

AGREEMENTS THAT DIVIDE: TRIPS VS. CBD AND PROPOSALS FOR MANDATORY DISCLOSURE OF SOURCE AND ORIGIN OF GENETIC RESOURCES IN PATENT APPLICATIONS

JONATHAN CARR*

In an attempt to unify the regulation of intellectual property, the TRIPS Agreement sets forth standards for intellectual property law. Recently, however, many countries have become divided on the issue of whether member countries should be required to disclose the source and origin of genetic resources used in patented technologies. Developing countries claim that enforcement of such a requirement would help remedy the global biopiracy problem. This article reviews and assesses the many proposals to amend the TRIPS Agreement as well as the responses from countries, such as the United States, opposing the proposals. Included is a brief discussion about the potential economic ramifications of such an amendment to TRIPS and discussion of alternative international agreements as potential venues for a similar disclosure requirement.

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* J.D. Candidate, Florida State University College of Law, May 2009; B.S., Brigham Young University. The author gratefully acknowledges Professor Frederick Abbott for his guidance and the Florida State University *Journal of Transnational Law & Policy* staff for their helpful editing and suggestions.

I. INTRODUCTION

The ownership of life always sparks debate and controversy, with no exception in the intellectual property realm. With recent years of rapidly advancing science, the world has struggled with not only defining life, but also determining how to deal with the patentability of the building blocks of life and their uses. In a decision that would dramatically impact U.S. patent law, Chief Justice Burger determined that a live, human-made microorganism is patentable, stating that “anything under the sun that is made by man” is subject matter worthy of patent protection.¹ After *Diamond v. Chakrabarty*, the United States and nations throughout the world raced to keep up with the influx of biotechnology and gene sequence patent applications encompassing living forms.

Biotechnology and genetic breakthroughs have added to the international controversy over such subject matter. Developing countries fear that patenting biological resources hands the world’s most valuable assets over to large corporations of the wealthy, industrialized nations. The United States and other developed countries benefit greatly from patenting biotechnology and claim that patent protection is vital to the advancement of science, technology, and global economic development. The tension between the two positions has grown significantly as developing countries claim their resources are wrongfully taken under acts of biopiracy, where corporations and industrialized nations allegedly steal and commercialize genetic resources of other biologically diverse countries.

At the center of the biopiracy debate are two international agreements that attempt to resolve the concerns of both sides, but in some ways have only widened the gap between them. The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and the Convention on Biological Diversity (CBD) expose the dividing lines between the biodiversity-rich developing countries and the technology-rich industrialized countries.² While TRIPS advocates stronger patent protection, the CBD promotes fair and equitable sharing of biological resources. In an attempt to reconcile the two agreements, developing countries have proposed an amendment that would require disclosure of genetic source and origin in patent applications. This paper discusses the general debate among countries about the relationship between TRIPS and the CBD, the proposed amendment, and reactions to the proposal.

1. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citation omitted).

2. Charles R. McManis, *Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally*, 11 CARDOZO J. INT’L & COMP. L. 547, 548 (2003).

A brief discussion of the potential effects of the proposed amendment is also included.

II. THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

The CBD and TRIPS are evidence that, in recent years, there has been growing worldwide concern for the protection of biological resources and rights to such resources. This concern has manifested itself strongly in the global debate over intellectual property rights regarding biological resources. At the United Nations Environment Programme (UNEP), in 1987, the United States proposed that UNEP “establish an ‘umbrella’ convention” to make the different conservation agreements throughout the world compatible with one another.³ Two years later, an Ad Hoc Working Group of Experts was created to draft a harmonized document for the conservation and sustainable use of biological diversity, while considering “the need to share costs and benefits between the developed and developing countries and the ways and means to support innovation by local people.”⁴ The three pillars of the CBD are conservation of biodiversity, sustainable use, and adoption of access and benefit sharing.⁵

The CBD aims to regulate biodiversity and the use of biological resources. Article I of the CBD states that “ ‘equitable sharing of benefits’ includes access to genetic resources and ‘the appropriate transfer of relevant technologies.’ ”⁶ In Article 15(7), the CBD mandates that use of biological resources be “fair and equitable”:

Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such

3. Dominic Keating, *Access to Genetic Resources and Equitable Benefit Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 525, 528 (2005).

4. *Id.* at 528 (citation omitted).

5. Greg K. Venbrux, *When Two Worlds Collide: Ownership of Genetic Resources under the Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 6 U. PITT. J. TECH. L. & POL'Y. 5, 5 (2005).

6. *Id.*

sharing shall be upon mutually agreed terms.⁷

Although this section does not specifically reference intellectual property rights, Article 16 of the CBD requires that “access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.”⁸ Also, the CBD asserts that genetic resources are the “common heritage of mankind” and that States have sovereign rights over their genetic resources.⁹ In Article 16(3), countries of origin, especially developing countries, are given access to technology that incorporates the use of that country’s biological resources.¹⁰ This includes patentable biotechnology.¹¹ A key aim of the CBD is to promote the sustainable use of natural resources, while incorporating power to impact the application of intellectual property rights on the biotechnological industry.¹²

Controversy over the CBD was evidenced through a mixed international response from developed and developing countries. The United States has taken varying views in regards to the CBD. At first, the United States refused to sign the CBD, reasoning that the provisions about intellectual property and technology transfer were unbalanced.¹³ The United States viewed the CBD as potentially forcing a developed country to transfer technology, while at the same time allowing a developing country to not recognize patent protection for a United States biotechnology corporation.¹⁴ Not surprisingly, the United States and other developed countries saw the CBD as harmful to the competitiveness of biotechnology corporations and as potentially giving developing countries the right to completely keep industrialized countries from accessing important resources in biodiverse countries.¹⁵ Developing countries, however, expressed their strong desire for the protection of their right to control access to their own countries’ biological resources. These countries were specifically appalled at the injustice of making royalty payments to foreign biotechnology companies that used

7. Convention on Biological Diversity art. 15(7), *opened for signature* June 5, 1992, 31 I.L.M. 818, 828.

8. *Id.* art. 16(2).

