

**The Need To Address Disclosure of Origin Requirements  
in Patent Law Harmonization Initiatives**

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**Introduction**

Good afternoon ladies and gentlemen, distinguished delegates. First, I would like to thank Deputy Director General Francis Gurry, Mr. Philippe Baechtold, and the WIPO Secretariat for inviting me to participate in this Open Forum on the Draft Substantive Patent Law Treaty (SPLT). I will address the timely and important issue of the need to include in the SPLT or other patent law harmonization initiatives mandatory legal requirements for the disclosure in patent applications of various kinds of information about genetic resources and associated traditional knowledge (GR/TK) relating in various ways to the subject matter of patented inventions (disclosure of origin requirements).

Second, I would like to thank WIPO and others who have contributed to my understanding of these issues. The WIPO Secretariat has performed an invaluable service in compiling national laws regarding disclosure of origin requirements and in analyzing their ramifications for the international patent system.<sup>1</sup> Many countries have now enacted legislation to implement the Convention on Biological Diversity (CBD) requirements for prior informed consent for access to genetic resources and traditional knowledge and for equitable benefit sharing of any commercial benefits derived from such access (access and benefit sharing, or ABS, requirements). Some countries have also enacted disclosure of origin requirements to identify the nature, source, and country of origin of GR/TK and to provide evidence of compliance with ABS requirements. I am grateful to the Public Interest Intellectual Property Advisors for requesting the Glushko-Samuelson Intellectual Property Law Clinic at the Washington College of Law to provide an analysis of the consistency of such national disclosure of origin requirements with existing international patent law treaties.<sup>2</sup> I am indebted to the United Nations Conference on Trade and Development for requesting, and to my co-author Carlos Correa for producing, an analysis of the issues relating to an international system of mandatory disclosure of origin requirements.<sup>3</sup>

I have one basic point to make today. **Any further initiative to harmonize substantive patent laws should address the issue of mandatory disclosure of origin requirements.** This is because:

1. The patent system itself should deter, rather than reward and perpetuate, unjust conduct.

2. Individuals, indigenous peoples, and governments from which GR/TK has been acquired illegally with whom or commercial benefits have not been equitably shared should not have to shoulder the entire burden of preventing and remedying unjust conduct, but rather the patent system should take some responsibility to address unjust conduct.
3. Mandatory disclosure of origin requirements will help to develop and potentially to harmonize the complex legal and equitable principles that govern rights to own and to benefit from patents.

At the end of my presentation, I will briefly mention a number of additional legal issues that I believe should be addressed in any initiative to harmonize substantive patent laws.

**1. Disclosure of Origin Requirements Are Needed to Help the Patent System Deter, Rather than Reward and Perpetuate, Unjust Conduct.**

Because inventors, patent owners, and others derive substantial material benefits from the patent system, the patent system itself has the potential to unjustly reward and perpetuate illegal or inequitable conduct, including violations of ABS requirements. Benefits may be provided by the patent system directly as the result of granting patents, or indirectly from the mere potential to obtain patents. Benefits obtained through the patent system may not be shared equitably pursuant to ABS requirements. The very existence of the patent system thus creates perverse incentives for illegal and unjust conduct.

For example, patent rights may unjustly reward inventors who derive inventions directly or indirectly from *illegally* acquired GR/TK. Even the mere filing of an application for a patent may unjustly reward such inventors. Such filing may facilitate information disclosures regarding inventions and may attract venture capital. As the Biotechnology Industry Organization recently stated, “[p]atents and the potential for exclusive rights attract venture capital, collaborative research, and licensing partners.”<sup>4</sup> The first two of these unjust rewards are not directly tied to commercial exploitation of any patents that issue, and all of these unjust rewards are likely to be retained by inventors even if granted patents are subsequently invalidated.

The benefits of applying for and obtaining patents on inventions that are derived legally from GR/TK may not be shared equitably with individuals, indigenous peoples, and governments from which the GR/TK is acquired. Patent owners may derive commercial benefits from such patents in the form of licensing revenue and competitive advantages obtained by threatening to enforce or by enforcing the exclusive rights. These benefits are not normally recouped when patents are invalidated administratively or judicially. Benefits also may be obtained by persons other than the patent owner, such as when an inventor assigns patent rights in exchange for monetary compensation or employment. These non-owner benefits are unlikely to be part of any equitable benefit sharing

contracts created as conditions of access to GR/TK. Failures to share benefits equitably thus may not necessarily be redressed through legal actions brought against patent owners.

