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Regulating Access to Traditional Knowledge and Genetic Resources: The Disclosure Requirement as a Strategy to Combat Biopiracy

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Regulating Access to Traditional Knowledge and Genetic Resources: The Disclosure Requirement as a Strategy to Combat Biopiracy

PAUL KURUK*

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I. INTRODUCTION

The legal protection of traditional knowledge¹ has assumed global importance propelled in large part by the interest of pharmaceutical companies and other biotechnology companies in the genetic resources² of developing nations. Within the pharmaceutical industry, indigenous people's knowledge and experiences of the medicinal properties of plants have played a pivotal role in the development of drugs.³ Similarly, the botanical industry has relied on traditional knowledge to develop commercial products, complement scientific testing, and verify laboratory research

1. The World Intellectual Property Organization (WIPO) has defined *traditional knowledge* as “tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.” In this context, *tradition-based* refers to “knowledge systems, creations, innovations and cultural expressions which have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; have generally been developed in a non-systematic way; and are constantly evolving in response to a changing environment.” WIPO, Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999), at 25 (2001), *available at* http://www.wipo.int/edocs/pubdocs/en/tk/768/wipo_pub_768.pdf [hereinafter Intellectual Property Needs]. Categories of traditional knowledge recognized under this definition include: (i) agricultural knowledge; (ii) scientific knowledge; (iii) ecological knowledge; (iv) medicinal knowledge, including related medicines and remedies; and (v) biodiversity related knowledge. The definition also includes “expressions of folklore” in the form of music, dance song, handicrafts, designs, stories and artwork; elements of languages, such as names, geographical indications and symbols; and, movable cultural properties. Excluded from this description of traditional knowledge are items not resulting from intellectual activity in the industrial, scientific, literary or artistic fields, such as human remains, languages in general, and “cultural heritage” in the broad sense. *Id.*

2. Genetic resources refer to genetic material of actual or potential value. Genetic material is any material “of plant, animal, microbial or other origin containing functional units of heredity,” example of which include “material of plant, animal, or microbial origin, such as medicinal plants, agricultural crops and animal breeds.” WIPO definition, <http://www.wipo.int/tk/en/genetic/>.

3. See Norman R. Farnsworth, *The Value of Plants Used in Traditional Medicine for Drug Discovery*, 109 ENVTL. HEALTH PERSPECTIVES 1, 69 (2001) (noting that 80% of 122 compounds of defined structure found in 94 species of plants have had an ethnomedical use identical or related to the current of the active elements of the plant). Farnsworth discusses the use of plants in traditional medicine as starting points for drug development and observed that “since plant-derived drug discovery began, the ethnomedical approach has been more successful.” *Id.* at 74.

results, including safety and efficacy.⁴ In the agriculture industry, traditional knowledge is applied not only in seed development programs to improve productivity, but also in crop protection programs to improve the resistance of crop plants to pests and diseases.⁵

The commercial exploitation of traditional knowledge has taken place amidst concerns about the erosion of community rights when non-indigenous parties successfully acquire intellectual property rights over the knowledge and resources of indigenous groups—a phenomenon referred to as biopiracy.⁶ Adverse implications of the legal monopolies obtained in this manner include the frequent failure of the rights holders to compensate indigenous groups⁷ as well as the expropriation of community interests in traditional knowledge.⁸

Persons demanding greater sensitivity to the economic interests of the creators of traditional knowledge insist on the equitable sharing of profits

4. KERRY TEN KATE & SARAH A. LAIRD, *THE COMMERCIAL USE OF BIODIVERSITY, ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING* 92 (1991).

5. For centuries, farmers in traditional areas improved varieties by adapting germplasm to local conditions and selecting the best seed for each season, and it is this knowledge that modern researchers have sought to tap through collaborative arrangements with indigenous farmers. Paul Kuruk, *The Role of Customary Law Under Sui Generis Frameworks of Intellectual Property Rights in Traditional and Indigenous Knowledge*, 17 *IND. INT'L & COMP. L. REV.* 67, n.8 (2007).

6. VANDANA SHIVA, ET AL., *THE ENCLOSURE AND THE RECOVERY OF THE COMMONS* 30 (1997).

7. Indigenous groups may not be properly rewarded for the exploitation of their traditional knowledge, perhaps due to the deliberate refusal of the exploiters to pay, difficulties in identifying the proper owners to whom payment is to be made, or simple mismanagement. *See generally* DARRELL POSEY & GRAHAM DUTFIELD, *BEYOND INTELLECTUAL PROPERTY: TOWARD TRADITIONAL RESOURCE RIGHTS FOR INDIGENOUS PEOPLES AND LOCAL COMMUNITIES* 33–41 (1996).

8. There is expropriation of community interests when valuable pieces of traditional knowledge are removed from the traditional communities and sent to western markets. While some of these items may have been sold or given away by traditional elders, in many cases, the items were probably illegally exported or even forcibly removed. Babacar Ndoye, *Protection of Expressions of Folklore in Senegal*, 25 *COPYRIGHT MONTHLY REV. WORLD INTEL. PROP. ORG.* 374, 375 (1989). Expropriation also occurs when farm seeds are collected by researchers under collaboration arrangements and stored *ex-situ* beyond the reach of traditional farmers who now have to pay high fees to acquire rights to improved varieties of the seeds. *See* Stephen B. Brush, *A Non-Market Approach to Protecting Biological Resources*, in *INTELLECTUAL PROPERTY RIGHTS FOR INDIGENOUS PEOPLES: A SOURCEBOOK* 131, 133 (Tom Greaves ed., 1994) [hereinafter *SOURCEBOOK*]. Furthermore, community rights are diminished where some parties successfully acquire intellectual property rights in other forms of traditional knowledge such as art and craft, music and dance. For example, copyright may be claimed for documentation of information about indigenous people, which is used commercially without appropriate acknowledgment as to source of material. *See* POSEY & DUTFIELD, *supra* note 7, at 36.

from the exploitation of traditional resources.⁹ Protection of traditional knowledge, it is urged, would not only complement current international efforts promoting the conservation and sustainable use of biological resources as a way of increasing food production worldwide,¹⁰ but also tackle problems associated with the widespread misrepresentation of products¹¹ and practices as indigenous,¹² cultural degradation¹³ and the

9. CARLOS M. CORREA, TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY 5 (2001).

10. For centuries, traditional farmers have bred crop varieties and applied farming techniques that suited their lands especially under adverse conditions. These practices are still relevant in the modern era and it is believed that recognizing and encouraging the role of farmers under a suitable protective regime would ensure the continued development of specialized crops at the local level. Farmers Rights have been recognized in international instruments on account of the critical role they play in food security. See *What Are Farmers' Rights?*, <http://www.farmersrights.org>.

11. The commercial exploitation of traditional knowledge creates problems of authenticity and misrepresentation as the need to satisfy the increased demand for traditional art and craft often leads to mass-production, inferior quality goods, and cheap imitations. Sandra Lee Pinel & Michael J. Evans, *Tribal Sovereignty and the Control of Knowledge*, in SOURCEBOOK, *supra* notes 8, 41, 47. The mass-produced items sold as traditional craft raise authentication problems to the extent they do not have the same attributes as the traditional items. Items of traditional knowledge express important values in traditional societies which the mass-produced items cannot possibly have since they did not originate in those societies. Indeed, one commentator has characterized the production and sale of fake indigenous items as “a cultural and psychological threat to the authentic practitioners of traditional arts and to the traditional groups whose values those arts express.” Alan Jabbour, *Folklore Protection and National Patrimony: Developments and Dilemmas in the Legal Protections of Folklore*, 17 COPYRIGHT BULL. 10, 11 (1983).

12. Concerns about cultural degradation are found in the entertainment industry. For example, some have charged that where African dances are copied and performed abroad, African culture is denigrated to the extent that the “non-African actors cannot lend the gestures that communicate warmth specific to Africa.” Ndoye, *supra* note 8, at 376. Another writer contends:

[I]t is possible to encounter groups and soloists who unscrupulously modernize works of folklore by arranging them in a new manner, by giving folk songs added rhythm and volume at the expense of their melodic character . . . Performances of folk songs often take the form of . . . banal impersonal shows devoid of the characteristics peculiar to . . . folk dances As for the garishly-colored costumes worn by the dancers, they are a travesty of the originals.

E.P. Gavrilov, *The Legal Protection of Works of Folklore*, 20 COPYRIGHT MONTHLY REV. WORLD INTELL. PROP. ORG. 76, 79 (1984). Such commoditization of traditional performances, it is feared, would eventually lead to the erosion of people’s cultural identity. POSEY & DUTFIELD, *supra* note 7, at 6.

13. Indigenous culture is viewed to be degraded when cultural items are displayed outside their traditional setting and for purposes different from those for which they were

unauthorized public disclosure and use of secret knowledge, images¹⁴ and other sensitive information¹⁵ pertaining to indigenous communities.

Responding to these concerns, the international community has over the years undertaken a number of initiatives, including model laws and recommendations on folklore, and provisions on cultural heritage and human rights.¹⁶ However, beginning with the Convention on Biological Diversity (CBD) in 1992,¹⁷ there is now international interest in a remedial solution premised on facilitating access to genetic resources in exchange for the sharing of benefits. The Bonn Guidelines which were adopted in 2002,¹⁸ elaborate on the CBD provisions. With the adoption of the Nagoya Protocol in 2010,¹⁹ the international community sought to improve the protection of traditional knowledge by transforming the guidelines into more specific commitments of governments. Earlier in 2001, the FAO

originally created as occurs for example, when religious artifacts are sold as mere decorative art. David Sassoon, *The Antiquities of Nepal: It is Time to Start Listening to Communities Whose Possessions Have Become Objects of International Consumption*, CULTURAL SURVIVAL Q., Fall 1991, 47, 49, available at <http://www.culturalsurvival.org/publications/cultural-survival-quarterly/nepal/antiquities-nepal-it-time-start-listening-communities>.

14. TERRI JANKE, OUR CULTURE, OUR FUTURE: REPORT ON AUSTRALIAN INDIGENOUS CULTURAL AND INTELLECTUAL PROPERTY RIGHTS 19 (1998).

15. In the United States, Native American groups have fought against the use of indigenous names in settings they perceive to be demeaning, such as in reference to mascots and sports teams. One commentator notes:

Images of Indians have advertised and identified products and services too numerous to list A search of the Trademarkscan-US Federal database in West law reveals that derogatory names-Injun, Braves, Red Man, Squaw, and Redskins-are used to sell everything from corn chips to football. Sports teams parade caricatured Indian mascots, such as Chief Wahoo (Cleveland Indians) or Illiniwek (Fighting Illini of Illinois). The Seminole activist Michale Haney describes many fans as “cultural cross-dressers” decked out in a day glo warpaint and turkey feathers.

Nell Jessup Newton, *Memory and Misrepresentation: Representing Crazy Horse*, 27 CONN. L. REV. 1003, 1006–07 (1995).

16. See generally Paul Kuruk, *Protecting Folklore Under Modern Intellectual Property Regimes: A Reappraisal of the Tensions Between Individual and Communal Rights in Africa and the United States*, 48 AM. U. L. REV. 769, 812–19 (1999).

17. See generally Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 76, available at <https://www.cbd.int/doc/legal/cbd-en.pdf>.

18. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of Their Utilization (2002), available at <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> [hereinafter Bonn Guidelines].

19. Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of Their Utilization to the Convention on Biological Diversity (2011) Secretariat of the Convention on Biological Diversity, <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf> [hereinafter Nagoya Protocol].

Plants Treaty was adopted reflecting some of the principles of the CBD, but applicable only to plant genetic resources.²⁰

To complement the global regime governing access to genetic resources and enhance its effectiveness in addressing the problem of biopiracy, calls have been made for the adoption of disclosure obligations in patent applications regarding the source or origin of genetic resources or traditional knowledge relevant to the claims in the application as well as evidence of the obtainment of consent from, and agreement to share benefits with, the rights holders of the traditional knowledge or genetic resources.²¹ Advocates for an improvement in the regulatory environment for traditional knowledge have turned to WIPO as a more appropriate forum for solutions given its jurisdiction on matters of international intellectual property policy.²² A major strategy WIPO has adopted in response is the preparation through text-based negotiations of instruments that would incorporate the disclosure requirement.²³

The objective of this Article is to examine the disclosure requirement as a measure to enhance the protection of traditional knowledge and genetic resources. Section Two illustrates the negative effects of biopiracy drawing on selected cases from Africa, India and the Americas while Section Three describes the international regime governing access to genetic resources and related traditional knowledge including rules on prior informed consent, mutually agreed terms and the fair and equitable sharing of benefits. Section Four traces the evolution of the obligation to disclose from provisions in national model laws and a draft treaty on folklore prepared by WIPO, to the CBD and the Bonn Guidelines as well as proposals before the TRIPS Council of the World Trade Organization. This section also discusses implications of the disclosure requirement, including triggers, legal bases for, scope and sanctions for non-compliance. Section Five reviews WIPO's current program on the disclosure requirement and evaluates the

20. International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 11, 2001, 2400 U.N.T.S. 303, *available at* <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf> [hereinafter *FAO Plants Treaty*].

21. *The Relationship Between the TRIPS Agreement on Biological Diversity and the Protection of Traditional Knowledge*, ¶ 4, June 18, 2003, WTO Doc. IP/C/W/403 [hereinafter *TRIPS Agreement and the CBD*].

22. *Infra* notes 347–55 and accompanying text.

23. WIPO, Background Brief No. 1, *Traditional Knowledge and Intellectual Property*, at 3. Other proposals concern defensive protection measures including the creation of databases on traditional knowledge. *Id.*

latest proposals contained in the draft texts being used as the basis of negotiations in WIPO for the adoption of international instruments on traditional knowledge and genetic resources.

The Article concludes that the draft negotiating texts developed so far by WIPO will require further refinement and alignment to be ready for adoption as binding instruments. For WIPO member countries that are generally supportive of the disclosure requirement, the discrepancies may be seen as minor ones that could be ironed out in future negotiating sessions. However, for others rigidly opposed to the requirement, such hopes may not be realistic, leaving the distinct possibility that consensus may not be found to submit even a significantly improved text to a diplomatic conference for consideration for eventual adoption by WIPO. In the end, if it proves impossible to restart the negotiations that have stalled at WIPO, there will be an urgent need for like-minded traditional knowledge provider countries in collaboration with interested traditional knowledge user countries to respond to the void by working to develop solutions under bilateral, regional or other multilateral arrangements for the protection of traditional knowledge.

II. BIOPIRACY: A SPECIAL CONCERN IN THE EXPLOITATION OF TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES

Biopiracy is the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions that seek exclusive monopoly control over the resources and knowledge usually through the acquisition of patents or other intellectual property rights.²⁴ It constitutes a major abuse in the commercial exploitation of traditional knowledge in terms of its adverse economic impacts on traditional communities as companies have amassed huge fortunes from such acts of misappropriation but failed to share those benefits with the communities from where the genetic resources were originally accessed.²⁵ On account

24. ETC Group, Patents & Biopiracy, <http://www.etcgroup.org/issues/patents-biopiracy> (last visited Sept. 10, 2015). For a general overview of biopiracy, see Patrick R. Mooney, *Why We Call it Biopiracy*, in *RESPONDING TO BIOPROSPECTING: FROM BIODIVERSITY IN THE SOUTH TO MEDICINES IN THE NORTH* 37, 37–44 (Hanne Svarstaf & Shivschar S. Dhillon eds., 2000); *see also* RAFI, *Biopiracy Update: A Global Pandemic*, COMMUNIQUÉ, Sept.-Oct. (1995); (attributing the definition of biopiracy to Patrick Mooney).

25. For example, between 1994-1998, some University of Wisconsin scientists obtained patents on ‘brazzein’ a super-sweet protein extracted from the berries of a West African plant, *Pentadiplandra brazzeana*. Apparently, the scientists had ‘discovered’ the super-sweet berries in Gabon, where local people had known and consumed the berries for many years. However, “[d]espite being the inspiration and origin for brazzein, neither

of the huge economic stakes involved, the international deliberations on measures to counter biopiracy have been intense²⁶ and strong lobbying by the pharmaceutical and biotechnology sectors has frustrated efforts to develop adequate solutions.²⁷ To situate the debate in context, it is useful to recall some of the well-known cases of biopiracy that have been reported.

A. Africa

Two prominent cases from Africa involve uses of the rosy periwinkle and the hoodia cactus plants, native to Madagascar and South Africa, respectively. In the first case, knowledge about the traditional uses of the rosy periwinkle played a key role in the development of the cancer-fighting medicines Vincristine and Vinblastine.²⁸ The use of the plant as a cure for diabetes initially attracted the attention of researchers, but its potential for cancer treatment was later examined.²⁹ Subsequently, the U.S. pharmaceutical company Eli Lilly obtained patents for Vincristine from which it reaped huge profits.³⁰ However, Eli Lilly offered no benefits

Gabon nor its people . . . share[d] the benefits.” Someschwar Singh, *Rampant Biopiracy of South's Biodiversity*, THIRD WORLD NETWORK (July 20, 2000), <http://www.twn.my/title/rampant.htm>.

26. See, e.g., *infra* notes 294–311 and accompanying text for a summary of the debate in the World Trade Organization concerning the obligation to disclose information about traditional knowledge in patent applications.

27. See ALEJANDRO ARGUMEDO & MICHEL PIMBERT, INTERNATIONAL INSTITUTE FOR ENVIRONMENT AND DEVELOPMENT, PROTECTING INDIGENOUS KNOWLEDGE AGAINST BIOPIRACY IN THE ANDES 3 (2006) (noting how “strong lobbying” by US biotech and pharmaceutical industries led to the exclusion of provisions ensuring that patents would not be granted in the US without authorization of traditional knowledge holders in the free trade agreement between Peru and the US).

28. Shayana Kadidal, *Plants, Poverty and Pharmaceutical Patents*, 103 YALE L.J. 223, 223 (1964) (explaining that vincristine and vinblastine are used in treating childhood leukemia and Hodgkin disease).

29. See, e.g., *Anti-Cancer: Rosy Periwinkle*, LIVING RAINFOREST, <http://www.livingrainforest.org/about-rainforests/anti-cancer-rosy-periwinkle/> (last visited July 1, 2015).