9. *Id.*

10. *Id.* art. 16(3).

11. Venbrux, *supra* note 5, at 6.

12. *Id.* at 5.

13. *Id.* at 6.

14. Michael D. Coughlin, Jr., *Recent Development, Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity*, 31 COLUM. J. TRANSNAT’L L. 337, 345-46 (1993).

15. *See* Venbrux, *supra* note 5, at 6.

their countries' genetic resources.¹⁶

Many companies in the United States later expressed fear that a refusal to sign the CBD could be even more detrimental than participating in the agreement, even though these companies were strongly opposed to the CBD.¹⁷ This change in sentiment led to the United States signing the CBD, but still not becoming a Party to the Agreement.¹⁸ As a result of the many contrasting views, the CBD ultimately incorporated some contradictory language and became known by both developing and developed countries as a "vague and confusing document with strictly exhortatory powers."¹⁹ However, the CBD helped begin worldwide discussions and negotiations over the trade of biotechnology and international intellectual property.²⁰

III. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Regulation of intellectual property rights has progressed significantly in the past one hundred years, since its beginnings in the Berne Convention and the Paris Convention of the 19th Century.²¹ In 1994, after efforts to bring together global ideas about intellectual property rights, the Uruguay Round under the General Agreements of Tariffs and Trade (GATT) culminated in the creation of the World Trade Organization (WTO) and the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which is administered by the World Trade Organization.²² Prior to the TRIPS Agreement, issues of international intellectual property rights were handled through the World Intellectual Property Organization (WIPO) treaties, bilateral agreements, and the GATT.²³ The TRIPS Agreement is binding on all members of the WTO and sets forth standards for intellectual property rights protection.²⁴ One such TRIPS standard is that patents must be awarded in all fields of technology, including products and processes.²⁵ Also, to be eligible for a patent, the invention must "involve an inventive step"

16. Coughlin, *supra* note 14, at 347-48; *see also* Venbrux, *supra* note 5, at 6.

17. Venbrux, *supra* note 5, at 6.

18. *See* Keating, *supra* note 3, at 529.

19. *See* KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 225 (2000).

20. *See* Venbrux, *supra* note 5, at 6-7.

21. *See* Doris E. Long, *The Impact of Foreign Investment on Indigenous Culture: An Intellectual Property Perspective*, 23 N.C. J. INT'L L. & COM. REG. 229, 247-54 (1998).

22. Keating, *supra* note 3, at 532.

23. *Id.*

24. Venbrux, *supra* note 5, at 7.

25. *Id.*

and have "industrial application."²⁶ Developed member countries are obligated to provide incentives for corporations within the country to transfer technology to other developing member countries.²⁷ TRIPS also requires developed countries to assist developing countries in implementing a legal infrastructure for intellectual property rights protection.²⁸

One view is that TRIPS benefits only the United States and other large industrialized nations. India in particular has experienced violent protests by farmers in reaction to the TRIPS agreement, due, *inter alia*, to its grant of monopolies on plants and seeds.²⁹ Some developed countries ignore TRIPS and patent laws of the United States and the European Union by locally producing essential medicines.³⁰ For example, in Argentina, domestic drug manufacturers often market generic drugs domestically at prices fifteen to eighty percent lower than the global market price.³¹ In addition to claiming economic disadvantage due to TRIPS, developing countries assert that compliance with TRIPS imposes huge burdens.³² Formal compliance with TRIPS requires countries to establish industrial property registries, develop enforcement mechanisms, combat piracy, and prosecute criminals.³³ The United Nations Conference on Trade and Development (UNCTAD) reported that in Bangladesh the fixed cost of establishing a TRIPS-compliant administration for intellectual property rights is approximately \$250,000, with annual costs for associated expenses, such as judicial work and equipment, over \$1 million.³⁴ In Chile and Egypt, the cost predictions are similar.³⁵ For a small or developing country, this can be a burdensome expense.

IV. REACTIONS TO THE RELATIONSHIP BETWEEN CBD AND TRIPS

Shortly after the CBD and TRIPS were adopted, several ideas surfaced regarding the incompatibility of the two international

26. Agreement on Trade-Related Aspects of Intellectual Property Rights art. (27)1, Apr. 15, 1994, 33 I.L.M. 1197 [hereinafter TRIPS]; Venbrux, *supra* note 5, at 7.

27. *Id.* art. 66.

28. *Id.* art. 67.

29. McManis, *supra* note 2, at 548-49.

30. Mark Ritchie et al., *Intellectual Property Rights and Biodiversity: The Industrialization of Natural Resources and Traditional Knowledge*, 11 ST. JOHN'S J. LEGAL COMMENT. 431, 442 (1996).

31. Venbrux, *supra* note 5, at 9; Ritchie, *supra* note 30, at 442.

32. Venbrux, *supra* note 5, at 9.

33. Coenraad J. Visser, *Making Intellectual Property Laws Work for Traditional Knowledge*, in POOR PEOPLE'S KNOWLEDGE, PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 207-08 (J. Michael Finger & Philip Schuler eds., 2004).

