

THE PROTECTION OF TRADITIONAL KNOWLEDGE IN PERU: A COMPARATIVE PERSPECTIVE

MANUEL RUIZ
ISABEL LAPEÑA
SUSANNA E. CLARK*

Patents, copyrights, trademarks, plant breeder rights, trade secrets and industrial designs are a few of the best known examples of intellectual property (IP) tools created to stimulate human innovation and creativity. The international legal IP regime rewards creators for their investment and efforts, which in turn provide society with useful innovations, whether they be a mechanical invention or procedure, an artistic creation, a distinctive mark, a biotechnologically-created new plant variety, a secret formula with economic value, or a particularly useful industrial design.

This international IP regime is premised on the recognition of a human right¹ for the protection of a creator's interests and a set of international instruments that regulate IP protection.² As a "western society development," IP tools have historically been oriented towards protecting western society's modern, scientific innovations and creations.³

* Manuel Ruiz, Director of the International Affairs and Biodiversity Program of the Peruvian Environmental Law Society (Sociedad Peruana de Derecho Ambiental, SPDA); Isabel Lapeña, Lawyer for the SPDA International Affairs and Biodiversity Program (MSc. 2000, in Environmental Policy, London School of Economics and Political Science); and Susanna E. Clark, Legal Research Associate for the SPDA International Affairs and Biodiversity Program (B.A. 1998, Cornell University; J.D. 2004, Washington University School of Law).

1. Article 27(2) of the Universal Declaration of Human Rights of 1948 establishes that: Everyone "... has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." Universal Declaration of Human Rights, G.A. Res. 217A, U.N. GAOR, 3d Sess., Supp. No. 13, at 71, U.N. Doc. A/810 (1948). This provision constitutes the legal foundation for a Human Rights basis for all modern IP developments.

2. The following is a sampling of international, multilateral instruments that provide a framework for the protection of different aspects of IP: Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 2, 828 U.N.T.S. 107 (last revised July 14, 1967); Berne Convention on the Protection of Literary and Artistic Works, Sept. 9, 1886, 25 U.S.T. 1341, 828 U.N.T.S. 221 (last revised July 24, 1971); Rome Convention on the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, Oct. 26, 1961, *available at* <http://www.wipo.int/treaties/en/ip/rome/index.html> (last visited June 1, 2004); Union for the Protection of New Varieties of Plants (UPOV), Dec. 2, 1961, 815 U.N.T.S. 89; Madrid Agreement Concerning the International Registration of Marks, Apr. 14, 1891, 828 U.N.T.S. 389; Agreement on Trade Related Aspects of Intellectual Property Rights (1994) [hereinafter TRIPs]; and Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 9 I.L.M. 978.

3. Article 2 of the Convention Establishing the World Intellectual Property Organization (1967) provides that intellectual property rights include rights related to: literary, artistic and scientific works; performances of performing artists; phonograms and broadcasts; inventions in all fields of human

Anthropologists, ethnobotanists, archeologists, and sociologists have long recognized, especially in relation to biodiversity, the importance of indigenous peoples'⁴ knowledge, innovations, and practices (often referred to as traditional knowledge, or TK for short).⁵ However, only relatively recently has the importance of TK been acknowledged by other disciplines and sectors of society, and it is now considered a subject of "protection" under IP laws.⁶ It is essential to preserve the benefits of TK for all of humankind because it is culturally, socially, and economically valuable,

endeavor; scientific discoveries, industrial designs, trademarks, service marks, commercial names and designations; protection against unfair competition; and all other rights resulting from industrial, scientific, literary, or artistic fields. Convention Establishing the World Intellectual Property Organization, *opened for signature* July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3 (as amended at Stockholm Sept. 28, 1979) [hereinafter WIPO Convention].

4. Determining the specific boundaries for the category of individuals characterized as "indigenous peoples" remains an ongoing conceptual and policy process. Covenant 169 of the International Labor Organization on Indigenous and Tribal Peoples in Independent Countries defines its established boundaries in article 1.1 as:

- (a) Tribal peoples in independent countries whose social, cultural and economic conditions distinguish them from other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulations;
- (b) Peoples in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonisation or the establishment of present State boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions.

See International Labor Organization Convention, (No. 169) Concerning Indigenous and Tribal Peoples in Independent Countries, June 27, 1989, 28 I.L.M. 1382, 1384–85 [hereinafter ILO Convention].

5. The WIPO Report on Fact Finding Missions on Intellectual Property and Traditional Knowledge (1998–1999) defines TK as:

[T]radition based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. "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; and, are constantly evolving in response to a changing environment. Categories of traditional knowledge could include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge; including related medicines and remedies; biodiversity-related knowledge; "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.

Intellectual Property Needs and Expectations of Traditional Knowledge Holders, WIPO Report on Fact Finding Missions on Intellectual Property and Traditional Knowledge (1998–1999) (WIPO Publication 768E), *available at* <http://www.wipo.int/tk/en/tk/ffm/report/index.html> (last visited June 1, 2004).

6. For an analysis of the use of IP tools as a means to protect indigenous knowledge, see Howard Mann, *Intellectual Property Rights, Biodiversity and Indigenous Knowledge: A Critical Analysis in the Canadian Context*, Report Submitted to the Canadian Working Group on Articles 8(j) of the Convention on Biological Diversity (Ottawa, 1996).

and can take generations to develop.⁷ TK has been directly and indirectly utilized by the “modern world” in many forms over time. Indeed, TK used to implicitly be considered part of the global commons, freely accessible for use by any interested person or institution. Today, there is an increased awareness of the need for the legal protection of TK at the international and national level. In this context, “biopiracy” has become a widely used concept to describe the illegal, unlawful, or inequitable use of TK.⁸

This Article analyzes the policy and legal context for the protection of traditional knowledge, focusing on Peruvian Law 27811, Regime for the Protection of Indigenous Peoples’ Collective Knowledge Associated with Biodiversity (enacted on July 24, 2002) [Law 27811], as a case study.⁹ Law 27811 developed out of a process initiated in 1996, which was led by the Peruvian national IP body, the National Institute for the Defense of Competition and Intellectual Property [INDECOPI]. The Law establishes a special (or *sui generis*) regime for the legal protection of indigenous peoples’ traditional knowledge, innovations, and practices as they relate to biodiversity and its components.

7. TK should be protected in order:

to support the maintenance and integrity of indigenous peoples’ cultures; to protect the pluricultural nature of global society; to maintain the body of global knowledge necessary for the design and implementation of sustainable development strategies; to secure the human rights of indigenous and local communities over their intellectual property; to prevent illegal use and theft of traditional knowledge; to ensure equity and justice; and to support poverty alleviation and economic development.

United Nations Univ. & Inst. of Advanced Studies, *The Role of Registers and Databases in the Protection of Traditional Knowledge* (Report Jan. 2004), available at http://www.ias.unu.edu/binaries/UNUIAS_TKRegistersReport.pdf (last visited June 1, 2004) [hereinafter *UNU-IAS Report*]. WIPO defines “preservation” as safeguarding TK against loss or dissipation, and “protection” as safeguarding TK against inappropriate or unauthorized use by others. Overview of Activities and Outcomes of the Intergovernmental Committee, WIPO Doc. WIPO/GRTKF/IC/5/12, at 7 (July 7–15, 2003), available at http://www.wipo.int/documents/en/meetings/2003/igc/index_5.htm (last visited June 1, 2004). Preservation serves the dual purposes of conserving the living social and cultural context of TK, including the customary framework in which TK is passed between generations and governed within traditional communities, and recording TK in a fixed form, including documentation and registration. *Id.*

8. “Biopiracy” was made popular by Mooney and the Rural Advancement Foundation International’s (RAFI, now the ETC Group) work on patents incorporating genetic resources and TK. See Pat Mooney, *Conserving Indigenous Knowledge: Integrating Two Systems of Innovation*, Independent Report Prepared by RAFI and UNDP (1994), at <http://www.etcgroup.org> (last visited June 1, 2004). Genetic Resources Action International Network (GRAIN) has also contributed to the widespread use of the concept through numerous papers and documents. See also <http://www.grain.org> (last visited June 1, 2004).

9. Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos (Protection of Indigenous Peoples’ Collective Knowledge Associated with Biological Resources) (enacted on July 24, 2002), available at <http://www.wipo.int/tk/en/laws/index.html> (last visited June 1, 2004) [hereinafter *Law 27811*].

Our Article is divided into three broad Parts. Part I addresses the global policy, legal context, and advances made in the protection of TK in a number of countries, representing different regions of the world. Progressive steps made under the auspices of the Convention on Biological Diversity (CBD),¹⁰ World Intellectual Property Organization (WIPO), and other international forums are also discussed. We highlight key issues in the international debate and provide an overview of existing national and regional legislative and policy advances, including draft laws and legislation oriented towards the protection of TK. Part II focuses on an in-depth analysis of Peruvian Law 27811. As the first national law of its kind in the world, it serves as a comparative tool for other countries and international fora. Law 27811 covers issues such as scope of protection, prior-informed consent, benefit-sharing, representation, registers and licenses for the use of TK. Finally, Part III draws conclusions regarding the critical elements to be considered in the development of any TK protection regime.

I. GLOBAL POLICY AND LEGAL CONTEXT FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

Most of the world's biodiversity is located in developing countries. Within these countries, biodiversity is primarily located in areas and among people (indigenous and local) who are often socially and economically marginalized.¹¹ These people have a very strong link to the use and study of biodiversity, which implies that biodiversity research of all types will almost certainly be carried out with the involvement of indigenous peoples and is likely to impact their livelihoods. This situation presents many ethical, sociological, political, and, certainly, legal implications.

In this context, the United Nations Educational, Scientific and Cultural Organization (UNESCO) first attempted to discuss the importance of the policy and legal aspects of TK during the 1960s. Expressions of folklore at the national, local, and community level were considered to be in need of protection, especially because copyrights could not offer appropriate legal protection to the increasingly economically valuable expressions of

10. Convention on Biological Diversity (1992) [hereinafter CBD], available at <http://www.biodiv.org/convention/articles.asp> (last visited June 1, 2004).

11. See Michael R. Dove, *Center, Periphery and Biodiversity: A Paradox of Governance and a Development Challenge*, in VALUING LOCAL KNOWLEDGE: INDIGENOUS PEOPLE AND INTELLECTUAL PROPERTY RIGHTS (Stephen B. Brush & Doreen Stabinsky eds., 1996).

indigenous and national cultures. These included songs, writings, crafts, garments, and the arts in general. UNESCO later produced a very basic draft treaty on the subject.¹²

During the late 1970s, Mooney's seminal work highlighted the political and legal aspects of what had been mostly a sidelined issue. His work dealt with the asymmetries in access to and benefits derived from the use of genetic materials between the South (traditionally poor economically, but extremely rich in terms of biodiversity) and the North (very poor in biodiversity, but possessing major technological and economic advantages allowing it to make use of the components of biodiversity, especially as part of the nascent biotechnological industry).¹³ TK was closely related to these uses and flows of information and resources and, thus, subject to similar asymmetries. At the time, genetic resources were considered the "common heritage of humankind," the result of centuries of scientific practices.¹⁴ However, IP had already begun to extend its scope over biologically-derived inventions and biotechnological processes (refer to Chakrabarty and Rote Taube Patents).¹⁵ The tension between these two incongruous situations soon became evident.

The United Nations Food and Agriculture Organization (FAO) International Undertaking on Plant Genetic Resources (1983) became the first international forum to address fully these issues in a political

12. Folklore and its expressions are not protected by copyrights. However, according to the TRIPs Agreement and the Berne Convention, collections and new works derived from folklore may be protected as compilations. TRIPs, *supra* note 2. UNESCO and WIPO have undertaken activities for many years on the legal protection of folklore and as a result of the collaboration of these organizations, the Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions were adopted in 1982.