Substantive patentability criteria alone cannot prevent the patent system from rewarding and perpetuating unjust conduct relating to ABS violations. When patented inventions are derived from illegally obtained genetic resources or traditional knowledge, the patents may never be challenged because the facts are not readily accessible and may not be disclosed by patent applicants. If the facts were discovered, the patents nevertheless may be valid and enforceable under substantive patentability criteria. Even if patents were successfully challenged and invalidated under such criteria, benefits obtained by the patent owner or by others will be unjustly retained. In contrast, substantive laws of ownership and equitable principles may provide legal grounds to address these concerns (as discussed in the next section). But those legal and equitable principles are unlikely to be invoked without discovery of the relevant facts regarding derivation of inventions and disposition of benefits.

**Mandatory disclosure of origin requirements thus are needed to provide transparency regarding the relevant facts, facilitating efforts to prevent the patent system from rewarding and perpetuating unjust conduct.** Mandatory disclosure of origin requirements will help to assure that individuals, indigenous peoples, and governments are better informed of the relevant facts regarding patent applications for inventions derived from GR/TK, benefits derived from the patent system, and compliance with ABS requirements. Disclosing such information will facilitate successful judicial challenges to patents and benefits derived illegally or unjustly. Based on substantive laws of ownership and equitable principles, courts may transfer ownership interests, order restitution, invalidate patents or render them unenforceable.

Mandatory disclosure of origin requirements also may oblige patent offices to review the contents of applicant disclosures and to refuse to process applications or to grant patents where required disclosures or declarations are omitted or are clearly defective. Existing national laws may authorize patent offices to make substantive determinations regarding laws of ownership and equitable principles, and thus to determine rights to apply for and own patents on GR/TK-derived inventions.<sup>5</sup> Mandatory disclosure of origin requirements will facilitate such ownership determinations. But whether or not patent offices are so authorized, disclosures will help to prevent acquisition of unjust patents and benefits therefrom. This is because such disclosures will facilitate judicial challenges by individuals, indigenous groups, and governments. In response to court orders, patent offices may then refuse to issue patents to applicants, or may invalidate granted patents.

Mandatory disclosures of origin requirements also help the patent system itself to deter illegal or unjust conduct. Mandatory disclosure of origin requirements may

oblige patent applicants to disclose GR/TK relating to the invention, to provide evidence of compliance with ABS requirements, and to make various declarations of their rights to apply for and benefit from patents. Sanctions relating to such disclosures may range from the potential invalidation of patent rights to criminal penalties for knowing false statements. Such sanctions help to deter unjust conduct, by discouraging applications on illegally or inequitably derived inventions and thus by removing incentives to benefit from the unjust conduct. The deterrent effect will become more pronounced as legal and equitable principles are further clarified over time.

**Mandatory disclosures of origin are particularly important when granted patents are *valid* under substantive patentability criteria.** If the patent is substantively *valid*, only challenges based on laws of ownership and equitable principles will deter the unjust conferral or retention of the benefits of the patent system. Information required to identify and bring such challenges normally is not required to be disclosed by applicants. Such information thus may not be discovered before the patent system transfers benefits to applicants. Mandatory disclosure of origin requirements help to assure such information is accessible, thereby facilitating successful challenges to the unjust acquisition or retention of benefits of the patent system. It is for this reason that mandatory disclosure of origin requirements are needed as part of the patent system.

WIPO and others have sometimes focused on the value of mandatory disclosure of origin requirements in regard to *invalid* patents, because such disclosures will improve substantive examination of patent applications.<sup>6</sup> But substantive patentability criteria already may require disclosure of information regarding GR/TK from which inventions are derived.<sup>7</sup> Based on such information, patent applications may be rejected, and improperly granted patent may be administratively or judicially invalidated. The potential to reject applications and to invalidate patents based on substantive patentability criteria provides at least some level of deterrence in regard to acquiring benefits unjustly from the patent system. This is because anyone interested in a patent must consider the potential for its invalidation. Such substantive patentability disclosure requirements and related sanctions thus demonstrate the need for mandatory disclosure requirements relating to ownership and equitable benefit sharing: Disclosure of relevant information is effective for deterring improper conduct and assists patent offices and courts to make proper legal determinations.