34. MASKUS, *supra* note 19, at 173.

35. *See id.*

agreements. At the center of the debate, Article 27 specifically calls for the review of the TRIPS Agreement itself, four years after its entry into force.³⁶ Ethiopia was one of the first members of the CBD to propose that the CBD “examine the relationship between TRIPS and the CBD.”³⁷ Specifically, Ethiopia recommended that the secretariat of the CBD

[r]equest the WTO/TRIPS Council to take into account and accommodate the concerns of the Contracting Parties to the [CBD] before taking any decisions or measures in relation with the TRIPS Agreement that may affect biological diversity and the protection of knowledge, innovations, and practices of local and indigenous communities.³⁸

In 1996, India became the first country to formally propose, directly to the WTO, that the Committee on Trade and the Environment (CTE) review the consistency between the CBD and TRIPS.³⁹ India’s argument was based upon the premise that the TRIPS Agreement would cause limited competition for “environmentally sound technologies and products,” driving up prices and reducing supplies of such technologies.⁴⁰ This led to India’s proposal that the CBD and TRIPS Agreement could be reconciled through a genetic resource disclosure requirement in patent applications, effectuated by means of an amendment to TRIPS.⁴¹ This proposal sparked ongoing international discussions regarding the controversial disclosure of genetic resources issue.⁴²

A strange event at a recent UN meeting demonstrated these divergent views. At the opening of this Ad Hoc Open-Ended Working Group on Access and Benefit Sharing meeting, a statement favoring amendment to TRIPS was presented on behalf of United Nations Environment Program (UNEP) Executive Director Klaus Töpfer.⁴³ Specifically, the statement argued that TRIPS and the CBD were inconsistent and that TRIPS must be amended to promote “access and benefit sharing.”⁴⁴ Australia, the European Un-

36. TRIPS, *supra* note 26, art. 27(3)(b).

37. Keating, *supra* note 3, at 530.

38. *Id.* at 531.

39. *See id.* at 533.

40. *Id.* at 533-34; *see also* Lara Ewens, *Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds*, 23 B.C. INT’L & COMP. L. REV. 285, 305 (2000).

41. Keating, *supra* note 3, at 533-34.

42. *Id.* at 534.

43. *Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing on the Work of its Third Meeting*, para. 11, UN Doc. UNEP/CBD/WG-ABS/3/7 (Mar. 3, 2005).

44. *See* Keating, *supra* note 3, at 531 n.24.

ion, Switzerland, New Zealand and the United States strongly opposed the statement, arguing instead that the two agreements are compatible.⁴⁵ After hearing the objections from these countries, the UNEP Secretary General stated that the previous Statement did not reflect the position of the UNEP Executive Director.⁴⁶

The Doha Declaration adopted in November, 2001 mandates further review of Article 27:

We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.⁴⁷

Many countries have subsequently submitted proposals and responses about how TRIPS can be reconciled with the UN Convention on Biological Diversity.⁴⁸

V. GENERAL VIEWS ABOUT THE CONFLICT BETWEEN AGREEMENTS

Generally speaking, the overriding question is whether there is any conflict at all between the CBD and TRIPS Agreement. If yes, then the question is whether TRIPS must be amended to resolve the conflict between the two documents.⁴⁹ More specifically, there are four categories of views expressed by Member States regarding the conflict issue: (1) there is no conflict and national governments can implement the two in a mutually supportive way; (2) there is no

45. *Id.* at 531.

46. *Id.* at 537 n.43.

47. World Trade Organization, Ministerial Declaration of 14 November 2001, art. 19, WT/MIN(01)/DEC/1, 41 I.L.M. 746, 749 (2002).

48. Council for Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, 3, IP/C/W/368/Rev.1 (Feb. 8, 2006) [hereinafter *Relation between TRIPS and CBD*].

49. *Id.* at 3.

conflict, yet further study regarding the patent system is required; (3) there is no inherent conflict; however, international intervention is needed in order to ensure the two Agreements are mutually supportive; (4) there is inherent conflict, thus requiring an amendment to TRIPS to resolve the conflict.⁵⁰

The fourth view is the subject of the most intense international debate on the issue and will be the focus of this paper. In general, the suggested amendment to TRIPS incorporates certain requirements of the CBD, such as: (1) patent applicants disclose the source and country of origin of any biological resources or traditional knowledge used in inventions, and (2) the applicants both obtain prior informed consent from the appropriate authority and enter into a fair and equitable benefit-sharing arrangement.⁵¹ The United States and other developed countries oppose the proposal, while developing countries such as Bolivia, Brazil, Columbia, Cuba, India, and Pakistan strongly support the TRIPS amendment.

VI. THE PROPOSED TRIPS AMENDMENT

It is no surprise that proponents of the proposed amendment are developing countries, whose biological resources are diverse and generally used by commercial enterprises of more industrialized, developed countries.⁵² Also, the developed countries are typically more likely to afford intellectual property rights to organic innovations than the developing countries.⁵³ Brazil, the most biodiverse country on the planet and the first signatory to the CBD, has been a strong proponent of the amendment.⁵⁴ Proposals from developing countries address the problem of biopiracy:

The hypocrisy of western demand for intellectual property protections is twofold: not only do developing countries pay a high premium for the patented products that are reintroduced in their countries (yet made from local resources), but developing countries are unable to use the intellectual property framework to protect against the piracy of their own indigenous

50. *Id.* at 4.

51. *Id.* at 7.

52. Burton Ong, *Harnessing the Biological Bounty of Nature: Mapping the Wilderness of Legal, Socio-Cultural, Geo-Political, and Environmental Issues*, in INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES 11 (Burton Ong ed., 2004).

