

Patents and Biopiracy:

The Search for Appropriate Policy and Legal Responses

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OVER THE LAST TWO DECADES, biomaterials have become increasingly important as inputs in industrial production. Pharmaceutical, biotechnological, and agricultural industries undertake research and development to create new technologies based on natural genetic material. Bioprospecting—the process of looking for potentially valuable genetic material and biochemical compounds in nature—has been the basis of pharmaceutical research and development for centuries and has led to the discovery of a number of important drugs.¹ The intellectual property rights regime facilitates this process of innovation by granting temporary exclusive rights to the innovator, thereby securing the results of research and development and guaranteeing profits from such investments. In 1997, a full 25 percent of the \$300 billion in pharmaceutical sales nationwide consisted of drugs produced through genetic-resources based research and development.²

During the same period, however, there have been recurrent incidents of unauthorized access to and misappropriation of genetic resources and traditional knowledge of biodiversity. This is what is known in the literature as “biopiracy.”³ One of the main driving forces in the negotiation of the Convention on Biological Diversity (CBD) was the quest of developing countries to ensure that they would benefit from the exploitation of their genetic resources was. The existing intellectual property rights regime has been viewed as supporting the continued exploitation of developing countries’ genetic resources without ensuring that benefits from

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research and development flow back to those countries.

A number of high profile biopiracy cases have reinforced this perception.⁴ In these cases, bio-prospectors from developed countries accessed genetic resources or related traditional knowledge from developing countries and used the existing intellectual property rights regime—patents in particular—to protect their interests without sharing any benefits with the countries of origin or with the indigenous communities that provided the traditional knowledge. The need has arisen for appropriate policy and legal responses that facilitate continued access to genetic resources, but that also provide protection against unauthorized access and misappropriation and promote benefit sharing. The recent revocation of the *Neem* patent by the European Patent Office underlines the urgency of such policy responses.⁵ This paper examines the intersections between the existing intellectual property rights regime, genetic resources and related traditional knowledge, and emerging policy responses at national, regional, and international levels.

GENETIC RESOURCES, TRADITIONAL KNOWLEDGE, AND INTELLECTUAL PROPERTY RIGHTS: THE CONVENTION ON BIOLOGICAL DIVERSITY

For decades, genetic resources were regarded as the common heritage of humankind—freely accessible without authorization from the country in which they were found and without any obligation to share benefits from their exploitation.⁶ Developing countries intended the Convention on Biological Diversity to redefine the conditions under which the benefits arising from the use of genetic resources would be shared with the countries of their origin. A key objective of the Convention, therefore, focuses on “the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.”⁷

The Convention also underlines the sovereign rights of states over their natural resources and the exclusive authority of national governments to determine access to genetic resources.⁸ Article 15 provides that access to these resources be subject to prior informed consent from the contracting party. Still, it requires that parties facilitate access to genetic resources and do not impose restrictions contrary to the objectives of the Convention. Contracting parties are required to take legislative, administrative, or policy measures to insure the fair and equitable sharing of the results of research and development and the benefits arising from the utilization, commercial or otherwise, of genetic resources.⁹

The Convention’s preamble acknowledges the traditional dependence of many local and indigenous communities on biological resources for traditional lifestyles. It also recognizes the desirability of sharing benefits that arise from the use of

traditional biodiversity-related knowledge, innovations, and practices. The Convention further elaborates the protection, preservation, and maintenance of traditional biodiversity-related knowledge in Article 8(j).

Of course, the access and benefit sharing provisions of the Convention are part of a broader regime. The Convention is the first international instrument to take a holistic view of the conservation of biological diversity by integrating ecological, social, and economic perspectives. Indeed, the core bargain between the North and the South in the negotiation of the Convention is the South's commitment to conserve biological diversity and the North's to share in the costs and benefits of sustainable use.

Sharing benefits with the countries that provide genetic resources offers an incentive for biodiversity conservation. It ensures the long-term interest of these countries in conservation and sustainable use programs, to the mutual benefit of both providers and users of genetic resources. Sharing benefits facilitates conservation efforts because it makes available badly needed financial and technical

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resources for conservation projects. Similarly, sharing benefits with indigenous and local communities guarantees effective participation and involvement of crucial actors at the local level in conservation and sustainable use activities.

More significantly, for those pursuing research and development, continued access to genetic resources and traditional knowledge is critically linked to effective benefit sharing arrangements. It is therefore in the interest of provider countries, user countries, and relevant stakeholders that measures are put in place at national and international levels to promote transparent, fair, and equitable access and benefit sharing arrangements.

