative of the European Communities, IP/C/M/39 (March 21, 2003) (noting willingness to consider a disclosure amendment); Minutes of Meeting, Representative of Indonesia, IP/C/M/32 (Aug. 23, 2001), Representative of Singapore, IP/C/M/32.

Appendix A:
Representative Membership in International Conventions
Relevant to Enhanced Disclosure Requirement

Country	CBD	**WTO/ TRIPS**	**PCT**	PLT	**EPC**	EU	**UPOV 91**	**UPOV 78**	UPOV 61/72	**Budapest Conv.**
Argentina	Y	**Y**						**Y**		
Australia	Y	**Y**	**Y**				**Y**			**Y**
Austria	Y	**Y**	**Y**		**Y**	Y		**Y**		**Y**
Belgium	Y	**Y**	**Y**		**Y**	Y			Y	**Y**
Brazil	Y	**Y**	**Y**					**Y**		
Bulgaria	Y	**Y**	**Y**		**Y**		**Y**			**Y**
Canada	Y	**Y**	**Y**					**Y**		**Y**
Chile	Y	**Y**						**Y**		
China	Y	**Y**	**Y**					**Y**		**Y**
Costa Rica	Y	**Y**	**Y**							
Cyprus	Y	**Y**	**Y**		**Y**					
Czech Republic	Y	**Y**	**Y**		**Y**		**Y**			**Y**
Denmark	Y	**Y**	**Y**		**Y**	Y	**Y**			**Y**
Egypt	Y	**Y**	**Y**							
Estonia	Y	**Y**	**Y**	Y	**Y**		**Y**			**Y**
Finland	Y	**Y**	**Y**		**Y**	Y	**Y**	**Y**		**Y**
France	Y	**Y**	**Y**		**Y**	Y		**Y**		**Y**
Germany	Y	**Y**	**Y**		**Y**	Y	**Y**			**Y**
Greece	Y	**Y**	**Y**		**Y**	Y	**--**	**--**		**Y**
Hungary	Y	**Y**	**Y**		**Y**		**Y**			**Y**
India	Y	**Y**	**Y**							**Y**
Ireland	Y	**Y**	**Y**		**Y**	Y		**Y**		**Y**
Israel	Y	**Y**	**Y**				**Y**			**Y**
Italy	Y	**Y**	**Y**		**Y**	Y		**Y**		**Y**
Japan	Y	**Y**	**Y**				**Y**			**Y**
Korea	Y	**Y**	**Y**				**Y**			**Y**

Country	CBD	**WTO/ TRIPS**	**PCT**	PLT	**EPC**	EU	**UPOV 91**	**UPOV 78**	UPOV 61/72	**Budapest Conv.**
Liechtenstein	Y	**Y**	**Y**		**Y**		**--**	**--**		**Y**
Luxembourg	Y	**Y**	**Y**		**Y**	Y	**--**	**---**		
Monaco	Y		**Y**		**Y**		**--**	**--**		**Y**
Netherlands	Y	**Y**	**Y**		**Y**	Y	**Y**			**Y**
New Zealand	Y	**Y**	**Y**					**Y**		
Norway	Y	**Y**	**Y**					**Y**		**Y**
Portugal	Y	**Y**	**Y**		**Y**	Y		**Y**		**Y**
Romania	Y	**Y**	**Y**		**Y**		**Y**			**Y**
Russian Fed.	Y		**Y**				**Y**			**Y**
Slovakia	Y	**Y**	**Y**	Y	**Y**			**Y**		**Y**
Slovenia	Y	**Y**	**Y**	Y	**Y**		**Y**			**Y**
S. Africa	Y	**Y**	**Y**					**Y**		**Y**
Spain	Y	**Y**	**Y**		**Y**	Y			Y	**Y**
Sweden	Y	**Y**	**Y**		**Y**	Y	**Y**			**Y**
Switzerland	Y	**Y**	**Y**		**Y**			**Y**		**Y**
Turkey	Y	**Y**	**Y**		**Y**					**Y**
UK	Y	**Y**	**Y**		**Y**	Y	**Y**			**Y**
Ukraine	Y		**Y**	Y				**Y**		**Y**
United States		**Y**	**Y**				**Y**			**Y**