53. *Id.*

54. See generally Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from Brazil: Review of the Provisions of Article 27.3(b)*, IP/C/W/164 (Oct. 29, 1999).

and local resources and knowledge.⁵⁵

The specific proposals for amendment to the TRIPS Agreement have come from the African Group, the Andean Community, Bolivia, Brazil, China, Columbia, Cuba, Ecuador, India, Indonesia, Kenya, Pakistan, Peru, Thailand, Venezuela, and Zimbabwe.⁵⁶

Along with Bolivia, Columbia, Cuba, India, and Pakistan, Brazil submitted a paper to the WTO in 2005 regarding the relationship between the TRIPS Agreement and the Convention on Biological Diversity.⁵⁷ The countries summarize the three types of disclosure requirements: “(1) disclosure of source and country of origin of the genetic materials and associated traditional knowledge used in developing the invention claimed in the patent application; (2) disclosure of the evidence of prior informed consent; and (3) disclosure of the evidence of a benefit-sharing agreement.”⁵⁸ The Source is defined as the country from where the applicant received the genetic material, while country of origin is the country to which the genetic resource is indigenous.⁵⁹ The paper claims that the intent of the disclosure requirement is to prevent the grant of bad patents and promote greater legal certainty.⁶⁰ Revocation of an erroneously granted patent is more expensive and burdensome than disclosure requirements.⁶¹ The disclosure requirement “would act as a crucial factor in the determination of the patentability of biotechnological inventions,” according to the proponents.⁶² The paper also contends that disclosure of origin would help build databases to aid in “the prior art information available to patent examiners and the general public.”⁶³ The amendment would make inclusion of the disclosure requirement mandatory in national laws and regulations.⁶⁴

Three proposed amendments to the TRIPS Agreements have been suggested, each with unique wording. First, an amendment to Article 27 itself has been suggested, adding an exception

55. Ewens, *supra* note 40, at 305 (citing Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-so-brave) New World Order of International Intellectual Property Protection*, 6 IND. J. GLOBAL STUD. 11, 47-50 (1998)).

56. *Relation between TRIPS and CBD*, *supra* note 48, at 28 n.135.

57. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from Bolivia, Brazil, Colombia, Cuba, India and Pakistan: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge*, IP/C/W/459 (Nov. 18, 2005) [hereinafter *Communication from Bolivia*].

58. *Id.* para. 5.

59. *Id.* para. 8.

60. *Id.* para. 6.

61. *Id.*

62. *Id.* para. 7.

63. *Id.*

64. *Relation between TRIPS and CBD*, *supra* note 48, para.72.

to patentability:

Members may also exclude from patentability: (c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing of benefits arising from their use.

Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity.⁶⁵

The second method is an amendment to Article 29, including one of the following wordings:

(1) Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.⁶⁶

(2) Where appropriate, Members shall require the disclosure of origin and legal provenance in the patent applications to be submitted.⁶⁷

In general, the proposals are an attempt to alleviate the developing countries' fear of continued biopiracy by increasing transparency regarding the use of genetic resources and responsibility to share benefits of their use.

65. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from Peru: Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore*, pt. VII, IP/C/W/447 (June 8, 2005) [hereinafter *Communication from Peru*].

66. Council for Trade-Related Aspects of Intellectual Property Rights, *Joint Communication from the African Group: Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*, 6, IP/C/W/404 (June 26, 2003).

67. *Communication from Peru*, *supra* note 65, at 14.

VII. OTHER FORUMS FOR THE MANDATORY DISCLOSURE
REQUIREMENT: PCT, IGC, AND SPLT

Primarily because of strong opposition to the TRIPS amendment proposal, proponents of the mandatory disclosure requirement have sought other places to effectuate such a requirement. Cuba has strongly supported the proposal that the Patent Cooperation Treaty (PCT) of WIPO be amended with essentially the same requirement as the TRIPS proposal.⁶⁸ Switzerland has suggested that the amendment allow for optional participation by Members, allowing a gradual change while both the national and international communities gain experience with the disclosure requirement “without prejudice to further international efforts.”⁶⁹ Switzerland has also stated that the disclosure requirement would not be a substantive requirement, but rather a formal one.⁷⁰ If the applicant fails to disclose, a sufficient period of time would be allowed for the applicant to satisfy the requirement before the PCT application process is either stalled or considered withdrawn for non-compliance.⁷¹

If a failure to disclose the source based on fraudulent intent is discovered after a patent has been granted, then the patent may be invalidated.⁷² National sanctions may include fines for such nondisclosure.⁷³ The PCT proposal states that the invention must be “directly based” on a “specific genetic resource to which the inventor has had access.”⁷⁴ A method of communication and notification about applications with foreign sources has been envisioned by the PCT amendment proposal. Switzerland has suggested that patent offices contact government agencies of the claimed source country when a patent application names the country as a source of the biological material.⁷⁵ This would relieve countries of the burden of monitoring worldwide patents to determine whether the

68. See World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, para. 117, IP/C/M/40 (June 4-5, 2003).

69. World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, para. 74, IP/C/M/46 (Dec. 1-2, 2004).

70. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from Switzerland: Further Observation by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, para. 7, IP/C/W/433 (Nov. 25, 2004).

71. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from Switzerland: Additional Comments by Switzerland on its Proposals Submitted to WIPO Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, para. 25, IP/C/W/423 (June 14, 2004).

72. *Id.* para. 26.

73. *Id.*

74. *Relation between TRIPS and CBD*, *supra* note 48, para. 85.