INTELLECTUAL PROPERTY RIGHTS

The negotiators of the Convention were well aware of the potential negative impact of intellectual property rights. In Article 16 (5) the contracting parties, "recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention," cooperated to ensure that such rights support the objectives of the Convention. The 1980 decision of the U.S. Supreme Court in *Diamond v. Chakrabarty*¹⁰ concerning the patenting of life forms had created serious misgivings in developing countries about the utility of intellectual property rights in safeguarding their interests and those of their local and indig-

enous communities. This case, along with the subsequent provision in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which allowed member states to grant patents for biological material and processes, brought to light the interplay between intellectual property rights and the access to genetic resources, and the traditional knowledge and benefit sharing provisions of the Convention.

Patent law is concerned with the provision of limited protection for inventions that are useful (capable of industrial application), new, and involve an inventive step. The protection conferred, like all intellectual property rights, involves granting temporary exclusive rights to prevent others from making and exploiting the subject matter of the invention.¹¹ The World Intellectual Property Organization-administered (WIPO) treaties and the World Trade Organization's (WTO) TRIPS Agreement established the international intellectual property rights regime that addresses patent issues.

The most central WIPO treaties are the Paris Convention on the Protection of Industrial Property of 1883,¹² the Patent Cooperation Treaty (PCT) of 1970, and the Patent Law Treaty (PLT) of 2000.¹³ While the international treaties set general legal standards that apply to patent laws, actual patent rights are defined, granted,

192 The existing international IPR regime does not require the disclosure...of either the country of origin of genetic resources or of the relevant traditional knowledge used in research and development.

exercised, and regulated under national (and some regional) laws.¹⁴ The Paris Convention establishes certain core principles that apply to national patent laws. The PLT sets standards for formalities and procedure with respect to national/regional patent

applications filed with national/regional offices, and to international applications under the PCT. The PCT is an international instrument that allows innovators to submit a single international patent application rather than processing applications in the national offices of many countries.

The Uruguay Round of trade negotiations (1986–1994) brought intellectual property rights into the GATT-WTO framework through the TRIPS Agreement. The scope of protection of intellectual property rights (IPRs) has varied widely between countries. The growth in international trade led to increasing pressure, especially from developed countries with strong high-technology sectors, for harmonization and strengthening of IPR systems. The TRIPS Agreement was an attempt to narrow the differences in protection and bring such rights under common international rules.

The conventional IPR framework is based on the protection of formal and private knowledge in sharp contrast to the informal, collective, and intergenerational nature of traditional knowledge. In this regard, the framework is considered to be at odds with the traditional value systems and, consequently, inappropriate for supporting traditional biodiversity-related knowledge.¹⁵

Indeed, Article 27(1) of the TRIPS Agreement limits patents to inventions that are “new, involve an inventive step, and are capable of industrial application.” Indigenous and local communities cannot, therefore, secure patent protection for their knowledge of the natural attributes of biological resources since such knowledge does not constitute an invention in terms of the TRIPS Agreement. Yet, in many cases such knowledge has constituted an important input to biotechnological innovation by modern industry.

Continued incidents of unauthorized access to and misappropriation of traditional biodiversity-related knowledge has underlined the urgent need to evolve some form of “defensive protection”—that is, preventing others from asserting or acquiring rights over traditional knowledge rather than the alternative approach of facilitating the establishment of specific rights for indigenous and local communities.¹⁶ Two types of defensive protection have been suggested: a certificate of source of traditional knowledge, including evidence of the prior informed consent of the holders of the knowledge, and the recognition of traditional knowledge as “prior art” accompanied with improved prior art—searching mechanisms.¹⁷

The conventional IPR regime is concerned with ensuring adequate protection and enforcement of intellectual property rights: issues of equity are not a central consideration. Indeed, the existing international IPR regime does not require the disclosure, in applications for intellectual property rights, of either the country of origin of genetic resources or of the relevant traditional knowledge used in research and development. On the other hand, the Convention on Biological Diversity is concerned with equitable sharing of benefits from genetic resources and traditional knowledge.

The inclusion of biological material in the TRIPS Agreement, either through patent or other forms of IPR protection, raises fundamental issues for the Convention on Biological Diversity. The provisions of Article 27 (3) (b) of the TRIPS Agreement are largely permissive, vesting member states with the discretion of deciding whether or not to grant patents for biological materials and processes. Now the TRIPS Council’s ongoing review of Article 27 (3) (b) may well result in a mandatory requirement for patent protection of such processes.