## **2. The Patent System Should Shoulder Some of the Burden Of Preventing Unjust Conduct By Requiring Disclosures of Origin.**

Various proposals for mandatory disclosures of origin requirements have been put forward. Such proposals may include requirements for applicants: (1) to evaluate and to identify the source and country of origin of GR/TK; (2) to declare and/or to provide evidence that such GR/TK was acquired in compliance with ABS requirements; (3) to declare and/or to provide evidence that equitable

benefit sharing has been or will be provided. Such proposals also may include requirements for patent offices: (4) to review submitted disclosures for completeness and formal adequacy, imposing varying consequences for inadequate submissions; and (5) to review submitted disclosures and declarations for substantive validity, imposing various consequences required under legal and equitable principles of ownership. All of these measures may assist the patent system to avoid rewarding unjust conduct. Each of these measures would impose different burdens on applicants, patent offices, courts, and individuals, indigenous peoples, and governments from which GR/TK was acquired or who should receive equitable sharing of benefits.

Numerous objections have been raised to mandatory disclosure of origin requirements as a tool to address ABS violations relating to patent applications. These objections include: (1) the lack of authority and capacity for patent offices to evaluate legality of access to GR/TK, validity of ownership rights, and fairness of benefit sharing; (2) the limited ability to address ABS violations, given that such violations may not result in patent applications; (3) the substantial burdens to businesses or government agencies of assessing the legality of access, ownership, and equitable interests, particularly for historic collections of GR/TK in their possession; (4) the potential deterrent effect on scientific research with GR/TK if patent rights are rendered more uncertain; and (5) the high cost of administering a mandatory disclosure system, particularly given the lack of empirical evidence that significant numbers of patent applications and patents involve illegally acquired GR/TK or inequitably shared benefits. These objections, however, miss the mark for two reasons.

**First, individuals, indigenous peoples, and governments whose GR/TK has been acquired illegally or with whom benefits have not been equitably shared should not have to shoulder the entire burden of preventing and remedying unjust conduct.** Nor should they have to shoulder the entire burden of preventing the patent system from rewarding and perpetuating such unjust conduct. In contrast, patent applicants are in the best position to make initial determinations and disclosures regarding the legality of materials that are in their possession or for which they are seeking to obtain and retain benefits of the patent system. Failing to require mandatory disclosures of origin will not make the underlying disputes regarding legality of ownership, compliance with ABS requirements, and the application of equitable principles go away. Rather, it will help to keep these disputes from becoming transparent and thus will systematically bias these disputes against individuals, indigenous peoples, and governments. Absent mandatory disclosure of origin requirements, the patent system will continue to impose a burden of discovery on individuals, indigenous peoples, and governments to find out when ABS violations have occurred and when the patent system is being used unjustly.

Mandatory disclosures of origin would simply place some of this burden of investigation on those in the best position to know the facts. Applicants are

clearly in the best position to know how GR/TK was acquired and how it relates to inventions for which patent rights are sought. Applicants are also in the best position to know what benefits have been or will be obtained through the patent system and how those benefits have been and will be shared. Courts and patent offices also will be in a better position to evaluate entitlements to apply for patents and to receive benefits of the patent system in light of such investigations and disclosures.

The idea that the people who possess property and government agencies should shoulder some of the burden of preventing and redressing illegal ownership and unjust benefits is neither new nor radical. For example, the United States has imposed specific requirements on museums and governmental agencies to determine the proper legal ownership or disposition of human remains and cultural artifacts, in regard to both new activities and historic collections. The 1990 Native American Graves Protection and Repatriation Act (NAGPRA) thus provides an elaborate process for museums and government agencies to review their collections, to determine rights of ownership or disposition, and to return remains and cultural artifacts to individuals, tribes, or organizations.<sup>8</sup> Like mandatory disclosure of origin requirements, the premise of NAGPRA requirements is to identify and publicize facts regarding the relevant materials, in order to facilitate legal actions to remedy past illegal or unjust conduct and to deter current illegal or unjust conduct.