30. See Andrew B. Cunningham, *Indigenous Knowledge and Biodiversity: Global Commons or Regional Heritage?*, CULTURAL SURVIVAL Q., Fall 1991, <http://www.culturalsurvival.org/ourpublications/csqa/article/indigenous-knowledge-and-biodiversity-global-commons-or-regional-heritag> (explaining how the patent netted the company approximately \$100 million, 88% of which was profit to the company); see also Kadidal, *supra* note 28, at 224.

either to Madagascar or the indigenous group from which knowledge of the medicinal uses of the plant had been obtained.³¹

With regards to the hoodia, it has traditionally been eaten by the San people of the Kalahari Desert as an appetite suppressant on long hunting trips³² and documented accounts dating back to 1798 by anthropologist Francis Masson confirm this use of hoodia.³³ After conducting detailed spectroscopic analyses, the South African Council for Scientific and Industrial Research (SACSIR) in 1995 applied for a patent for hoodia in South Africa for use of the active components of the plant responsible for suppressing appetite.³⁴ SACSIR later signed an exclusive licensing agreement in 1997 with Phytopharm, a UK company which in turn transferred to Pfizer in 1998 the rights to develop and market a potential slimming drug and cure for obesity from hoodia in exchange for \$32 million in royalty and milestone payments.³⁵

The companies involved in the patenting and commercialization of hoodia were criticized by non-governmental organizations for not contacting the San people to seek their prior informed consent and also for failing to set up appropriate benefit-sharing arrangements.³⁶ Faced with threats of lawsuits in 2001 by the San people for biopiracy,³⁷ SACSIR signed a memorandum of understanding in March 2002, which recognized the San as the custodians of traditional knowledge associated with the Hoodia plant.³⁸ The following year, SACSIR set up the “San Hoodia Benefit-

31. James O. Odek, *Biopiracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141, 147 (1994).

32. ETC Group, *Worst Excuse: Winner-Phytopharm Inc.*, COMMUNIQUÉ, Mar./Apr. 2002, at 4.

33. DANIEL F. ROBINSON, CONFRONTING BIOPIRACY: CHALLENGES, CASES AND INTERNATIONAL DEBATES 61 (2010).

34. Rachel Wynberg, *Rhetoric, Realism and Benefit-Sharing: Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant*, 7 J. WORLD INTELL. PROP. 851–56 (2004).

35. ETC Group, *supra* note 32, at 4.

36. ROBINSON, *supra* note 33, at 61–62.

37. In its defense, Phytopharm contended it had conducted extensive enquiries but had not been able to find any of the “knowledge holders,” whose numbers had dwindled and who apparently were living in a tented camp some 1,500 miles from their tribal lands. On its part, the South African Council for Scientific Industrial Research claimed they had planned all along to inform the San about the research and also share the benefits with them, but wanted to make sure the drug proved successful before doing so. PRADEEP KUMAR GANGWAR, TRADITIONAL KNOWLEDGE AND IPRs: RELEVANCE FOR SUSTAINABLE DEVELOPMENT 176 (2011).

38. *Id.*

Sharing Trust” which entitled the San to milestone payments and a share of the royalties from the commercialization of hoodia.³⁹

The Edmonds Institute, in cooperation with the African Centre for Biosafety, presented a report in 2006 to a meeting of the Conference of Parties to the Convention on Biological Diversity in which the Institute identified thirty-six examples of the development of medicines, cosmetics, and agricultural and horticultural products from the biodiversity resources in various African countries.⁴⁰ In many of the cases, patents were obtained from the use of African traditional knowledge by researchers and biotechnology companies without the prior consent of, or sharing of benefits with the traditional rights holders.

The report noted patents issued to Bayer in the U.S., Europe, and Australia covering use of a microbe from Lake Ruiru in Kenya in the production of Acarbose, a drug for the treatment of diabetes;⁴¹ a patent obtained in the U.S. by Phytopharm covering the use of extracts of *Artemesia judaica*, a Libyan medicinal plant for the treatment of diabetes;⁴² a patent obtained by Glaxo-Smithline for a streptomyces strain isolated from a termite hill in the Gambia used both as an anti-fungal and as an immunosuppressant;⁴³ a U.S. patent obtained by Merck for a substance produced by a fungus found in the dung of giraffes in a national park in northern Namibia;⁴⁴ and a U.S. patent granted to Sutherland Maciver, an individual, for a drug made from proteins produced by amoeba from Mauritius and used for the treatment of bacterial infections.⁴⁵

Other cases cited in the report include a U.S. patent obtained by Option Biotech, a Montreal based company covering the seeds of *Afromomum stipulatum*, obtained from the Congo and used in an anti-impotency drug called “Biovigora”;⁴⁶ a US patent granted to a researcher from Tennessee for a drug produced from *milletia ferruginea*, a medicinal plant found in Ethiopia, with claims against “breast cancer, leukemia, melanoma, and

39. GRAHAM DUTFIELD, INTELLECTUAL PROPERTY, BIOGENETIC RESOURCES AND TRADITIONAL KNOWLEDGE 53 (2004).

40. Jay McGown, *Out of Africa: Mysteries of Access and Benefit Sharing* (Beth Burrows ed., Edmonds Institute, 2006).

41. *Id.* at 1.

42. *Id.* at 2.

43. *Id.* at 3.

44. *Id.* at 3–4.

45. *Id.* at 4.

46. *Id.* at 5.

myeloma,” and “viral infection, diabetes, Parkinson’s disease, tuberculosis, or fungal infections;”⁴⁷ and a European patent issued to the German company Max Planck Institut fur Kohlenforschung for claims covering antibiotic compounds from countries along the West coast of Africa stretching from Sierra Leone to Nigeria and used for treating infections.⁴⁸

References were also made to a U.S. patent issued to an individual, covering Iboga, a plant from Central and West Africa, for treating drug addictions;⁴⁹ a U.S. patent granted to a Tennessee inventor for use of Kombic acid, a component of Kombo butter from Central and West Africa, to lower cholesterol and fight cancer;⁵⁰ U.S. patent issued to Unigen covering an extract from *Aloe ferox*, a plant found in Southern Africa and used as a skin whitener in personal care products;⁵¹ a U.S. and European patents issued to a French company, the Dior Group, with claims on the Okoume tree resin from Gabon and West Central Africa for use in cosmetics and pharmaceuticals;^{52,53} and U.S. patents issued to the Cognis Corporation for skin care with claims for a simple extract from the bambara groundnut grown in Sub-Saharan Africa.⁵⁴

B. India

Patent rights in the turmeric plant, the neem tree and basmati rice were at issue in three cases from India. The first case involved the grant of a patent in 1995 to two Indian nationals at the University of Mississippi Medical Centre for use of turmeric in wound healing.⁵⁵ Subsequently, the India-based Council of Scientific and Industrial Research (CSIR) filed a request for re-examination with the U.S. Patent and Trademark Office (USPTO) arguing on prior art grounds that turmeric had been used for thousands of years for healing wounds and rashes⁵⁶ and supported its claims with documentary evidence of traditional knowledge, including an ancient Sanskrit text and a paper published in 1953 in the Journal of the

47. *Id.* at 7.

48. *Id.* at 10.

49. *Id.* at 11.

50. *Id.* at 12.

51. *Id.* at 13.

52. *Id.* at 14.

53. *Id.* at 16.

54. *Id.* at 18.

55. U.S. Patent No. 5,401,504.

56. Turmeric spice powder from the turmeric plant (*curcuma longa*) is widely used in India for the treatment of wounds since the natural antibacterial agents of the powder inhibit infection. ROBINSON, *supra* note 33, at 71.

Indian Medical Association.⁵⁷ In 1997, the USPTO upheld the objections of the CSIR and revoked the patent.⁵⁸

In the second case, Robert Larson, a U.S. timber importer received a patent in 1995 for a pesticide from a neem extract called Margosan-O, which he later sold to W.R. Grace & Co., a multinational chemical corporation.⁵⁹ Extracts of the neem tree have traditionally been used in pesticides, fungicides, soaps, candles, and cosmetics and as an anti-inflammatory, or a preventive measure against malaria.⁶⁰ In India, where it is said to originate, it is referred to as a “natural pharmacy”⁶¹ or “curer of all ailments,”⁶² and there is documentation of its use for over 2000 years for agricultural and medicinal purposes.⁶³ Following a legal challenge by the Indian government on grounds of prior art, the pesticide patent granted to Robert Larson was overturned in 2005.⁶⁴

With regard to the third case, the USPTO in September 1997 granted a patent on basmati rice lines and grains to a Texas-based company, RiceTec Inc.⁶⁵ Basmati is a common variety of rice that has been domesticated and bred for centuries in India,⁶⁶ and much of which is now exported to Asia, Europe and the U.S.⁶⁷ The grant of a patent on basmati rice sparked a lot of outrage from Indian farmers and activists who feared it would create an outright monopoly on basmati that could be used to curtail exports to

57. GANGWAR, *supra* note 37, at 174.

58. RAFI Communiqué, *Basmati Rice Patent Update*, Sept./Oct. 1997, at 8.

59. Other individuals and corporate entities also obtained patent on extracts of the neem tree, including the US Department for a patent to extract an antifungal agent from the tree, and American and Japanese companies for patents for various products derived from the tree such as toothpaste, a traditional use of the plant. GANGWAR, *supra* note 37, at 172.

60. POSEY & DUTFIELD, *Beyond Intellectual Property*, *supra* note 7, at 80.

61. ROBINSON, *supra* note 33, at 71.

62. GANGWAR, *supra* note 37, at 172.

63. ROBINSON, *supra* note 33, at 71.

64. BBC News, *India Wins Landmark Patent Battle*, Mar. 9, 2005, <http://news.bbc.co.uk/2/hi/science/nature/4333627.stm>; see also GANGWAR, *supra* note 37, at 172–73.

65. U.S. Patent No. 5,663,484; Basmati Rice Update, in RAFI Communiqué May/June 2000.

66. VENDANA SHIVA, PROTECT OR PLUNDER: UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS 56–57 (2001); see generally Rai, M. Genetic Diversity in Rice production: Past Contribution and the Potential of Utilization for Sustainable Rice Production, in Van Tran, D. (Ed) *Sustainable Production for Food Security: Proceedings of the 20th Session of the International Rice Commission, Bangkok, Thailand, July 23–26, 2002*, FAO, Rome.

67. See Shiva, *supra* note 66, at 56–57.

the U.S.⁶⁸ Responding to pressure, the Indian government filed an application for re-examination of the patent and a settlement agreement was reached with RiceTec for a withdrawal of some of the claims.⁶⁹ As part of the agreement, certain claims⁷⁰ were cancelled and descriptions of the rice were altered in the re-examination certificate, but the claims for novel rice lines were maintained.⁷¹

While the settlement was seen as a significant victory in the fight against biopiracy, concerns lingered about the claims that had not been withdrawn, especially given that the germplasm used to cross breed was noted in the application to have originated in South Asia.⁷² Critics argued that the process described in the claims was a simple crossbreed that was obvious to anyone trained in plant breeding and was not novel on account of the existing prior art in India regarding the basmati rice's qualities.⁷³ However, such arguments did not sway the USPTO because under the U.S. standards of novelty and obviousness, references to the contributions of Indian farmers relevant to the invention were to be disregarded to the extent the contributions had not been described in a printed publication in India at the time of the patent application.⁷⁴

68. Public reaction may have been fueled by the rather broad wording and scope of the patent. The patent claims were for a specific rice plant (Claims 1–11, 14), for seeds that germinate the patented rice plant (Claim 12), for the grain that is produced by the rice plant (Claims 13, 15–17) and for the method of selecting plants for breeding and propagating particular grains of rice (Claims 18–20). Shubha Ghosh, *Globalization, Patents and Traditional Knowledge*, 17 COLOM. J. ASIAN L. 73, 101 (2003).

69. *Id.*

70. Claims 1–7, 10 and 14–20. *Id.*

71. *Id.*

72. One commentator has explained the lingering concerns as follows: Analysis of the description of the patent document indicates that Claims 8, 9 and 11 refer to crossed lines varieties) to develop plant varieties that exhibit some similar characteristics to basmati rice grains. Under US patent law, novel plant varieties are eligible for protection—most countries in the world do not allow plant patents. South Asian activists are particularly frustrated by this because it appears that the germplasm used to cross the varieties was originally obtained from the region. The patent description for the breeding of [the] . . . rice lines indicates that:

Twenty-two basmati lines from the USDA [United States Department of Agriculture] World Germplasm Collection, Beltsville, Md. and thirteen semi-dwarf, long-grain lines were selected for the initial crosses. The basmati seeds from the USDA were identified as having come from Pakistan. (USPTO Patent Number 5,663,484).

ROBINSON, *supra* note 33, at 48.

73. See generally SHIVA, *supra* note 66, at 56.

74. The relevant provisions on prior art in the U.S. are as follows:

C. The Americas

Ayahuasca and Enola bean were the subject of two cases from the Americas. The first case concerned a U.S. plant patent obtained by Loren Miller in 1986,⁷⁵ which granted him rights over an alleged variety of the *Banisteriopsis caapi* plant that he called “Da Vine.”⁷⁶ In the patent application, the Da Vine was described as a plant “discovered growing in a domestic garden in the Amazon rain-forest of South America,” which represented a new and distinct variety primarily because of the color of the flower.⁷⁷ For centuries, shamans of indigenous tribes throughout the Amazon Basin used the bark of the *Banisteriopsis caapi* tree to produce a ceremonial drink with hallucinogenic properties known as “ayahuasca,” which means “vine of the soul.”⁷⁸ Indeed, there is extensive documentation of the use of ayahuasca in religious and healing ceremonies to induce visions believed to enable the shamans to diagnose and treat illnesses, meet with spirits, and divine the future.⁷⁹

In March 1999, on behalf of a group of over 400 indigenous groups in the Amazon basin, the Center for International Environmental Law (CIEL) filed for re-examination of the patent on the grounds that a review of the prior art revealed Da Vine to be neither new nor distinctive.⁸⁰ In November 1999, upon consideration of the prior art provided by CIEL, the USPTO rejected the patent claim, agreeing that Da Vine was not distinguishable from the prior art presented by CIEL and therefore was neither distinctive nor novel.⁸¹

A person shall be entitled to a patent unless – (a) the invention is known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before he invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States.

35 U.S.C. § 102.

75. ETC Group, COMMUNIQUE, Mar./Apr. 2002, at 2.

76. GANGWAR, *supra* note 37, at 174.

77. ROBINSON, *supra* note 33, at 68.

78. GANGWAR, *supra* note 37, at 174.

79. Naranjo P., *Hallucinogenic Plant use and Related Indigenous belief Systems in the Ecuadorian Amazon*, 1 J. ETHNOPHARMACOLOGY 121–45 (1979).

80. See generally Glenn Wiser, *Legal Elements of the “Ayahuasca” Patent Case*, CTR. FOR INT’L ENVTL L. (1999).

81. *Id.*

However, despite a final action notice, in a surprise development, the USPTO allowed Miller to present new evidence and arguments *ex parte* without giving CIEL a similar opportunity.⁸² In January 2001, on the basis of the new evidence submitted by Miller, the USPTO reversed its earlier decision and allowed the patent to stand for the remaining two years of its term.⁸³ Apparently, after conducting a side-by-side comparison of images of the Da Vine plant with a number of other examples submitted by Miller, the patent examiner determined that the leaf size and shape differed sufficiently between the images of Da Vine and other ayahuasca plants.⁸⁴ In addition, the examiner considered the fact that the plant had been found in a cultivated area (i.e. a domestic garden) as significant.⁸⁵ Ultimately, these distinctions were deemed sufficient to qualify for protection under the U.S. Patent Act.⁸⁶

The Enola Bean case arose following a series of events stemming from Larry Proctor's time in Mexico. While vacationing in Mexico, Proctor bought a bag of different varieties of beans that he found interesting because of their yellow colour.⁸⁷ Upon his return to the United States, he began a selective breeding program,⁸⁸ and two years later received a patent⁸⁹ for an invention relating to a new field bean variety, which he called Enola.⁹⁰ The patent claims covered a specific yellow-coloured bean seed, plants produced by growing the seed, all other plants with the same physiological and morphological characteristics, and also the breeding

82. *Id.*; see also *Protecting Traditional Knowledge: Ayahuasca Patent Dispute*, CIEL, <http://www.ciel.org/project-update/protecting-traditional-knowledge-ayahuasca/> (last visited Nov. 23, 2015).

83. *Id.*

84. Reexamination Certificate, U.S. Patent No. PP5,751 C1 (filed Mar. 30, 1999) (reexamination cert. issued Apr. 17, 2001).

85. *Id.*

86. For plant patent requirements, see 35 U.S.C. § 161, which provides: The US Patent Act provides in relevant part:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore, subject to the conditions and requirements of this title.

US Patent Act, Section 35 U.S.C. § 161.

87. See ROBINSON, *supra* note 33, at 51.

88. *Id.*

89. U.S. Patent No. 5,894,079 (filed Nov. 15, 1996); see generally ETC Group, *Enola Patent Ruled Invalid: Haven't We Bean Here Before? (Yes, Yes, Yes, Yes and Yes)* (July 14, 2009), available at <http://www.etcgroup.org/content/enola-patent-ruled-invalid-haven%E2%80%99t-we-bean-here-yes-yes-yes-yes-and-yes-0>.

90. See ROBINSON, *supra* note 33, at 51.

methods employed.⁹¹ Proctor aggressively defended his patent by suing other companies that grew the bean and requesting royalties on imports from Mexico.⁹² His tough stance affected export sales from Mexico, which dropped over ninety percent, causing severe economic damage to more than 22,000 farmers in northern Mexico who depended on sales from this bean.⁹³

Although Proctor acknowledged that his Enola bean originated in Mexico,⁹⁴ he claimed that the bean was novel because it had a distinctive yellow color and had never been grown in the U.S.⁹⁵ However, information from the Mexican government contradicted this claim, pointing out that yellow beans known as mayocoba had been grown for generations in Mexico and were the likely source for Proctor's so-called invention. There was also evidence that beans similar to Enola beans had been grown in the U.S. since the 1930s.⁹⁶

Armed with the expert studies indicating that Proctor's Enola bean was identical to the Mexican bean,⁹⁷ and with support from Food Agriculture Organization, the Colombia-based International Centre for Tropical Agriculture challenged the patent in 2000.⁹⁸ In April 2008, the USPTO rejected all of the patent claims for Enola, a decision that was welcomed by many, but to others was a hollow victory and a travesty because the U.S. patent system had "allowed the owner of a flagrantly unjust patent to

91. *Id.*

92. See ETC Group, *Proctor's Gamble: Yellow Bean Patent Owner Sues 16 Farmers and Processors in US* (Dec. 17, 2001), <http://www.etcgroup.org/content/proctors-gamble>.

93. GANGWAR, *supra* note 37, at 177; see also *Protecting Traditional Knowledge: Ayahuasca Patent Dispute*, CIEL, <http://www.ciel.org/project-update/protecting-traditional-knowledge-ayahuasca/> (last visited Nov. 23, 2015).