13. A preliminary report by Mooney calculated that, overall, the North actually owed the South billions of dollars in order to account for the pirated knowledge and resources utilized in the North's food, agricultural, biotechnological, and pharmaceutical industries. Mooney calculated the difference between the better known figures regarding pirated goods in developing countries, vis-à-vis uncompensated or unauthorized use of TK (biopirated) incorporated into a wide range of inventions in developed countries' biotechnological, pharmaceutical, and agroindustrial fields. Mooney, *supra* note 8. Though his methodology may be subject to criticism, it nonetheless offers an interesting perspective on the debate between the North and South. See RAFI, *The Conservation and Development of Indigenous Knowledge in the Context of Intellectual Property Systems*, REPORT FOR UNDP (1993).

14. Hobhouse has produced an excellent publication analyzing the impact and implications of the domestication and inter-continental movement of five plants that transformed the world at different periods of time. See HENRY HOBHOUSE, *SEEDS OF CHANGE: FIVE PLANTS THAT TRANSFORMED MANKIND* (1986). In this book, he describes the social, cultural, and economic transformations following the introduction and widespread use of quinine, sugar, tea, cotton, and the potato, all of which originated in what now are developing countries. *Id.*

15. Depalma, *Biotechnology and Patents*, 12 INDUSTRIAL PROPERTY L. REV. No. 34 (Apr., 1990).

context.¹⁶ After identifying the critically important relationship between small farmers and their efforts in the conservation and maintenance of plant genetic resources, “Farmers Rights” were formally recognized as rights

arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in the centers of origin/diversity. Those rights are vested in the international community, as trustees for present and future generations of farmers and supporting the continuation of their contributions as well as the attainment of overall purposes of the International Undertaking.¹⁷

However, it was not until the CBD was adopted at the Earth Summit in Rio de Janeiro in June 1992, and entered into force on December 29, 1993, that pressure to adopt international, regional and national processes addressing the need for legal protection of TK began to intensify. To date, there are 188 Parties to the Convention, whose principal objective is to promote “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.”¹⁸ At the core of TK-related issues in the CBD is article 8(j), which requires parties, subject to national legislation, to respect, preserve, and maintain the knowledge, innovations, and practices of indigenous and local communities, especially those that embody traditional lifestyles relevant to the conservation and sustainable use of biodiversity.¹⁹ Additionally, under article 8(j), parties must promote the wider application of these standards (with the approval and involvement of knowledge-holders) and encourage equitable sharing of the benefits arising from the utilization of such knowledge, innovation and practices.²⁰

The CBD provisions relating to the protection of TK also include: article 10(c), which calls on parties to protect and encourage the customary use of biological resources in accordance with traditional cultural

16. For a detailed analysis of the origins and evolution of the genetic resources political debate, see ROBIN PISTORIUS, *SCIENTISTS, PLANTS AND POLITICS: A HISTORY OF THE PLANT GENETIC RESOURCES MOVEMENT* (1997).

17. FAO, Resolution 5/89 on Farmers’ Rights, *available at* <ftp://ext-ftp.fao.org/ag/cgrfa/Res/C5-89E.pdf> (last visited June 1, 2004).

18. CBD, *supra* note 10, art. 1.

19. *Id.* art. 8(j).

20. *Id.*

practices;²¹ article 17.2, which lists “indigenous and traditional knowledge” as one of the elements of information that should be exchanged between Parties;²² and article 18.4, which requires Parties to encourage and develop methods of cooperation for the development and use of technologies, indigenous and traditional, pursuant to the CBD’s objectives.²³

Each of the six CBD Conferences of the Parties (COP) that have been convened to date has addressed TK. The fourth and fifth COP merit special mention for their creation of two ad hoc working groups with the task of providing advice to the COP and the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA) with regard to two issues: the implementation of CBD article 8(j), and access and benefit-sharing mechanisms.²⁴ The ad hoc Open-ended Working Group on Access and Benefit Sharing (ABS), in collaboration with the Panel of Experts on Access and Benefit Sharing (established in Decision IV/8), conducted research that led to the adoption of the Bonn Guidelines on Access to Genetic Resources and Benefit Sharing. These guidelines were finally adopted by Decision VI/24 at the Sixth COP and have been important for motivating further policy and legal debates at the national and regional levels.²⁵

The ad hoc Open-ended Inter-sessional Working Group on article 8(j) and Related Provisions was established to provide advice on the application and development of legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities that embody traditional lifestyles relevant to the conservation and sustainable use of biodiversity. It was also to develop a

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

22. *Id.* art. 17.2.

23. *Id.* art. 18.4.

24. The working groups created are the ad hoc Open-ended Working Group on Access and Benefit Sharing (ABS) (established in Decision V/26) and the ad hoc Open-ended Inter-sessional Working Group on Article 8(j) and Related Provisions (Decision IV/7). Decision V/26, Access to Genetic Resources, at <http://www.biodiv.org/decisions/default.aspx?m=cop-05> (last visited June 1, 2004); Decision IV/7, Forest Biological Diversity, at <http://www.biodiv.org/decisions/default.aspx?m=cop-04> (last visited June 1, 2004). To consult the development of the Third Meeting of the ad hoc Open-ended Inter-sessional Working Group on Article 8(j) and Related Provisions that was celebrated on December 8–12, 2003, in Montreal, Canada, see *Earth Negotiations Bulletin-IISD*, at <http://www.iisd.ca/biodiv/wg8j-3> (last visited June 1, 2004). To consult the development of the Second Meeting of the ad hoc Open-ended Working Group on Access and Benefit Sharing that was celebrated on December 1–5, 2003, in Montreal, Canada, see *Earth Negotiations Bulletin-IISD*, at <http://www.iisd.ca/biodiv/abs-wg2> (last visited June 1, 2004).

25. Decision VI/24, Access and Benefit-Sharing as Related to Genetic Resources, at <http://www.biodiv.org/decisions/default.aspx?m=cop-06> (last visited June 1, 2004).

work program and identify objectives and activities falling within the scope of the CBD (and recommend priorities, including equitable benefit-sharing). Finally, it was to provide advice on measures to strengthen international cooperation among indigenous and local communities.

Similar technical and assessment work is being realized at WIPO through the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).²⁶ The IGC was established in 2000 to promote discussion of three interrelated issues, namely: access and benefit-sharing, the protection of TK, and the protection of expressions of folklore. Apparent overlaps in subject matter addressed at the CBD forum led to a formalized system of collaboration between the CBD and the WIPO Secretariat, evidenced by a Memorandum of Understanding adopted in 2002, which outlines institutional cooperation and information exchange between the parties.²⁷

Since its founding in 2000, the IGC has held five sessions in which Member States have discussed legal, policy, economic and scientific aspects of TK, including case studies of TK protection, analysis of IP principles, *sui generis* alternatives for the protection of TK, and revision of national legislation on TK. It is within this forum that the more significant debate on TK has taken place.²⁸

A. *TK Policy and National Legislative Examples Around the World*

The last few years have witnessed considerable progress in the development of policies and legislation geared towards the protection of TK in different parts of the world.²⁹ Usually in the form of policies and draft legislation or laws, these instruments underscore the commitment by

26. For information on the services and activities of the IGC, see the program, available at <http://www.wipo.int/tk/en/igc/index.html> (last visited June 1, 2004).

27. Report, WIPO Doc. WIPO/GRTKF/IC/3/17, at 20, available at http://www.wipo.int/documents/en/meetings/2002/igc/pdf/wipo_grtkf_ic_3_17.pdf (last visited June 1, 2004).

28. To consult the IGC's documents, see Intergovernmental Committee, *Documentation Center*, at <http://www.wipo.int/tk/en/igc/documents/issues.html#1> (last visited June 1, 2004). The recently created UN Permanent Forum on Indigenous Issues is also a forerunner in the area and plays an important role in defining the issues at hand.

29. Information documents of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore sessions offer abundant references and examples of the policies and laws for the protection of TK. See Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO Doc. WIPO/GRTKF/IC/5/8 (July 7–15, 2003), at http://www.wipo.int/documents/en/meetings/2003/igc/index_5.htm (last visited June 1, 2004).

a growing number of countries and regions to offer legal protection for the intellectual efforts of indigenous peoples.³⁰

1. Protection of TK in Brazil

A provisional law in Brazil,³¹ while primarily regulating access to and use of genetic resources, also contains provisions regarding TK.³² The law expressly recognizes the link between genetic resources and TK and assigns an Inter-Ministerial Council with the task of protecting TK from illegal use and exploitation. While the law provides for protection of TK via registration, it also specifies that this protection will not affect any other pre-existing intellectual property rights.³³ Nevertheless, in order to receive an IP right in Brazil, an applicant must indicate the origin of any genetic resources and TK that may be incorporated.³⁴ However, the law does not expressly require an indication of whether the resources and TK were legally accessed as a condition for processing an IP rights application, rather only the geographical origin need be stated.³⁵

Indigenous communities, under the law, have the right to: the recognition of the origin of TK in all publications; a prohibition on the dissemination of TK-related data by non-authorized third parties; and economic compensation for any direct or indirect exploitation of TK.³⁶ Additionally, a provision that is atypical of TK-related legislation recognizes the existence of individual rights *within* communities, as opposed to granting rights to the community as a whole.³⁷

30. For a detailed analysis of national policies, drafts, and legislation on TK protection in South America, see MANUEL RUIZ, *PROTECCIÓN SUI GENERIS DE LOS CONOCIMIENTOS INDÍGENAS EN LA AMAZONÍA* (2002).

31. For an analysis of the content of the Medida Provisória, with regard to TK, see Instituto Socio Ambiental, *Quem Cala Consente? Subsídios para a protecao aos conhecimentos tradicionais*, *Documentos ISA* 8 (Mar. 2003). See also WIPO Doc. WIPO/GRTKF/IC/5/8, *supra* note 29.

32. Medida Provisória No. 2.186-16 (2001), regulating Access to Genetic Heritage, Protection of and Access to Associated Traditional Knowledge, sharing of Benefits, and Access to and Transfer of Technology for their Conservation and Use, available at <http://www.wipo.int/tk/en/laws/index.html> (last visited June 1, 2004).

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

2. *Protection of TK in Costa Rica*

The general biodiversity law of Costa Rica (Law 7788) includes a chapter specifically regarding access to genetic resources and the protection of TK.³⁸ Prior informed consent is required for access and use of the TK of indigenous and local communities. These communities may object on cultural grounds to any activity that may be contrary to their interests related to TK. The law also recognizes “Community Sui Generis Intellectual Rights” over TK. No declaration or register is needed for the formal recognition of these rights, although traditional intellectual property rights cannot conflict with them. The exact nature and scope of the right is determined by secondary legislation and a participatory process, which establishes who may hold such a right and who may invoke the right. The law also recognizes defensive protection measures.

3. *Protection of TK in India*

The Plant Variety Protection and Farmers’ Rights Act protect farmers’ rights—including the protection of native crops, compensation for traditional farmers, and recognition of their contribution to conservation—in India.³⁹ Rather than focusing narrowly on compensation, the act grants legal protection to farmers’ varieties under new criteria that varies from those applied to traditional “modern” varieties.⁴⁰

India is also developing a Traditional Knowledge Digital Library (TKDL), intended to document and disclose TK as a means of preventing biopiracy.⁴¹ However, active documentation and disclosure of TK through databases or registers is still a contentious issue. While the TKDL may serve to prevent biopiracy by assisting patent authorities in their analysis of prior art and the novelty and inventiveness requirements, the register must be carefully structured to avoid compromising other interests of

38. Costa Rica’s timely effort to protect TK is particularly interesting because the country is home to only a small number of indigenous peoples. Small-scale rural farmers do exist, but their linkage to ancestral, indigenous, and native cultures is nearly nonexistent in comparison to the Mayas in Guatemala or the Aztecs in Mexico.