NAGPRA's investigation and evaluation requirements (which help to make transparent the lack of rights of possession) were initially resisted by museums and government agencies based on the burdens and complexity of performing extensive investigations and complex legal evaluations for very large collections of artifacts. Shifting some of the burden of investigation and evaluation has proved highly successful in returning improperly acquired human remains and cultural artifacts. Nevertheless, Native Americans continue to bear the ultimate burden of investigation and evaluation, as they must request and (if legal actions are required) prove their rights to repatriation of such materials. Mandatory disclosure of origin requirements would effectuate a similarly effective system.

**Second, the intellectual property system should take some responsibility to address unjust conduct, as it is otherwise complicit in rewarding and perpetuating such conduct.** As discussed above, the patent system may reward and perpetuate unjust conduct by providing benefits to patent applicants, patent owners, and others. The patent system thus has a moral responsibility to avoid rewarding such illegal or unjust conduct, and thereby to avoid providing incentives for such conduct. The patent system, moreover, is not merely an innocent bystander in regard to unjust conduct. Not only may it facilitate additional injustice but may itself benefit directly in the process (such as through patent application fees on inventions developed from illegally acquired GR/TK).

The problem of institutions improperly rewarding and perpetuating illegal and unjust conduct is not new. Nor is it a radical idea to require those institutions to take some responsibility to avoid rewarding and thus to deter illegal and unjust conduct. For example, the same problem has been recognized in regard to use of the international financial system to “launder” or obtain profits from illegally acquired personal and governmental property, such as money obtained from illegal drug trafficking or gold illegally acquired during wartime. Moreover, financial institutions themselves benefit from using the illegally acquired property (by investing or lending deposited funds). Financial institutions have not been successful in their efforts to disclaim any responsibility to avoid being improperly used to perpetuate unjust conduct. Rather, intergovernmental organizations and governments have adopted principles and laws requiring financial institutions to undertake specific measures that help to assure that their practices do not unjustly reward and perpetuate illegal conduct.<sup>9</sup>

Patent applicants and patent offices thus must take a more active role than in the past to protect the integrity of the patent system. The patent system should not continue to ignore or to avoid resolving fairly the ownership and equitable disputes lying hidden deep within it. To do so, any initiative to harmonize substantive patent laws should address mandatory disclosure of origin requirements, carefully considering the burdens of investigation and evaluation that are most appropriate to impose in light of the objectives to be accomplished and the costs that will be incurred.

### **3. Mandatory Disclosure of Origin Requirements Will Help to Develop and Potentially To Harmonize Legal and Equitable Principles.**

Disputes over rights to apply for, own, and obtain benefits from patents have rarely been addressed by courts, and even more rarely have been resolved by patent offices. In making such determinations, courts and patent offices apply laws of ownership and equitable principles, but the paucity of resolved disputes has left substantial uncertainties in regard to the application of these legal and equitable principles. For example, U.S. law may prohibit acquiring patent rights in or may impose equitable restitution on inventions developed using illegally acquired property or information.<sup>10</sup> But so few cases exist it is difficult to identify patterns of application of the principles that would permit refining the relevant principles to provide greater specificity and predictive value to new factual contexts.

Although mandatory disclosure of origin requirements would not themselves define ownership rights and equitable principles for patent law,<sup>11</sup> they would help to make existing disputes transparent and thus facilitate legal actions to fairly resolve such disputes. In this way, mandatory disclosure of origin requirements may help develop clearer understandings of how these legal and equitable principles apply to the patent system. Such clearer understandings may potentially lead to initiatives to harmonize relevant laws of ownership and

equitable principles. Such clearer understandings also will help to deter unjust conduct, by assisting inventors, patent owners, and others to acquire patents legally and to share benefits equitably.

Again, NAGPRA provides a good example of how mandatory disclosure obligations can lead to clarification of the relevant legal principles. NAGPRA does not itself impose new requirements regarding ownership. It simply adopts a process that makes explicit that existing dispositions of property may not reflect rights of possession under applicable legal rules of ownership (including complex questions of colonial era authority, treaty laws, and laws of indigenous groups regarding ownership and restrictions on alienation of property). By doing so, it makes transparent existing but hidden disputes over ownership, allowing the courts to fairly and equitably resolve ownership and thereby to clarify the relevant legal principles through their application.