There are critical ethical considerations regarding the patenting of life forms. For example, European public opinion has been against genetic engineering partly

on moral grounds. Taking into account the same moral considerations, The African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources does not recognize patents over life forms and biological processes.¹⁸

Granting patents over plants, animals, and essential biological processes also raises the issue of the privatization of biological resources. This would not only create restrictions on continued access to genetic resources, in particular by indigenous and local communities and farmers who depend on biological resources, but would also lead to a rapid depletion of such resources. Introducing IPR protection to plant genetic material, for example, is likely to constrain farmers' use of seeds and lead to dependence on commercial seed supplies. Over time, this could reduce breeding alternatives, resulting in higher genetic uniformity of crops and other commercialized plant species and increasing these plants' vulnerability to pests and diseases. In promoting genetic erosion, IPR protection can undermine the very objectives of the Convention on Biological Diversity: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits of the utilization of genetic resources.

POLICY RESPONSES AT INTERNATIONAL, REGIONAL, AND NATIONAL LEVELS

Concerns over the potential impact of intellectual property rights on the regime of the Convention on Biological Diversity have led to a number of policy reform initiatives at international, regional, and national levels. At the international level, despite a number of ongoing discussions, such initiatives have not yet crystallized into binding legal frameworks. A number of countries, however, have taken concrete policy measures at national and regional levels to ensure that intellectual property rights support the overall objectives of the Convention. These developments may well influence policy choices at the international level.

INTERNATIONAL INITIATIVES: DEVELOPMENTS WITHIN THE CBD

In order to promote and ensure effective implementation of the access and benefit sharing provisions of the Convention, the Bonn Guidelines on Access to Genetic Resources and Benefit sharing¹⁹ (ABS) were adopted in April 2002. The Guidelines were intended to bridge the gap between the broad objectives of the Convention and practical implementation at the national level by providing the elements of a transparent and predictable framework for both users and providers of genetic resources. The Guidelines were developed to assist parties in establishing adminis-

trative, legislative, or policy measures on access and benefit sharing and in negotiating contractual arrangements for access to genetic resources and benefit sharing.

The Guidelines require that contractual agreements regarding access and benefit sharing make provisions for the use of intellectual property rights including joint research, obligations to implement rights on inventions obtained, and the provision of joint licenses by common consent.²⁰ Joint ownership of intellectual property rights may be provided in Material Transfer Agreements and should be an integral part of benefit sharing arrangements.²¹ Material Transfer Agreements should also contain provisions relating to the assignment, transfer, or exclusion of the right to claim rights over the genetic resources received.

In addition, the Conference of the Parties to the Convention invited parties and governments to encourage the disclosure of the country of origin of genetic resources as well as the origin of relevant traditional knowledge in applications for intellectual property rights.²² Such disclosure would assist in tracking and monitoring compliance with prior informed consent, and the mutually agreed terms on which access to such resources and traditional knowledge was granted. This would greatly minimize incidents of misappropriation through intellectual property rights claims.

Regarding traditional biodiversity-related knowledge, the Conference of the Parties at its fourth meeting established the Ad Hoc Open-Ended Inter-sessional Working Group on Article 8(j) and Related Provisions of the Convention.²³ The mandate of the Working Group is to provide the Conference of the Parties with advice on, among other things, the application and development of legal and other appropriate forms of protection of traditional biodiversity-related knowledge, innovations, and practices. A program of work on Article 8(j) and related provisions of the Convention was adopted by the Conference of the Parties at its fifth meeting.²⁴ Among the tasks the Working Group is currently addressing is the development of *sui generis* systems for the protection of traditional knowledge, innovations, and practices.

During the final negotiations of the Bonn Guidelines, developing countries felt that although the Bonn Guidelines provided useful assistance in the development of national systems of regulation, it did not represent an effective international framework for addressing issues of misappropriation benefit sharing. Thus, following the adoption of the Guidelines, the Group of Like-Minded Megadiverse Countries²⁵ (LMMC) declared the need to go a step further toward this end. In September 2002, prompted by the LMMCs, governments at the World Summit on Sustainable Development called for action "to negotiate within the framework of the Convention on Biological Diversity ... an international regime to promote

and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.”²⁶ At its 57th session, the United Nations General Assembly endorsed this call for action and invited the Conference of the Parties to take appropriate steps toward this commitment.²⁷ In February 2004, the Conference of the Parties mandated the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing “elaborate and negotiate an international regime on access and benefit sharing with the aim of adopting instruments to effectively implement the provisions of Article 15 and Article 8(j) of the Convention and the three objectives of the Convention.”²⁸