75. *Id.* para. 86.

country is being declared as a source of particular genetic materials and determine whether the patent applicant had fulfilled access and benefit sharing requirements.⁷⁶

The European Communities have proposed a change be rendered through the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of WIPO. This proposal requires that each country enforce a country of origin or source of genetic resources disclosure requirement in patent applications.⁷⁷ Like the PCT proposal, this would also be a formal and not substantive requirement. Once a patent is granted which has failed to disclose source or origin of genetic resources, the legal effect of nondisclosure would fall outside the power of patent law.⁷⁸ Sanctions in civil or administrative law would be needed to enforce the requirement.⁷⁹ Just like the PCT proposal, the invention must be directly based on the specific genetic resource.⁸⁰ WIPO and the CBD are the proposed keepers of a list of government agencies that would be used to obtain information about applications containing a declaration of the source of genetic resources; patent offices would send information or inquiries to these agencies upon receipt of an application.⁸¹

The draft Substantive Patent Law Treaty (SPLT) is another forum in which developing countries are generating debate over biopiracy and mandatory disclosure requirements. Article 2 of the draft upholds the freedom of countries to protect “genetic resources, biological diversities, traditional knowledge and the environment.”⁸² The draft SPLT also supports disclosure of genetic resources in patents:

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

76. World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, para. 115, IP/C/M/49 (Jan. 31, 2006).

77. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the European Communities: 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*, para. 45-58, IP/C/W/383 (Oct. 17, 2002) [hereinafter *Communication from European Communities*].

78. *Relation between TRIPS and CBD*, *supra* note 48, para. 88.

79. *Communication from European Communities*, *supra* note 77, paras. 45-58.

80. *Relation between TRIPS and CBD*, *supra* note 48, para. 89.

81. *Id.* para. 91.

82. World Intellectual Property Organization, Standing Committee on the Law of Patents, *Draft Substantive Patent Law Treaty*, art. 2(2), WIPO Doc. SCP/10/2 (Sep. 30, 2003) [hereinafter *Draft SPLT*].

other areas of public interest in sectors of vital importance for their social, economic, and technological development.⁸³

Although the language in the draft SPLT may sound like a significant change to the international regulation of intellectual property, the disclosure language simply outlines “a permissive requirement for [countries] to adopt if they so choose.”⁸⁴ In addition, there has been significant debate over these provisions of the draft SPLT, and the substantive discussions have been postponed or eliminated from the agenda.⁸⁵ Developing countries are having little success moving forward with the disclosure requirement in the WIPO arena.

VIII. OPPOSITION TO THE PROPOSAL

The U.S. strongly opposes the proposal for the TRIPS amendment. In 2001, the U.S. submitted one of its first papers to the WTO stating its position that the U.S. sees no conflict between the TRIPS Agreement and the CBD.⁸⁶ The U.S. reasoned that the WTO review called for under Article 27(b)(3) should be limited to its own subparagraph and not encompass other international treaties.⁸⁷ However, the U.S. stated that a “serious discussion of the provisions of both agreements, rather than negative rhetoric” would be helpful in understanding the issue.⁸⁸ The paper thoroughly discussed particular sections of the CBD and concluded that it and the TRIPS Agreement are mutually supportive, not conflicting.⁸⁹ For example, the U.S. argues that the absence of provisions regarding theft and misappropriation of genetic resources in the TRIPS Agreement is not a conflict, but rather evidence that such issues are not within the purview of the TRIPS Agreement and “are appropriately the domain of a separate regulatory system.”⁹⁰

83. *Id.* arts. 13(4), 14(3).

84. Cynthia Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J. L. REFORM 433, 501 (2006).

85. Ho, *supra* note 84, at 501; *Draft SPLT*, *supra* note 82, art.2(2), n.1.

86. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the United States: Views of the United States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreement*, IP/C/W/257 (June 13, 2001).

87. *Id.* at 1.

88. *Id.* at 2.

89. *See id.*

90. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the United States: Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, para. 4, IP/C/W/469 (Mar.

A theme throughout the U.S. arguments is that member countries must enact national access and benefit sharing systems and that any disclosure requirement in TRIPS would create “legal uncertainty and other negative consequences.”⁹¹ The U.S. supports and has proposed national contract-based systems to deal with issues of prior informed consent and access and equitable benefit sharing.⁹² Throughout its papers submitted to the WTO, the U.S. argues for a fact-based discussion, centered on an analysis of national experiences regarding access and benefit sharing systems already in place.⁹³

In its most recent submission, the U.S. responds to specific assertions made by developing countries—particularly Peru—and papers submitted to the WTO which list “bad patents” and claim benefits of the TRIPS amendment proposal.⁹⁴ The United States perceives that other countries assume that because an applicant got a genetic resource from a foreign country, the resource must have been obtained “illegally, irregularly, or questionably.”⁹⁵ Of course, the U.S. views this assumption by developing countries as illogical.⁹⁶

The U.S. also addresses the difficulty of determining the exact origin or source of genetic material. For example, many biological resources are sold throughout the world for purposes of industrial processing, which even Peru recognizes as making it difficult to assess source and origin, thus identifying illegal access.⁹⁷ This raises the question of whether “commercial channels” are a legitimate way of procuring genetic resources.⁹⁸ The “bad patents” that Peru cited in an earlier submission are found to have actually contained disclosures of genetic source and origin and therefore the U.S. claims that such a disclosure requirement would have had no effect or benefit.⁹⁹ A vital issue to the debate is whether extracts or other products isolated from large quantities of raw material, legitimately exported from foreign countries, that have “travel[ed] through the normal channels of commerce,” are exempt from access and benefit sharing agreements and disclosure requirements. The U.S. suggests that this issue would not be covered by

13, 2006) [hereinafter *Communication from US: Article 27.3(B)*].

91. *Id.* para. 5.

92. *Id.* para. 7.

93. *See id.* paras. 6, 9.

94. *Id.* paras. 6-29.

95. *See id.* para. 12.

96. *See id.*

97. *Id.* para. 13.