39. Plant Variety Protection and Farmers’ Rights Act (on file with author).

40. *Id.*

41. UNU-IAS Report, *supra* note 7, at 17–19. The TKDL project seeks to document in digitized format the Ayurveda medical system, based on documents that are already in the public domain. The *Traditional Knowledge Resource Classification*, which is a classification system based on the *International Patent Classification* structure and designed to assist patent examiners in their search for novelty and inventiveness in patent applications, complements this effort. This defensive system of protection has been criticized regarding its organization and facilitation of access to TK, even though it handles TK already in the public domain.

indigenous peoples. Systematizing TK and placing it in the public domain, and the resulting increased availability of TK, may cause indigenous groups to lose control over it. However, a concerted effort seeking the prior informed consent of all affected communities should help to ensure adequate protection. In contrast, the Biozulua Database in Venezuela has confronted considerable criticism from local indigenous groups for not always requiring prior informed consent.⁴²

India also offers an interesting example of how private initiatives from NGOs and grassroots organizations can foment support for the protection and recognition of local communities' innovations and efforts. In particular, the People's Biodiversity Register⁴³ and the Honey Bee Network⁴⁴ are projects aimed at documenting TK and recognizing and compensating local community innovators for their efforts. This mechanism was successfully implemented in several Indian States, including Karnataka, Kerala, and Tamil Nadu. Although not yet recognized by law, these private sector efforts have strengthened and enhanced awareness of biodiversity and TK ownership in the country.

42. Ramiro Royero, the Database's proponent and coordinator, explained the Biozulua project in a paper presented in 2001. Ramiro Royero, *An Experience in the Andean Region on Documentation of TK and Biodiversity: A Venezuelan Experience*, Paper presented at the WIPO National Seminar on IP rights, TK and genetic resources, WIPO Doc. OMPI/GRTK/QUI/01/4, (Ecuador, Nov. 2001), available at <http://www.wipo.int> (last visited June 1, 2004).

43. The People's Biodiversity Register collects, systematizes, and organizes local knowledge and information related to biodiversity, for the benefit of local communities in India. K.P. Achar, *People's Biodiversity Register at Mala Village Panchayat, Karkala, Karnataka State: Documentation of People's Knowledge and Perceptions about Biodiversity and Conservation* (Biodiversity Conservation Prioritization Project et al. eds., 1997).

44. The Honey Bee Network:

[I]s a knowledge network that pools solutions developed by people across the world in different sectors and links not just the people but also formal and informal science . . . SRISTI [Society for Research and Initiatives for Sustainable Technologies], a non-governmental organization set up a few years ago provides organizational support . . . It is a network of oddballs who experiment and do things differently. Many of them end up solving problems in a very creative and innovative manner. But the unusual thing about these innovations is that they remain localized and are sometimes unknown to other farmers in the same village. . . . Farmers have developed unique solutions for controlling pests or diseases in crops and livestock, conserving soil and water, improving farm implements. . . . Scientific papers should acknowledge those who supplied the information and knowledge upon which they are based, and research results should be shared with those who contributed their knowledge, in local languages and useful forms.

Anil Gupta, *The Honey Bee Network: Transforming the Paradigm of Benefit Sharing*, in *BIODIVERSITY AND TRADITIONAL KNOWLEDGE: EQUITABLE PARTNERSHIPS IN PRACTICE* 104-05 (Sarah Laird ed., 2002). See also <http://sristi.org>; <http://nifindia.org> (last visited June 1, 2004).

4. *Protection of TK in Nepal*

In Nepal, the Draft Policy on Access to Genetic Resources and Benefit Sharing,⁴⁵ prepared by the Ministry of Forests and Soil Conservation, includes specific mandates for the protection of TK. Plans are underway to develop a law that will recognize local communities' rights over their TK, including skills and technologies. Communities will have priority over access to benefits derived from resources belonging to the government and which may be related to particular TK. As in other countries, the first priority will be to document (possibly through databases or registers) the uses, significance, utility, technologies, and other details related to TK.

The Nepalese Genetic Resources Act⁴⁶ implements a defensive protection mechanism by documenting biodiversity and TK in official and non-official registers. These registers will be validated by the national authority and will be used in prior art patent searches.

5. *Protection of TK in Panama*

Panama recently passed a law establishing the Special Regime for Intellectual Property related to the Collective Knowledge of Indigenous Peoples and for the Protection and Defense of their Cultural Identity and Traditional Knowledge.⁴⁷ The Panamanian legal framework protects the cultural patrimony of indigenous peoples, particularly in the area of expressions of folklore (traditional dress, garments, and cultural designs). Registering the collective right will provide indigenous peoples, represented by their National Congress or Authorities, with the exclusive right to produce, the right to prevent commercialization of these products by third parties in the territory of Panama, and the right to grant licenses.⁴⁸ The national IP rights authority in Panama (DIGERPI) will assess applications and grant rights. Finally, the act provides for civil and criminal penalties for violations of the TK protection regime.

45. The Draft Policy on Access to Genetic Resources and Benefit Sharing, *available at* <http://www.iucnnepal.org> (last visited June 1, 2004).

46. The Genetic Resources Act, 2058, was passed in 2001 (on file with author).

47. Law No. 20 of June 26, 2000, and its accompanying regulations under Executive Decree No. 12 of March 20, 2001, form the Special Regime for Intellectual Property related to the Collective Knowledge of Indigenous Peoples and for the Protection and Defense of their Cultural Identity and Traditional Knowledge, *at* <http://www.wipo.int/tk/en/laws/index.html> (last visited June 1, 2004); *see also* UNU-IAS Report, *supra* note 7, at 22. For detailed information on the nature of the protection regime in Panama, *see supra* note 29.

48. An exception is made for artisans of the Province of Chiriqui who have traditionally marketed reproductions of indigenous crafts.

The TK regime in Panama has two important limitations: (1) the jurisdictional reach of the regime, which is only applicable in Panama; and (2) the commercial focus of the regime. The narrow focus may be explained by the close connection between the communities and the Panamanian tourist market—a relationship that highlights the perverse effect of markets on traditional cultures and the need to prevent cultural erosion resulting from such contacts.⁴⁹

6. *Protection of TK in the Philippines*

The Philippine example also includes a number of laws found in a variety of areas with the aim of protecting TK. The Executive Order on Access to Biological Resources establishes prior informed consent requirements for bio-prospecting activities carried out on indigenous lands or territories.⁵⁰ While the legal regime restricts access to lands occupied by indigenous groups, it does not directly protect TK, and has been strongly criticized for its impact on general research efforts.

In 1997, Republic Act 8423 was passed to promote and validate the use of traditional medicine and practices in the Philippines.⁵¹ Although clearly related to TK—a definition of traditional healers is provided—surprisingly, there is no reference to benefit-sharing or the need to protect and maintain the TK of indigenous healers.

Republic Act 8371⁵² recognizes, protects, and promotes indigenous cultural communities and peoples by creating a commission for the purpose. The Act provides that indigenous communities and peoples have a right to their traditions and customs and a right to the restitution of intellectual property taken without their consent. They are entitled to full ownership, control, and protection of their cultural and intellectual rights over genetic resources, seeds, medicinal plants, arts, and designs, etc. Access to and use of TK is permitted only with the prior informed consent of indigenous peoples. Although this Act offers a more positive form of protection (one focused on prior informed consent and the recognition of

49. See generally UNU-IAS Report, *supra* note 7, at 22–40.

50. Executive Order 247 (on Access to Biological Resources) and its accompanying regulations were issued in 1996 (on file with author).

51. Republic Act 8423 created the Institute of Traditional and Alternative Health Care (PITAHC) in 1997 (on file with author). A Traditional Alternative Health Care Development Fund was created to support the Institute's activities.

52. Republic Act 8371 (on file with author).

ownership rights), it must be implemented with more specific regulations in order to effectively realize the rights that it intends to confer.⁵³

B. TK Policy and Regional Legislative Examples

1. The OAU Model Law for the Protection of the Rights of Communities, Farmers and Breeders, and for the Regulation of Access to Genetic Resources

The African Model Law (1999) protects the rights of local communities, breeders and farmers.⁵⁴ Access to TK and biological resources is premised on obtaining prior informed consent from communities and establishing measures for benefit-sharing.⁵⁵ Community rights are collectively held and based on local tradition and customs. Farmers' rights—a key element of the Model Law—are a collection of access, compensation, and certification measures, which as a whole seek to reward traditional farmers for their conservation efforts. Various countries in Africa are in the process of incorporating the Model Law into their national legislation.⁵⁶

2. Decision 391 of the Andean Community and TK Protection

Andean Decision 391 on a Common Regime on Access to Genetic Resources (1996) regulates access to genetic resources and benefit-sharing in Bolivia, Colombia, Ecuador, Peru, and Venezuela.⁵⁷ Specifically referencing TK and its protection, the law provides indigenous communities with the right to permit access to and use of TK related to genetic resources and their derivatives.⁵⁸ This right may be realized through use of a contract to supplement the main "Access to Genetic Resources Contract" between an applicant and the State authority.⁵⁹

53. *Id.*

54. African Model Law for the Protection of the Rights of Land Communities, Farmers and Breeders, and for the Regulation and Access to Biological Resources, at <http://www.grain.org/brl/oau-model-law-en.cfm> (last visited June 1, 2004).

55. *Id.*

56. For further details on the current status of the OAU Model Law, see Johnson Ekperere, *The African Union Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources*, in *TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY* (Christophe Bellman et al. eds., 2003).

57. Andean Decision 391 on a Common Regime on Access to Genetic Resources (1996).

58. *Id.*

59. In practice, a know-how license under Peruvian Law 27811, for example, would be annexed

Decision 391 establishes that the Andean Community as a whole should develop a common regime for the protection of TK.

Although progress has been made in each of the five Member States, the development of a regional regime for the protection of TK has stalled at the Andean Community level. Decision 391 is currently undergoing a review focused specifically on its limited practical implementation, especially with regard to TK issues. These limitations are the result of a series of factors, such as high transaction costs arising from the complexity of administrative procedures, the large number of contracts to be negotiated, and the uncertain status of resources. However, with the recent enactment of the Regional Biodiversity Strategy (Decision 523) and the establishment of a Permanent Working Group for Indigenous Peoples (Decision 524) in 2003, the Andean Community has initiated policy negotiations with a view towards completing the development of a regional regime.

3. *Decision 486 of the Andean Community and Defensive Protection*

In 1996, Decision 391 became the first law in the world to establish general principles for the protection of TK. Decision 486 on the Common Industrial Regime for the Community built upon these principles and created further measures for the defense of TK.⁶⁰ As a general principle, the grant of a patent or any other IP right is conditioned upon respecting and safeguarding the biological patrimony and related TK of all Andean Community members.⁶¹ This is, in and of itself, a groundbreaking principle for a specific IP rights legal instrument. In practice, patent applications for biologically-derived inventions, produced for example in the field of biotechnology, will have to provide evidence that the genetic

to an access contract.

60. Andean Decision 486 on a Common Industrial Property Regime (entered into force Dec. 1, 2000).

61. Article 3 of Decision 486 conditions a granting of IP rights on a common understanding to respect and safeguard the interests of Andean countries related to their biological patrimony and TK. *Id.* art. 3. This principle, in practice, would imply that if specific legislation on biodiversity or genetic patrimony (i.e. legislation on access to genetic resources) were violated, such a violation could be a cause for restricting IP grants, especially in the case of patents related to biotechnological inventions. Furthermore, articles 26 and 75 determine that during patent procedures, if the national IP authority has evidence that the invention under analysis incorporates genetic material or TK from any one of the five Member States of the Andean Community, then the patent application may not be processed, or a granted patent may be annulled (if the authority verifies that TK was utilized in the invention without prior informed consent from indigenous peoples). *Id.* arts. 26, 75. For an in-depth analysis of Decision 486, see Manuel Ruiz, *The Andean Decision: A Step Forward? Synergies between the CBD and the Industrial Property Regime*, 3 BRIDGES No. 2, 4–5 (2000).

resources and TK incorporated in the invention were legally accessed in accordance with regional legislation and Decision 391.

If the patent is granted and evidence is later presented showing that resources and TK were illegally obtained, the national authority may declare the patent invalid. This remedy, however, has been questioned—as an alternative to patent invalidation, critics suggest that the patent holder could be required to share the benefits of any commercial exploitation of the patent with the country of origin and the indigenous peoples whose TK was misappropriated. Requiring disclosure of the origin of TK in patent applications assists the patent office in its prior art search. There is also a need for a requirement to provide evidence of prior informed consent for the use of the TK, regardless of whether or not it is in the public domain. Once a source of TK or genetic resources is identified in a patent application, the patent officer can contact the relevant national IP rights body, which in turn would contact the indigenous community, thus giving the source country an opportunity to compile information that should be registered as prior art.