Two elements are at the core of the negotiations: (1) the disclosure of country of origin of genetic resources and the source of relevant traditional knowledge in applications for intellectual property rights and (2) an international certificate of origin, source, or legal provenance of genetic resources. In addition to the statements of the Conference of the Parties at their sixth meeting, further analytical work has been carried out by WIPO on disclosure issues. This work has examined the possibility of including disclosure requirements in appropriate international agreements, but nothing definite has been set down.²⁹ No consensus has been reached with respect to whether the disclosure requirement should be voluntary or mandatory, or regarding the legal consequences of failure to comply with such a requirement.

The establishment of an international certificate of origin is currently being examined as a possible mechanism for ensuring compliance with the terms and conditions of access to genetic resources.³⁰ Such a certificate could accompany the genetic material along its life cycle and could be verified at various points of that cycle, including during the application for intellectual property rights. The certificate could thereby increase transparency and traceability. It would ensure legal certainty for users of genetic resources and provide assurances to providers that their resources are used in compliance with legal obligations.

DEVELOPMENTS AT THE WTO

WTO opinion on this issue is divided and little substantive progress has been made either in the TRIPS Council or the Committee on Trade and Environment.³¹ According to some developing country member states, there is an inherent conflict between the TRIPS Agreement and the CBD. Therefore, there is a need to amend the TRIPS Agreement to accommodate some essential elements of the Convention. Such an amendment could place three requirements on applicants for patents of biological materials or traditional knowledge: First, applicants must disclose the

source and country of origin of the biological resource or traditional knowledge used. Second, applicants must give evidence of prior informed consent of authorities under the relevant national regimes. Third, applicants must give evidence of fair and equitable benefit sharing.³²

A proposal submitted to the TRIPS Council meeting on 21 September 2004 by Brazil, India, Pakistan, Peru, Thailand, and Venezuela clearly underlined the expectations of developing countries on these issues.³³ The proposal suggests a legally binding obligation to disclose the source and country of origin of a biological resource or traditional knowledge.

Some members have emphasized the need to create an international instrument that would provide a *positive protection* of traditional knowledge at the national and regional levels. Another group of members has argued that, from a legal perspective, the CBD and the TRIPS Agreement were mutually supportive. Nevertheless, their implementation could create conflicts. Hence, both bodies of law needed to be implemented in a mutually supportive way in order not to undermine their respective objectives.

DEVELOPMENTS WITHIN WIPO

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established in October 2000 as a forum for debate and dialogue on issues relating to intellectual property, genetic resources and traditional knowledge, and cultural expressions. These themes were thought to cut across the conventional branches of intellectual property law and therefore did not fit into other WIPO bodies.³⁴

In response to an invitation from the Conference of the Parties to the Convention on Biological Diversity, WIPO undertook a technical study on disclosure requirements related to genetic resources and traditional knowledge.³⁵ The technical study invited WIPO to carry out additional work on this issue³⁶ at the seventh meeting of the Conference of the Parties.³⁷ While certain countries believed that the IGC was the most appropriate body to respond to such an invitation, other countries expressed the view that the protection of genetic resources and traditional knowledge against misappropriation must be addressed by patent-related legal instruments and, in particular, by introducing the neces-

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sary changes to those instruments. They claimed such a measure would ensure provision for disclosure of the country of origin or source of genetic resources, or related traditional knowledge. These countries suggested that the issue of disclosure be addressed in the context of the PCT reform and of the discussions regarding the Substantive Patent Law Treaty (SPLT).

In May 2003, at the fourth session of the Working Group on Reform of the Patent Cooperation Treaty (PCT), Switzerland submitted proposals regarding transparency measures.³⁸ These measures would enable national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications if the invention was directly based on such resources and traditional knowledge. Additional comments on these proposals were submitted to the sixth session of this Working Group with the aim of promoting a more substantive discussion on the proposals.³⁹ Divergent views were expressed in response to these proposals and the Working Group agreed to discuss the issue again at the end of November 2004.⁴⁰

In September / October 2004, at its fifteenth extraordinary session, the WIPO General Assembly decided the WIPO should accept the invitation from the Conference of the Parties. They established a timetable and method for addressing the issue, including an ad hoc intergovernmental meeting in May 2005 to submit a revised draft to the General Assembly at its ordinary session in September 2005.