98. *See id.*

99. *Id.* para. 14.

the current proposed TRIPS amendment.¹⁰⁰

The U.S. repeatedly argues that source and origin rarely are relevant to patentability and would not prevent the issuance of what India calls “bad patents,” such as in the turmeric case.¹⁰¹ Turmeric (*curcuma longa*), a plant found in India, is well known there for both culinary use and as a traditional medicine.¹⁰² Apparently, the plant was also used medicinally by Greeks and Romans.¹⁰³ Two expatriate Indian scientists at the University of Mississippi patented turmeric, in 1995, for use in wound healing.¹⁰⁴ The patent was then challenged by the Council of Scientific and Industrial Research in India and subsequently invalidated by the United States Patent and Trademark Office (USPTO) for lack of novelty due to prior art in Indian traditional knowledge.¹⁰⁵

The turmeric case is the first instance where the USPTO invalidated a patent based on traditional knowledge.¹⁰⁶ The U.S., in its paper to the WTO, claims that any disclosure of genetic resources would not have remedied the problem of the erroneously granted turmeric patent, given that the country of origin was identified in the patent application.¹⁰⁷ According to the U.S., origin had little to do with patentability in the turmeric case.¹⁰⁸ In place of a specific genetic resource source and origin disclosure requirement in the patent application, the U.S. argues for improvement upon existing procedures, such as post-grant opposition and re-examination practices, along with a general requirement that the applicant disclose all information relevant to patentability.¹⁰⁹

The U.S. emphasizes that what is known about a genetic resource before the invention occurs is not typically relevant to the reasoning behind using that resource in the invention.¹¹⁰ The U.S. claims that mandatory “disclosure requirements . . . may upset the careful balance created by the patent system to promote innovation.”¹¹¹ The U.S. fears that developing countries are overlooking

100. *Id.* para. 15.

101. *Id.* paras. 6, 28.

102. Murray Lee Eiland, *Patenting Traditional Medicine*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 45, 61 (2007).

103. *Id.*

104. *Id.*

105. Reexamination Certificate of U.S. Patent No. 5,401,504 (issued Apr. 21, 1998); Graham Dutfiend, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 248 (2001).

106. R.A. Mashelkar, *Intellectual Property Rights and the Third World*, 81 CURRENT SCI. 955, 960 (2001) (sidebar).

107. *Communication from the U.S.: Article 27.3(B)*, *supra* note 90, para. 28.

108. *Id.*

109. *Id.* para. 29.

110. *See id.* para. 31.

111. *Id.* para. 35.

the massive risk of investing in research and development activities, where commercialization of products as a result of research is arguably uncommon.¹¹² To demonstrate this principle, the United States cites the development of the anti-cancer drug TAXOL®, a story well known to many at Florida State University, where the final stages of the research took place.¹¹³ Bristol-Meyers Squibb (BMS) reportedly invested more than \$1 billion USD over 30 years, using the results of a mass-screening program of more than 100,000 plant and 16,000 animal extracts.¹¹⁴ Finally, the extract from the Pacific Yew, originally found in Washington State, was determined to have the needed anti-cancer properties, which were entirely unknown before the research and trial-and-error type testing had begun.¹¹⁵ The U.S. claims that the TRIPS Agreement proposal completely ignores the risks involved in developing a commercially successful product.¹¹⁶

Contracts between countries and national access and benefit sharing systems appear to be the solution, according to the U.S. Merck Sharp and Dome (Merck) and the National Institute of Biodiversity of Costa Rica (InBio) entered into a contract agreement where InBio supplied “10,000 samples of plants, animals, and soil to Merck” in exchange for \$1 million USD up front.¹¹⁷ The agreement also gave Merck receiving rights to research the samples for two years with retention rights to any resulting patents and Merck agreed to pay royalties to BIO for any products commercialized from the samples.¹¹⁸ InBio has since claimed significant benefits from this original agreement and the two subsequent extension agreements between Merck and InBio.¹¹⁹ The U.S. views such international contract agreements as the ultimate “way to trace an intangible asset, such as the intellectual contribution of a biological resource.”¹²⁰

Noting that the Merck and InBio agreement has not yet produced any patentable inventions, the U.S. claims that such contracts created under access and benefit sharing systems are effective in producing all the benefits sought by developing countries

112. *Id.*

113. See Frank Stephenson, *A Tale of Taxol*, FLA. ST. U. RES. IN REV., Fall 2002, available at <http://www.rinr.fsu.edu/fall2002/taxol.html>.

114. *Communication from the U.S.: Article 27.3(B)*, *supra* note 90, para. 32.

115. *Id.*

116. See *id.* paras. 35, 36.

117. Coughlin, *supra* note 14, at 356.

118. *Communication from the U.S.: Article 27.3(B)*, *supra* note 90, para. 34.

119. Letter from the Biotechnology Industry Organization to Ambassador Rob Portman, U.S. Trade Representative (Dec. 6, 2005) (on file with author).

120. *Communication from the U.S.: Article 27.3(B)*, *supra* note 90, para. 36 (citation omitted).