94. In his patent application, Proctor stated "The yellow bean 'Enola' variety is mostly likely a landrace from the azufrado-type varieties" (which originate in Mexico). ETC Group, *Cancel the Enola Bean Patent!*, <http://www.etcgroup.org/content/cancel-enola-bean-patent>.

95. Erin Donovan, *Beans, Beans, the Patented Fruit: The Growing International Law Conflict over the Ownership of Life*, *LOY. L.A INT'L & COMP. L. REV.* 117, 120–21 (2003).

96. *Id.* at 125–26.

97. See GANGWAR, *supra* note 37, at 177 (explaining that scientific studies had concluded that "probability calculations of matching the specific Enola fingerprint showed that the most likely origin of Enola is by direct selection within pre-existing yellow-bean cultivars from Mexico, most probably 'Azufrado Peruano'").

98. ETC Group, *Whatever Happened to the Enola Bean Challenge* (Dec. 21, 2005), <http://www.etcgroup.org/content/whatever-happened-enola-bean-patent-challenge>.

legally monopolize markets and destroy competition . . . for close to half the 20-year term.”⁹⁹

III. THE INTERNATIONAL LEGAL REGIME GOVERNING ACCESS TO GENETIC RESOURCES AND RELATED TRADITIONAL KNOWLEDGE

A. Articulating the Principles: The Convention on Biological Diversity

The Convention on Biological Diversity (CBD) was adopted in 1992 to provide for “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.”¹⁰⁰ Protection of biological diversity was considered critical to stem the rapid erosion of such diversity by human activities not only because of the “intrinsic value of biological diversity and of [its] ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values”¹⁰¹ but also its importance “for evolution and for maintaining life sustaining systems of the biosphere.”¹⁰² Specifically, conservation of biological diversity was urgently needed to meet the “food, health and other needs of the growing world population.”¹⁰³

Premised on the principle that “[s]tates have . . . the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction and control do not cause damage to the environment,”¹⁰⁴ the CBD provides for various measures concerning conservation and sustainable use,¹⁰⁵ duties of

99. ETC Group, *Hollow Victory: Enola Bean Patent Smashed At Last (Maybe)* (Apr. 30, 2008), <http://www.etcgroup.org/content/hollow-victory-enola-bean-patent-smashed-last-maybe>.

100. Convention on Biological Diversity, *supra* note 17, art. 1.

101. *Id.* at Preamble.

102. *Id.*

103. *Id.*

104. *Id.* art. 3.

105. Under the CBD, Contracting States should “[d]evelop national strategies, plans or programmes for the conservation and sustainable use of biological diversity . . . [and] . . . [i]ntegrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.” *Id.* art. 6.

identification and monitoring,¹⁰⁶ and measures related to in-situ¹⁰⁷ and ex-situ¹⁰⁸ conservation, access to genetic resources¹⁰⁹ and access to and transfer of technology.¹¹⁰

106. Contracting States are obligated to:

- (a) [i]dentify components of biological diversity important for its conservation and sustainable use . . . (b)[m]onitor, through sampling and other techniques, the components of biological diversity identified . . . above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use; (c)[i]dentify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and (d) [m]aintain and organize, by any mechanism data, derived from identification and monitoring activities [specified].

Id. art. 7.

107. With regards to *in-situ* conservation, Contracting States are required among other things, to:

- (a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity; (b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity; (c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use; (d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings; (e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas; (f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, inter alia, through the development and implementation of plans or other management strategies; (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health; (h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species; (i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components; . . . [and] (k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations. . . .

Id. art. 8.

108. As to *ex-situ* measures, the Contracting States are expected to:

- (a) Adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components; (b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and microorganisms, preferably in the country of origin of genetic resources;

The provisions of the CBD dealing with the protection of biological resources “reflect a compromise between the need by parties from the North for access to biological resources of the South versus the demands of the South to restrict such access,”¹¹¹ and the balance was struck “to facilitate access to biological resources while ensuring the transfer of some benefits to providers of such resources”¹¹² in the hope in part, that such returns “would in turn provide the incentive for the preservation of environmentally sound practices.”¹¹³ To this end, Article 8(j) of the CBD calls on Contracting States to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.”¹¹⁴ In addition to promoting the wider application of such knowledge, innovations, and practices, with the approval and involvement of the holders thereof, the CBD encourages the equitable sharing of the benefits arising from the utilization of such knowledge, innovations, and practices.¹¹⁵ Significantly, one of the measures recommended for supporting the sustainable use of components of biological diversity is the protection and encouragement of the use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.¹¹⁶

While the CBD recognizes both the sovereign rights of States over their natural resources and the authority to determine access to genetic resources found in their territories,¹¹⁷ it urges contracting parties to create conditions to facilitate access to genetic resources for environmentally sound uses and not to impose restrictions that run counter to the objectives of this Convention.¹¹⁸ In general, such access is to be based on the prior informed

(c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions; [and] (d) Regulate and manage collection of biological resources from natural habitats for ex-situ conservation purposes so as not to threaten ecosystems and in-situ populations of species. . . .

Id. art. 9.

109. *Id.* art. 15.

110. *Id.* art. 16.

111. Kuruk, *Role of Customary Law*, *supra* note 5, at 73.

112. *Id.*

113. *Id.*

114. Convention on Biological Diversity, *supra* note 17, art. 8(j).

115. *Id.*

116. *Id.* art. 10(c).

117. *Id.* art. 15(1).

118. *See id.* art. 15(2).

consent of the Contracting Party providing such resources¹¹⁹ and on mutually agreed upon terms.¹²⁰ It also calls upon parties to share 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.”¹²¹ Article 16 calls upon parties to provide and/or facilitate access to and transfer of technology to developing countries “on fair and most favourable terms”¹²² and to adopt the necessary legislative, administrative or policy measures to ensure the private sector facilitates the access to, joint development and transfer of developing countries.¹²³ The Article also calls for international cooperation in achieving the objectives of the Convention.¹²⁴

However, the three basic principles introduced in the CBD regarding prior informed consent, fair and equitable sharing of benefits, and mutually agreed terms, are not elaborated in the CBD. This lack of clarity may leave some doubt regarding the precise scope of their application—it was to remedy this deficiency that the Conference of the Parties set in motion a process that led first to the adoption of the Bonn Guidelines, and more recently, the Nagoya Protocol.

B. Transforming Principles to Guidelines: The Bonn Guidelines

The Bonn Guidelines were intended to assist governments in “developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit-sharing.”¹²⁵ They were also designed to inform the practices and approaches of stakeholders (users and providers) in access and benefit-sharing arrangements;¹²⁶ improve capacity-building in developing countries;¹²⁷ promote the transfer of technology to developing countries; and positively influence the development of laws that recognize

119. *Id.* art. 15(5).

120. *Id.* art. 15(6).

121. *Id.* art. 15(7).

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

123. *See id.* art. 16(4).

124. *Id.* art. 16(5).

125. Bonn Guidelines, *supra* note 18, at 1.

126. *Id.* § 11(d).

127. *Id.* § 11(e).

the protection of customary law of indigenous communities.¹²⁸ With the exception of human genetic resources, all genetic resources, associated traditional knowledge, innovations, and practices covered by the CBD, and benefits arising from the commercial and other utilization of such resources are covered by the Bonn Guidelines.¹²⁹

Under the Bonn Guidelines, prior informed consent is required for access to genetic resources.¹³⁰ The decisions on applications for access are to be rendered in a timely manner.¹³¹ Prior informed consent is associated with the specific uses for which consent is granted.¹³² Thus, any change in use following the grant of consent would require a new application.¹³³ Further, permission granted to access genetic resources would not necessarily imply permission to use associated knowledge, and vice versa.¹³⁴ To assist in the development of a system of prior informed consent, the Bonn Guidelines elaborate on the key principles¹³⁵ and elements¹³⁶ of the system. They also elaborate on minimum requirements¹³⁷ and elements¹³⁸ for

128. *Id.* § 11(g).

129. *Id.* § 9.

130. *Id.* § 24.

131. *Id.* § 28.

132. *Id.* § 34.

133. *Id.* § 34.

134. *Id.* § 37.

135. The basic principles are listed as:

- (a) Legal certainty and clarity; (b) Access to genetic resources should be facilitated at minimum cost; (c) Restrictions on access to genetic resources should be transparent, based on legal grounds, and not run counter to the objectives of the Convention; (d) Consent of the relevant competent national authority(ies) in the provider country . . . [and] . . . consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained.

Id. § 26.

136. The elements of a prior informed system are identified as “(a) Competent authority(ies) granting or providing for evidence of prior informed consent; (b) Timing and deadlines; (c) Specification of use; (d) Procedures for obtaining prior informed consent; (e) Mechanism for consultation of relevant stakeholders; (f) Process.” *Id.* § 27.

137. In terms of the basic requirements for mutually agreed terms, the following are noted:

- (a) Legal certainty and clarity; (b) Minimization of transactions costs; (c) Inclusion of provisions on user and provider obligations; (d) Development of different contractual arrangements for different resources and for different uses and development of model agreements; (e) Different uses may include, inter alia, taxonomy, collection, research, commercialization; (f) Mutually agreed terms should be negotiated efficiently and within a reasonable period of time; (g) Mutually agreed terms should be set out in a written agreement.

Id. § 42.

138. The following are identified as guiding parameters in a contractual arrangements.

mutually agreed terms, which are illustrated in an indicative list, including type and quantity of genetic resources, and the geographical/ecological area of activity.¹³⁹

The fair and equitable sharing of benefits is no doubt the most important scheme in the CBD from the standpoint of indigenous peoples and developing countries. To this end, the Bonn Guidelines mandate that the terms of access include the conditions, obligations, procedures, types, timing, distribution and mechanisms of benefits to be shared.¹⁴⁰ For this purpose, near-term, medium-term and long-term benefits are to be considered, including up-front payments, milestone payments and royalties, with the time-frame of benefit-sharing being clearly stipulated.¹⁴¹

Appendix II contains an illustrative list of monetary and non-monetary benefits deemed to satisfy the objectives of the CBD. The monetary benefits include: access fees; up-front payments; milestone payments; payment of

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- (a) Regulating the use of resources in order to take into account ethical concerns of the particular Parties and stakeholders, in particular indigenous and local communities concerned; (b) Making provision to ensure the continued customary use of genetic resources and related knowledge; (c) Provision for the use of intellectual property rights include joint research, obligation to implement rights on 'inventions obtained and to provide licenses by common consent; (d) The possibility of joint ownership of intellectual property rights according to the degree of contribution.

Id. § 43.

139. The indicative list of typically mutually agreed terms is outlined as

- (a) Type and quantity of genetic resources, and the geographical/ecological area of activity; (b) Any limitations on the possible use of the material; (c) Recognition of the sovereign rights of the country of origin; (d) Capacity-building in various areas to be identified in the agreement; (e) A clause on whether the terms of the agreement in certain circumstances (e.g., change of use) can be renegotiated; (f) Whether the genetic resources can be transferred to third parties and conditions to be imposed in such cases, e.g. whether or not to pass genetic resources to third parties without ensuring that the third parties enter into similar agreements except for taxonomic and systematic research that is not related to commercialization; (g) Whether the knowledge, innovations and practices of indigenous and local communities have been respected, preserved and maintained, and whether the customary use of biological resources in accordance with traditional practices has been protected and encouraged; (h) Treatment of confidential information; (i) Provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products.

Id. § 44.

140. *Id.* § 45.

141. *Id.* § 47.

royalties; license fees in case of commercialization; special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; salaries and preferential terms where mutually agreed; research funding; joint ventures; and joint ownership of intellectual property rights.¹⁴² On the other hand, notable examples of non-monetary benefits include: sharing of research and development results; collaboration, cooperation and contribution in scientific research and development programmes (particularly biotechnological research activities); participation in product development; and food and livelihood security benefits.¹⁴³

The Bonn Guidelines require each Contracting State to designate one focal point for access and benefit-sharing and to make such information available through a clearinghouse mechanism.¹⁴⁴ It is the responsibility of the focal point to disclose to prospective applicants for access to genetic resources information about the relevant indigenous groups and stakeholders.¹⁴⁵ Such disclosure would go a long way in reducing instances of misappropriation of identities of the proper owners and would enable applicants to seek the approval of indigenous groups—a necessary precondition to obtaining the prior informed consent of the national competent authority.¹⁴⁶

Section 14 of the Bonn Guidelines requires national competent authorities to advise on mechanisms for effective participation of indigenous groups in the different stages in the process of access and benefit-sharing.¹⁴⁷ For example, these required advising mechanisms would ensure that the decisions and processes are made available in a language understandable to relevant indigenous peoples.¹⁴⁸ Additionally, national consultative committees are required to be set up.¹⁴⁹ Advice provided by these institutions would further the education of indigenous people about their rights and thus assure that they understand fully the implications of the contractual arrangements into which they may enter. Indeed, the duties imposed on competent national authorities are consistent with the Bonn Guidelines' requirement that states support measures "to enhance indigenous and local communities' capacity to represent their interests fully at negotiations."¹⁵⁰

142. *Id.* Appendix II (1).

143. *Id.* Appendix II (2).

144. *Id.* § 13.

145. *Id.* § 13.

146. *Id.* § 26.

147. *Id.* § 14(g).

148. *Id.* § 14(h).

149. *See id.* § 19.

150. *Id.* § 16(a)(vii).

Under the Bonn Guidelines, access to and use of biological resources must comply with and must not violate the customary rights of indigenous groups.¹⁵¹ Thus, Section 16(a)(iii) calls on States to take steps “to ensure that the commercialization and any other use of genetic resources [does] not prevent traditional use of genetic resources.”¹⁵² Furthermore, in the implementation of mutually agreed terms, “users are to respect customs, values and customary practices of indigenous communities.”¹⁵³ The indicative list of mutually agreed terms includes a reference to “whether knowledge, innovations and practices of indigenous and local communities have been respected, preserved and maintained, and whether the customary use of biological resources in accordance with traditional practices has been protected and encouraged.”¹⁵⁴ Guarantees are also provided in the instrument for the fair and equitable sharing of benefits with all those who have been identified as having contributed to the resource management, scientific and/or commercial process, including institutions and indigenous and local communities.¹⁵⁵

Significantly, the Bonn Guidelines call on countries to adopt measures “to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights.”¹⁵⁶ These disclosures would be highly relevant in tackling cases of improper patent grants where examining authorities fail to take into account prior uses of associated traditional knowledge in other countries. Ultimately, these disclosures could be used to deny or revoke patents derived from traditional knowledge.

C. From Guidelines to Binding Commitments: The Nagoya Protocol

1. The Provisions

While the access and benefit provisions in both the CBD and the Bonn Guidelines contain several provisions potentially benefitting indigenous

151. *Id.* § 16.

152. *Id.* § 16(a)(iii).

153. *Id.* § 16(a)(iii).

154. *Id.* § 44(g).

155. *See id.* § 48; *see also* § 16.

156. *Id.* § 16(d)(ii).

groups, the exhortatory nature of the provisions in the CBD, coupled with the voluntary nature of the Bonn Guidelines, render those instruments of little use in a State that is determined not to recognize the rights of its indigenous groups. Without a binding international framework that imposes specific commitments on states, the goals and objectives under the two instruments will not be adequately realized. For, the contract-based solutions in the CBD and Bonn Guidelines are largely domestic strategies and are simply inadequate for tackling certain problems associated with the use of genetic resources which have international dimensions and tend to require international cooperation with regards to jurisdictional and enforcement matters.¹⁵⁷ In light of these considerations, the international community continued with efforts to establish an enhanced regime to complement those instruments leading to the adoption of the Nagoya Protocol in October 2010.

a. Fair and Equitable Benefit Sharing

Under the Nagoya Protocol, benefits arising from the utilization of genetic resources as well as from subsequent applications and commercialization are to be shared in a fair and equitable way and on mutually agreed terms, with the Provider Party that is the country of origin or a Party that has acquired the genetic resources in accordance with the Convention,¹⁵⁸ or relevant indigenous and local communities.¹⁵⁹ Benefits are defined in this

157. As noted elsewhere,
... the best drafted contract is meaningless if the party who breaches the contract moves out the state where the contract was entered into and establishes residence in another country. Without cooperation from the second country, courts in the first country cannot acquire jurisdiction over that party to make him account for the breach. Similar issues will arise if the party moved out of the first country to avoid paying a judgment issued against him for breach of an access- and benefit-sharing contract. Without cooperation from the second country, it will be impossible to enforce the judgment. Furthermore, if the party in breach of the contract were to acquire in the second country intellectual property rights related to the genetic resources obtained in the first country, again, without the second country moving cooperatively to revoke the intellectual property rights, the indigenous groups in the first country who have ownership claims in the resource in general would have no adequate legal remedies. Their only option might be to travel to the second country to initiate legal action there, but that could be an expensive strategy and full of uncertainties for the indigenous groups lacking of familiarity with foreign laws.

Paul Kuruk, *Mutual Recognition Agreements and the Protection of Traditional Knowledge*, 38 COMMONWEALTH TRADE HOT TOPICS 1, 3–4 (2004).

158. Nagoya Protocol, *supra* note 19, art. 5(1).

159. *Id.* art. 5(2), (5).

context¹⁶⁰ and identified in an Annex to the Protocol to include monetary¹⁶¹ and non-monetary benefits.¹⁶² The Nagoya Protocol obligates each Party to encourage the development and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms,¹⁶³ as well as voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.¹⁶⁴ Mutually agreed terms are to be set out in writing and may include, *inter alia* provisions on: dispute settlement; benefit-sharing, including in relation to intellectual property rights; third-party uses; and changes of intent, where applicable.¹⁶⁵

160. *Id.* art. 5(4).

161. *Id.* Annex § 1. The monetary benefits are listed as:

- (a) access fees/fee per sample collected or otherwise acquired; (b) up-front payments;
- (c) milestone payments; (d) payment of royalties; (e) license fees in case of commercialization; (f) special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; (g) salaries and preferential terms where mutually agreed; (h) research funding; (i) joint ventures; and (j) joint ownership of relevant intellectual property rights.

162. *Id.* Annex § 2. The non-monetary benefits may include, but not be limited to:

- (a) sharing of research and development results; (b) collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources; (c) participation in product development; (d) collaboration, cooperation and contribution in education and training; (e) admittance to ex situ facilities of genetic resources and to databases; (f) transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity; (g) strengthening capacities for technology transfer; (h) institutional capacity-building; (i) human and material resources to strengthen the capacities for the administration and enforcement of access regulations; (j) training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries; (k) access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies; (l) contributions to the local economy; (m) research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources; (n) institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities; (o) food and livelihood security benefits; (p) social recognition; and (q) joint ownership of relevant intellectual property rights.