II. LAW 27811 FOR THE PROTECTION OF COLLECTIVE KNOWLEDGE IN PERU

Peru is located in the northwestern area of South America and covers a territory of over 1,285,215 km². It includes coastal, Andean, and Amazonian regions within its borders and is regarded as a mega-diverse country due to its extremely high level of biodiversity. It is home to over forty-four ethnically and culturally diverse indigenous groups, located mostly in the Andean and Amazonian regions. Furthermore, Peru has over 4,000 known medicinal plants and over 130 native crop species. Five domesticated animal species originated in Peru, including alpaca, llamas, vicunas, cochinitilla and cuy, and it has one of the world's largest number of bird, reptile and mammal species.

Therefore, it is not surprising that calls for the development of a regime to protect TK in Peru have been well-received at all decision-making levels of government. Protecting TK has been perceived as a means of promoting equity and ensuring that indigenous communities are empowered to make the decisions that impact their TK and, ultimately, their cultural patrimony. Indeed, the protection of TK is an essential tool in the creation of viable livelihoods and the sustainable development of communities throughout the country.

A. *Policy Context That Set the Stage for Law 27811*

A series of parallel and interrelated circumstances paved the way for the advances made in Peru in the development of national legislation for the protection of TK. In 1993, discussions began in the Andean Community with regard to regional legislation intended to protect new plant varieties, and Decision 345 on a Common Regime created a UPOV-type regime for the Protection of the Rights of Breeders of New Plant Varieties (1994).⁶² Decision 345 offers legal protection for plant breeders who generate varieties that are new, stable, homogeneous and distinctive. During the negotiations, some civil society institutions and other organizations questioned the fact that Decision 345 limited its protection to plant varieties, which, while complying with the aforementioned requirements, were created through the use of “scientific methods applied to plant improvement.”⁶³

Many indigenous communities in the Andes and Amazon have long been recognized for their role in both conservation and the breeding of different and new varieties of crops. However, their breeding methods do not strictly fit under the concept of “scientific,” as understood in western society. In this context, the obvious question was whether indigenous TK was being unwisely excluded from potential protection under article 4 of Decision 345. This specific debate triggered a new wave of policy and conceptual discussions—especially in Peru and Colombia—on the need to find mechanisms to effectively protect not only native crops and traditional indigenous breeding methods, but also TK in general.

An interesting and relevant feature of Decision 345 was its role in linking the plant breeders’ regime with ongoing access to genetic resources and benefit-sharing discussions underway in the CBD forum. The reasoning was that many new plant varieties protected under Plant Breeders’ Rights (PBR) were derived from local and native crops and genetic resources. If no legal protection was in place for these “original” breeding materials, at least a legal mechanism could be designed that would regulate access to and use of these materials.⁶⁴

62. Andean Decision 345 on a Common Regime for the Protection of the Rights of Breeders of New Plant Varieties (1994), art. 4.

63. *Id.*

64. The Third Transitory Disposition of Decision 345 established that Member States of the Andean Community should adopt a common regime on access to genetic resources in accordance with CBD principles before December 1994. *Id.* at Third Transitory Disposition. This provision established a definite link between access to genetic resources regimes, PBR, and IP rights systems in general, particularly in relation to new plant varieties and biotechnological inventions. *Id.*

Negotiations for Decision 391 were underway by late 1993. Because of the essential connection between genetic resources and traditional knowledge,⁶⁵ specific recognition was given to the right of indigenous communities to decide on the use of their particular TK.⁶⁶ Under Decision 391, bio-prospecting projects that involve the use of TK are regulated through contracts as an annex to the main access contracts. As a general principle, conditions are to be negotiated between indigenous peoples and the access applicant where indigenous TK will be utilized in any phase of the research process.

Subsequently, article 63 of Legislative Decree 823 of the Industrial Property Law (1996) recognized the need for the establishment of “. . . a special regime for the protection of the knowledge of indigenous and native communities” that may include provisions for the registration of TK. Decree 823 became the first IP law to include an explicit reference to TK in its text. This provision was incorporated into the Decree by the National Institute for the Defense of Competition and Intellectual Property (INDECOPI) and set the legal foundation for developing a specific regulation to protect TK. Soon thereafter, Law 26839, entitled Law for the Conservation and Sustainable Use of Biodiversity (1997), specifically determined that the knowledge, innovations, and practices—the TK—of indigenous communities are part of their cultural patrimony and that specific mechanisms and tools should be developed to regulate their use and dissemination.

Finally, a very important milestone in the development of national TK protection legislation was the International Cooperative Biodiversity Group Program (ICBG), known as the Peru Initiative.⁶⁷ Initially started in 1993, this bio-prospecting project involved the following actors: the Natural History Museum of Peru, the Cayetano Heredia University of Peru, Washington University in St. Louis, Searle Pharmaceuticals, and the

65. For a detailed analysis of the history and background of the negotiation process of Decision 391, see JORGE CAILLAX ET AL., *EL RÉGIMEN ANDINO DE ACCESO A LOS RECURSOS GENÉTICOS: LECCIONES Y EXPERIENCIAS* (1999). See also Monica Rosell, *Access to Genetic Resources: A Critical Approach to Decision 391*, “*Common Regime on Access to Genetic Resources*,” *REV. EUROPEAN CMTY. & INT’L ENVTL. L.* (Nov. 1997).

66. Law 27811, *supra* note 9, art. 7.

67. The ICBG is a U.S.-based grant program sponsored by the National Institute of Health (NIH). ICBG grants bring together public and private corporations, conservation groups, academic and research institutions, and development agencies from a wide range of countries around the world. Its projects seek to undertake research and development on medicinal plants from different regions of the world. ICBG Projects have been sponsored in Peru, Suriname, Chile, Uruguay, Argentina, Nigeria, and Mexico. For a review of the ICBG program, see Joshua Rosenthal, *Drug Discovery, Economic Development and Conservation: The International Cooperative Biodiversity Groups*, 37 *PHARMACEUTICAL BIOLOGY* (1999).

Aguaruna indigenous communities of the Peruvian Amazon, who were represented by the National Confederation of Amazonian Nationalities (CONAP). The ICBG project sought to undertake research and development on medicinal plants of the Peruvian Amazon, while accessing traditional uses by indigenous communities in Peru. A variety of contractual relationships were established between participating institutions and organizations. Most importantly, a “know-how license”⁶⁸ agreement was established between the Aguaruna communities (represented by CONAP) and Searle Pharmaceuticals. This license set forth the conditions for the use of Aguaruna’s medicinal plants. It also established short and long-term benefit-sharing provisions, which included initial payments, milestone payments, and royalty rates. This project became the model upon which a regulatory framework was designed, and by 1996, INDECOPI had convened a group of institutions to design and develop a law for the protection of TK, resulting in Law 27811.⁶⁹

B. Overview of Key Elements in Law 27811

Law 27811 is the first law protecting TK in the world. The law utilizes existing legal tools and mechanisms—including registers, licenses, and trade secret and competition law principles—and structures and adapts them for the purpose of protecting indigenous peoples’ TK-related

68. See Brendan Tobin, *Know-how Licenses: Recognizing Indigenous Rights Over Collective Knowledge*, BULLETIN OF THE WORKING GROUP OF TRADITIONAL RESOURCE RIGHTS 17–18 (1997).

69. The multidisciplinary group convened was composed of the following groups: INDECOPI (the coordinating body), the Peruvian Environmental Law Society (Sociedad Peruana de Derecho Ambiental—SPDA), DESCO, the National Institute for Agricultural Research (INIA), the National Environmental Council (CONAM), the National Institute for Natural Resources (INRENA), and a wide range of regular invitees, including indigenous peoples’ representative organizations. Meetings and workshops were organized in which indigenous peoples’ representatives were invited to participate and provide insights and ideas for potential alternatives for TK protection. As part of the process, working groups were formed to undertake research on the legal precedent of TK protection worldwide (which was non-existent at the time), benefit-sharing mechanisms within communities, and development of educational awareness materials for indigenous peoples. Regional workshops with indigenous communities were organized in Cusco and Lima in 1998. A first draft proposal was published for comment in the Official Gazette *El Peruano* in October 1999. A second draft proposal was published for comment in *El Peruano* in 2001. Some have criticized the process by which Law 27811 was created on grounds that the participation of indigenous communities and their representatives was too limited. See Brendan Tobin, *Redefining Perspectives in the Search for Protection of Traditional Knowledge: A Case Study From Peru*, 10 REV. EUROPEAN CMTY. & INT’L ENVTL. L. Others, however, feel that, given the political circumstances of the moment and the circumstances surrounding the process itself, participation was as extensive as practically possible. Indeed, all participatory processes will have their limitations in terms of the quality and quantity of participants and although the Peruvian process may have had its limitations in this regard, considering the novelty of the subject matter as a political issue and the scarce resources available, INDECOPI did as much as possible to seek broad participation.

interests. Proponents of the law see it as a dynamic tool that will need adjustment throughout its implementation process. It is not an end in and of itself, but rather a mechanism to promote fairness and equity in the access to and use of TK. It is also designed to be a complementary alternative to traditional IP rights tools, which over time have proven ineffective in the protection of TK.

1. Objectives of Law 27811

Article 1 of Law 27811 recognizes the right and ability of indigenous peoples to determine what uses they will make of their TK (or “collective knowledge,” as specifically proposed in Law 27811—see Part II.B.2, *infra*) and to structure their dealings with third parties. This is a basic, fundamental right of all persons and is recognized in traditional IP rights doctrine.⁷⁰ At the same time, Law 27811 guarantees indigenous peoples the right to set their own priorities for the process of development, as it affects their lives, beliefs, institutions, and spiritual well-being. It also grants them the right to exercise control over their economic, social, and cultural development.⁷¹

Following this concept, article 5 of Law 27811 establishes the following as its primary objectives: (a) the protection, preservation, and development of collective knowledge; (b) the fair and equitable distribution of benefits derived from the use of collective knowledge; (c) the use of collective knowledge to benefit indigenous peoples and mankind in general; (d) the assurance that any use of collective knowledge is conditioned on receipt of the prior informed consent of indigenous peoples; (e) the promotion of indigenous capacity to share and distribute collectively generated benefits; and (f) the prevention of patents for inventions based on collective knowledge of Peruvian indigenous peoples without proper acknowledgement.⁷²

These objectives focus primarily on two key issues: first, ensuring a degree of control by communities over the use of their knowledge and receipt of benefits thereby derived; and second, preventing biopiracy through controlled use of the patent system. The issues addressed in Law

70. This right is recognized in the Peruvian Constitution of 1993, Decision 391, and other laws. It also corresponds to the provisions of the Convention Concerning Indigenous and Tribal Peoples in Independent Countries, which contemplates government responsibility for developing measures that protect the rights of indigenous peoples and guarantee respect for their integrity. See ILO Convention, *supra* note 4, art. 2.1.

71. *Id.* art. 7.1.

72. Law 27811, *supra* note 9, art. 5.

27811 reflect international concern regarding the flows and use of TK, and stress the importance of finding tools to ensure its adequate protection.⁷³ It should be noted, however, that national protection of TK is limited by jurisdictional factors. Therefore, it is essential that internationally agreed-upon rules (whether under the CBD or WIPO umbrella) are eventually used to guarantee international recognition of protection standards. In order to accomplish this, these rules must be incorporated in the development and negotiation of an international regime on TK protection.⁷⁴

2. *Scope of Law 27811*

Under Law 27811, protection is afforded to the collective knowledge⁷⁵ of indigenous peoples associated with biological resources. According to article 2, “collective knowledge” is defined as “the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity.”⁷⁶ The key feature of the regime is its focus on collectively generated traditional knowledge held by one or more indigenous groups.⁷⁷ Although the law operates without prejudice to individual rights among peoples and within communities, the resulting

73. The UNU-IAS Report identifies the potential uses of registers and databases, including to: promote documentation, preserve and maintain TK; provide a means to assist patent search procedures and identify prior art; identify communities which might be entitled to benefit sharing, and assign exclusive rights; provide the means for recording the existence of TK over which positive rights have been recognized under national or customary law; serve as the mechanism for obtaining protection of TK through *sui generis* database protection.