(prior informed consent, equitable sharing of benefits, and monitoring of the use of the resource) even absent a patentable invention.¹²¹ The European Communities have argued that it would not be feasible for a patent office to verify evidence of prior informed consent, especially since terms and conditions of a contract often remain confidential.¹²² Japan has argued that a disclosure requirement would violate multiple provisions of the TRIPS Agreement.¹²³ Specifically, the disclosure requirement is proposed to be applicable to only particular fields of technology, violating Article 27.1, which provides for non-discrimination in patent availability between fields of technology.¹²⁴ Japan also argues that the proposed amendment would violate Article 62.1 of the Agreement since only reasonable procedures and formalities are provided for under TRIPS.¹²⁵

IX. RESPONSE TO THE OPPOSITION

Strong opposition to the proposed TRIPS amendment from developed countries such as the U.S. and Japan has been met with equally powerful support for the amendment from Bolivia, Brazil, Columbia, Cuba, India, Pakistan, and other developing countries. In a paper submitted to the WTO in 2005, developing countries in favor of the proposed TRIPS amendment argued that the nation-based contract systems proposed by the U.S. is by no means sufficient to deal with the problems of misappropriation, bad patents, and illegitimate bioprospecting.¹²⁶ Referring to the original claim of conflict between the CBD and TRIPS, the countries argue that the current TRIPS Agreement treats all biological resources as if they are part of the public domain and open to appropriation by anyone.¹²⁷ Bolivia and fellow proponents reason that the U.S. is misguided in its view of the burden of the proposal. A disclosure requirement would only require “reasonable efforts on the part of patent applicants” to acquire the source and origin information, which would already be a component of a larger set of information submitted by the applicant.¹²⁸

121. *Id.* para. 34.

122. See Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, para. 34, IP/C/M/44 (July 19, 2004).

123. Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, para. 155, IP/C/M/29 (Mar. 6, 2001).

124. *Id.*

125. *Id.*

126. *Communication from Bolivia*, *supra* note 57, para. 4.

127. *Id.* para. 2.

128. *Id.* para. 6.

Without specifically addressing the turmeric case, Bolivia and other developing countries argue that a new disclosure requirement is essential to determination of the novelty and inventive step and would prevent patent offices from issuing patents, like the US turmeric patent, erroneously.¹²⁹ Also, as countries build databases about origin, source, and perhaps agreements between countries, the burden on patent offices regarding verification will lighten.¹³⁰ Developing countries counter the U.S. argument about confusion of goods that have traveled through the normal channels of commerce by stating that the source is simply the country from where the applicant received the genetic material and the country of origin is the country to which the genetic resource is indigenous.¹³¹ After the patent office has received the origin and source information from the applicant, it may request further information from the source or origin countries and the applicant to ensure that bad patents are not granted.¹³²

As far as contracts and national access and benefit sharing systems, the developing countries defend the proposed TRIPS amendment by arguing that a contract-based system will not ensure international enforcement and a binding international obligation is necessary.¹³³ Also, proponents of the proposal offer reassurance that the requirement is not overly burdensome, since a simple statement by the patent applicant of compliance with prior informed consent and benefit sharing requirements will serve as prima facie evidence of compliance with the requirement.¹³⁴

X. EXPERIENCES OF OTHER COUNTRIES WITH DISCLOSURE LEGISLATION

Several nations and groups have implemented national rules regarding disclosure of genetic resources. In 1998, the European Communities adopted a directive regarding legal protection of biotechnological inventions.¹³⁵ The directive states that patent applications for inventions based on biological material of plant or animal origin, or inventions using such material, should include information on the geographical origin of the genetic material, if

129. *See id.* para. 7.

130. *See id.* para. 6.

131. *Id.* para. 8.

132. *Id.* para. 11.

133. *Id.* para. 10.

134. *Id.* para. 27.

135. World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, para. 127, IP/C/M/49 (Jan. 31, 2006).

known and where appropriate.¹³⁶ Disclosure is not a requirement; rather, the directive is “regarded as an encouragement to mention the geographical origin of biological material in the patent application.”¹³⁷ According to the European Communities, this directive supports the CBD in terms of equitable benefit sharing.¹³⁸ It is important to note, however, that the directive is not an obligation and no penalties are associated with failure to disclose origin or source.¹³⁹

Peru also has passed two specific laws regarding disclosure of genetic resources, both carrying more force than that of the European Communities.¹⁴⁰ Peru’s Law Establishing the Regime for Protection of the Collective Knowledge of Indigenous Peoples Relating to Biological Resources states:

Where a patent application relates to products or processes obtained from collective knowledge, the applicant shall be required to submit a copy of the licence contract, as a prerequisite for the granting of the relevant right, unless the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be grounds for refusing to grant the patent or, where appropriate, declaring it void.¹⁴¹

Peru claims that the purpose of the Law is to protect the traditional knowledge of Peru’s indigenous peoples.¹⁴² In 2004, Peru passed the Law on Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples, establishing a specific commission to deal with the issue of biopiracy. Peru defines biopiracy as access and use without authorization from and compensation to the indigenous people, which Peru states specifically violates the CBD.¹⁴³ The Commission for Prevention of Acts of Bio-piracy, established by the 2004 law, has several far-reaching purposes:

To identify and follow up patent applications made or patents granted abroad that relate to Peru-

136. *Id.*

137. *Id.*

138. *Id.*

139. *Id.*

140. *See Relation between TRIPS and CBD, supra* note 48, para. 101.

141. *Id.*

142. *Id.*

143. *Id.* paras. 102, 103.

vian biological resources or collective knowledge of the indigenous peoples of Peru . . . [t]o lodge objections or institute actions for annulment concerning patent applications made or patents granted abroad that relate to Peruvian biological or genetic material or the collective knowledge of the indigenous and native peoples of Peru.¹⁴⁴

Unlike the European Communities law, Peru makes disclosure mandatory and provides for penalties and investigatory means to ensure compliance with the requirement.