163. *Id.* art. 19(1).

164. *Id.* art. 20(1).

165. *Id.* art. 6(3)(g).

b. Prior Informed Consent

As part of the exercise of sovereign rights over natural resources, access to genetic resources for their utilization is subject to the prior informed consent of the Provider Party¹⁶⁶ and, in accordance with domestic law, the Parties must take appropriate measures to ensure that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.¹⁶⁷

Each Party requiring prior informed consent is obligated to adopt appropriate legislative, administrative or policy measures to provide for legal certainty, clarity and transparency of its domestic access and benefit-sharing legislation or regulatory requirements; fair and non-arbitrary rules and procedures on accessing genetic resources; information on how to apply for prior informed consent; and clear and transparent written decisions by a competent national entity, in a cost-effective manner and within a reasonable period of time.¹⁶⁸ The Party should also provide for the issuance of a permit or its equivalent as evidence of the decision to grant the prior informed consent and of the establishment of mutually agreed terms.¹⁶⁹ Where applicable, and subject to domestic legislation, the Party should set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities.¹⁷⁰

c. Global Multilateral Benefit Sharing Mechanism and Transboundary Cooperation

The Nagoya Protocol obligates Parties to explore the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits from the use of genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.¹⁷¹ The benefits shared by users of genetic resources and associated traditional knowledge through this mechanism are to be used to support the conservation of biological diversity and the sustainable use of its components globally.¹⁷²

166. *Id.* art. 6(1).

167. *Id.* art. 6(2).

168. *Id.* art. 6(3).

169. *Id.*

170. *Id.*

171. *Id.* art. 10.

172. *Id.*

Where the same genetic resources are found *in situ* within the territory of more than one Party, or where the same associated traditional knowledge is shared by one or more indigenous and local communities in several Parties, those Parties are to cooperate in the implementation of the Protocol with the involvement of the relevant indigenous and local communities.¹⁷³

d. National Focal Points and Competent National Authorities

Each Party is to designate a national focal point to act as liaison with the CBD Secretariat and provide information¹⁷⁴ concerning competent national authorities, relevant indigenous and local communities and relevant stakeholders. To applicants seeking access to genetic resources or associated traditional knowledge, the focal points are to provide information on procedures for obtaining prior informed consent or approval and involvement of indigenous and local communities, and establishing mutually agreed terms including benefit-sharing.¹⁷⁵

Each Party is also expected to designate one or more competent national authorities to be responsible for granting access or issuing written evidence that access requirements have been met and to be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.¹⁷⁶ However, if it chooses to do so, a Party may designate a single entity to fulfill the functions of both focal point and competent national authority.¹⁷⁷

e. The Access and Benefit Sharing Clearing House

The Protocol established an Access and Benefit-sharing Clearing-House to serve as a means for sharing information and to provide access to relevant information made available by each Party,¹⁷⁸ including legislative, administrative and policy measures on access and benefit-sharing; information on the national focal point and competent national authority or authorities; and permits or their equivalent issued at the time of access

173. *Id.* art. 19.

174. *Id.* art. 13(1).

175. *Id.*

176. *Id.* art. 13(2).

177. *Id.* art. 13(3).

178. *Id.* art. 14(1).

as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.¹⁷⁹ Other information available through the Clearing-House includes the competent authorities of indigenous and local communities; model contractual clauses; methods and tools developed to monitor genetic resources; and codes of conduct and best practices.¹⁸⁰

f. Compliance with Domestic Legislation or Regulatory Requirements of Other Party

The Protocol obligates each Party to take appropriate, effective and proportionate legislative, administrative or policy measures to ensure that genetic resources or associated traditional knowledge utilized within its jurisdiction have been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities. It also requires that mutually agreed upon terms be established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.¹⁸¹ In addition, each Party is to provide appropriate, effective and proportionate remedial measures to address situations of non-compliance¹⁸² and to cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements of the other parties.¹⁸³

g. Monitoring Utilization of Genetic Resources

To monitor and to enhance transparency about the utilization of genetic resources, the Parties are expected to set up checkpoints,¹⁸⁴ and encourage users and providers to adopt provisions in their contracts agreeing to share information on the implementation of their obligations, including through reporting requirements.¹⁸⁵ It is the responsibility of a checkpoint to collect or receive relevant information related to prior informed consent, source of the genetic resource, establishment of mutually agreed terms, and/or utilization of genetic resources.¹⁸⁶ A Party may impose an obligation on users of genetic resources to provide such information at a designated

179. *Id.* art. 14(2).

180. *Id.* art. 14(c).

181. *Id.* art. 15(1), 16(1).

182. *Id.* art. 15(2), 16(2).

183. *Id.* art. 15(3), 16(3).

184. *Id.* art. 17(1)(a).

185. *Id.* art. 17(1)(b).

186. *Id.* art. 17(1)(a)(i).

checkpoint and take appropriate, effective and proportionate measures to address situations of non-compliance.¹⁸⁷ The information obtained by the checkpoints would in turn be provided to national authorities, to the Party providing prior informed consent, as well as to the Access and Benefit-sharing Clearing-House.¹⁸⁸

A permit or its equivalent issued at the time of access to genetic resources and made available to the Access and Benefit-sharing Clearing-House, is deemed to be an internationally recognized certificate of compliance.¹⁸⁹ As such, it would serve as evidence that the genetic resource which it covers was accessed in accordance with prior informed consent and that mutually agreed terms had been established.¹⁹⁰ For this purpose, the certificate must include certain basic information specified in the Protocol.¹⁹¹

h. Dispute Settlement

The Parties are required to encourage providers and users of genetic resources and/or associated traditional knowledge to incorporate dispute settlement provisions in their contracts including jurisdiction, applicable law and/or options for alternative dispute resolution, such as mediation or arbitration.¹⁹² The Parties should also provide opportunities for legal recourse where disputes arise under such agreements,¹⁹³ and take effective measures regarding access to justice and the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.¹⁹⁴

187. *Id.* art. 17(1)(a)(ii).

188. *Id.* art. 17(1)(a)(iii).

189. *Id.* art. 17(2).

190. *Id.* art. 17(3).

191. The information that must be provided in the certificate include:

(a) issuing authority; (b) date of issuance; (c) the provider; (d) unique identifier of the certificate; (e) the person or entity to whom prior informed consent was granted; (f) subject-matter or genetic resources covered by the certificate; (g) confirmation that mutually agreed terms were established; (h) confirmation that prior informed consent was obtained; and (i) commercial and/or non-commercial use.

Id. art. 17(4).

192. *Id.* art. 18(1).

193. *Id.* art. 18(2).

194. *Id.* art. 18(3).

2. Assessment of the Nagoya Protocol

The Nagoya Protocol not only addresses familiar themes in the CBD and Bonn Guidelines, but has significantly enhanced the scheme of protection available under those themes and also introduced new ones. As described earlier, the Bonn Guidelines contain provisions on national focal points,¹⁹⁵ competent authorities,¹⁹⁶ and responsibilities of contracting parties, users, and participation of stakeholders.¹⁹⁷ The Bonn Guidelines also elaborate on specific steps in the access and benefit sharing process including the identification of the relevant steps,¹⁹⁸ prior informed consent,¹⁹⁹ mutually agreed terms,²⁰⁰ benefit sharing²⁰¹ and national monitoring and reporting requirements.²⁰² The survey of the Nagoya Protocol reveals that it deals with all these matters as well and introduces new themes such as the global multilateral benefit sharing mechanism,²⁰³ transboundary cooperation,²⁰⁴ the need for compliance with domestic legislation on access and benefit sharing,²⁰⁵ and financial mechanism and resources.²⁰⁶

Through the improvements on the themes of the Bonn Guidelines and the introduction of other themes, the Nagoya Protocol has responded quite effectively to criticisms of the Bonn Guidelines noted above.²⁰⁷ For example, unlike the Bonn Guidelines, which were to be applied on a voluntary basis,²⁰⁸ the Nagoya Protocol is intended to impose binding and enforceable obligations on States. The Nagoya Protocol is a treaty the provisions of which are considered to be enforceable by and against States that ratify or accede to it.²⁰⁹ In terms of style, the Nagoya Protocol refers extensively

195. See, e.g., Bonn Guidelines, *supra* note 18, § 13.

196. *Id.* §14–15.

197. *Id.* § 16.

198. *Id.* § 23.

199. *Id.* § 24–40.

200. *Id.* § 41–44.

201. *Id.* § 45–50.

202. *Id.* § 55–58.

203. See Nagoya Protocol, *supra* note 19; art. 10.

204. See *id.* art. 11.

205. *Id.* arts. 15, 16.

206. *Id.* art. 25.

207. See Kuruk, *Mutual Recognition Agreements*, *supra* note 157 and accompanying text.

208. See Bonn Guidelines, *supra* note 18, § 7.

209. Vienna Convention on the Law of Treaties art. 26, May 23, 1969, 1155 U.N.T.S.

331 (“Every treaty in force is binding upon the parties to it and must be performed by them in good faith.”).

to the word “shall” in stating the responsibilities of States,²¹⁰ and employs to much lesser degree, terms common to the Bonn Guidelines such as “should,”²¹¹ “encourage,”²¹² “endeavor,”²¹³ etc. In this regard, the obligations of states under the Nagoya Protocol are mandatory and not exhortatory.

Unlike the Bonn Guidelines, the Nagoya Protocol does not rely exclusively on a contract model for the protection of genetic resources and associated traditional knowledge, but imposes commitments on States with regard to such protection. For example, States are required to adopt laws providing for legal certainty and transparency in their access and benefit sharing laws, to make available information on how to apply for prior informed consent and to ensure that decisions regarding access are made in a cost-effective manner and within a reasonable period of time.²¹⁴ The provisions regarding proof of evidence of access to genetic resources; procedures to verify the establishment of mutually agreed terms;²¹⁵ involvement of stakeholders in the negotiation and approval process; review of mutually agreed terms by national competent authorities;²¹⁶ public disclosure of agreements; and domestic enforcement mechanisms²¹⁷—all respond to and mitigate to a significant degree, the problems of a contractually based regime.²¹⁸

Dispute settlement provisions in the Nagoya Protocol are also laudable. By stipulating that contracts must include minimum terms regarding jurisdiction and applicable law,²¹⁹ the Protocol ensures that such crucial terms would not be omitted intentionally or inadvertently to the detriment of indigenous groups. In addition, by requiring States to facilitate access to judicial mechanisms for resolving disputes and also enhance the

210. See, e.g., Nagoya Protocol, *supra* note 19, art. 5 (“Each party *shall* take legislative, administrative or policy measures. . . .”) (emphasis added).

211. See, e.g., Bonn Guidelines, *supra* note 18, § 47 (“Near-term, medium-term, and long-term benefits *should* be considered. . . .”) (emphasis added).

212. *Id.* § 16(a)(i)-(ii) (“Contracting parties . . . should be *encouraged* to review their policy, administrative, and legislative measures. . . .”) (emphasis added).

213. *Id.* § 24 (“[E]ach Contracting Party. . . shall *endeavour* to create conditions to facilitate access to genetic resources. . . .”) (emphasis added).

214. See Nagoya Protocol, *supra* note 19, art. 6.3(a), (c)-(d).

215. See *id.* art. 6(3).

216. See *id.* art. 13(1)(c), 13(2).

217. See *id.* art. 6.

218. See Kuruk, *Mutual Recognition Agreements*, *supra* note 157 and accompanying text.

219. See Nagoya Protocol, *supra* note 19, art. 18(1)(a)-(b).

recognition of foreign judicial decisions,²²⁰ the Nagoya Protocol has significantly improved the system of resolving disputes over access and use of genetic resources.

The most innovative parts of the Nagoya Protocol are the responsibilities it imposes on both user and provider countries in terms of cooperation in connection with jurisdictional and enforcement matters and allocation of benefits. For example, the global multilateral benefit sharing mechanism²²¹ responds to the lack of a mechanism under the Bonn Guidelines for sharing benefits arising from the use of genetic resources that occur in transboundary situations. Cooperation by parties where the resources are found *in situ* in the territory of more than one Party,²²² would make it difficult for companies to play one indigenous community against the other in a bid to obtain the lowest prices for their resources.

The obligation imposed on States to ensure that genetic resources and associated traditional knowledge are accessed with the prior and informed consent and that mutually agreed terms²²³ have been established is especially useful to cases of biopiracy with international dimensions. It would require that the Party to whose territory a traditional knowledge user had moved after departing from the provider country, take appropriate measures to verify that the relevant consent was obtained, and that mutually agreed terms were in place before the access to genetic resources. Where this was not the case, the user Country must make available remedial measures to address situations of non-compliance and cooperate in cases of alleged violation of the domestic and access and benefit sharing regulatory requirements of the provider country.²²⁴ Such cooperation will clearly be useful where a user has moved to the user Country specifically to escape the jurisdiction of the provider country and therefore avoid liability, or to avoid paying a judgment against him in the provider country.

Because the benefit-sharing obligation applies not only to the utilization of genetic resources, but also to subsequent applications and commercialization,²²⁵ it will be useful where a person acquires intellectual property rights in a Contracting State derived from traditional knowledge related genetic resources obtained in another Contracting State, but does not share the

220. *See id.* art. 18(3).

221. *See id.* art. 10.

222. *See id.* art. 11.

223. *See, e.g., id.* art. 15.

224. *See id.* art. 15(2)-(3), 16(2)-(3).

225. *Cf. id.* art. 3 (“This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources....”).

royalties with the Provider Contracting State and relevant indigenous groups. Under those circumstances, the user Country where the intellectual property rights are obtained will be required to take remedial steps to ensure compliance with the access and benefit sharing laws of the source Country.²²⁶

Finally, the clearinghouse mechanism²²⁷ is a useful depository for information relevant to the implementation of the Protocol, which could be resorted to identify the types of genetic resources or associated traditional knowledge in Contracting States. Such information could be referred to in biopiracy litigation to show that patents derived from genetic resources or associated traditional knowledge did not meet prior art intellectual property criteria on account of well-known documented uses already found in the database of the clearinghouse mechanism prior to the issuance of the patents, and should therefore be invalidated.

While the Nagoya Protocol is quite comprehensive in terms of the scope of its provisions on access to and benefit sharing of traditional knowledge and genetic resources, it does not deal directly with an important issue relevant to biopiracy cases. Specifically, the need to ensure that *at the time of examination* of a patent application, the authorities have access to information that may indicate whether the subject-matter of a patent application was based on or derived from use of traditional knowledge or genetic resources. The mechanisms developed under the Nagoya Protocol such as the Access and Benefit-sharing Clearing House, national focal points, competent authorities and checkpoints constitute valuable sources of information regarding the different types of genetic resources and how they are accessed, but the information available through those mechanisms are unlikely to be sought by the examining authority until there is a reason for it. While such grounds invariably exist *after* a patent has already been granted and was being challenged, there would appear to be no need for such contacts *before* the patent grant.

A logical and feasible way to make the information relevant at the time of processing the patent application is to require the applicant to indicate any use of traditional knowledge or genetic resources in developing the

226. See, e.g., *id.* art. 16(2) (“Each Party shall take appropriate, effective, and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1....”).

227. See *id.* art. 14.

subject matter of its claims. This information could be relied on by the examining authority to conduct additional investigation with the relevant entities about the use, if necessary, or by the relevant rights holders, who could then oppose the patent application. These concerns could have been tackled under the Nagoya Protocol through a provision calling on Contracting Parties, with or without making changes to their intellectual property law, to adopt administrative rules requiring patent applicants to simply check a box in a questionnaire during the patent application process, verifying whether or not a claimed invention was based on or derived from traditional knowledge or genetic resources.

D. The FAO Plants Treaty

In November 2001, the Food and Agricultural Organization (FAO) adopted the Plants Treaty to provide for the “conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.”²²⁸ The FAO Plants Treaty contains provisions regarding the conservation, exploration, collection, evaluation and documentation of plant genetic resources,²²⁹ and calls upon Parties to adopt policy and legal measures to promote the sustainable use of plant genetic resources.²³⁰

The FAO Plants Treaty provides for Farmers Rights in recognition of “the enormous contribution that farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.”²³¹ However, responsibility for realizing Farmers Rights is imposed on national governments who are to protect such rights “in accordance with their needs and priorities” and subject to national legislation.²³²

Farmers Rights recognized under the instrument include the “protection of traditional knowledge relevant to plant genetic resources for food and agriculture” and the right to “equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture” as well as the right to “participate in making decisions, at the national level,

228. FAO Plants Treaty, *supra* note 20, art. 1.1.

229. *See id.* art. 6.2.

230. *See id.* art. 6.

231. *Id.* art. 9.1.

232. *Id.* art. 9.2.

on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.”²³³

The FAO Plants Treaty acknowledges “the sovereign rights of States over their own plant genetic resources for food and agriculture [and that] the authority to determine access to those resources rests with national governments and is subject to national legislation.”²³⁴ In exercise of such rights, parties to the FAO Plants Treaty are called upon to “agree to establish a multilateral system, which is efficient, effective, and transparent, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis.”²³⁵ The multilateral system referred to includes plant genetic resources identified in an annex to the FAO Plants Treaty and is subject to review.²³⁶ Access to plant genetic resources is to be facilitated under specific conditions laid down in the FAO Plants Treaty.²³⁷ Benefits accruing from such access

233. *Id.* art. 9.2(a)-(c).

234. *Id.* art. 10.1.

235. *Id.* art. 10.2.

236. *Id.* art. 11.4.

237. The conditions for access are spelt out as follows:

(a) Access shall be provided solely for the purpose of utilization and conservation in research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses. In the case of multiple-use crops (food and non-food), their importance for food security should be the determinant for their inclusion in the Multilateral System and availability for facilitated access; (b) Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved; (c) All available passport data and, subject to applicable law, any other associated available non-confidential descriptive information, shall be made available with the plant genetic resources for food and agriculture provided; (d) [Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, [or their genetic parts or components,] [in the form] received from the Multilateral System); (e) Access to plant genetic resources for food and agriculture under development, including material being developed by farmers, shall be at the discretion of its developer, during the period of its development; (f) Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws; (g) Plant genetic resources for food and agriculture accessed under the Multilateral System and conserved shall continue to be available to the Multilateral System by the recipients of those plant genetic

are to be shared “fairly and equitably” through exchange of information,²³⁸ access to and transfer of technology,²³⁹ capacity-building,²⁴⁰ and the sharing of monetary benefits and other benefits from commercialization.²⁴¹

Although some provisions in the instrument refer to intellectual property rights, none of them state an obligation to disclose in patent applications²⁴² the source or origin of plant genetic resources that may be relevant to the subject matter of the application.