UNU-IAS Report, *supra* note 7, at 8.

74. Calls for an international regime for the protection of TK have been particularly intense in the WIPO's Intergovernmental Committee. See *supra* note 26. Calls were also vigorously made by the Like-Minded Group of Megadiverse Countries (composed of the world's fifteen most mega-diverse countries) at a conference in Cancun, Mexico in February 2002. See Cancun Declaration of Like-Minded Megadiverse Countries, at http://www.megadiverse.org/armado_ingles/PDF/three/three1.pdf (last visited June 1, 2004). The latest Cusco Declaration of the Group on Access to Genetic Resources, Traditional Knowledge and Intellectual Property Rights on November 29, 2002, signaled the need for the development of a special, international regime for the protection of indigenous peoples' knowledge, innovations and practices. See Declaración del Cusco, del Grupo de Países Megadiversos, Sobre Acceso a Recursos Genéticos, Conocimientos Tradicionales y Derechos de Propiedad Intelectual, at http://www.rolac.unep.mx/deramb/publicaciones/declaracion_cusco.pdf (last visited June 1, 2004).

75. This type of knowledge is most often referred to as traditional knowledge in other countries and resources, whereas Law 27811 refers to TK as “collective knowledge,” emphasizing the collective nature of the TK that is the subject of protection. We will use both of the concepts of “traditional” and “collective” knowledge interchangeably.

76. Law 27811, *supra* note 9, art. 2.

77. *Id.* art. 10.

distribution of benefits is on a community level, and Law 27811 does not protect individual rights.⁷⁸ Individual rights are upheld by traditional customs and practices.⁷⁹ Due to the collective nature of indigenous communities, indigenous peoples must exercise their rights through their representative organizations (whether federations, confederations, or associations), which are structured in harmony with traditional forms of community organization.⁸⁰ Collective knowledge forms part of the cultural heritage of indigenous peoples,⁸¹ and as such, indigenous peoples' rights over their collective knowledge are inalienable and inalienable.⁸² Law 27811 begins with Peruvian recognition of the rights and powers of indigenous peoples and communities to make decisions regarding their collective knowledge.⁸³ Under the protective regime, indigenous peoples must be represented by their chosen representative organizations, which are to be structured in harmony with traditional forms of indigenous social organization,⁸⁴ including their customs and local laws.

The UNU-IAS report elaborates on two types of *sui generis* regimes, one constitutive and the other declarative. On the one hand, Peru's Law 27811 establishes a declaratory regime setting forth indigenous peoples' rights over their TK, based on ancestral rights.⁸⁵ On the other hand, the constitutive regime of Panama grants exclusive property rights over TK.⁸⁶

78. This is incompatible with current IP concepts that focus on individual inventors or institutions. Although an individual from an indigenous group could develop, for example, a product or work of art that is protectable through traditional IP rights rules, the typical manner in which indigenous peoples organize themselves and their work (through cultural-based unions) is not covered by conventional IP tools.

79. Some authors, such as Gupta, Ruiz, and Tapia, have repeatedly highlighted the importance of individual creative and innovative efforts within communities. In the context of the Andes and Amazon, there are considerable differences in how knowledge and innovations are generated and used. In the Andean region in particular, conservation efforts are clearly undertaken by individual members of communities or families. Although the distribution of benefits tends to follow traditionally accepted notions of collectivity and reciprocity, the actual innovation process is circumscribed to specific individuals. The GEF-funded project in Peru, *In Situ Conservation of Native Crops and their Wild Relatives*, has identified small centers of diversity in the Peruvian Andes and Amazon, which have extremely high concentrations of genetically diverse native crops (and their wild relatives). The project has also identified, within these centers, specific individuals and farmers, who in the case of the Andean communities, spend considerable time and intellectual effort in maintaining, conserving, improving, enhancing, and disseminating native crops. See *In Situ Conservation of Native Crops and their Wild Relatives Project*, at <http://www.insitu.org.pe/english.htm> (last visited June 1, 2004).

80. Law 27811, *supra* note 9, art. 14. Law 27811 is also characterized by its express recognition of and deference to customary law.

81. *Id.* art. 11.

82. *Id.* art. 12.

83. *Id.* art. 1.

84. *Id.* art. 14.

85. UNU-IAS Report, *supra* note 7, at 7.

86. *Id.*

Under both regimes, TK is recognized as the cultural patrimony of indigenous peoples, which creates obligations on the part of the state and grants some protection against third party acquisition. The rights under Law 27811's regime are independent of those generated within an indigenous group, which may regulate the distribution of benefits based on traditional systems already in place.⁸⁷ Furthermore, the collective knowledge addressed in Law 27811 is limited in scope to knowledge pertaining to biological resources.⁸⁸ For the purposes of this regime, "biological resources" include genetic resources, organisms (or parts thereof), and either populations themselves or any other biotic component of ecosystems having real or potential value or use for mankind.⁸⁹

The scope of Law 27811 is further limited by its premise, which is that indigenous peoples and communities create TK. Indigenous peoples are considered by Law 27811 to be those who have original rights that pre-date the first Constitution of Peru and who maintain their own culture, territory, and self-identity.⁹⁰ This concept includes communities in voluntary isolation, as well as farmers and other indigenous communities.⁹¹ Legal protection may extend, for example, to collective knowledge regarding the uses and nutritional values of native crops, the characteristics and properties of medicinal plants or extracts, and cultivation and conservation techniques and technologies.

87. Law 27811, *supra* note 9, art. 10.

88. "Collective knowledge" is defined as accumulated and transgenerational knowledge evolved from indigenous peoples and communities, and related to biological diversity's properties, uses, and characteristics. *Id.* arts. 2–3.

89. Law 27811, *supra* note 9, art. 2. Different communities objected to the narrow scope of the second proposal of Law 27811, which was linked exclusively to the relation of TK to biological resources. Many of those communities consulted argued that the regime's scope should extend to protect their customs, sacred icons, handicrafts, ceramics, and any knowledge associated with their spirituality, which is also susceptible to commercialization by third parties. See *Working Document on the Conclusions of the Regional Consultation with Indigenous Peoples in the Ucayali Region* (May 7–9, 2001); *The Conclusions of the Regional Consultation with Shipibo Conibo Indigenous Peoples in the Loreto—Kontamana Region* (June 7–9, 2001).

90. Law 27811, *supra* note 9, art. 2.

91. *Id.* The definition also clarifies that the denomination "indigenous" includes, and can be used as a synonym for, "aboriginal," "traditional," "ethnic," "ancestral," and "native," among others. Indigenous peoples represent more than forty-one percent of the Peruvian population: eight million Quechuas, two million Aymaras, and approximately 300,000 indigenous Amazonian peoples. Alongside these statistics, one should also take into account that there are 2.5 million people with Afro-Peruvian origins. See Despacho de la Primera Dama de la Nación, *El tema indígena en debate, Aportes para la reforma constitucional* (2003). In the Peruvian Amazon alone, there are sixty different ethnic groups out of a total of 379 that live in the Amazon as a whole. See *Amazonia, Biodiversidad, Comunidad y Desarrollo*, Proyecto RLA/92/G 31, 32, 33, FIDA, GEF, PNUD, and UNOPS (1998) (text on file with author).

The concept is also narrowed by its link to a “tradition” requirement: TK must be accumulated and transgenerational. Tradition-based knowledge refers to knowledge systems that have been transmitted from generation to generation, are associated with the cultural context of a community, and are constantly evolving in response to a changing environment. Thus, Law 27811 introduces a notion of guardianship in addressing the responsibility of present generations of indigenous peoples to preserve, develop, and administer their knowledge for their own benefit and for the benefit of future generations.⁹² They are the custodians of their TK and should be wary of its distortion or culturally insensitive use. Throughout the centuries, indigenous peoples have identified uses for plants and vegetation and isolated their properties for medicinal or other purposes.⁹³ Special and novel protection regimes are necessary to protect the goals of what could at first blush appear to be widely divergent interest groups: researchers developing new pharmaceuticals, food or chemical products; and indigenous peoples seeking to preserve and develop their knowledge for future generations. These pursuits will benefit both groups. For example, researchers and their affiliates may introduce natural products to a wider consumer market, and the indigenous peoples may receive positive incentives to actively protect their culture by promoting the conservation and further improvement of their knowledge.

Present generations are not considered the owners, but rather the custodians and administrators, of the collective knowledge they possess. Therefore, they are not allowed to transfer it to a third party, but only to permit its use through licenses.⁹⁴ Additionally, as holders of TK, communities have the right to deny access or to grant and determine the level of access to their collective knowledge. This also coincides with efforts worldwide to legally protect TK. It relates to an underlying assumption within Law 27811 that TK is culturally and economically valuable, and its use without the consent or provision for appropriate compensation to indigenous peoples is wrong.⁹⁵

92. Law 27811, *supra* note 9, art. 9

93. Today, indigenous groups need more protection than ever as they face increasing pressures to associate and integrate themselves into the dominant culture. This integration contributes to the erosion of their traditional knowledge.

94. Begoña Venero, *The Peruvian Law on Protection of Collective Knowledge of Indigenous Peoples Related to Biological Resources*, in *TRADING IN KNOWLEDGE* 285–89 (Christophe Bellman et al. eds., 2003).

95. The “biopiracy” phenomenon has historically been especially acute in Peru. Going back to the movement of *Solanum* (potatoes) in the fifteenth century in Europe and the rest of the world, there are multiple documented examples of the use of TK related to Peruvian biological resources in a wide range of products. More recently, patents over Peruvian resources and related TK have been widely

One exception to the subject matter regulated by Law 27811 is collective knowledge that is in the public domain.⁹⁶ Law 27811 defines public domain as knowledge that has been made accessible to persons other than indigenous peoples by means of mass media (such as publication). The uses or characteristics of a biological resource that have become extensively known in the outside world are also in the public domain.⁹⁷ However, this exception is controversial—a significant amount of knowledge has passed into the public domain, and while indigenous peoples may have consented to its use, they may not have consented to its dissemination. In this context, Law 27811 establishes a very important precedent: if collective knowledge has passed into the public domain within the previous twenty years, a percentage of the value of the gross sales resulting from the marketing of goods developed on the basis of that knowledge shall be set aside for the Fund for the Development of Indigenous Peoples (Fund).⁹⁸ In these cases, indigenous peoples will not have the right to oppose the use of the particular TK by third parties, but they are entitled to compensation through the Fund. Another exception excludes the traditional exchange of collective knowledge among indigenous peoples from the protection regime.⁹⁹ The rationale underlying this exception, as in the case of collective knowledge that has passed into the public domain, resides in part in the difficulty of determining the origin of such knowledge.¹⁰⁰ In these cases, practical considerations and the feasibility of implementation measures to be carried out by national authorities are given priority in the protection regime.

publicized as the issue becomes more recognized. See WIPO Doc. WIPO/GRTKF/IC/5/13 (July 7–15, 2003), available at http://www.wipo.int/documents/en/meetings/2003/igc/index_5.htm (last visited June 1, 2004). The report was presented before the fifth session of the IGC at WIPO and is the result of the work of an ad hoc Committee, comprised of Peruvian authorities, indigenous peoples' and farmers' associations, and experts, in relation to patents referring to a Peruvian biological resource called *maca*. *Id.*

96. Preserving TK by entering it into the public domain not only serves the purpose of making it available to researchers and other interests, but also promotes recognition of TK's important "role as part of the collective cultural heritage of humanity." See WIPO Doc. WIPO/GRTKF/IC/5/12, at 7 (July 7–15, 2003), available at http://www.wipo.int/documents/en/meetings/2003/igc/index_5.htm (last visited June 1, 2004).

97. Law 27811, *supra* note 9, art. 13.

98. *Id.* For a description of the structure and elements of this Fund, see Law 27811, *supra* note 9, art. 37 *et seq.* A proposed South Pacific model law on TK provides even more protection by not applying the principle of the public domain in instances where TK has entered the public domain "as the result of a breach of confidence or misappropriation, or where its use would undermine the cultural integrity of indigenous peoples." UNU-IAS Report, *supra* note 7, at 7.