An Andean Community decision mandates that member countries implement access requirements for patent applicants.¹⁴⁵ The decision on a Common Regime on Access to Genetic Resources of 1996 mandates that national offices require that the applicant give the registration number of the access contract and supply a copy of the contract.¹⁴⁶ The national patent offices are to require such information when it is reasonably perceived that the invention contains “genetic resources or their by-products originating in any one of the Member Countries.”¹⁴⁷ Also, the Andean Community decision includes an enforcement clause, stating:

The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components [including traditional knowledge], that were obtained or developed through an access activity that does not comply with the provisions of this Decision.¹⁴⁸

Another Andean Community decision requires a copy of the access contract and, if applicable, a copy of the document certifying the license or authorization to use the traditional knowledge where either genetic resources or knowledge originated from any of the member countries.¹⁴⁹ Under the decision, no patent is valid where the applicant failed to submit either a copy of the access contract or the licence or authorization documents.¹⁵⁰

Another country has also passed national legislation to further

144. *Communication from Peru*, *supra* note 65, at 10.

145. *Relation between TRIPS and CBD*, *supra* note 48, para. 99.

146. *Id.*

147. *Id.* (citation omitted).

148. *Id.* para. 99.

149. *Id.* para. 100 (citation omitted).

150. *Id.*

the aims of the CBD. Under new amendments to the country's patent laws, Norway requires that patent applicants include the country of origin of biological material.¹⁵¹ Evidence of prior informed consent should also be provided in the patent application, if the source country requires.¹⁵² Civil penalties associated with giving false testimony are enforced against applicants who fail to meet the disclosure requirement.¹⁵³

XI. CONCLUSION

The TRIPS Agreement and the CBD attempt to strike a balance among the interests of nations within the global economic community. However, these international agreements appear to divide as much as they unite. As can be seen from the constant debate and skepticism among countries, it is obvious that the intellectual rights for genetic resources will not be won or lost easily, and the solution is still far from reach. A disclosure requirement, however, must be advanced to realize any progress in protecting the developing countries' interests of maintaining biodiversity and preserving rights to the resources located within their own countries.

Certainly, industrialized countries have a valid fear of losing protection and revenues if more barriers to patent protection are implemented. A recent study by the Pacific Research Institute estimates that uncertainty about patent protection would create a twenty-seven percent decrease in biotechnical and pharmaceutical research throughout twenty-seven industrialized nations by the year 2025.¹⁵⁴ Approximately 150 to 200 drugs would be lost, with a cost of over \$144 billion to those twenty-seven countries alone. Also, the proposed TRIPS amendment and its accompanying, potentially burdensome, requirements may dramatically impede the investment flows to biotechnological start-up companies and investment in important drugs.¹⁵⁵ The economic impacts for developing countries, however, are likely just as serious if no action is taken to remedy the existing biopiracy issues. With over eighty percent of

151. *Communication from Peru*, *supra* note 65, at 12 (quoting Norwegian Patents Act § 8(b) (in effect since March 2004)).

152. *Id.*

153. *Id.*

154. TIMOTHY A. WOLFE & BENJAMIN ZYCHER, BIOTECHNOLOGICAL AND PHARMACEUTICAL RESEARCH AND DEVELOPMENT INVESTMENT UNDER A PATENT-BASED ACCESS AND BENEFIT-SHARING REGIME 2 (2005).

155. See Jonathan Curci, *The New Challenges to the International Patentability of Biotechnology: Legal Relations Between the WTO Treaty on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity*, 2 INT'L L. & MGMT. REV. 1, 37 (2006).

the world's biodiversity, developing countries are perhaps helplessly foreseeing the inevitable, unauthorized, use of their resources continuing into the future.¹⁵⁶

With no absolute answer in the foreseeable future, it may be a matter of waiting to see the effect of national legislation in Norway, Peru, and other nations that have begun to implement a local version of the proposed amendment. Whether the proposed TRIPS amendment is a "flawed approach" and only gaining popularity among WTO, WIPO, and CBD members because of "well-orchestrated" political efforts by developing countries, is yet to be determined.¹⁵⁷ An amendment to TRIPS is not, however, a simple matter since an agreement by two-thirds of member states is required.¹⁵⁸ In addition, there is the "political reality" disfavoring any amendments, given that TRIPS already reflects the existing laws of industrialized nations, giving no incentive to alter the Agreement.¹⁵⁹ Other evidence, such as the lengthy debate preceding the only other TRIPS amendment, and movement of the disclosure requirement discussion to other forums may even suggest that an amendment to TRIPS is even less likely.¹⁶⁰

As proposed by some countries, an alternative to a TRIPS amendment is likely to be the more successful avenue for accomplishing the disclosure requirement objective. The developing countries' three part amendment to the PCT incorporates the essential elements of the proposed TRIPS amendment: disclosure of source and country of origin, evidence of prior informed consent, and evidence of a benefit-sharing agreement. Although the focus is on international patent applications, this would constitute substantial progress in combating large corporations that gain patent protection in countries from which the resources were obtained without consent and then assert patent rights in those foreign countries.

An effective amendment would call for automatic invalidation of any patent not in noncompliance with the disclosure requirement. Sanctions in civil or administrative law may not adequately deter nondisclosure. Although developed industrialized countries argue that the disclosure would be overly burdensome in light of the quantity of materials used for genetic and biotechnological research, these institutions likely document such resource information meticulously and could comply with a disclosure requirement

156. See Venbrux, *supra* note 5, at 16.

157. See Keating, *supra* note 3, at 547.

158. Ho, *supra* note 84, at 490.

159. *Id.*

160. *Id.* at 491.

with less effort than is claimed. Whether the corporations had permission to use material obtained through commercial means or channels, as a resource for scientific research and development, is an issue that must be resolved.¹⁶¹ As with the vast majority of multilateral legislation, an amendment incorporating a genetic resource disclosure requirement would take years to implement effectively, but it is a necessary step in the movement toward appropriate protection of countries' rights to their own biological resources.

161. See *Communication from the U.S.: Article 27.3(B)*, *supra* note 90, para. 13.