IV. THE OBLIGATION TO DISCLOSE SOURCE OR ORIGIN OF TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES AS A POLICY RESPONSE

A. Origins of the Obligation to Disclose

1. Acknowledgement of Source of Folklore

Early references to the disclosure requirement in international instruments on traditional knowledge can be found in WIPO’s Model Provisions on National Laws on Folklore²⁴³ adopted in 1982 (1982 WIPO Model Provisions); and the Draft Treaty for the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions (1984 WIPO Draft Treaty).²⁴⁴ Under the 1982 WIPO Model Provisions, protection is to be

resources for food and agriculture, under the terms of this Undertaking; (h) Without prejudice to the other provisions under this Article, the Contracting Parties agree that access to plant genetic resources for food and agriculture found in in situ conditions will be provided according to national legislation. . . .

Id. art. 12.3.

238. *Id.* art. 13.2(a).

239. *Id.* art. 13.2(b).

240. *Id.* art. 13.2(c).

241. *Id.* art. 13.2(b).

242. *See, e.g., id.* art. 12(d)-(e).

243. *See generally* United Nations Educational, Scientific and Cultural Organization [UNESCO] and World Intellectual Property Organization [WIPO], *Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions* (1985), <http://www.wipo.int/edocs/lexdocs/laws/en/unesco/unesco001en.pdf> [hereinafter WIPO Model Provisions].

244. *See generally* Secretariat of the World Intellectual Property Organization [WIPO], *Final Report on National Experiences with the Legal Protection of Expressions of Folklore*, Draft Treaty for the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions, Annex IV, WIPO/GRTKF/IC/3/10 (Mar. 25, 2002) [hereinafter WIPO Draft Treaty].

extended to folklore whether it is expressed verbally,²⁴⁵ musically,²⁴⁶ by action,²⁴⁷ or in tangible form.²⁴⁸ Where protected expressions of folklore are to be used both with gainful intent and outside their traditional or customary context,²⁴⁹ prior approval must be obtained from a competent authority²⁵⁰ designated as the main repository of rights to folklore.²⁵¹ Applications to use an expression of folklore must be made in writing to the authority²⁵² which may impose fees for such use with the understanding that the revenues so collected would be used to promote or safeguard national folklore.²⁵³

Significantly, the 1982 WIPO Model Provisions require that:

In all printed publications, and in connection with any communications to the public of any identifiable expression of folklore, its source shall be indicated in an appropriate manner by mentioning the community and/or geographic place from where the expression utilized has been derived.²⁵⁴

However, the requirement to acknowledge the source of folklore does not apply to creations of original works inspired by expressions of folklore or to incidental uses of expressions of folklore.²⁵⁵

The 1982 WIPO Model Provisions allow criminal penalties to be imposed for: failing to obtain the required written consent prior to use of protected folklore;²⁵⁶ failing to acknowledge the source of folklore;²⁵⁷ misrepresenting the origin of expressions of folklore;²⁵⁸ and distorting

245. WIPO Model Provisions, *supra* note 243, art. 2, § 2(i).

246. *Id.* § 2(ii). Examples of protected musical expressions include folk songs and instrumental music.

247. *Id.* § 2(iii). Examples of protected expressions of action include folk dances, plays and artistic forms or rituals, whether or not reduced in material form.

248. *Id.* § 2(iv). This would include productions of folk art such as drawings, paintings, carvings, sculptures, pottery, terracotta, mosaic, metal ware, jewelry, basket weaving, needlework, textiles, carpets, costumes, musical instruments and architectural forms.

249. *Id.* § 3. This would apply to “(i) any publication, reproduction and distribution of copies of expressions of folklore; (ii) any public recitation or performance, any transmission by wireless means or wire, and any other form of communication to the public, of expressions of folklore.”

250. *Id.*

251. *Id.* § 11.

252. *Id.* § 10(1).

253. *Id.* § 10(2).

254. *Id.* § 5.

255. *Id.* § 5(2).

256. *Id.* § 6(2).

257. *Id.* § 6(1).

258. *Id.* § 6(3).

works of folklore in any manner considered prejudicial to the honor, dignity or cultural interests of the community from which it originates.²⁵⁹ In addition, objects made in violation of the 1982 WIPO Model Provisions and any profits made therefrom can be seized.²⁶⁰ These remedies may be imposed along with damages and other civil remedies.²⁶¹

After promulgating the 1982 WIPO Model Provisions, the Committee of Experts proceeded to prepare the 1984 WIPO Draft Treaty,²⁶² which closely tracks the 1982 WIPO Model Provisions in terms of definition of subject-matter,²⁶³ remedies for unauthorized use²⁶⁴ and acknowledgement of the sources of folklore.²⁶⁵ Indeed, the wording of the disclosure principle differs only slightly from the 1982 WIPO Model Provisions as follows.

In all printed publications, and in connection with any communications to the public of any identifiable expression of folklore, its source shall be indicated in an appropriate manner by mentioning the community and/or geographic place in which it has originated.²⁶⁶

Under 1984 WIPO Draft Treaty, each contracting state would designate a competent authority to administer the protection of expressions of folklore within the state. This authority could request that the other states protect expressions originating in the contracting states' own territory²⁶⁷ and the written permission of that authority would be required prior to permitting commercial uses²⁶⁸ of folklore in other contracting states. To facilitate the implementation of this provision, the state-appointed authority is required to provide information pertaining to the main characteristics and the source of expressions of folklore originating in its territory.²⁶⁹ The request to use

259. *Id.* § 6(4).

260. *Id.* § 7.

261. *Id.* § 8.

262. *See* WIPO Draft Treaty, *supra* note 244.

263. *See id.* art. 1.

264. For example, criminal penalties, seizure and damages relief are also contained in Articles 8, 9 and 10 of each instrument. However, unlike the model provisions, the draft treaty would impose civil penalties for any use of folklore that “causes economic harm to the State or community in which the utilized expression of folklore has originated.” *Id.* art 10.

265. *Id.* art. 7.

266. *Id.* art. 7(1).

267. *Id.* art. 3(1).

268. Permission would be required in connection with the publication, reproduction, distribution or importation, for purpose of distribution to the public, of reproductions or recordings of recitations or performances of expressions of folklore; or for the public recitation or performance of expressions of folklore, as well as any broadcast of expressions of folklore. *See id.* art. 4(1).

269. *Id.* art. 4(2).

an expression of folklore would be made to the competent authority in the state in which the expression of folklore originates.²⁷⁰ With few exceptions, authorization is expected to be automatic and expeditious,²⁷¹ but may be conditioned on the payment of adequate compensation, which would be fixed by the competent authority in the absence of agreement.

However, due to opposition from some member states the 1984 WIPO Draft Treaty was never finalized for adoption and consequently lacks legal significance.²⁷²

2. Access and Benefit Sharing Considerations

In the context of genetic resources, however, the obligation to disclose can be traced to the Convention on Biological Diversity (CBD). As noted earlier, the CBD provides that access to genetic resources shall be “on mutually agreed terms”²⁷³ and subject to the prior informed consent of the Contracting State providing such resources.²⁷⁴ Each Contracting Party is required “to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity”²⁷⁵ and also “encourage the *equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.*”²⁷⁶ However, there is no explicit reference to a disclosure requirement in the CBD.

In furtherance of the goals of the CBD, the Conference of the Parties to the CBD (COP) adopted the Bonn Guidelines to “serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions” of the CBD.²⁷⁷ Significantly, the Bonn Guidelines call on Parties and Governments to “encourage the disclosure of *the country of origin of the genetic resources and of the origin of traditional knowledge innovations and practices in*

270. *Id.* art. 5(1).

271. A request may be denied where the intended use would be prejudicial to the honor or dignity of the originating country or community. The competent authority is required to justify in writing, any decision it has taken to denying a request. *Id.* art. 5(2).

272. Kuruk, *Protecting Folklore*, *supra* note 16, at 818–19.

273. Convention on Biological Diversity, *supra* note 17, art. 15(4).

274. *Id.* art. 15(5).

275. *Id.* art. 8.

276. *Id.*

277. Bonn Guidelines, *supra* note 18, § 1.

applications for intellectual property rights.”²⁷⁸ The COP decision adopting the Bonn Guidelines elaborates on this by calling for such disclosure where the subject matter of the patent application *concerns or makes use of genetic resources*²⁷⁹ or *traditional knowledge, innovations and practices* of indigenous and local communities relevant for the conservation and sustainable use of biological diversity.²⁸⁰ As justification, the COP notes that disclosure would make “a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted.”²⁸¹

Like the Bonn Guidelines, the Nagoya Protocol addresses the question of access to genetic resources and the fair and equitable sharing of benefits arising from their utilization and in this context, imposes on States various undertakings including rules regarding prior informed consent, mutually agreed terms, benefit sharing, and trans-boundary cooperation. The Nagoya Protocol set specific obligations to support compliance with the domestic legislation or regulatory requirements of countries providing genetic resources and contractual obligations reflected in mutually agreed terms.²⁸² Thus, it sought to transform into binding commitments the principles first articulated in the CBD, and later the Bonn Guidelines. However, while the Bonn Guidelines contain explicit provisions on the disclosure requirement in the context of the implementation of the principles, the Nagoya Protocol omits a similar reference, perhaps suggestive of difficulties with reaching an agreement on the disclosure requirement during negotiations leading up to the adoption of the Nagoya Protocol.

3. Incorporating a Disclosure Requirement Under Patent Laws

To complement the access and benefit-sharing regime, and prevent biopiracy or facilitate the prosecution of biopiracy cases, governments and indigenous groups have called for patent laws to be amended to include a disclosure requirement. For example, at the fourth session of the Working Group on Reform of the Patent Cooperation Treaty in May 2003, Switzerland

278. *Id.* § 16(d)(ii).

279. *The Role of Intellectual Property Rights in the Implementation of Access and Benefit Sharing Arrangements*, Decision VI/24/C, ¶ 1, in *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Conference of the Parties to the Convention on Biological Diversity, U.N. Doc. UNEP/CBD/COP/6/20 (May 27, 2002) [hereinafter COP Decision VI/24/C].

280. *Id.* ¶ 2.

281. *Id.* ¶ 1.

282. Nagoya Protocol, *supra* note 19, Introduction.

introduced proposals regarding the declaration of the source of genetic resources and traditional knowledge in patent applications²⁸³ which it repeated at other fora including sessions of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing of the CBD,²⁸⁴ the WTO TRIPS Council,²⁸⁵ WIPO's Ad-Hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements,²⁸⁶ and WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.²⁸⁷

In its proposals, Switzerland identified transparency, traceability, technical prior art, and mutual trust as policy specific objectives underlying the disclosure requirement.²⁸⁸ It explained that the disclosure of source of traditional knowledge “would increase transparency in access and benefit sharing with regard to genetic resources and traditional knowledge”²⁸⁹ and also “allow the providers of genetic resources and traditional knowledge to keep track of the use of their resources or knowledge in research and development resulting in patentable inventions.”²⁹⁰ Furthermore, such

283. WIPO, Working Group on Reform of the Patent Cooperation Treaty, *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO Doc. PCT/R/WG/4/13 (May 5, 2003).

284. Convention on Biological Diversity, *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, U.N. Doc. UNEP/CBD/WG-ABS/3/INF/7 (Jan. 31, 2005).

285. WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *Article 27.3(b), The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge, Communication from Switzerland*, WTO Doc. IP/C/W/400/Rev.1 (June 18, 2003).

286. WIPO, Ad Hoc Intergovernmental Meeting on Genetic Resources and Disclosure Requirements, *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO Doc. WIPO/IP/GR/05/INF/4 (May 19, 2005).

287. WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Proposals by Switzerland Regarding Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO Doc. WIPO/GRTKF/IC/20/INF/10 (Oct. 17, 2011).

288. WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications* ¶ 12, WIPO Doc. WIPO/GRTKF/IC/10 (June 6, 2007) [hereinafter *Swiss Proposals*].

289. *Id.* ¶ 12(a).

290. *Id.* ¶ 12(b).

disclosure would be useful to patent examiners and judges in the determination of the prior art, as it “would simplify searching the databases on traditional knowledge that are increasingly being established at the local, regional and national level.”²⁹¹ Moreover, the disclosure of the source would enhance mutual trust among stakeholders who may be providers and/or users of genetic resources and traditional knowledge, including developing and developed countries, indigenous and local communities, private companies and research institutions.²⁹² This will not only deepen “mutual trust in the North—South—relationship,” but also “strengthen the mutual supportiveness between the access and benefit sharing system and the patent system.”²⁹³

Similarly, during discussions in the World Trade Organization (WTO) in 2003 regarding a review of Article 27.3(b) of the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement),²⁹⁴ a group of countries including Brazil, Cuba, Ecuador, India, Peru, Thailand, Venezuela, Zambia and Zimbabwe called for Article 29 of the TRIPS Agreement²⁹⁵ to be amended to provide that an applicant for a patent relating to biological materials or to traditional knowledge provide, as a condition of patent rights, (i) the disclosure of the source and country of the biological resource and traditional knowledge used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regime; and (iii) evidence of fair and equitable benefit sharing under the relevant national regime.²⁹⁶

291. *Id.* ¶ 12(c).

292. *Id.* ¶ 12(d).

293. *Id.*

294. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27.3(b), Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement]. Under Article 27.3(b) of the TRIPS Agreement on patentable subject matter, it is provided that: “Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.”

Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), art. 27.3(b), available at https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

295. TRIPS Agreement, art. 29.

296. *TRIPS Agreement and the CBD*, *supra* note 21, ¶ 1.

Proponents of the disclosure requirement at the WTO²⁹⁷ contended that such disclosure would promote the objectives of the patent system by reducing instances of bad patents; enabling patent examiners to ascertain more effectively the “inventive” step claimed in a particular patent application; and enhancing the ability of countries to track down and challenge instances of bad patents.²⁹⁸ However, these claims were strenuously opposed by the U.S., which argued that the “most effective” means to achieving the international community’s goals regarding access, benefit sharing and the prevention of the issuance of erroneously issued patents is rather “through tailored, national solutions to meet practical concerns and actual needs . . . [and that the] introduction of a new patent disclosure would not achieve those important objectives but may have significant negative consequences.”²⁹⁹

Specifically, the US pointed out that a new disclosure requirement would not, per se, ensure that benefits are equitably shared, as “such a requirement would merely convey the information requested but have no mechanism to transfer benefits between parties.”³⁰⁰ On the matter of preventing erroneously granted patents, the US noted as well that “information indicating country of origin, *ex situ* collection sites, etc., would do little to ensure ascertainment of appropriate inventorship, novelty or inventive step, because such information does not generally address the considerations underlying these requirements, such as acts of invention or the state of the relevant art.”³⁰¹ A negative consequence of the disclosure requirement, “particularly where the sanctions for non-compliance include invalidation of a patent,” the U.S. argued, would be the creation of “a ‘cloud’ of uncertainty over the patent right by opening a new avenue for litigation and other uncertainties that would undermine the role of the patent system in promoting innovation and technological development.”³⁰² Moreover,

297. For an analysis of the debate surrounding the disclosure requirement, see generally, Nuno Pires Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL’Y 371, 371–401 (2000).

298. *TRIPS Agreement and the CBD*, *supra* note 21, ¶ 7.

299. Council for Trade-Related Aspects of Intellectual Property Rights, *Article 27.3(b), The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge, Communication from the US*, ¶ 6, WTO Doc. IP/C/W/434 (Nov. 6, 2004).

300. *Id.* ¶ 9.

301. *Id.* ¶ 13.

302. *Id.* ¶ 14.

the patent disclosure requirement would impose “significant administrative burdens for the patent offices of members that would in turn create additional costs, particularly with respect to those requirements that demand compliance with foreign laws.”³⁰³

Some developing countries countered the arguments of the United States regarding uncertainties,³⁰⁴ administrative costs,³⁰⁵ monitoring difficulties³⁰⁶ and relevance to patent protection.³⁰⁷ While not discounting the usefulness of well-functioning national systems, those countries stressed the need for an international solution to complement the national systems.³⁰⁸ According to them, both national and international mechanisms are critical to provide the cooperation required to tackle cases of biopiracy with significant international dimensions. They also noted that the disclosure requirement

303. *Id.* ¶ 15.

304. Brazil and India argue that rather than create uncertainties regarding patent rights, the establishment of clear internationally agreed rules on disclosure, prior informed consent and benefit sharing would rather create certainties and facilitate access by researchers biological resources and/or traditional knowledge which the United States has identified to be of significance to researchers and bio-prospectors that use the patent system. *See Council for Trade-Related Aspects of Intellectual Property Rights, The Relationship Between the Trips Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge, Technical Observations on Issues Raised in a Communication by the United States (IP/C/W/434), Submission from Brazil and India, ¶ 18, WTO Doc. IP/C/W/443 (Mar. 18, 2005).*

305. As to the fear of increased administrative costs, Brazil and India denied that the expectation on applicants under the disclosure requirement to employ all reasonable measures to determine the country of origin and source of the material “would in any way be burdensome . . . [rather . . . such a burden would generally be subsumed in, or at least not be more burdensome than, the usual burden befalling the patent applicant to make out a case for his claims under current patent procedures and practices.” *See id.* ¶ 19.

306. On the issue of monitoring, it was pointed out that “given the enormous number of patents granted worldwide, the disclosure requirement will facilitate the monitoring of those patents by the owners of the biological material and associated traditional knowledge with a view to check whether prior informed consent and benefit sharing arrangements are being adhered to by the patent owners upon commercialization.” *See id.* ¶ 13.

307. Contrary to the assertions of the United States, Brazil and India contended that the disclosure requirement would be relevant in determining the existence of prior art, inventorship or scope of the patent “to the extent that the disclosed information will help determine whether the biological resources and/or traditional knowledge was used: to form part of the claimed invention; during the process of developing the claimed inventions; as a necessary prerequisite for the development of the invention; to facilitate the development of the invention; and/or as necessary background material and/or information for the development of the invention.” *See id.* ¶ 17.

308. Brazil and India insisted that such an approach “would be akin to arguing that in order to ensure the effective operation of the patent system, for example, only national patent laws are needed and not international agreements such as the TRIPS Agreement.” *See id.* ¶ 6.

was not unique, but was similar to disclosure requirements in patent laws “including disclosure of best mode, and in other jurisdictions such as the United States, a requirement to disclose all information material to patentability.”³⁰⁹ In this sense, therefore, the proposed requirement was “no different from those obligations the fulfillment of which has not been shown to impose any unnecessary burden on applicants.”³¹⁰

However, nothing concrete came out of the debate at the WTO and the TRIPS Agreement was not amended to include the disclosure requirement. Some members considered WIPO to be a more appropriate forum to develop solutions to the problem of biopiracy and urged that the debate be conducted there instead.³¹¹

B. Implications of the Disclosure Requirement

A number of issues arise from the disclosure requirement which require closer examination, namely, the nature of the relationship that must exist between a claimed patent invention and traditional knowledge to trigger disclosure; the legal principles upon which the disclosure requirement would be based; the scope of duties imposed on the patent applicant; and the consequences of failure to comply with the requirement.