99. Law 27811, *supra* note 9, art. 4.

100. See Venero, *supra* note 94.

On the one hand, the requirement that TK be part of the public domain in order to be recognized as prior art in patent application review comes with the high price of eliminating the future rights of indigenous peoples over it. On the other hand, this public domain dilemma can be overcome, at least in part, by promoting the alternative use of license contracts between parties seeking access to and use of the TK of a particular indigenous community. License contracts may be structured to respect the desire of the indigenous community to keep the TK confidential.

A final note on the scope of Law 27811 for future consideration is the issue of whether the protection regime is limited to “technical” knowledge related to biological resources, or whether it also includes expressions of culture and folklore that are inherently linked to such biological resources. As we have noted, Law 27811 only refers to collective knowledge as that which addresses “properties, uses, and characteristics of . . . biological diversity.”¹⁰¹ However, this separation of TK into separate forms in order to give the various classes of TK differing levels of legal treatment and protection, albeit complying with a common understanding,¹⁰² may well come to be considered as artificial, unrealistic, and impossible. Studies show that spiritual and practical elements of TK are intertwined and difficult to compartmentalize: they are embedded in a community’s way of life and deeply interconnected with each other. These circumstances clearly call for a holistic approach.¹⁰³ Indeed, it is this holistic quality of TK that intensifies the difficulty of designing a regime of protection that responds comprehensively to such characteristics.

3. *General Principles of Law 27811*

a. *Prior Informed Consent*

Law 27811¹⁰⁴ requires that anyone interested in accessing collective knowledge for scientific, commercial, or industrial application must first

101. Law 27811, *supra* note 9, art. 2.

102. See Final Report on National Experiences with the Legal Protection of Expressions of Folklore, WIPO Doc. WIPO/GRTKF/IC/3/10 (June 13–21, 2002), available at http://www.wipo.org/documents/en/meetings/2002/igc/doc/grtkfic3_10.doc (last visited June 1, 2004); Elements of a *Sui Generis* System for the Protection of Traditional Knowledge, WIPO Doc. WIPO/GRTKF/IC/4/8 (Dec. 9–17, 2002), available at http://www.wipo.org/documents/en/meetings/2002/igc/pdf/grtkf_ic_4_8.pdf (last visited June 1, 2004).

103. *Traditional Knowledge and Intellectual Property: New Prospects and New Directions*, WIPO MAGAZINE, May–June 2003.

104. Law 27811 is independent from other intellectual property legislation in force. Law 27811, *supra* note 9, First Complementary Provision.

request the prior informed consent of the representative organizations of the indigenous peoples possessing the collective knowledge.¹⁰⁵ Prior informed consent is defined as authorization granted (within the framework of Law 27811's protection regime) for a particular activity involving collective knowledge. Authorization requires the parties to convey sufficient information as to the purposes, risks and implications of the activity in question, including any eventual uses of the collective knowledge and its value.¹⁰⁶

Once the representative organization of the indigenous peoples receives an application for its prior informed consent, it should inform as many of the indigenous peoples in possession of this knowledge as possible that such a negotiation is forthcoming.¹⁰⁷ This is particularly critical when TK is shared among communities and when culturally sensitive factors may be at stake (i.e. religious concerns). In practice, it will be virtually impossible to ensure participation of all of the implicated communities in the decision-making process. However, best efforts should be made to inform all relevant groups about upcoming negotiations.¹⁰⁸ Finally, the information relayed to outside parties will be limited to the collective knowledge related to the biological resource that forms the subject of the negotiation, thereby safeguarding potential interests of the parties in maintaining the secrecy of the negotiation's details.¹⁰⁹

b. Benefit-Sharing

As a general principle, indigenous peoples have the right to grant prior informed consent for the use of their TK, which is most effectively accomplished with a license agreement.¹¹⁰ The license should specify benefit-sharing conditions and be written and registered at INDECOPI. As part of the benefit-sharing scheme, Law 27811 establishes two minimum royalty rates. First, the license should also include an initial direct payment for the use of TK and an agreement to pay at least five percent of the net sales, before taxes, of goods developed directly or indirectly from the TK.¹¹¹ Second, a percentage not less than ten percent of the value, before taxes, of the net sales resulting from the marketing of goods with content

105. *Id.* art. 6.

106. *Id.* art. 2.

107. *Id.* art. 6.

108. *Id.*

109. *Id.*

110. *Id.* art. 7.

111. *Id.* art. 27.

based on TK is to be deposited into the Fund for the Development of Indigenous Peoples. Parties may agree on a higher percentage depending upon the degree to which the knowledge is directly used or incorporated in the final product, or the degree to which it leads to reduced research and development costs for derived products.¹¹²

4. *Protection Tools of Law 27811*

Law 27811 utilizes two key instruments for the protection of TK or collective knowledge: “know-how” licenses¹¹³ (contracts) and registers. Licenses establish the conditions under which TK may be accessed and utilized for commercial and industrial purposes, while registers assist in providing defensive protection, especially for prior art patent searches.

a. Registers of Collective Knowledge Under Law 27811

The Peruvian model is an example of a system of registers with varying degrees of confidentiality protection that conform to the flexibility required by the dynamic nature of TK. Registers under Law 27811 do not constitute or grant rights over collective knowledge. Instead, they serve a two-fold purpose of providing defensive protection against patents by sharing information with INDECOPI in order to assist in the performance of thorough patent reviews; aiding in prior art search requests; and maintaining indigenous peoples’ collective knowledge.¹¹⁴

Registers function as a defensive measure¹¹⁵ by providing for: (1) the compilation of TK to help ensure its preservation; (2) control by indigenous communities over the dissemination and recording of TK;¹¹⁶ and (3) the blocking of patent applications that do not acknowledge the use of TK. By facilitating patent offices’ access to information, these registers may prevent, at least in part, the unlawful use of traditional

112. *Id.* art. 8.

113. *See generally* Tobin, *supra* note 69.

114. Law 27811, *supra* note 9, art. 16.

115. Positive protection refers to mechanisms that uphold indigenous peoples’ rights to their TK. Negative or defensive protection refers to the use of mechanisms to impede the misappropriation of TK. Due to the ability of current patent systems to provide positive protection of TK, there is an increasing willingness to rely on defensive measures to achieve these purposes. The systematization of TK in registers can serve the function of making TK accessible to patent authorities in the examination of prior art.

116. Prior informed consent should also be required before including information that is not already in the public domain in databases or registers.

knowledge that occurs when a TK-based product is patented without the consent of indigenous peoples.¹¹⁷

There are three different types of registers designed to preserve and safeguard the rights of indigenous peoples that are related to their collective knowledge:¹¹⁸ (a) a Public National Register, (b) a Confidential National Register, and (c) Local Registers.¹¹⁹ First, the Public National Register is to be developed and organized by INDECOPI.¹²⁰ All information and data related to indigenous knowledge already in the public domain will be systematized and used to assist patent authorities worldwide in the novelty and inventiveness analyses of patent applications involving subject matter that may be directly or indirectly based on TK. INDECOPI will submit the necessary information to these authorities when it identifies situations where additional information may be needed for a comprehensive and effective prior art search. Second, the Confidential Register was proposed by indigenous communities during the development of Law 27811, with the aim of protecting TK that, for whatever reason, indigenous peoples prefer to keep confidential. In accordance with these wishes, such TK will be safeguarded by INDECOPI and will be inaccessible to third parties.¹²¹ Third, the Local Registers

117. With regard to their primary uses, a distinction should be drawn between the use of databases as a form of defensive protection to aid patent offices in completing more thorough prior art searches, and the use of registers in providing positive protection of TK. UNU-IAS Report, *supra* note 7, at 9. Specifically, a register can consist of databases, but it is set apart by its provision of legal rights over the information, putting others on notice that the information is on the record. *Id.* at 11. Furthermore, while a register must be open to the public, a database is a systematized collection of information that can be used by the public or restricted to private use. *Id.*

118. Law 27811, *supra* note 9, art. 15.

119. Protection regimes can use different levels of registers to serve a variety of purposes and degrees of defense. A first-level register includes TK currently in the public domain, in order to further publicize information and improve the efficiency of patent research processes. A second-level register could include TK that the communities wish to maintain confidential, and therefore, would be accessible only to patent offices for the purposes of reviewing applications under strict confidentiality. A third-level register could incorporate TK that the communities have agreed to maintain as strictly confidential, in order that such knowledge only be accessible to community members. Such a register would serve to: record knowledge on which the communities have not come to an agreement, while protecting TK that the communities do not want to share for religious or other reasons; and provide an infrastructure for insuring the preservation of the system of orally recording information to preserve it for future generations.

120. Law 27811, *supra* note 9, art. 17.

121. *Id.* art. 18. Each indigenous peoples' representative organization may apply to register its collective knowledge with INDECOPI for inclusion in one of the first two registers. *Id.* art. 19. An application for registration must be filed with INDECOPI and should include: the identity of the indigenous people seeking registration of its knowledge; the identity of the representative organization; the designation of the biological resource that is the subject of the collective knowledge (it is possible to use the indigenous name but a sample or photograph must be presented simultaneously to allow INDECOPI to register the resource under its scientific name); a description of

recognize local initiatives that document and maintain control over collective knowledge for the benefit of indigenous peoples themselves.¹²² Accordingly, communities may establish specific mechanisms, based on their own customs or laws, to organize these registers and protocols, thereby allowing them either to limit access to members of their own communities, or allow access by third parties.

While registers perform the important function of safeguarding TK by providing information that can be used as evidence of prior art in patent applications, the protection regime's purpose calls for more. Registers indirectly promote the rights of indigenous peoples by giving parties an incentive to perform detailed prior art searches and to obtain prior informed consent. It is therefore fundamental that defensive protection be accompanied by positive protection in the form of legal mechanisms that actively assert indigenous peoples' TK ownership rights¹²³ in current IP rights or other *sui generis* regimes.¹²⁴

*b. License Contracts for the Use of Collective Knowledge in Law
27811*

Licenses play an integral role in current national efforts to protect TK, by formalizing equitable and just conditions for the use of TK under contract law.¹²⁵ Law 27811 has established a framework of rules for

the indigenous peoples' use(s) of the biological resource; a clear and complete description of the collective knowledge in question; and an instrument containing proof that the indigenous community has consented to registration of the collective knowledge. *Id.* art. 20. INDECOPI will verify that the application is complete within ten days, and the representative organization will have a renewable period of six months to complete or abandon it. *Id.* art. 21. INDECOPI then sends the information in the Public National Register to patent offices worldwide that will be used to dispute patents for goods or processes that have been developed using unaccounted-for collective knowledge, especially at the stage of the inventiveness or novelty examinations. *Id.* art. 23.

122. *Id.* art. 24. INDECOPI will provide technical assistance if requested. *Id.* This practice is already in place in some other communities, such as in the Indian states of Karnataka, Karata, and Tamil Nadu (see Part I.A.3), where TK is documented in an effort to prevent its loss or erosion.

123. In Peru, indigenous peoples' rights over their TK stem from the State's recognition that TK is part of their cultural patrimony. Law 27811, *supra* note 9, art. 6.

124. *Id.* art. 42. Positive protection emphasizes measures, such as evidentiary requirements of an indigenous community's prior informed consent to the access or commercial use of TK in the public domain. Due to the fact that widespread development of protection regimes for TK is still in its initial phases, there is a need to provide interim measures that do not require the registration of TK in a database before some form of protection is granted. UNU-IAS Report, *supra* note 7, at 40. Disclosure of origin requirements in patent application procedures alleviates some of the pressure on indigenous communities by providing notice and allowing for targeted efforts to gather information that might not yet be registered. It also aids in meeting requirements for prior informed consent. *Id.* at 39. The promotion of prior informed consent as an element of a patent application, in turn, advances the use of benefit-sharing agreements.