REGIONAL INSTRUMENTS AND INITIATIVES

There are three regional legal instruments addressing issues at the intersection of intellectual property rights and ABS: the Andean Pact Decision 391 on the Common Regime on Access to Genetic Resources (1996), the Andean Pact Decision 486 on the Common Intellectual Property Regime (2000), and the African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (2000). There are also two regional initiatives on the issue: the Draft Central American Agreement on Access to Genetic Resources and Bio-chemicals and related Traditional Knowledge, and the Draft ASEAN Framework Agreement on Access to Biological and Genetic Resources (2000).

The instruments address a number of essential issues for ensuring transparency and accountability and safeguarding the interests of provider countries and indigenous and local communities. These include the establishment of competent national authorities to provides prior informed consent, procedures for granting prior informed consent, and the elements of mutually agreed terms including ben-

efit sharing and compliance measures.⁴¹

Each of the agreements provides for the establishment of a competent national authority to facilitate the granting of prior informed consent. With the exception of the African Model Law, each also provide for the establishment of a regional committee composed of representatives from each national competent authority and, in certain cases, other relevant stakeholders.⁴² These committees' mandates are defined in each agreement and generally include regional coordination and exchange of information.

The instruments provide a minimum list of elements to be included in Material Transfer Agreements.⁴³ Both the African Model Law and the ASEAN Agreement involve indigenous and local communities in the negotiation of access and benefit sharing agreements.⁴⁴ In all the instruments, ABS contracts are to include both monetary and non-monetary benefits, as appropriate.⁴⁵

All of these instruments, save the Draft ASEAN Agreement, address intellectual property rights. The two Andean Pact Decisions establish the most elaborate regime regarding intellectual property rights and access to genetic resources and benefit sharing. Decision 391 provides that member countries shall not acknowledge any rights over genetic resources, by-products, or synthesized products, and associated intangible components that were obtained or developed through activities outside the provisions of the Decision. Affected member countries may also request nullification and bring action against countries who grant rights or protective title documents.⁴⁶ These provisions are reinforced by the 2000 Decision 486 of the Andean Community on the Common Intellectual Property Regime.

The Draft Central American Agreement (Article 26) provides that relevant intellectual property authorities need to request the legal certificate of origin establishing the legality of access prior to the registration of products and processes which may involve the use of genetic resources and traditional knowledge. If the certificate of origin is not presented or access laws or the conditions of the access contract are not respected, the grant of intellectual property rights shall be denied. Finally, the African Model Law does not recognize patents over life forms and biological processes.⁴⁷

Regional instruments generally provide for sanctions in specific circumstances, such as unauthorized access to genetic resources and failure to respect the terms of the contract or of the legislation on access and benefit sharing. Depending on the agreement, sanctions may include the revocation of the authorization to access genetic resources,⁴⁸ the termination or nullification of a contract,⁴⁹ fines, or other sanctions. In the Draft Central America Agreement, appropriate legal mechanisms to prevent biopiracy of genetic resources, bio-chemicals, and associated traditional

knowledge are to be established by member states at the national level.⁵⁰

NATIONAL LEGISLATIVE DEVELOPMENTS

A growing number of developing countries which are party to the CBD have taken legislative measures to ensure a more transparent process of access to genetic resources, to prevent misappropriation of genetic resources and related traditional knowledge, and to guarantee fair and equitable sharing of benefits.⁵¹ Such regimes address a range of issues including the granting of prior informed consent by competent national authorities, mutually agreed terms and benefit sharing arrangements in access agreements, and intellectual property rights.

Some developed countries have put in place complementary measures to support compliance with prior informed consent from countries of origin and mutually agreed terms on which access was granted.⁵²

In every country, some type of application for access must be made to the competent national authority in order to obtain access to genetic resources. The competent national authority has the responsibility of evaluating the application for access to genetic resources. However, a majority of the measures also require the prior informed consent of the relevant authority or resource provider in the geographical area where the genetic resources are found. These resource providers are generally indigenous and local communities or other relevant stakeholders.⁵³

Some countries have adopted different requirements for access depending on the type of applicant. For example, the Indian Biological Diversity Act provides for different procedures for nationals and foreigners who wish to obtain access to genetic resources.⁵⁴ Other countries, such as Costa Rica and the Philippines, established different requirements depending on whether access is to be granted for commercial or non-commercial purposes.⁵⁵

Most national frameworks require that an access agreement set out mutually agreed terms for access and benefit sharing. Generally, access agreements must be approved by the competent national authority. However, some measures provide that the contract is to be negotiated between indigenous and local communities or any relevant stakeholder and the applicant.⁵⁶

Most of the measures require that standard clauses be incorporated in the contract.⁵⁷ Such clauses include the geographical area where the genetic resources are to be accessed, the quantity to be accessed, the purpose of the access, and the duration of the contract.