1. Triggers

References in the literature to the disclosure requirement reveal varying triggers.³¹² For example, the COP of the CBD refers to disclosure requirements concerning material that is “utilized in the development of the claimed inventions”³¹³ or that is simply “utilized in the claimed inventions.”³¹⁴ The COP would encourage disclosure where in its development “the subject matter of the application concerns or makes use of genetic resources”³¹⁵

309. *Id.* ¶ 20.

310. *Id.*

311. Council for Trade-Related Aspects of Intellectual Prop. Rights, *Note by the Secretariat: The Protection of Traditional Knowledge and Folklore; Summary of Issues Raised and Points Made*, WTO Doc. IP/C/W/370/Rev.1 (Mar. 9, 2006), ¶ 10.

312. WIPO Technical Study on Patent Disclosure Requirements Related to Genetic Resources, and Traditional Knowledge (2004) at 3 [hereinafter WIPO Tech. Study].

313. COP Decision VI/24/C, *supra* note 279, at 12.

314. *Id.*

315. *Id.* at 11.

or “[traditional] knowledge.”³¹⁶ On their part, the Bonn Guidelines note, as a national monitoring mechanism, the possibility of using “applications for patents and other intellectual property rights relating to the material supplied.”³¹⁷

In this context, regional and national instruments make references to certain related concepts such as: (a) “an invention is based on biological material of plant or animal origin or if it uses such material;”³¹⁸ (b) “obtained or developed through an access activities;”³¹⁹ (c) products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries;³²⁰ (d) “a process or product obtained using samples or components of the genetic heritage;”³²¹ (e) “innovations involving elements of biodiversity;”³²² and (f) “biological material . . . when used in an invention” and “biological material used for the invention.”³²³

These examples indicate a range of possible linkages between traditional knowledge and a patented invention, such as whether the relationship was necessary or contingent, and whether traditional knowledge was actually part of the process that led to the invention.³²⁴ The contributions of traditional knowledge to the inventiveness reflected in the product or process patent could range from first, a general pointer to the line of research that led to the invention,³²⁵ second a more direct pointer to the invention,³²⁶ third,

316. *Id.*

317. Bonn Guidelines, *supra* note 18, ¶ 55(c).

318. Recital 27 of Directive 98/44/EC of the Eur. Parl. and of the Council of 6 July 1998 on the Legal Prot. of Biological Inventions, WIPO/GRTKF/IC/1/8, 1998 O.J. (L 213/15).

319. Article 35 of the Andean Cmty. Decision 391 of 2 July 1996 on Access to Genetic Res., WIPO/GRTKF/IC/1/8 at ¶ 17(a).

320. SILKE VON LEWINSKI. INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY 246 (Silke von Lewinski ed., 2nd ed. 2008).

321. Article 31 of Brazilian Provisional Measure No. 2186-16, Aug. 23, 2001; *see also* WIPO/GRTKF/IC/INF/2.

322. L. 7,788. 1988, art. 81, BIODIVERSITY LAW, (COSTA RICA).

323. Patent (Amendment) Act, 1924, No. 38, Leg. Dep., 2002 (India) at § 10(4), 25(1).

324. Comment On Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, ¶ 98, WIPO/GRTKF/IC/5/1 (May 2, 2003), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_5/wipo_grtkf_ic_5_10.pdf [hereinafter Draft Tech. Study].

325. *Id.* ¶ 100.

326. Traditional knowledge that a plant has certain medicinal properties may lead researchers to explore other possible medicinal properties of active compounds in the plant. *Id.*

direct contributions to the inventive concept;³²⁷ or fourth, a component of the inventive concept itself.³²⁸ In each of these cases, while the invention may derive from the access to the traditional knowledge, the nature of the obligation to disclose could differ considerably. Thus, in the first case, the traditional knowledge could be “used as part of the descriptive background to the invention”; in the second case, “form part of prior art that may be caught by obligations to disclose material prior art”;³²⁹ in the third case, it might be considered to be either “relevant prior art or arguably form part of the invention itself”; and, in the last case, it might form “part of the invention as claimed, leading to an obligation to name the [traditional knowledge] holder as an inventor or co-inventor.”³³⁰

2. *Legal Bases*

In general, there are two forms of the disclosure requirement: those that directly use, or adapt and extend existing patent law mechanisms, and those that are intended to be distinct new requirements and are based on separate legal principles.³³¹ Disclosure requirements of the first type are based on existing disclosure obligations in patent law such as disclosure necessary to enable the invention to be carried out, disclosure of the best mode or preferred embodiment of the invention, disclosure of the actual inventor or inventors, and disclosure of known prior art.³³² Complementing the patent related disclosure rules are legislative or judicial doctrines which seek to remedy cases where patents may have been obtained through fraudulent behavior,³³³ including the equitable concepts of “clean hands,” fraudulent procurement and misappropriation.³³⁴

327. Traditional knowledge that a certain plant extract was effective in treating skin infections may have led researchers to conclude that active compounds in the plant were effective antibiotics. *Id.*

328. A traditional knowledge holder may have communicated to a researcher a new or undisclosed medicinal property of a plant extract, when this property is central to the invention as claimed. *Id.*

329. WIPO Tech. Study, *supra* note 312, ¶ 100.

330. *Id.*

331. *Id.* ¶ 111.

332. *Id.*

333. *Id.* ¶ 125.

334. *Id.* ¶ 124.

However, other proposals on the disclosure requirement appear to be directed more clearly towards the implementation of non-patent laws and obligations. In the latter group of cases, the patent process is used merely as a means of giving effect to obligations under distinct legal or ethical systems, such as compliance with access regulations that may also require prior informed consent and the equitable sharing of benefits.³³⁵ Because the laws on access and benefit sharing are premised on contractual arrangements between the owners and users of traditional knowledge, such contracts are sometimes viewed as underlying considerations in enforcing the disclosure requirement.³³⁶

3. *Scope of the Obligation*

It is also useful to assess what the applicant must do to meet the obligation to disclose.³³⁷ For example, would the applicant be required to investigate and determine the source of relevant traditional knowledge and disclose it or merely use reasonable efforts or best endeavors to determine the source? Related to this issue is the burden of proof, or the degree to which an application or granted patent is deemed *prima facie* to be compliant with a disclosure requirement.³³⁸ For example, would this require proof by the applicant, where applicable, that traditional knowledge was accessed in compliance with the laws of the source country, or would that be assumed to be case in the absence of evidence to the contrary? Some proposals distinguish between *primary* sources, such as states providing genetic resources and indigenous and local communities on the one hand, and *secondary* sources including ex-situ collections and local communities.³³⁹ Under one approach, applicants “must declare the primary source to fulfill the requirement if they have information about the primary source”³⁴⁰ and declare the secondary source only if they have no information about the primary source.³⁴¹

335. *Id.* ¶ 115.

336. *Id.* ¶ 118, 129.

337. *Id.* ¶ 136

338. *Id.* ¶ 137.

339. WIPO, Working Group on Reform of the Patent Cooperation Treaty, *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, ¶ 20, WIPO Doc. PCT/R/WG/8/7 (2006).

340. *Id.* ¶ 21.

341. As the Swiss Proposals explain:

[I]f the patent applicant knows that the source of the genetic resource is the Contracting Party providing this resource, this Contracting State must be disclosed as the source; in contrast, if the applicant received the genetic resource from a

4. Sanctions

Potential consequences of failure to meet requirements to disclose certain information in a patent application may include the narrowing or invalidation of patent claims; administrative and criminal penalties; denial of the application; and invalidation or unenforceability of the patent after its grant.³⁴² However, the sanctions applied in a given case may depend on the legal basis of the disclosure requirement, the stage reached in the processing of the patent, the steps taken to remedy the failure, the restrictions that may apply after the issuance of the patent, the considerations as to whether the failure was unintentional or done with fraudulent intent, and the reliance on the undisclosed material for support.³⁴³ Under the Swiss proposals, sanctions contemplated under the Patent Cooperation Treaty and the Patent Law Treaty would also apply to failure to declare the source or wrongful declaration of the source of genetic resources and traditional knowledge in patent applications.³⁴⁴ Thus non-compliance during the processing of the application could result in a rejection of the application,³⁴⁵ but non-compliance after a patent grant will not lead to the revocation of the patent except in cases involving fraudulent intent.³⁴⁶

V. WIPO'S WORK PROGRAM ON THE DISCLOSURE REQUIREMENT

A. *Emerging Strategy*

1. *WIPO'S Mandate on Intellectual Property*

The most sustained and comprehensive work to date on the disclosure principle has been carried out by WIPO, which is generally acknowledged to be the best forum to tackle issues of biopiracy in light of its global

botanical garden, but does not know the Contracting Party providing the genetic resource, the botanical garden must be disclosed as the source.

Id.

342. Draft Tech. Study, *supra* note 324, at ¶ 149.

343. *Id.* ¶ 154.

344. WIPO, Working Group on Reform of the Patent Cooperation Treaty, *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, ¶ 7, WIPO Doc. PCT/R/WG/8/7 (Apr. 21, 2006).

345. *Id.* ¶ 26.

346. *Id.* ¶ 27.

mandate. Indeed, WIPO was established on July 14, 1967³⁴⁷ to “promote the protection of intellectual property throughout the world through cooperation among States and . . . in collaboration with any other international organization,” and also to “ensure administrative cooperation among the Unions.”³⁴⁸

To attain these objectives, WIPO is mandated to “promote the development of measures designed to facilitate the efficient protection of intellectual property throughout the world and to harmonize national legislation in this field.”³⁴⁹ It is also authorized to “encourage the conclusion of international agreements designed to promote the protection of intellectual property,”³⁵⁰ offer legal-technical assistance to States³⁵¹ and “assemble and disseminate information concerning the protection of intellectual property, carry out and promote studies in this field, and publish the results of such studies.”³⁵² Finally, it is required to “maintain services facilitating the international protection of intellectual property and . . . provide for registration in this field and the publication of the data concerning the registrations.”³⁵³

2. *Establishment of the Intergovernmental Committee*

In November 1997, the new Director-General of WIPO, Dr. Kamil Idris, established the Global Intellectual Property Issues Division (GIPID) to enable WIPO to “remain at the forefront of global IP developments by responding to . . . challenges facing the IP system in a rapidly changing world.”³⁵⁴ One of the main tasks of the GIPID was “to identify and explore the intellectual property needs and expectations of new beneficiaries, including the holders of indigenous knowledge and innovations, in order

347. Convention Establishing the World Intellectual Property Organization, art. 1, (Sept. 28 1979), http://www.wipo.int/edocs/lexdocs/treaties/en/convention/trt_convention_001en.pdf. [hereinafter WIPO Convention]. Membership in WIPO is open to any State that is a member of any of the Unions, or the United Nations or a party to the Statute of the International Court of Justice. It is managed by a Secretariat headed by a Director General, with its headquarters in Geneva, Switzerland. *Id.* arts. 5, 9 and 10.

348. *Id.* art. 3. The term “Unions” refers to groups of countries participating in pre-existing major international intellectual property instruments, including the Paris Convention and the Berne Convention, as well as other international agreements on intellectual property the administration of which is assumed in the future by WIPO. *See id.* art. 2(vii).

349. *Id.* art. 4(i).

350. *Id.* art. 4(iv).

351. *Id.* art. 4(v).

352. *Id.* art. 4(vi).

353. *Id.* art. 4(vii).

354. Intellectual Property Needs, *supra* note 1, at 16.

to promote the contribution of the IP system to their social, cultural and economic development.”³⁵⁵

To this end, WIPO conducted nine fact-finding missions between June 1998 and November 1999 to twenty-eight countries in the South Pacific, Southern and Eastern Africa, South Asia, North America, Central America, West Africa, Arab countries, South America, and the Caribbean.³⁵⁶ WIPO also organized round tables in July 1998 and November 1999 to facilitate an “exchange of views among policymakers, indigenous peoples and other holders of TK on the more effective application of the IP system for the protection of traditional and indigenous knowledge.”³⁵⁷

In line with the objectives of the newly created GIPID, WIPO’s activities on genetic resources began in 1998³⁵⁸ when it joined with the United Nations Environment Programme (UNEP) to commission a study on the role of IP rights in the sharing of benefits arising from the use of biological resources and associated traditional knowledge.³⁵⁹ Issues related to intellectual property and genetic resources were also discussed by WIPO at the third session of the Standing Committee on the Law of Patents (SCP) in September 1999 during which Colombia requested the following language to be included in the proposed Patent Law Treaty:

1. All industrial property protection shall guarantee the protection of the country’s biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired legally.
2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.³⁶⁰

The request by Colombia may have marked the first time that the disclosure requirement was raised in a WIPO forum in the context of

355. *Id.* at 19.

356. *See id.* at 16.

357. *Id.*

358. WIPO, Genetic Resources: Factual Update of International Developments, ¶ 3, WIPO Doc. WIPO/GRTKF/IC/11/8(b) (May 30, 2007) [hereinafter Factual Update].

359. *Id.* ¶ 3.

360. Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL’Y 371, 377 (2000).

genetic resources. As an outcome of the meeting, the SCP requested the WIPO Secretariat to include the issue of protection of biological and genetic resources on the agenda of a forthcoming meeting of Working Group on Biotechnological Inventions at which a questionnaire was prepared to gather information from Member States regarding national protection of biotechnological inventions, including certain aspects regarding intellectual property and genetic resources.³⁶¹

In response to an invitation from the SCP, WIPO organized a Meeting on Intellectual Property and Genetic Resources in April 2000 to discuss intellectual property issues surrounding access to, and in situ preservation of, genetic resources.³⁶² The meeting resulted in a consensus that:

WIPO should facilitate the continuation of consultations among Member States in coordination with the other concerned international organizations, through the conduct of appropriate legal and technical studies, and through the setting up of an appropriate forum within WIPO for future work.³⁶³

Informal consultations held at WIPO prior to the Diplomatic Conference for the Adoption of the Patent Law Treaty in May 2000, produced a resolution that discussions concerning genetic resources would continue at WIPO but with the format of the discussions to be left to the Director General's discretion, in consultation with WIPO Member States.³⁶⁴ Further consultations were held after the Diplomatic Conference, resulting in a proposal to establish a distinct body within WIPO to facilitate the discussions on traditional knowledge.³⁶⁵

Accordingly, at the twenty-sixth session of the WIPO General Assembly in October 2000, the Member States established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).³⁶⁶ It was agreed that deliberations at the IGC would proceed on three themes identified during the consultations: intellectual property issues that arise in the context of (i) access to genetic resources and benefit sharing; (ii) protection of traditional knowledge, whether or not associated with those resources; and (iii) the protection of expressions of folklore.³⁶⁷

361. Factual Update, *supra* note 358, ¶ 4.

362. *Id.*

363. *Id.* ¶ 6.

364. *Id.* ¶ 7.

365. *Id.* ¶ 8.

366. *See generally* WIPO General Assembly, Sept. 25-Oct. 3, 2000, WIPO Doc.WO/GA/26/10 (Oct. 3, 2000).

367. WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, ¶ 14, WIPO Doc. WO/GA/26/6 (Aug. 25, 2000).

3. *Focus on Genetic Resources and Related Traditional Knowledge*

During its first session in May 2001, the IGC identified as possible elements of a work program on intellectual property and genetic resources, the development of guide practices, guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing. These would take into account “the specific nature and needs of different stakeholders, different genetic resources, and different transfers within different sectors of genetic resource policy.”³⁶⁸

At its second session, in December 2001, the IGC agreed on a two-step approach which would entail first, a complete and systematic survey of intellectual property clauses used in existing contracts, and, second, the preparation of guide practices or model intellectual property clauses based on the existing practices and clauses.³⁶⁹ It was agreed that the clauses would deal only with intellectual property aspects; be non-binding; without prejudice to, and consistent with, the work of the CBD and FAO; and be developed with the full and effective participation of all stakeholders, in particular indigenous and local communities.³⁷⁰ The IGC also discussed other issues such as disclosure of the origin of genetic resources, prior informed consent, the sovereignty of states over their genetic resources, transfer of technology, education and legal assistance to indigenous and local communities, and the legal status of genetic resources under international law.³⁷¹

A few months after the second IGC meeting, the Conference of the Parties (COP) invited WIPO in April 2002 to:

Prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, inter alia: (a) genetic resources utilized in the development of the claimed inventions; (b) the country of origin of genetic resources utilized in the claimed inventions; (c) associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions; (d) the source of associated traditional knowledge, innovations and practices; and, (e) evidence of prior informed consent.³⁷²

368. Factual Update, *supra* note 358, ¶ 11.

369. *Id.* ¶ 14.

370. *Id.*

371. *Id.* ¶ 15.

372. *Id.* ¶ 16.

The IGC discussed this invitation at its third session, agreed to respond positively to the CBD's request and adopted a work schedule to enable the completion and transmission of the study in time for the seventh meeting of the COP.³⁷³ Between the IGC's third and fourth sessions, the WIPO Secretariat circulated a questionnaire to Member States soliciting views on national practices relevant to the intellectual property issues identified for study in the COP's invitation.³⁷⁴

At its fifth session, the IGC was presented a report, the "Draft Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge," which had been prepared on the basis of the responses received from Member States.³⁷⁵ The IGC resolved to submit the report to the WIPO General Assembly with the recommendation that it be transmitted as a technical reference document to the Conference of Parties of the CBD, a recommendation which was later approved and acted on by the WIPO General Assembly.³⁷⁶

On its part, after receiving the WIPO Report, the COP issued yet another invitation at its meeting in February 2004 requiring WIPO to:

Examine . . . issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, including, inter alia: (a) options for model provisions on proposed disclosure requirements; (b) practical options for intellectual property rights application procedures with regard to the triggers of disclosure requirements; c) options for incentive measures for applicants; (d) identification of the implications for the functioning of disclosure requirements in various WIPO administered treaties; (e) intellectual property related issues raised by a proposed international certificate of origin/source/legal provenance. . . .³⁷⁷

373. *Id.* ¶ 22.

374. *Id.*

375. *Id.* ¶ 27.

376. *Id.* The report was transmitted subject to the following understanding:

The attached draft technical study has been prepared to contribute to international discussion and analysis of this general issue, and to help clarify some of the legal and policy matters it raises. It has not been prepared to advocate any particular approach nor to expound a definitive interpretation of any treaty. It is to be regarded as a technical input to facilitate policy discussion and analysis in the Convention on Biological Diversity and in other fora, and it should not be considered a formal paper expressing a policy position on the part of WIPO, its Secretariat or its Member States.