Mandatory disclosures of origin also may help to develop clearer understandings of related areas of law. There currently exists substantial uncertainty in regard to the legal status of ownership rights and equitable interests in collections of GR/TK, and in regard to GR/TK that might be acquired in countries that have ratified the CBD but have not yet adopted ABS implementing legislation. There is substantial uncertainty regarding ownership rights and equity of benefit sharing arrangements under national laws implementing CBD ABS requirements. Finally, there is substantial uncertainty as to whether and under what circumstances national governments will recognize and enforce (under principles of comity<sup>12</sup> or otherwise) legal and equitable principles of other governments and indigenous peoples.

#### **4. Additional Patent Law Issues For Harmonization**

I have focused so far solely on why any initiative to harmonize patent laws should address mandatory disclosure of origin requirements: to protect the integrity of the patent system; as a matter of basic fairness; and to help clarify and potentially harmonize legal and equitable principles. But there are many other aspects of the patent system that can and should be improved. Substantial concerns have been raised that the international patent system as currently configured harms the progress of technological and scientific innovation for human benefit.<sup>13</sup> These concerns reflect: the ever-broadening scope of patentable subject matter and claimed rights in proportion to disclosed inventions or inventive effort; the lower thresholds for patentability standards; the increasing tendency to restrict or eliminate earlier limitations on and exceptions to exclusive rights; the increasing tendency to view patent rights as conveying immunity from competition and other regulatory laws; and the uniformity of patent rights and terms across all fields of technology, notwithstanding the substantial differences that exist in regard to innovation incentives and commercial applications.<sup>14</sup>

Assuming these concerns are valid, the social harms of the current patent system affect not just the public in countries where patents are too easily acquired and too broad rights are granted and enforced. The public in such countries pay the direct and indirect costs of higher prices and fewer alternatives to patented goods and services. But the social harms of foregone or delayed technological and scientific innovation adversely affect all people in all countries. All countries would benefit from the diffusion of technological and scientific progress. Thus, if these concerns are valid, there are substantial reasons to harmonize patent protection downward from the existing high levels. Such harmonization may require not only taking greater account of existing flexibilities in international patent law treaties but also revising some of the most troubling provisions of those treaties. The need to revise existing high levels of protection was recently recognized when Article 31(f) of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was revised. Of course, such harmonization does not necessarily require uniformity, as due account should continue to be taken of relevant differences among countries regarding levels of economic and technological development and patterns of commercial activity.

Accordingly, I briefly identify below a number of issues (some of which may be addressed by others presenters at the Open Forum) that would warrant further initiatives to internationally harmonize patent laws, so as to better assure that technological and scientific progress is not impeded. This is not meant to be an exhaustive list, but only to point out the need to address initiatives to harmonize patent law in a holistic manner.

- A. Patentable subject matter. It is widely recognized that laws of nature, scientific principles, and naturally occurring organisms in an unaltered state should not be patentable. However, patentable subject matter has in recent years been extended to such inventions as isolated and purified naturally occurring materials, genetically modified organisms and materials, business methods, diagnostic treatment methods, etc. The TRIPS Agreement did not clearly harmonize requirements regarding these new areas of inventive activity, as reflected in current discussions over Article 27.3. This expansion of patentable subject matter raises significant questions regarding whether patent law should be limited to the field of technical industrial application or should apply more broadly to scientific discoveries and commercial activities.<sup>15</sup> Concerns over such extensions range from the lack of any need for incentives to invent and disclose in these fields to the extremely broad application of rights that are obtained.
- B. Scope of claiming. Domestic patent laws vary widely regarding the permissible breadth and timing of claims for generic inventions, in light of disclosures of particular species actually reduced to practice or contemplated by inventors. Such broad early claims may reflect little innovative effort and little identification of the uses of identified inventions (e.g., running a nucleic acid sequencing machine and identifying research

uses for the identified sequences) and little financial investment (e.g., being the first to apply a common business practice to the internet, requiring only the drafting of limited amounts of computer code). In contrast, such early and broad generic claims may apply to a very wide range of potential uses and new (even patentable) inventions, dominating these uses and impeding sequential innovation. Further, domestic patent laws vary in regard to whether such broad generic claims will apply for exclusion purposes to later-arising technological substitutes for requirement elements of the claimed inventions. Such substitutes arguably were not part of the generic invention that was claimed, particularly if the meaning of claim language is considered fixed as of the filing date of the application. For harmonization purposes, the question is whether the scope of inventions that can be claimed imposes too great a restraint on sequential innovation and unjustly enriches patentees beyond the scope of their actual inventive contribution.<sup>16</sup>