125. For a thorough discussion of WIPO's extensively researched proposal for contractual

dealings between third parties interested in gaining access to TK and indigenous peoples' representatives. These rules take the form of licenses that call for benefit-sharing measures and prior informed consent.¹²⁶ Communities may enter into license agreements either individually or as a group; however, a decision not to enter into a license agreement would not limit their rights. A license agreement will neither exclude non-signatory or non-participating indigenous communities from receiving benefits that accrue to the Fund, nor will it preclude their entering into other agreements with regard to the same TK.¹²⁷

Applications for the registration of a license are processed by INDECOPI and remain confidential thereafter.¹²⁸ The registration of a license contract with INDECOPI is both mandatory and subject to numerous minimum requirements.¹²⁹ First, the license must be in writing, available in both Spanish and the relevant native language, and be renewable for at least one year and not more than three years.¹³⁰ Second, the license must identify the parties and describe the collective knowledge in question. Third, a contract must include a condition guaranteeing an equitable distribution of the benefits derived from any access granted to TK.¹³¹ Another objective is to increase contributions dedicated to building indigenous peoples' capacity to make use of their collective knowledge relating to biological resources.¹³² Fourth, the license must provide

practices related to the protection of TK, specifically on the "development of contractual practices, guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources, and different transfers within different sectors of genetic resource policy," see *Contractual Practice and Clauses Relating to Intellectual Property, Access to Genetic Resources and Benefit-sharing*, WIPO Doc. WIPO/GRTKF/IC/5/9, at 2 (July 7–15, 2003), available at http://www.wipo.org/documents/en/meetings/2003/igc/doc/grtkf_ic_5_9.doc (last visited June 1, 2004). WIPO also addresses the license requirements under Law 27811. *Id.* at 8–10. See also *Composite Study on the Protection of Traditional Knowledge*, WIPO Doc. WIPO/GRTKF/IC/5/8, at 37–39 (July 7–15, 2003), available at http://www.wipo.org/documents/en/meetings/2003/igc/doc/grtkf_ic_5_9.doc (last visited June 1, 2004).

126. Law 27811 defines a license contract for the use of collective knowledge as "an express agreement concluded between the organization of indigenous peoples possessing collective knowledge and a third party that incorporates terms and conditions for the use of said collective knowledge." Law 27811, *supra* note 9, art. 2.

127. *Id.* art. 32. The rights of future generations to continue the use and development of licensed knowledge are also protected under this article. *Id.*

128. The contract can only be consulted by third parties with the express permission of both parties. *Id.* art. 28. They must include a copy of the written agreement signed by the indigenous peoples' representative. *Id.* Noncompliance results in the denial or nullification of the application or patent. *Id.* at Second Complementary Provision.

129. *Id.* art. 25.

130. *Id.* art. 26.

131. *Id.* art. 7. For details on the benefit-sharing provisions, see Part II.3.b.

132. *Id.* art. 27.

adequate information regarding the purposes, risks, and implications of the agreed-upon activity, as well as the eventual uses of the collective knowledge and an estimation of its value. Finally, the license must include an obligation to periodically inform the licensor in general terms regarding the progress of the research, industrialization, and marketing of the goods developed. In addition, INDECOPI is also charged with the protection of environmental concerns and will investigate, and refuse if necessary, license contracts that create a risk of negatively affecting the environmental status quo of areas inhabited by indigenous peoples.

5. *Protection and Capacity Building Institutions Under Law 27811*

a. *Fund for the Development of Indigenous Peoples*

The Fund for the Development of Indigenous Peoples under Law 27811 is intended to contribute to improving the living conditions of indigenous communities in general—not just the communities that are parties to the agreement—by financing development projects. These projects should be planned by the communities according to their needs and presented to an administrative committee¹³³ by their representative organizations.¹³⁴ The Fund will be sustained by a number of sources, including: (1) the benefits accrued in the marketing of products developed using collective knowledge;¹³⁵ (2) the State budget; (3) international technical cooperation and donations; and (4) the monetary sanctions imposed by Law 27811's regime.¹³⁶

133. The administration committee will be responsible for evaluating and approving development projects and for determining the final allocation of resources. In order to guarantee the independence of the adjudication process, the Fund has technical, administrative, and financial autonomy. Furthermore, the administrative committee is subject to surveillance by the Indigenous Knowledge Protection Council. *Id.* arts. 37, 66.

134. There is no requirement that sustainable development or biodiversity conservation measures form part of a proposal in order to qualify for receipt of the Fund's resources.

135. With regard to the first source of income, the Law states that not less than ten percent of the value, before taxes, of the gross sales resulting from the marketing of products developed from collective knowledge will be added to the Fund. *Id.* art. 8. It also provides that in the case of collective knowledge that has passed into the public domain during the past twenty years, an unspecified percentage of the value, before taxes, of the gross sales resulting from marketing of the products developed from the TK, will be deposited in the Fund. *Id.* art. 13.

136. *Id.* art. 41.

b. Indigenous Knowledge Protection Council

Law 27811 creates this special body, which has a general mandate to protect TK and oversee the protection regime. Its functions include: (a) monitoring and overseeing implementation of the protection regime; (b) supporting the administrative committee of the Fund and INDECOPI's department of "inventions and new technologies"; (c) providing an opinion on the validity of license contracts incorporating terms for the use and protection of TK; (d) advising representatives of indigenous peoples, at their request, on matters related to this regime and, in particular, on the formulation and execution of projects within the framework of this regime; and (e) supervising the administrative committee of the Fund in the performance of its functions.¹³⁷

The Indigenous Knowledge Protection Council is configured as an independent and superior body in order to maximize the regime's effectiveness. It will be composed of five experts, *ad honorem*, three of which will be designated by representative organizations of indigenous peoples, while the National Commission will designate two for the Andean, Amazonian, and Afro-Peruvian Peoples.¹³⁸ The Council's powers include the right to demand administrative information, order inspections and audits, name a representative to participate on the administrative committee, and apply sanctions to members for wrongdoing.¹³⁹

6. Protection Inferred Under Law 27811

Law 27811's protection regime centers on the recognition of rights associated with TK,¹⁴⁰ which are largely based on restraining others from using the protected knowledge without authorization. Along these lines, article 42 establishes that: "Indigenous peoples possessing collective knowledge shall be protected against the disclosure, acquisition or use of

137. *Id.* art. 66.

138. *Id.* art. 65. The National Commission for the Andean, Amazonian and Afro-Peruvian Peoples was created in 2001 as an authority, dependent on the Government, in charge of farmers and indigenous communities' affairs. See Comisión Nacional de los Pueblos Andinos, Amazónicos y Afroperuanos, at <http://www.conapa.gob.pe> (last visited June 1, 2004).

139. As a potential future improvement, the independence of these bodies could be increased by not having the same groups name their members. As it stands, representative organizations and the National Commission for the Andean, Amazonian, and Afro-Peruvian Peoples are both given competency for determining the composition of the Administration Committee and the Indigenous Knowledge Protection Council.

140. To better evaluate the relation between intellectual property rights and the rights of traditional knowledge holders, see GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY (2000).

that collective knowledge without their consent and in an improper manner provided that the collective knowledge is not in the public domain.”¹⁴¹ The prohibition against use of TK “in an improper manner” implies a prohibition on any unauthorized disclosure of TK.¹⁴² The regime provides a form of trade secret¹⁴³ protection for knowledge that is confidential or still within the control and ambit of indigenous peoples (and not in the public domain). This trade secret protection is reciprocal, and applies to the content, ideas, and information passed on by indigenous communities (i.e. the traditional use of a medicinal plant).¹⁴⁴ Furthermore, article 43 protects indigenous peoples from unauthorized disclosure by a third party who may have legitimately accessed the knowledge, but has attempted to disclose the information while bound by a confidentiality agreement.¹⁴⁵ As previously mentioned, a party to an agreement may be tempted to share information gathered under the agreement. This type of information exchange, when not clearly included in the terms of the original agreement, should only occur under a new agreement. The information may have cultural, spiritual, or commercial value, the preservation of which calls for secrecy and, thus, the information should not be readily available to third persons that could compete with the parties.

141. Law 27811, *supra* note 9, art. 42.

142. Unfair competition is being regulated in Peru under the “Texto Unico Ordenado del Decreto Ley 26122, Ley sobre Represión de la Competencia Desleal” (unfair competition law) *published in* the Official Gazette *El Peruano*, Dec. 30, 1992. This could limit the effectiveness of the protection system because the Law itself does not define what should be understood as “improper.” Rather, it seems to leave this determination to national authorities and thereby mistakenly places the elucidation of the right’s content on the interpretation of administrative authorities outside of a legal framework.

143. Trade secrets are discussed in the TRIPs Agreement under article 39, which states that:

Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information: (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex-1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81, art. 39, ¶ 2 (1994).

144. Third parties cannot consult the National Confidential Register on Collective Knowledge. Law 27811, *supra* note 9, art. 18.

145. It refers, therefore, to cases in which third parties are not allowed to disclose the information provided by communities to other parties, and in the case that information was provided by communities (i.e. recorded or documented) without their full understanding of its implications. *Id.* art. 43.

Several measures designed to protect confidentiality are contemplated in Law 27811. First, the representative organization whose prior informed consent has been requested is to inform other responsible organizations that the negotiation process has been initiated. The only information that the representative organization may share with these other organizations is that regarding the particular biological resource and its related TK. The interests of the organization's counterpart in the negotiations are kept confidential.¹⁴⁶ Second, confidentiality agreements provide greater certainty of protection of third party interests by maintaining the secrecy of information with potential commercial value. Third, the law provides that the parties' obligations should be expressly stated in writing and should be incorporated into a license contract,¹⁴⁷ and third parties are prohibited from consulting the license without manifest consent.¹⁴⁸

If unauthorized use or disclosure of the collective knowledge occurs (or in instances where there is a danger that it may occur), indigenous peoples have the right to initiate an administrative infringement action through INDECOPI. In these cases, INDECOPI may itself initiate actions, *ex officio*, or an action claiming ownership and indemnification may also be initiated through the local judicial system. Furthermore, in a case alleging infringement of indigenous peoples' rights, the burden of proof is on the defendant.¹⁴⁹

7. *Defensive Protection and Administrative Procedures in Law 27811*

The protection contemplated in Law 27811 responds primarily to the basic features of any intellectual property defensive regime. Accordingly, it primarily focuses on preventing unauthorized parties from acquiring IP rights over TK subject matter, thus ensuring that TK is used with approval and also creating arrangements for the use and dissemination of TK. Furthermore, it gives TK holders the right to enforce their interests against third parties and to grant or withhold the use of protected TK. As has already been stated, this defensive regime may be exercised through a series of mechanisms, including, *inter alia*: disseminating information related to TK in order to impede the granting of IP rights over TK in the public domain; using registers as "defensive" databases to ensure that patent examiners take TK into account when researching prior art; creating

146. *Id.* art. 6.

147. *Id.* art. 27.

148. *Id.* art. 28.

149. *Id.* art. 44

licenses to protect against unauthorized use by third parties and to ensure that parties comply with prior informed consent and benefit-sharing measures; requiring that information related to TK be disclosed in a patent application; and, finally, allowing for the use of administrative, civil, or criminal actions.

Apart from the administrative actions that will be addressed below, Law 27811 includes two special measures that should be emphasized. First, article 23 establishes the competence of INDECOPI to send information in the Public National Register to the main patent offices of the world in order that TK be treated as prior art in the examination of the novelty and inventiveness requirements for a patent application.¹⁵⁰ This is done with a view towards challenging certain patent applications or granted patents. Second, Law 27811 provides that:

Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.¹⁵¹

The protection regime also foresees the possibility of certain administrative actions, including administrative sanctions and provisional and cautionary measures, to enforce TK-holders' rights. The Office of Inventions and New Technologies of INDECOPI hears an administrative infringement action in the first instance, and the Intellectual Property Chamber of the Tribunal for the Defense of Competition and Intellectual Property of INDECOPI decides all appeals.

In an administrative infringement action, Law 27811 regulates the procedure before administrative authorities. Representative organizations are the entities empowered to bring an infringement action before the Office of Inventions and New Technology of INDECOPI. The only requirements when instigating an administrative infringement action include the need to identify: the indigenous representative organization that is bringing the action; the offender; the number by which the TK is designated in the register or, in its absence, a description of the TK and related biological resource; a description of the acts that led to the present

150. *Id.* art. 23.

151. *Id.* at Second Complementary Provision.

action; the proofs presented; and the cautionary measures solicited.¹⁵² A key fact, therefore, is that the protection arises automatically from the subject matter, without the need for a formal requirement such as previous registration or formal recognition of the TK.