Some legislative measures appear to focus on non-monetary benefits, such as the involvement of local institutions in the research, collection, and technological

development.⁵⁸ Others focus on monetary benefits derived from the commercial utilization of the resources accessed, through the sharing of royalties. Some countries also allow for the establishment of funds in which benefits not allocated to stakeholders will be kept.⁵⁹ Finally, some measures establish conditions for the transfer of genetic resources to third parties.⁶⁰

ABS regimes address intellectual property rights to varying degrees.⁶¹ A number of measures consider intellectual property rights in the context of benefit sharing through the sharing of royalties.⁶² Besides the Andean Pact countries, only a limited number of countries include specific requirements for the disclosure of origin of genetic resources and traditional knowledge in intellectual property rights applications.⁶³ Certain countries, however, including some which have not developed specific measures related to access and benefit sharing, have addressed the issue of disclosure through their patent legislation.⁶⁴

Some countries have specific measures relating to consultations between national ABS authorities and national patent offices as well as the ex post facto review of patents and other intellectual property rights. For example, legislation in Costa Rica requires that the authority on intellectual property rights consult the competent national authority before granting intellectual property protection to innovations involving components of biodiversity to ensure that the proper requirements have been met.⁶⁵ The Indian Biodiversity Act requires that prior approval from the competent national authority be obtained before innovators apply for intellectual property rights for an invention based on a biological resource available in India.⁶⁶ Other countries, such as Peru⁶⁷ and Venezuela,⁶⁸ allow authorities to review patents and other intellectual property rights registered outside their respective countries in order to either claim their nullity or benefits arising from their utilization.

Among the Scandinavian countries, Denmark has revised—and Sweden and Norway are currently revising—their respective national patent laws in order to accommodate the disclosure imperative. Denmark incorporated a new provision in its Patent Law that requires patent applicants to provide information on the origin of the genetic resources used in the invention for which a patent is sought. In cases of non-compliance, no sanctions are provided in the patent system; however, under criminal law, sanctions are established for the provision of false information to public authorities.⁶⁹

In Norway, the objective of the 2003 legislative proposal for a new paragraph

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8(b) of the Patent Law is to support compliance with prior informed consent of the contracting party that provides the resources.⁷⁰ It requires the disclosure of the country of origin of biological material as well as evidence of prior informed consent of the country providing the material. Failure to provide information is subject to penalties in accordance with the General Civil Penal Code. Nevertheless, the duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents.

Similarly, the Indian Patents (Amendment) Ordinance (2004)⁷¹ provides that non-disclosure of source and geographical origin of biological material used in an invention and anticipation of invention by the knowledge available within any local or indigenous community in India or elsewhere would constitute grounds to oppose granting a patent.⁷²

CONCLUSIONS

The foregoing analysis underscores the intersections between intellectual property rights, genetic resources, and traditional biodiversity-related knowledge. Those intersections raise complex legal and policy issues relating to conservation, sustainability, ownership, governance, and equity. The international intellectual property rights regime will need to accommodate legitimate concerns relating to access to and utilization of genetic resources and traditional knowledge. Discussions within relevant international forums indicate an increasing appreciation by the international community of the issues at stake and the need for appropriate policy responses. Such international responses must achieve a realistic balance between facilitating access to genetic resources and traditional knowledge for purposes of research and development, promoting the conservation and sustainable use efforts of provider countries and communities, and harnessing and sharing in an equitable manner the benefits arising from commercialization. Developments at regional and national levels contain crucial lessons regarding the direction of desired change and should inform policy choices at the international level. 

NOTES

1. Kerry ten Kate and Sarah A. Laird, *The Commercial Use of Biodiversity* (London: Earthscan Publications, 1999).

2. Ibid.

3. See Vandana Shiva *Biopiracy: The Plunder of Nature & Knowledge* (Cambridge, Mass.: South End Press, 1997), 31.

4. See for example, "The Ayahuasca patent case" (CIEL, 2003); Vandana Shiva, *The Biopiracy Factsheet: Basmati Rice* (2004); *Case Study: Hoodia Cactus* (Case Western Reserve University, 2004).