C. Experimental use/academic use/product regulatory approval use/fair use.

Particularly for patents on inventions having use in further research, many countries around the world have excepted from exclusive rights scientific and various academic uses of patented inventions.<sup>17</sup> Freedom to experiment, analyze, and discuss inventions is necessary to assure that patents are not improperly granted (in regard to enablement and scope of claimed inventions) and to rapidly develop sequential innovations. This is particularly true in regard to patents on inventions for which written description requirements have been met by deposits of biological materials.<sup>18</sup> However, such experimental use exceptions, including exceptions for experimentation that is a predicate to product regulatory approvals, have recently been called into question in some jurisdictions.<sup>19</sup> The nature and scope of these exceptions is not internationally harmonized. To the extent that broader exceptions – including general noncommercial exceptions similar to copyright fair use – would promote technological progress or otherwise benefit society without imposing correspondingly great costs, such exceptions should be expanded by international harmonization initiatives.

D. Relationship of patent laws to other laws. Numerous issues exist in regard to the relation of patent laws to other laws. These issues include questions such as: whether the grant of patent rights exclude application of regulatory laws (such as pharmaceutical price regulations<sup>20</sup>) or competition laws (such as abuse of dominant position or essential facility doctrines); whether and to what extent patent terms should be extended or other forms of market exclusivity should be provided in regard to product regulatory approval decisions; etc.

E. Compulsory licensing, government use, and injunctive remedies.

Numerous issues exist in regard to the circumstances that exclusive rights of patents should be overridden to effectuate public purposes or to avoid undue hardship to the public,<sup>21</sup> and the degree of compensation (if any) that should be provided in those circumstances.

- F. Patent misuse and contractual license restrictions. Numerous issues exist in regard to what conduct will constitute patent misuse, precluding patents from being enforced. In particular, issues exist regarding whether patent licenses may override default statutory policies (such as exhaustion of patent rights by first sale) or prohibit traditional practices with patented products (such as prohibitions against farmers saving patented seed).
- G. Patent term. Numerous issues exist in regard to whether patent terms should be uniform across all fields of technology and the circumstances in which patent terms should be extended for delays in examining applications or in obtaining access to markets.

## **Conclusion**

I call on the distinguished delegates here today to include disclosure of origin requirements in any WIPO initiative to harmonize substantive patent laws. Although I believe that the WTO is the most appropriate forum in which to adopt an international instrument to address mandatory disclosure of origin requirements (and that such requirements should be included in the TRIPS Agreement), disclosure of origin requirements should not be divorced from other initiatives to harmonize substantive patent laws. The patent system must assure that patents do not reward and perpetuate unjust conduct.

I would like to commend WIPO again for their prior work regarding disclosure of origin issues and for including these issues in the program for this Open Forum. Thank you for your attention, and I would be happy to answer any questions that you may have.

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<sup>1</sup> See, e.g., WO/GA/30/7 Add.1, *Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge*; WIPO/GTRK/IC/Q.3, *Questionnaire on various requirements for Disclosure relating to Genetic Resources and Traditional Knowledge in Patent Applications*; WO/GA/32/8 Annex, *Draft Examination of Issues Regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Applications (Third Draft)*.

<sup>2</sup> See Joshua D. Sarnoff, Memorandum for Public Interest Intellectual Property Advisors (PIIPA), *Compatibility With Existing International Intellectual Property Agreements of Requirements for Patent Applicants to Disclose Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing* (2004), available at <http://www.piipa.org/library.asp>.

<sup>3</sup> See Joshua D. Sarnoff & Carlos M. Correa, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, UNCTAD\_DITC\_TED\_2005\_14, reproduced in CBD-WG-ABS-4-INF-2, available at <http://www.biodiv.org/doc/meeting.aspx?mtg=ABSWG-04&tab=1>.

<sup>4</sup> See Brief of *Amicus Curiae*, Biotechnology Industry Organization, in Support of Neither Petitioner Nor Respondent, *Merck KGaA v. Integra LifeSciences I Ltd.*, No. 03-1237, at 3 (U.S. Supreme Court, Feb. 22, 2005) (emphasis added).

<sup>5</sup> See, e.g., 37 C.F.R. § 3.73(b)(1) (under U.S. law, assignees “must establish [their] ownership of the patent ... to the satisfaction of the Director.”).