Id. ¶ 28.

377. *Id.* ¶ 31.

During its seventh session, the IGC examined a document dealing with the question of patent disclosure requirements relating to genetic resources,³⁷⁸ which addressed both the factual background on work within WIPO concerning the disclosure requirement as well as the existing proposals for possible further work on the matter.³⁷⁹

4. *Authorization to Negotiate Instruments*

Following a review of progress made by the IGC with its work program on traditional knowledge and genetic resources, the WIPO General Assembly renewed the mandate of the IGC in September 2009³⁸⁰ and authorized it to “undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs.”³⁸¹ The WIPO General Assembly directed that the focus of the IGC’s program “build on the existing work carried out by the Committee and use all WIPO working documents,”³⁸² including three specific ones, each of which focused on one of the thematic areas of cultural expressions, traditional knowledge, and genetic resources.³⁸³ They were “to constitute the basis of the Committee’s work on text-based negotiations.”³⁸⁴ The WIPO General Assembly also requested the IGC to submit the text (or texts) of an international legal instrument (or instruments) agreed upon for a decision to be made by the General Assembly on whether to convene a diplomatic conference to adopt the instrument(s).³⁸⁵

For the next six years, the IGC continued to deliberate on those documents during its regular sessions, and even convened some intersessional meetings

378. *See generally* WIPO, Patent Disclosure Requirements Relating to Genetic Resources and Traditional Knowledge: Update, WIPO Doc. WIPO/GRTKF/IC/7/10 (Oct. 15, 2004).

379. Factual Update, *supra* note 358, ¶ 38.

380. WIPO General Assembly, Rep. of the Thirty-Eighth (19th Ordinary) Sess., Sept. 22-Oct. 1, 2009, ¶ 217, WIPO Doc. WO/GA/38/20 (Oct. 1, 2009) [hereinafter WIPO General Assembly Rep., Thirty-Eighth Sess.].

381. *Id.* ¶ 217(a).

382. *Id.* ¶ 217(c).

383. *See id.*

384. *Id.*

385. *Id.* ¶ 217(d).

to expedite the process.³⁸⁶ At its twenty-sixth and twenty-seventh sessions, in February and March 2014 respectively, the IGC developed three texts: (i) Consolidated Document Relating to Intellectual Property and Genetic Resources Rev. 2³⁸⁷ (hereinafter referred to as “Consolidated Document on Genetic Resources”); (ii) The Protection of Traditional Knowledge Draft Articles Rev. 2³⁸⁸ (hereinafter referred to as “Draft Articles on Traditional Knowledge”); and (iii) The Protection of Traditional Cultural Expressions: Draft Articles Rev. 2³⁸⁹ (hereinafter referred to as the “Draft Articles on Traditional Cultural Expressions”).

Out of the three texts, only the Consolidated Document on Genetic Resources and the Draft Articles on Traditional Knowledge deal specifically with the disclosure requirement. They will therefore be the primary focus of the discussion in the next section, and will be referred to collectively as “Draft Negotiating Texts.” However, it must be cautioned that many of the provisions in the instruments are qualified by terms in parentheses, reflecting proposed additions to or subtractions from the substance of the texts. The instruments should therefore be read as incomplete in their current form and constitute works in progress that are subject to further negotiations to refine and align them as consensus is obtained on key points in the future.

386. WIPO Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, First Intersessional Working Group, WIPO/GRTKF/IWG/1/2 (July 23, 2010), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_iwg_1/wipo_grtkf_iwg_1_2_prov.pdf; WIPO Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Third Intersessional Working Group, WIPO/GRTKF/IWG/3/16 (Mar. 4, 2011), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_iwg_3/wipo_grtkf_iwg_3_16.pdf; WIPO Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Third Intersessional Working Group, WIPO/GRTKF/IWG/3/16 (Mar. 4, 2011), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_iwg_3/wipo_grtkf_iwg_3_16.pdf.

387. WIPO Secretariat, Consolidated Document Relating to Intellectual Property and Genetic Resources Rev. 2, WIPO/GRTKF/IC/28/4 (June 2, 2014), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_28/wipo_grtkf_ic_28_4.pdf [hereinafter Consolidated Document Relating to Genetic Resources].

388. WIPO Secretariat, The Protection of Traditional Knowledge: Draft Art. Rev. 2, WIPO/GRTKF/IC/28/5 (June 2, 2014), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_28/wipo_grtkf_ic_28_5.pdf [hereinafter Draft Articles on Traditional Knowledge].

389. WIPO Secretariat, The Protection of Traditional Cultural Expressions: Draft Art. Rev. 2, WIPO/GRTKF/IC/28/6 (June 2, 2014), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_28/wipo_grtkf_ic_28_6.pdf.

B. Current Proposals on the Disclosure Requirement

1. Positions of Countries

In the debates at the IGC, the developing countries led by Brazil, Peru, India, China Namibia and South Africa have emerged as very strong advocates for a mandatory disclosure requirement while the United States, Japan and Korea have vigorously opposed it, with the EU maintaining a middle ground.³⁹⁰

China, which houses the largest patent office in the world, views the disclosure requirement to be an improvement to the existing intellectual property system that “would help align the . . . system with the CBD, as well as promote the implementation of prior informed consent and benefit sharing in the use of genetic resources”³⁹¹ To Peru, the disclosure requirement would be a “vital part of patent applications” providing sufficient information to patent offices to enable them to determine “whether there was an inventive step to grant a patent.”³⁹² In this regard, the patent office would “serve as a check point or control point because that [is] where the decision would be made on whether or not a particular product could be commercialized.”³⁹³ Brazil also supports the disclosure requirement as “the most effective solution” to the problem of the misappropriation of genetic resources and proposes sanctions, including revocation, for cases of non-compliance.³⁹⁴

In contrast, the U.S. argues that a disclosure requirement aimed at promoting access and benefit-sharing arrangements would fall outside the mandate of the IGC and it would be inappropriate to seek to use the patent system “as a mechanism to enforce contracts.”³⁹⁵ In its view, “the patent office could not be required to take on a new role as an enforcement agency to regulate non-patent related issues such as source or origin of a

390. See Edward Hammond, *WIPO Patent Disclosure Negotiations Stay on Track but Consensus Will Prove Difficult*, THIRD WORLD NETWORK (Feb. 26, 2013), <http://www.twn.my/title2/biotk/2013/biotk130201.htm>.

391. WIPO Secretariat, Report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, ¶ 35, WIPO/GRTKF/IC/23/8 Prov. 2 (Apr. 26, 2013), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_24/wipo_grtkf_ic_24_ref_grtkf_23_8_prov_2.pdf [hereinafter IGC Report, Twenty-Third Session].

392. *Id.* ¶ 37.

393. *Id.*

394. *Id.* ¶ 89.

395. *Id.* ¶ 33.

[genetic resource].”³⁹⁶ Furthermore, the “patent examination process was not a suitable mechanism for ensuring compliance with unrelated regulatory requirements.”³⁹⁷ The U.S. is also concerned that a new patent disclosure requirement would be burdensome³⁹⁸ to the patent applicant and add new uncertainties to the patent system, including opening up a new avenue for litigation.³⁹⁹ Moreover, “[b]inding or mandatory norms on [genetic resources] disclosure in patent law would limit each country’s policy space.”⁴⁰⁰

Like the U.S., Japan contends that access and benefit sharing issues have no place in patent law and “should only be considered in the context of implementation of the Nagoya Protocol.”⁴⁰¹ To Japan, “mandatory disclosure requirements would have a chilling effect on industries’ motivation for applying for patents.”⁴⁰² It explains that “the risks involved in identifying source or origin in patent applications [are] enormous and the difficulties of traceability could render the patent system one that discouraged rather than encouraged innovation.”⁴⁰³

As an intermediate position, the EU “accept[s] the need for a disclosure requirement but seek[s] it in a less robust form than developing countries.”⁴⁰⁴ At the very beginning of the debates at the IGC in 2005, the EU circulated a document on its preferred approach,⁴⁰⁵ which it described as “fair, balanced and proportionate”⁴⁰⁶ to access and benefit sharing issues and which is “conscious of the importance of not introducing fresh burdens to

396. *Id.* ¶ 90.

397. *Id.*

398. According to the U.S.,

[i]n order to promote prompt disclosure and incentivize innovation, the requirements placed upon the patent applicant must not be burdensome. Burdens must only be those that were necessary to ensure that ordinary skilled persons in the same area of technology could remake the invention, or burdens that were required to ensure clarity in the claims of the patent application so that the scope of the claims could be understood.

Id. ¶ 33.

399. *Id.* ¶ 62.

400. *Id.*

401. *Id.* ¶ 60.

402. *Id.*

403. *Id.*

404. Edward Hammond, *WIPO Patent Disclosure Negotiations Stay on Track but Consensus Will Prove Difficult*, THIRD WORLD NETWORK (Feb. 26, 2013), <http://www.twn.my/title2/biotk/2013/biotk130201.htm> [hereinafter TWN, WIPO Patent Disclosure Negotiations].

405. See Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications, Submitted by the European Community and Its Member States, WIPO/GRTKF/IC/8/11 (May 17, 2005), http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_8/wipo_grtkf_ic_8_11.pdf [hereinafter EC Proposal].

406. WIPO IGC Report, Twenty-Third Session, *supra* note 391, ¶ 27.

innovation, and more specifically, the patent examination process.”⁴⁰⁷ According to the EU, disclosure of origin “should be a set of formal requirements, rather than an issue which required scrutiny during the examination process [and] issues which arose from difficulties with this method [a]re best remedied at the national level.”⁴⁰⁸

2. *The Draft Negotiating Texts*

a. *Consolidated Document on Genetic Resources*

The preamble of the Consolidated Document on Genetic Resources identifies as important considerations for the disclosure requirement, the building of trust, the strengthening of the supportiveness of intellectual property and the access and benefit sharing system⁴⁰⁹ and minimization of the harm to indigenous peoples caused by the patenting of genetic resources.⁴¹⁰ These considerations are elaborated as specific policy objectives with reference to the need to prevent the misappropriation of genetic resources,⁴¹¹ enhance transparency in the patent and access and benefit-sharing regime⁴¹² and ensure complementarity with relevant international instruments.⁴¹³

With regards to the scope of the disclosure requirement, it is provided in the Consolidated Document on Genetic Resources that where the subject matter of a patent application is based on or derived from traditional knowledge and genetic resources, a Contracting State should require applicants to “[d]isclose the [country of origin [and]] [or if unknown,] source of the genetic resources, [their derivatives] and/or [associated traditional knowledge] [traditional knowledge associated with genetic resources].”⁴¹⁴ In addition, the applicants should be mandated to “[p]rovide relevant information, as required by the national law of the [IP] [patent] office, regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where

407. *Id.*

408. *Id.*

409. Consolidated Document on Genetic Resources, *supra* note 387, Preamble.

410. *Id.*

411. *Id.* Policy Objectives, ¶ (a).

412. *Id.* Policy Objectives, ¶ (b).

413. *Id.* Policy Objectives, ¶ (c).

414. *Id.* art. 3.1(a).

appropriate.]”⁴¹⁵ However, if the source or country of origin is not known, the applicants are to provide a declaration to that effect.⁴¹⁶

The proposed disclosure requirement does not obligate patent offices to verify the contents of the disclosure, but envisages a technical assistance role to enable applicants meet the requirement.⁴¹⁷ Provision is also made for notification⁴¹⁸ and public disclosure of information received by the patent offices.⁴¹⁹

The Consolidated Document on Genetic Resources exempts human genetic resources, derivatives, commodities and genetic resources acquired before the adoption of the CBD from the disclosure requirement.⁴²⁰ The proposed instrument is not intended to have retroactive effect and consequently, would not apply to patents filed before its entry into force.⁴²¹

415. *Id.* art. 3.1(b).

416. *Id.* art. 3.1(c).

417. Under one of the proposals, it is understood that:

The disclosure requirement [shall/should] [does] not place an obligation on the [IP] [patent] offices to verify the contents of the disclosure. [But [IP] [patent] offices are required to provide effective guidance to [IP] [patent] applicants on how to meet disclosure requirements, and to provide an opportunity for applicants to obtain from [IP] [patent] offices a positive decision that disclosure requirements have been met.].

Id. art. 3.2.

418. Regarding notification, the proposed instrument notes,

[a] simple notification procedure shall/should be introduced by the [patent] [IP] offices that receive a declaration. [It would be adequate to identify in particular the Clearing House Mechanism of the CBD/ITPGRFA as the central body to which the [IP] [patent] offices shall/should send the available information.].

Id. art. 3.3.

419. Under the Consolidated Document on Genetic Resources, “[e]ach Party shall/should make the information disclosed publically available at the time of publication.]”

Id. art. 3.4.

420. The exceptions and limitations are identified as follows:

A [IP] [patent] disclosure requirement related to genetic resources [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] shall/should not apply to the following:

- (a) [All [human genetic resources] [genetic resources taken from humans] [including human pathogens];]
- (b) [Derivatives];
- (c) [Commodities];
- (d) [Traditional knowledge in the public domain];
- (e) [Genetic resources from areas beyond national jurisdictions [and economic zones]]; and
- (f) [All genetic resources [acquired] [accessed] before [entry into force of the Convention on Biological Diversity] [before December 29th 1993].]

Id. art. 4.1.

421. The Consolidated Document on Genetic Resources provides,

However, it contemplates revisions of relevant international patent instruments to incorporate the disclosure requirement.⁴²²

The scope of remedies for failure to meet the disclosure requirement distinguishes between pre-grant and post-grant sanctions. The pre-grant sanctions include termination of further processing of the application, withdrawal of the application or denial of a patent,⁴²³ while the post-grant sanctions would include fines or other damages, and publication of judicial decisions on the failure to disclose.⁴²⁴ Depending on the circumstances, and in accordance with national law, revocation could also be applied as a post-grant sanction.⁴²⁵ It has been proposed that the failure to meet the disclosure requirement not affect the enforceability of the patent, although

[[m]ember States shall/should not impose the disclosure requirement in this instrument on [IP] [patent] applications filed before entry into force of this instrument[, subject to national laws that existed prior to this instrument].]

Id. art. 4.2.

422. As stated in the Consolidated Document on Genetic Resources,

The [PCT] and [PLT] shall/should be amended to [include] [enable Parties to the [PCT] and [PLT] to provide for in their national legislation] a mandatory disclosure requirement of the origin and source of the genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources]. The amendments shall/should also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.]

Id. art 5.1.

423. The Consolidated Document on Genetic Resources provides

[Each [Party] [country] shall/should put in place appropriate, effective and proportionate legal and administrative measures to address non-compliance with paragraph 3.1[, including dispute resolution mechanisms]. Subject to national legislation, sanctions and remedies [shall/should] [may] [include, inter alia] consist of:

(a) Pre-Grant.

(i) Preventing further processing of [IP] [patent] applications until the disclosure requirements are met.

(ii) A [IP] [patent] office considering the application withdrawn [in accordance with national law].

(iii) Preventing or refusing to grant an [IP right] [patent].

Id. art. 6.1, 6.1(a).

424. The post-grant sanctions include “(i) publication of judicial rulings regarding failure to disclose” and “(ii) [Fines or adequate compensation for damages, including payment of royalties.]” *Id.* art. 6(b)(i), (ii).

425. The instrument states that “[o]ther measures [including revocation] may be considered depending on the circumstances of the case, in accordance with national law.” *Id.* art. 6(b)(iii).

an alternative provision would limit that proposal only to cases not involving fraud.⁴²⁶

As a major opposition to the disclosure requirement, alternative language has been proposed that would severely curtail and limit the disclosure requirement only to purposes related to the patent criteria of novelty, inventive step, industrial applicability or enablement.

[IP] [patent] applicants may only be required to state where the genetic resource can be obtained if that location is necessary for a person skilled in the art to carry out the invention. Therefore no disclosure requirements can be imposed upon patent applicants or patentees for patents related to genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources], for reasons other than those related to novelty, inventive step, industrial applicability or enablement.].⁴²⁷

b. Draft Articles on Traditional Knowledge

The Draft Articles on Traditional Knowledge provide for disclosure of “information on the country from which the [inventor or the breeder] applicant collected or received the knowledge (the providing country), and the country of origin if the providing country is not the same as the country of origin of the traditional knowledge.”⁴²⁸ The applicant is also required to disclose “whether prior informed consent or approval and involvement to access and use has been obtained. . . .”⁴²⁹ If the required information is unknown to the applicant, he is nevertheless to state the immediate source from which he collected or received the traditional knowledge.⁴³⁰

An application that does not comply with the disclosure requirement will not be processed and the patent office is given the discretion to select a time for compliance failure, at which time the application would be rejected.⁴³¹ One of the proposals would prohibit revocation of patents on grounds of non-compliance with the disclosure requirement, but allow criminal sanctions including fines.⁴³² However, an alternative proposal would permit revocation and render the patent unenforceable for non-

426. Under the Consolidated Document on Genetic Resources,
[Failure to fulfill the disclosure requirement, [in the absence of fraud], shall/
should not affect the validity or enforceability of granted [IP] [patent] rights.]

Id. art. 6.2.

427. *Id.* art. 7.1.

428. Draft Articles on Traditional Knowledge, *supra* note 388, art. 4 BIS.1.

429. *Id.*

430. *Id.* art. 4 BIS.2.

431. *Id.* art. 4 BIS.3.

432. *Id.* art. 4 BIS.4.

compliance with the disclosure requirement or for providing fraudulent information.⁴³³ Finally, like the Consolidated Document on Genetic Resources, the Draft Articles on Traditional Knowledge contain language that would prohibit disclosure of information unless it was material to the patentability criteria of novelty, inventive step or enablement.⁴³⁴

3. Assessment

Some initial conclusions can be drawn from the Draft Negotiating Texts, incomplete as they are, and an attempt made to define a way forward. As described in the preceding survey, the main elements addressed in the Draft Negotiating Texts include objectives, scope of the disclosure requirement, exceptions and limitations, and remedies. The objectives of preventing acts of misappropriation and enhancing transparency and the supportiveness of the intellectual property system to the access of traditional knowledge appear to be relatively non-controversial and could be further refined to secure a cleaner text.

The provisions on exceptions and limitations also do not reveal significant differences sufficient to scuttle agreement on the draft instruments, although there could be some uneasiness in limiting the application of the instruments only to access to genetic resources made *after* the entry into force of the CBD.⁴³⁵ With respect to sanctions, the proposal to apply revocation in post-grant proceedings could turn out to be a sticking point, with some countries opposed to it altogether,⁴³⁶ while others would limit it only to cases involving fraud.⁴³⁷

From the Draft Negotiating Texts, it is clear that even the critics are agreeable to a disclosure requirement regarding traditional knowledge as

433. *Id.* Alternative art. 4 BIS.4.