5. In a landmark decision on 8 March 2005, the European Patent Office (EPO) upheld a decision to revoke in its entirety a patent on a fungicidal product derived from seeds of the Neem, a tree indigenous to the Indian subcontinent. The historic action resulted from a legal challenge mounted ten years ago by three opponents: the renowned Indian environmentalist Vandana Shiva, Magda Aelvoet, then MEP and President of the Greens in the European Parliament, and the International Federation of Organic Agriculture Movements (IFOAM). Their joint legal opposition claimed that the fungicidal properties of the Neem tree had been public knowledge in India for many centuries and that this patent exemplified how international law was being misused to transfer biological wealth from the South into the hands of a few corporations, scientists, and countries of the North. The EPO's Technical Board of Appeals dismissed an appeal by the would-be proprietors—the United States of America and the company Thermo Trilog— and maintained the decision of its Opposition Division five years ago to revoke the Neem patent in its entirety, thus bringing to a close this ten-year battle in the world's first legal challenge to a biopiracy patent: see further information at <http://www.greens-efa.org/en/press/detail.php?id=2359> (accessed on 1 April 2005).

6. See J. Mugabe, et al., eds., *Access to Genetic Resources*, (ACTS, WRI & IUCN, 1997), 7.
7. Article 1.
8. Article 15, paragraph 1.
9. Article 15, paragraph 7.
10. 447 U.S. 303; See also G. Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Aldershot, U.K., Ashgate, 2003).
11. G. Wei, "Fitting Biological Products within the Intellectual Property Framework: Challenges Facing Policy Makers" in Burton Ong, ed., *Intellectual Property and Biological Resources* (Singapore: Marshall Cavendish International, 2004) 31.
12. As revised in Stockholm on 14 July 1967.
13. Not yet in force.
14. See WIPO, *WIPO Technical Study on Patent Disclosure Requirements Related to Genetic Resources & Traditional Knowledge*, Study No. 3 (WIPO, 2004), 17.
15. For a recent critical examination of the role of IPRs, see Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights* (London, 2002).
16. A full discussion of positive and defensive protection is provided in WIPO document WIPO/GRTKF/IC/5/12, paragraphs 19-30.
17. See G. Dutfield, "Outstanding Issues in the Protection of Traditional Knowledge," Technology Policy Brief 3, no. 2 (Maastricht: UNU Institute of Technology, 2004).
18. See Article 9(1).
19. See COP decision VI/24A.
20. See paragraph 43 of the Guidelines.
21. See Appendices I and II of the Guidelines.
22. See decision VI/24C on the role of intellectual property rights in the implementation of ABS arrangements.
23. See COP decision IV/9.
24. See COP decision V/16.
25. The Group of Like Minded Megadiverse Countries includes Bolivia, Brazil, China, Colombia, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela. It was created by the Cancun Declaration of February 2002 as a mechanism to promote a common agenda relating to the conservation and sustainable use of biological diversity. The Group claims to hold nearly 70 percent of the global biological diversity.
26. Paragraph 44(o) of the WSSD Plan of Implementation.
27. See UNGA resolution 57/260 of 20 December 2002.
28. The mandate of the Working Group on ABS is set out in decision VII/19D, paragraph 1.
29. 447 U.S. 303; See also Dutfield, *Intellectual Property Rights*.
30. For further information on the certificate of origin/source/legal provenance, see document UNEP/

CBD/WG-ABS/3/5.

31. See, for example, WTO document WT/CTE/8.

32. See WTO documents IP/C/W/356 and IP/C/W/403. In the submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela, available in WTO document IP/C/W/403, dated 24 June 2003, it is stated that "Disclosure of the source and the country of origin and evidence of PIC and fair and equitable benefit sharing in a patent application would play a significant role in preventing biopiracy and misappropriation and in some cases, prevent the issue of 'bad patents' awarded without due regard to the prior use and knowledge with regard to the resource."

33. See IP/C/W/429.

34. For further details see www.wipo.int/tk/en/igc/

35. See decision VI/24 C, paragraph 4.

36. Decision VII/19E, paragraph 8.

37. See UNEP/CBD/COP/7/INF/17.

38. WIPO document PCT/R/WG/5/11.

39. These comments were submitted to the SCBD by the Government of Switzerland and are also available as WIPO document PCT/R/WG/6/11.