Once the action has been admitted, the defendant is notified and has five years to respond to the claim. Nevertheless, prior to notification, INDECOPI may carry out any inspections and research that it considers convenient.¹⁵³ Parties may present any proof referred to by Law 27811, including, *inter alia*, expert opinion, documents, copies, maps, videos, and inspections. INDECOPI also allows alternative forms of proof to be relied upon in addition to the ones expressly provided for under Law 27811.¹⁵⁴

Additionally, INDECOPI can adopt provisional measures, along with the administrative procedures mentioned, in order to ensure the enforcement of the final decision, whether *ex officio* or at the parties' insistence. Such provisional measures may consist of the temporary closing of an establishment. It may also involve the confiscation of goods by customs authorities in an effort to impede the transit of goods based on the collective knowledge in question. Other measures may include halting activities involving such goods.¹⁵⁵ Monetary sanctions may be granted when a party fails to comply with an imposed provisional measure. Although no appeal is admitted against INDECOPI's decision for cautionary measures, a public audience of the parties will be held before the final resolution takes place, if the case merits it.¹⁵⁶ Monetary sanctions will be determined after consideration of several factors, including whether the defendant is a repeat offender, the economic benefit obtained by the defendant, the economic prejudice caused to indigenous communities, and the defendant's cooperation during the proceedings. Law 27811 does not provide a defined list of structured sanctions; instead, it merely mentions the maximum economic sanctions that may be applied.¹⁵⁷ That same office may consider an appeal from the final resolution by the Office of Inventions and New Technology of INDECOPI if significant new proof is presented. A final appeal may be brought before the Intellectual Property Chamber of the Tribunal for the Defense of

152. *Id.* art. 47.

153. *Id.* art. 48.

154. *Id.* art. 53.

155. *Id.* art. 49.

156. *Id.* art. 57.

157. *Id.* art. 65. The maximum monetary sanction foreseen is of 150 UIT, which is equal to approximately US\$139,130.

Competition and Intellectual Property of INDECOPI.¹⁵⁸ One concern is that this extensive system of appeals may hamper the regime's overall effectiveness, especially when a rapid determination is needed. A stricter and more structured system of sanctions, along with more expeditious remedies, would be desirable in order to deter abuses of TK and increase the system's overall efficiency.

Finally, while Law 27811 refers to private law in its regulation of ownership claims and compensation actions, it does not contemplate a special action (or more expeditious procedure) apart from standard private actions and judiciary procedures. Accordingly, Law 27811 states that indigenous peoples' representative organizations may bring claims and compensatory actions available to them under Law 27811, "against a third party who, in a manner contrary to the provisions of this regime, has directly or indirectly made use of said collective knowledge."¹⁵⁹ Because this action is independent of the administrative infringement action, the parties may interpose two different actions simultaneously: one before administrative bodies and another before private judges. Law 27811 also refers to dispute resolution measures as another possibility for resolving these conflicts.¹⁶⁰

Article 51 states that the administrative authority may send the parties to a dispute resolution proceeding, regardless of the stage at which the claim may be—including before the infringement action is admitted.¹⁶¹ If an accord is reached, then it is considered an acceptable extra-judicial act. Parties themselves may also submit the case to arbitration or mediation. If parties submit the case to arbitration, they must immediately agree to the particular arbitration convention that applies and follow the decision. Nevertheless, INDECOPI may decide, *ex officio*, to continue with the process if a third party's interests are at stake.

Conflicts between indigenous peoples arising from the implementation of this regime (for example, during the consultation process for prior informed consent requests) will be resolved by traditional forms of dispute resolution. In such cases, the intervention of a superior representative organization may be appropriate. These provisions respond to the particular needs of Peru's multicultural society, which is composed of a

158. Law 27811 provides that a register of sanctions will be created in order to inform the general public and to detect posterior cases of relapse. *Id.* art. 61.

159. *Id.* art. 45.

160. *Id.* arts. 51, 52.

161. *Id.* art. 51.

multitude of ethnic groups and languages, as they respect indigenous peoples' customary dispute resolution mechanisms.¹⁶²

III. CRITICAL ASPECTS OF PERUVIAN LAW 27811 AND LESSONS FOR THE DEVELOPMENT OF SOUND POLICIES AND LEGISLATION FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

A. *Shared Knowledge and Benefits*

Indigenous peoples' traditional knowledge is, more often than not, shared among different communities within a country and even across national borders. With a few exceptions, knowledge regarding plant properties, uses of extracts, or cultivation technologies is widely dispersed. Under these circumstances, equity issues immediately arise with regard to the participation of indigenous groups or communities in the benefits derived from access to and use of a particular form of TK. Under Law 27811, the Fund seeks to ensure that whether or not individual communities are actively involved in a process where TK is accessed and utilized, they will at the very least have a right to participate in the monetary benefits the Fund may generate at some future time.

B. *Who Can Legitimately Grant Prior Informed Consent?*

Under the likely scenario that TK is shared amongst multiple indigenous peoples' groups, it is necessary to address the issue of prior informed consent.¹⁶³ Given that a unanimous decision to grant prior informed consent for access to and use of shared TK is unlikely, it is clear that tensions and conflicts may arise. Indigenous communities' interests range from those that are quite progressive and seek to develop a close relationship with the modern world, to those that oppose integration or any type of interaction related to accessing and using their TK.

The aforementioned ICBG-Peru project, for example, reflects precisely this scenario: there is a group of communities in favor of participating in a bio-prospecting project (represented by the *Confederación de Nacionalidades Amazónicas del Perú*) and another opposed to it (represented by the *Consejo Aguaruna y Huambisa*).¹⁶⁴ In this case, it is essential to uphold the central role of communities' customary rules and

162. Article 89 of the 1993 Peruvian Constitution expressly describes the State's respect for the cultural identity of farmer and indigenous communities. PERU CONST., art. 89 (2000).

163. For an in-depth discussion of the prior informed consent requirement, see *supra* Part II.B.3.a.

164. See generally *supra* note 67.

traditional practices in their decision-making processes (including the grant of prior informed consent). Furthermore, indigenous groups' customary law principles and rules should be recognized and adequately reflected in national policies and laws.

Law 27811 has established that prior informed consent for access to and use of TK will be granted by representative organizations according to their customs, practices and organizational structures. Although these organizations should in theory fully represent their communities' interests, many times they fall short of this goal. Another complication arises when communities with a common ethnicity or from the same indigenous nation are represented by different organizations that do not necessarily share similar views. Though acquiring prior informed consent may still be possible under these circumstances, its legitimacy in relation to who grants it could be subject to question, particularly in terms of whether the representative organization effectively represents the key interests of all communities involved. This may be especially relevant with regard to the role of broader national representative organizations.

C. TK in the Public Domain

One of the most complex issues in TK-related policy and legislative processes is the treatment of TK that is already in the public domain (such as in publications, databases, or as part of research projects) and is regularly and extensively used not only by indigenous communities, but by researchers and society in general. Though recognizing rights over this TK is possible, exercising an ownership right and effectively controlling its use is extremely complicated in practice for a number of reasons. Law 27811 determines that indigenous peoples are entitled to a percentage of the economic benefits (distributed through the Fund) derived from the use of TK (for which they claim a right) that entered the public domain within the last twenty years and was utilized as part of an industrial or commercial product.¹⁶⁵ In the case of products utilizing TK, but that entered the market more than twenty years ago, indigenous groups will be entitled to the right over their TK but not to benefits derived from its use.

165. It is not clear what an industrial or commercial product is in this context. For example, would small-scale production of medicinal plant-based products need to contribute to the Fund? Is existing widespread commercialization of medicinal plants in rural markets also subject to this requirement? Practical considerations make it difficult to envision how this specific provision may be realized and implemented.

Perhaps a more practical approach would limit the focus of TK laws to TK that has not yet been made widely and extensively available and is still kept confidential to some degree by communities and indigenous peoples in general. In these cases, the successful use of trade secret mechanisms and other IP tools (including a *sui generis* rights system) may be more feasible and realistic.

D. Transaction Costs in TK Law

It seems highly unlikely that geographically, politically and socially marginalized indigenous peoples' groups will have the capacity to make effective and active use of TK laws if such laws are overly complicated in their substantial and procedural requirements. Centralized administrative systems may also have the unintended consequence of impeding active access by communities. Transaction costs for communities may include many or all of the following factors: cost of developing and negotiating contracts and licenses; fees for registering licenses; cost of initiating legal actions if necessary; cost of enforcement; and the cost of raising awareness. Even if indigenous groups are fully represented by their national, regional or local representative organizations, the limitations imposed by high transaction costs is a key concept to bear in mind when developing policies and laws related to TK.

To date, seemingly conceptually sound proposals—including Law 27811—face considerable challenges at the implementation stage. These difficulties increase progressively the more the social, economic and cultural contexts of indigenous communities, albeit mostly inadvertently, are sidelined or even misunderstood. It is the tension between these nuanced factors and the need for greater efficiency that affects the possibility of generating workable sound policies and legal instruments. Therefore, detailed and in-depth baseline research is critical to inform TK policy-making processes.

E. Universal Recognition of TK Legal Principles and Rules

Protection of TK at the national level will only partially assist in preventing its misuse. Just as the traditional IP rights system has over time developed into a regime with international implications, an international *sui generis* regime for the protection of TK should eventually uphold universally recognized and accepted standards. Similarly, protective instruments will ensure that benefit-sharing derived from flows of TK is equitable.

National principles and rules (such as those proposed by Law 27811) include numerous concepts that have been debated and should be considered in the process of developing an international regime. It is worth noting that the CBD and WIPO processes, which represent the consensus of the group of mega-diverse countries, have acknowledged that there is a need to seriously consider the development of an international *sui generis* regime for the protection of TK.

F. Defensive Protection

When taken together, Law 27811 and Decisions 391¹⁶⁶ and 486¹⁶⁷ show that the legal system of Peru has established a basic structure for defensive protection of TK. As mentioned in Part II.B.4, defensive protection implies ensuring that IP rights (specifically patents) are granted subject to the inclusion and consideration of TK-related information in patent search procedures in order to determine whether inventions are sufficiently novel and pass the inventiveness requirement. National (and regional) legislation has recognized this principle, though it is, at present, only applicable at the national level in Peru and regional level of the Andean Community. INDECOPI is undertaking efforts to implement national TK registers for this purpose and, furthermore, special working groups have been created to analyze granted and pending patents over national biological resources and related TK.

Defensive protection seems to have become a very practical option for the protection of TK. Not only have Peru and the Andean Community adopted this type of measure, but Brazil, Costa Rica, India, and many other countries are also considering this alternative, which links the patent system to access and use of biological resources and related TK.¹⁶⁸ An overall goal is for this connection to advance the realization of the CBD's benefit-sharing objective.

166. Andean Decision 391, *supra* note 57.

167. Andean Decision 486, *supra* note 60.

168. For an in-depth analysis of country studies, see *supra* Part I.A.

G. Growing Awareness of the TK Issue

The Peruvian TK policy and legal process has been extremely positive in many aspects. The issue of TK is now fully incorporated into national development agendas. Peru has consolidated its position with regard to TK by continuously supporting calls for the need to protect TK in a series of processes including those instigated by the WTO, CBD, FAO, and WIPO. In the context of a Free Trade Agreement for the Americas (FTAA) and bilateral trade negotiations underway with the United States, the Peruvian Ministry of Tourism and Trade has expressly stated that the protection of TK is at the core of Peru's IP rights policy position.

Furthermore, a draft regulation is under consideration by the Peruvian government to formally establish a "National Working Group for the Prevention of Biopiracy," which if approved, will be led and coordinated by INDECOPI with the support of a wide range of public and private institutions, including indigenous peoples' representatives. Policy and legal issues related to TK are now also increasingly part of regular discussions among indigenous peoples' groups in a wide range of forums. This open environment enables policy makers to undertake initiatives to review and develop a broad spectrum of regulations and laws related to TK, and indigenous peoples' interests in general. Indeed, society's interest and awareness of indigenous peoples' TK-related concerns has been greatly heightened as part of this ongoing process. As a result, TK should be an increasingly important topic on the future agenda of the international community.