<sup>6</sup> See, e.g., WO/GA/30/7 Add.1, at ¶¶ 42-44.85-87.

<sup>7</sup> See, e.g., 37 C.F.R. § 1.56 (duty to disclose information material to patentability under U.S. patent law).

<sup>8</sup> See, e.g., 25 U.S.C. §§ 3002 (requirements for ownership or control on tribal or federal lands), 3003 (requirements for museums to inventory items and identify their geographical and cultural affiliation and to

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provide notices), 3005 (requiring return of items upon request, following a prima facie demonstration of the lack of a right of possession and an opportunity to rebut the demonstration).

<sup>9</sup> See, e.g., The Financial Action Task Force on Money Laundering, *Forty Recommendations*, available at <http://www.fatf-gafi.org/dataoecd/7/40/34849567.PDF>.

<sup>10</sup> See, e.g., *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 809–810, 815, 819–820 (1945) (upholding dismissal of an action to enforce patents that were obtained based on fraudulent statements regarding the date of invention and that may also have involved incorrect inventorship); *Seismograph Service Corp. v. Offshore Raydist*, 135 F. Supp. 342, 347–48, 353–56 (E.D. La. 1955) (case under United States law invalidating on prior art grounds a patent that was based on misappropriated information and possible false inventorship, and suggesting that an equitable remedy of a royalty free licence would have been appropriate had the patent been held valid), *affirmed in pertinent part*, 263 F.2d 5, 22 (5<sup>th</sup> Cir. 1959).

<sup>11</sup> The failure to comply with such disclosure requirements nevertheless might affect rights to acquire, own, and enforce patents, or might affect their validity.

<sup>12</sup> See, e.g., *Hilton v. Guyot*, 159 U.S. 113, 163–164 (1895) (comity is “the recognition that one nation allows within its territory to the legislative, executive, or judicial acts of another, having due regard both to international duty and convenience and to the rights of its own citizens or others protected by its laws”).

<sup>13</sup> See, e.g., Federal Trade Comm’n, *To Promote Innovation: The Proper Balance of Competition and Patent Law* (Oct. 2003), available at <http://www.ftc.gov/reports/index.htm>.

<sup>14</sup> See, e.g., John R. Allison, et al., *Valuable Patents*, 92 Geo. L.J. 435 (2004); Michael J. Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 Boston College L. Rev. 509 (2003); Wesley M. Cohen, et al., *Protecting Their Intellectual Assets: Appropriability Conditions and why U.S. Manufacturing Firms Patent (or not)*, available at <http://papersdev.nber.org/papers/W7552>.

<sup>15</sup> These concerns may be addressed in the pending United States Supreme Court case of *Laboratory Corp. of Am. Holdings v. Metabolite Labs., Inc.*, No. 04-607. See *Metabolite Labs., Inc. v. Laboratory Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004) (finding a diagnostic test service company indirectly liable for inducing doctors to perform a patented diagnostic method of measuring an amino acid level using prior art technology and mentally performing the newly discovered correlation of the measured level to a disease condition).

<sup>16</sup> I have previously addressed some of these concerns in regard to the history of claim scope and the doctrine of equivalents under United States patent law. See, e.g., Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future after Festo*, 19 Berkeley Tech. L.J. 1157 (2004); Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future, Part I (1790-1870)*, 87 J. Pat. & Trademark Off. Soc’y 371 (2005); Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future, Part II (1870-1952)*, 87 J. Pat. & Trademark Off. Soc’y 411 (2005).

<sup>17</sup> See, e.g., Carlos M. Correa, *The International Dimension of the Research Exception*, at 19–25 (2004), available at <http://sippi.aaas.org/Correa%20-20International%20Exception.doc>.

<sup>18</sup> See, e.g., *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed.Cir. 2002).

<sup>19</sup> See, e.g., *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002); *Merck KGaA v. Integra LifeSciences I Ltd.*, 125 S.Ct. 2372 (2005).

<sup>20</sup> See, e.g., *Pharmaceutical Research and Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005).

<sup>21</sup> The standards for denying injunctive relief are currently at issue in the United States Supreme Court in *eBay, Inc. v. MercExchange, L.L.C.*, No. 05-130. See *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323 (Fed.Cir. 2005).