434. *Id.* Alternative art. 4 BIS.

435. For a discussion on how Ghana has proposed that access to genetic resources even before the adoption of the Convention on Biological Diversity be subject to the disclosure requirement, *see* WIPO Intergovernmental Comment On Intellectual Property & Genetic Resources, Traditional Knowledge & Folklore, Feb. 3-7, 2014, 26th Sess. Report Adopted by the Committee, ¶ 120, WIPO Doc. WIPO/GRTKF/IC/26/8 (Mar. 24, 2014).

436. *See* WIPO IGC Report, Twenty-Third Session, *supra* note 391, ¶ 94 (citing Australia's opposition to revocation as a sanction); EC Proposal, *supra* note 405, ¶ 6 (discussing how the EU does not consider revocation to be an appropriate remedy for non-compliance with the disclosure requirement).

437. *See* Swiss Proposals, *supra* note 288, ¶ 27.

long as it was related to patent policy.⁴³⁸ The main area of divergence arises in connection with matters that are perceived not to be relevant to patent policy, such as access and benefit sharing regulations. As a compromise, it may be possible to work out a framework for mandatory disclosure of source or origin of genetic resources focusing specifically on patent related grounds of novelty, utility, non-obviousness, and enablement. To enhance the effectiveness of the proposed framework, the patent-related conditions should be stated in broad terms and not in restrictive language as found in some national laws.⁴³⁹ For example, the novelty standard could be described to encompass knowledge or uses of inventions outside the country without limitation to descriptions in printed publications, which proved problematic in the biopiracy case involving basmati rice from India.⁴⁴⁰ As part of the compromise, the option would be given to countries to recognize additional considerations for disclosure related to the implementation and monitoring of access and benefit sharing regulations.

To advance the objectives underlying the disclosure requirement, information collected by the patent office should be made available to the public as has been proposed in the Draft Negotiating Texts. Patent offices should be required to cooperate and exchange general information amongst themselves, and also send, receive, and respond to specific requests for information. Such cooperation will be of tremendous value during the examination of patent applications or prosecution of biopiracy cases.

While efforts can be made to find some areas of compromise as suggested in this section, whether such consensus can be developed will ultimately depend on the political will of the WIPO member countries. Overall, the biggest threat to the adoption of an instrument regarding disclosure appears to be a perceived uncompromising attitude between proponents of the requirement and their critics.⁴⁴¹ The latter may not be favorably disposed to change their minds regardless of the persuasive force or logic in arguments advanced by the proponents.

438. The alternative proposal tabled in the Consolidated Document on Genetic Resources by critics of the disclosure requirement provides that “no disclosure requirements can be imposed . . . for reasons other than those related to novelty, inventive step, industrial applicability or enablement.” Consolidated Document on Genetic Resources, *supra* note 387, art. 7.1.

439. *See, e.g.*, U.S. Patent Act, 35 U.S.C. § 102 (2015) (stating that a valid prior art references outside the US are limited to inventions described in printed publications in “a foreign country.”). Section 102 of the U.S. Patent Act, valid prior art references outside the US are limited to inventions described in printed publications in “a foreign country.”

440. *Supra* notes 64–73 and accompanying text.

441. *See generally* TWN, WIPO Patent Disclosure Negotiations, *supra* note 404.

4. *Comparisons with the 1982 WIPO Model Provisions and the 1984 WIPO Draft Treaty*

It is useful to compare the Draft Negotiating Texts to both the 1982 WIPO Model Provisions and the 1984 WIPO Draft Treaty to ascertain whether there are any gaps in, and what improvements could be made to, the Draft Negotiating Texts. An obvious area of difference is the scope of application. While the 1982 WIPO Model Provisions and the 1984 WIPO Draft Treaty apply to “expressions of folklore,”⁴⁴² the Draft Negotiating Texts cover genetic resources or related forms of traditional knowledge as distinguished from folklore.

Under the 1984 WIPO Draft Treaty, disclosure of source is required in “all printed publications, and in connection with any communications to the public, of any identifiable expression of folklore,”⁴⁴³ by mentioning in an appropriate manner, “the community and/or geographic place in which it has originated.”⁴⁴⁴ An identical disclosure requirement is provided for in the 1982 WIPO Model Provisions.⁴⁴⁵

Similar to the prior informed considerations of the access and benefit sharing rules proposed in the Draft Negotiating Texts, the 1984 WIPO Draft Treaty requires the prospective user of an expression of folklore to submit in advance to the competent authority of the Contracting State in which the expression of folklore originates, an application which “shall unequivocally specify, in written form, the expression of folklore intended to be used, its source, as well as the nature and extent of utilization.”⁴⁴⁶ This condition also applies to intended uses in other Contracting States outside the jurisdiction where the expression of folklore originated.⁴⁴⁷ While prior authorization for use of folklore is required under the 1982 WIPO Model Provisions, the authorization controls are not as specific as found in the 1984 WIPO Draft Treaty.⁴⁴⁸

442. 1984 WIPO Draft Treaty, *supra* note 244, art. 1; 1982 WIPO Model Provisions, *supra* note 243, § 2.

443. 1984 WIPO Draft Treaty, *supra* note 244, art 7(1).

444. *Id.* art. 7(2).

445. 1982 WIPO Model Provisions, *supra* note 243, at § 5(1).

446. 1984 WIPO Draft Treaty, *supra* note 244, art. 5(1).

447. *Id.* art. 4(1).

448. The 1982 WIPO Model Provisions merely require that authorization be obtained from the competent authority of the community concerned. 1982 WIPO Model Provisions, *supra* note 243, § 3; 1984 WIPO Draft Treaty, *supra* note 244, art. 4(1).

Like the Draft Negotiating Texts, both the 1982 WIPO Model Provisions and the 1984 WIPO Draft Treaty provide for exceptions and limitations, as well as criminal and civil sanctions. The 1982 WIPO Model Provisions and the 1984 WIPO Draft Treaty do not apply where folklore is to be used for educational purposes,⁴⁴⁹ to create original literary or artistic works,⁴⁵⁰ or for incidental purposes.⁴⁵¹ Significantly, the 1984 WIPO Draft Treaty makes it criminal offense punishable by appropriate sanctions, to engage in any act of: (i) willful or negligent non-compliance with the requirement to obtain authorization prior to use folklore; (ii) willful or negligent non-compliance with the requirement to acknowledge source of folklore; and (iii) willful deception of others in respect of the origin of folklore.⁴⁵² Damages and other civil remedies are available “where the utilization was made without the required authorization or payment or in any manner causing economic harm to the State or community in which the utilized expression of folklore has originated.”⁴⁵³ The comparable provisions in the 1982 WIPO Model Provisions are far more general and would criminalize willful and negligent failure to indicate the source of identifiable expression of folklore⁴⁵⁴ or obtain authorization prior to its use.⁴⁵⁵ These criminal penalties are to be applied “without prejudice to damages or other civil remedies.”⁴⁵⁶

A noteworthy provision found in the 1982 WIPO Model Provisions, but not in either the 1984 WIPO Draft Provisions or Draft Negotiating Texts, concerns the protection of expressions of folklore developed and maintained in foreign countries. Under the 1982 WIPO Model Provisions, such expressions are to be protected “subject to *reciprocity* or on the basis of international treaties or other agreements.”⁴⁵⁷ As argued elsewhere, the reciprocity principle would allow a country that may be reluctant to make

449. 1982 WIPO Model Provisions, *supra* note 243, § 4(1)(i); 1984 WIPO Draft Treaty, *supra* note 244, art. 6(1)(i).

450. 1982 WIPO Model Provisions, *supra* note 243, § 4(1)(iii); 1984 WIPO Draft Treaty, *supra* note 244, art. 6(1)(ii).

451. 1982 WIPO Model Provisions, *supra* note 243, § 4(2); 1984 WIPO Draft Treaty, *supra* note 244, art. 6(2).

452. 1984 WIPO Draft Treaty, *supra* note 244, art. 8.

453. *Id.* art. 10.

454. 1982 WIPO Model Provisions, *supra* note 243, § 6(1).

455. *Id.* § 6(2).

456. *Id.* § 8.

457. 1982 WIPO Model Provisions, *supra* note 243, § 14.

changes to its national laws, to enter into appropriate arrangements with foreign governments to protect foreign folklore found in its territory.⁴⁵⁸

From a review of the provisions of the 1984 WIPO Draft Treaty, the conclusion is inescapable that it contains all the key principles reflected in the current Draft Negotiating Texts, including disclosure, prior informed consent, and sanctions. It is quite remarkable that the 1984 WIPO Draft Treaty states those principles with perhaps greater clarity and more succinctly than found in the current Draft Negotiating Texts. A legitimate question to ask in this context, therefore, is whether it was worth all the time, resources and effort of the IGC to produce the Draft Negotiating Texts, which do not appear to be much of an improvement on the earlier instruments. In hindsight, it would have been a far more efficient process for the IGC to have begun its deliberations on a possible international instrument using as a template the 1984 WIPO Draft Treaty. As the work product of an Expert Committee created by WIPO in 1984, it certainly qualified for serious consideration by the IGC as a recommendation coming from the previous WIPO committee.

C. Fate of the Intergovernmental Committee

During its twenty-eighth session in July 2014, the IGC discussed the cross cutting elements of the Consolidated Document on Genetic Resources and the Draft Articles on Traditional Knowledge.⁴⁵⁹ It confirmed that the texts as developed during previous sessions would be transmitted to the WIPO General Assembly in September 2014,⁴⁶⁰ but the IGC was unable to agree on the language of a recommendation to submit to the WIPO General Assembly proposing specific action to be taken with respect to the documents. In lieu of a recommendation, the IGC decided that “statements made on this matter during the final discussion in the Twenty-Eighth session . . . be transmitted to the WIPO General Assembly for its consideration.”⁴⁶¹

458. Paul Kuruk, *Goading a Reluctant Dinosaur: Mutual Recognition Agreements as a Policy Response to the Misappropriation of Foreign Traditional Knowledge in the United States*, 34 PEPP. L. REV. 629, 697 (2007).

459. WIPO, *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO/GRTKF/IC/28/11 Prov. 2, ¶ 110 (2014).

460. *Id.*

461. *Id.* ¶ 112.

In the absence of a proposed draft decision from the IGC for consideration by the WIPO General Assembly, the Chairman of the WIPO General Assembly by default and on her own initiative⁴⁶² prepared and submitted a draft decision for consideration calling on the IGC to “meet in 2015 in order to make a recommendation to the 2015 General Assembly as to the mandate of the IGC for the 2016/2017 biennium.”⁴⁶³ However, after some intense deliberations, the WIPO General Assembly was not able to arrive at a consensus on the proposed draft, and no decision was taken with regards to the Chairman’s proposals.⁴⁶⁴ The practical effect of this development was that the mandate of the IGC was not renewed for 2015.

Statements made during the WIPO General Assembly debates reveal the wide gaps in the various positions held by the delegations that proved difficult to bridge. Speaking on behalf of the African Group, Kenya noted that the IGC had made very substantive progress and was ready to take the final decision to convene a diplomatic conference in accordance with the mandate of the IGC.⁴⁶⁵ Accordingly, the African Group proposed to amend the Chairman’s proposals to allow for the convening of a diplomatic conference in 2016 to adopt a legally binding instrument or instruments for the effective protection of genetic resources, traditional knowledge and traditional cultural expressions.⁴⁶⁶

In the same vein, India observed that the IGC process had made considerable and significant progress pointing to the three texts that had been developed.⁴⁶⁷ It noted that there had been a fair amount of productive engagement, and that the texts had improved substantially. India proposed that the IGC continue its text-based negotiations with a view to deciding on convening a diplomatic conference in 2016, that three thematic sessions be held in 2015, and that a stock-taking meeting follow these sessions, to allow countries and groups to voice their opinions and engage constructively on the texts and thereby arrive at a decision at the 2015 WIPO General Assembly.⁴⁶⁸

462. Report of the World Intellectual Property Organization General Assembly, 46th Sess., ¶ 152, WO/GA/46/12 (2014).

463. *Id.*

464. *Id.* ¶ 154–73.

465. *Id.* ¶ 153

466. *Id.*

467. *Id.* ¶ 159.

468. *Id.*

Brazil also praised the quality of the work done by the IGC but bemoaned what it saw as a calculated effort to derail the IGC process.⁴⁶⁹ According to Brazil, there were only a few minor issues on the subject of genetic resources that remained to be resolved so it was possible that a diplomatic conference could be convened in the near future. It attributed the success of the IGC to the tiered approach that had been adopted and that made it possible to agree on “an international legal instrument or instruments with the necessary flexibility to accommodate the different concerns expressed by delegations.”⁴⁷⁰

In contrast to the preceding optimistic views, Japan asserted that throughout the IGC process in 2014, there had been a lack of common understanding on policy objectives and guiding principles, which had led to a divergence.⁴⁷¹ According to Japan, further technical work was required to lead to a shared understanding of the key issues and that the IGC had not reached the phase where a political decision was required.⁴⁷² The US supported the statement made by Japan noting that it could “neither agree to convene a diplomatic conference, nor agree on the nature of an instrument before knowing its contents.”⁴⁷³

On its part, the European Union delegation remarked that the discussions of the IGC in 2014 had been fruitful and some limited progress had been made.⁴⁷⁴ However, a significant number of issues that were fundamentally important needed to be resolved before the next stages of the work could be considered. The European Union reiterated its understanding that any international instrument(s) to be created should be “non-binding, flexible, evidence-based and sufficiently clear.”⁴⁷⁵

On account of these divergent views, it was not possible to arrive at a consensus on a work program for the IGC. Accordingly, unless the WIPO General Assembly decides to renew the mandate of the IGC in the near future, work by the IGC on traditional knowledge, including the disclosure requirement has effectively ceased.

469. *Id.* ¶ 166.

470. *Id.*

471. *Id.* ¶ 155.

472. *Id.*

473. *Id.* ¶ 170.

474. *Id.* ¶ 158.

475. *Id.*

VI. CONCLUSION

Examination of the provisions in the most recent negotiating texts developed by WIPO reveals that they are incomplete and contain alternative and sometimes conflicting provisions that will require further refinement and alignment to be ready for adoption as binding instruments. For those WIPO Member countries that are generally supportive of the disclosure requirement, the discrepancies may be seen as minor which could be ironed out in future sessions of the IGC.⁴⁷⁶ However for others that remain rigidly opposed to the requirement, such hopes may not be realistic, leaving the distinct possibility that consensus may not be found to submit even a significantly improved text to a diplomatic conference for consideration for eventual adoption by WIPO. Because opponents of the disclosure requirement also happen to be countries where most of the acts of biopiracy have taken place, including the US and the European Union, even if an instrument on traditional knowledge were to be adopted by WIPO, it will not be effective in tackling the problem to the extent those countries or regions refuse to ratify it.

That it has taken more than 14 years to cover so little ground at the IGC suggests the lack of interest by the traditional knowledge user countries and may even be evidence of their efforts to stall the process and drag it out interminably.⁴⁷⁷ In this context, it is quite disconcerting that the WIPO General Assembly could not agree to extend the mandate of the IGC whose activities have now practically ground to a halt. If it proves impossible to renew the IGC's mandate to continue its work, there will be an urgent need for like-minded traditional knowledge provider countries in collaboration with interested traditional knowledge user countries to respond to the void by working to develop solutions under bilateral, regional or other multilateral arrangements for the protection of traditional knowledge.

Under those circumstances, advocates for an enhanced protective regime would need to consider the development of a new instrument perhaps using the 1984 WIPO Draft Treaty as a template to be adapted to cover the unique aspects of traditional knowledge and genetic resources.

476. *See id.* ¶ 166.

477. The U.S. may not be quite enthused about the development by WIPO of an international instrument on traditional knowledge. As one commentator has noted, American support for WIPO's program on traditional knowledge was provided after assurances from WIPO that it was "not 'on a norm setting track'; that is to say, that its work is not intended to feed into a process which would end with the creation of a treaty or recommendations." Michael Halewood, *Indigenous and Local Knowledge in International Law: A Preface to Sui Generis Intellectual Property Protection*, 44 MCGILL L.J. 953, 986 (1999).

For example, *utilization* of folklore as a trigger for the disclosure of the source or origin in the 1984 WIPO Draft Treaty could be extended in the new instrument by defining utilization to include the acquisition of intellectual property in traditional knowledge and genetic resources in or outside the provider country and mandating disclosure as part of the intellectual property rights acquisition process where the rights are based on or derived from the traditional knowledge or genetic resources. The applicant should be required to verify whether any portion of its claims are based on or derived from traditional knowledge or genetic resources, perhaps by simply checking a box in the application. Access and benefit sharing considerations could be dealt with in a similar manner by also requiring applicants to verify whether they have complied with the relevant prior informed consent and benefit sharing rules.

To assuage the concerns of intellectual property rights purists, it should be clarified that the proposed instrument would not require amendments to substantive intellectual property laws. Instead, for purposes of implementing the instrument, appropriate administrative guidelines would be issued to patent examining authorities. While access and benefit sharing policies will continue to be relevant under the proposed framework, they are not likely to spark the same level of outrage as when stated specifically as *conditions* for patent rights.

Although the proposed framework maybe somewhat weakened by not calling for revisions of substantive patent laws to incorporate the disclosure requirement, it would still be useful and have practically the same effect as the proposed revisions of patent laws by establishing a legal basis suggesting at a minimum that the disclosure considerations could not be ignored altogether. The verification system recommended here would be sufficient to prompt investigation by examining authorities regarding uses of traditional knowledge and genetic resources to inform the patent examination process, or by right holders to enable them seek compensation and/or challenge the patent application, as the case may be. It is submitted that such a compromise position may be acceptable to a greater number of countries and increase the chances of agreeing on the text of an international instrument addressing the essential objectives of the disclosure requirement.

Negotiations on the development of such a text could be carried under the auspices of WIPO if there is a consensus to that effect, or outside the WIPO framework led by interested countries or regions. The treaty resulting from this process by the like-minded countries would be opened for later ratification by others who may come to perceive benefits in so doing after

the treaty has been in force for some time. Even for countries that refuse to ratify it, the principles of protection outlined in the new treaty could inform and be the subject of bilateral agreements they may choose to enter into with the traditional knowledge provider countries and which may include commitments to protect traditional knowledge under notions of reciprocity.⁴⁷⁸

478. See, e.g., Kuruk, *Goadng a Reluctant Dinosaur*, *supra* note 458, at 695–711.