40. See Report of the meeting in WIPO document PCT/R/WG/6/12.

41. The text of these measures is included in the database on ABS measures available at <http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx>

42. See Article 51 of Decision 391; Article 39 of the Draft Central American Agreement; Article 8 of the Draft ASEAN Agreement.

43. See Article 11 of the Draft ASEAN Agreement; Chapter III of Decision 391; Article 17 of the Central American Agreement; Article 8, African Model Law.

44. See Article 7 of African Model Law and Article 11 of the Draft ASEAN Agreement.

45. See, for example, Articles 17 and 35 of Decision 391.

46. Second provision under "Complementary provisions."

47. Article 9(1) of the African Model Law.

48. See, for example, Article 14, African Model Law.

49. See Article 39 of Decision 391 and Article 19 of Draft Central American Agreement.

50. Article 27.

51. Legislative measures examined were from the following countries: Bolivia, Brazil, Costa Rica, Guyana, India, Malawi, Philippines, Peru, South Africa and Venezuela. The legislative texts and national submissions can be accessed at the CBD ABS Database at www.biodiv.org.

52. For example, Denmark and Norway.

53. For example, see Article 63 of Costa Rica Biodiversity Law, Malawi, Section E(8) of the Procedures and Guidelines; and Article 82 of the South Africa Biodiversity Act (2004).

54. For example, the prior informed consent of the National Biodiversity Authority is mandatory for foreigners as defined under Chapter II, Section 3(2) of the Biological Diversity Act, 2002. Different procedures are established for Indian nationals under Chapter IV of the same Act.

55. For example, see Article 71 of the Costa Rica Biodiversity Law (1998) and Sections 14 and 15 of the Philippines Republic Act (No. 9147 of 2001), Wildlife Resources Conservation & Protection Act.

56. For example, see South-Africa Biodiversity Act, Article 82 (3) (b).

57. For example, see Article 37 of the Bolivian Decreto Supremo 24676-Aprueba reglamento de la decision 391 de la Comision del acuerdo de Cartagena y el reglamento sobre biodiversidad (1997); Articles 83-84 of the South African Biodiversity Act.

58. For example, the Malawi Procedures and Guidelines, Sections H(1) and E(2) & (3) and the Venezuela Biodiversity Law, Article 74(4), address non-monetary benefits.

59. For example, India Biological Diversity Act 2002, Chapter V, section 21(3) and Chapter VII, section 27(2); South Africa Biodiversity Act, 2004, Article 85.

60. See India Biological Diversity Act, Chapter V, Article 20; Venezuela Biodiversity Law, Article 74-3; South Africa Biodiversity Act, Article 84 (VII).

61. See measures adopted by Brazil, Costa Rica, Guyana, India, Peru, Philippines and Venezuela. It

should be noted that for Andean Pact countries, intellectual property rights related to access and benefit sharing are addressed by decisions 391 and 486 of the Andean Community.

62. For example, Article 5 of the Costa Rica Regulations (Decreto No. 31 514) provides for the obligation to pay up to 50 percent of royalties.

63. The Brazilian Medida Provisoria No. 2.186-16 (2001), in Article 31, provides that "the person or institution applying for the property rights must inform the origin of the genetic material and the genetic knowledge and the associated traditional, as appropriate" and the Costa Rican Biodiversity Law, in Article 80, states that prior to awarding intellectual property protection for inventions which involve elements of biodiversity, intellectual property authorities must obtain the certificate of origin issued by the ABS competent national authority and evidence of its prior informed consent. Opposition of the competent national authority will prevent the registration of a patent or protection of the innovation.

64. For example, Denmark, Egypt, and Norway.

65. Article 80 of the Costa Rica Biodiversity Law (1998).

66. See Sections 6(1) and 19(2) of the Indian Biological Diversity Act (2002).

67. See Article 4 c) of the Peruvian Ley de proteccion al acceso a la diversidad biologica Peruana y los Conocimientos Colectivos de los Pueblos Indigenas (Law No. 28216 of 2004).

68. See Article 83 of the Venezuela Biodiversity Law.

69. See Act No. 412 of 31 May 2000 amending the Danish Patent Act (Consolidated Patent Act No. 926 of 22 September 2000) with a view to implement EU Directive 98/44/EC on biotechnological inventions.

70. Submission by the Government of Norway to the CBD.

71. Ordinance No. 7 of 2004.

72. Ibid, Article 23.

73. The views expressed in this article are the personal views and opinion of the author and do not in any way represent and/or reflect the views of the United Nations Convention on Biological Diversity

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