

Answering the Call: Public Interest Intellectual Property Advisors

Michael A. Gollin*

Despite the growing debate about the complex global role of intellectual property over the past decade, and the diversity of policy initiatives and academic studies spawned by (and contributing to) this debate, little has been done to meet the practical demands of developing countries and public interest organizations for access to intellectual property expertise on a case-by-case basis. Wealthier organizations and private industry have access to such expertise, by paying for the services of the intellectual property professionals that are concentrated in developed countries. In contrast, in developing countries, there are few intellectual property professionals and many organizations cannot afford to pay for their services. Moreover, many intellectual property professionals are ill-equipped to meet the needs of public interest clients. Society benefits when all people have access to good information and competent advice, and fairness dictates that when poor and excluded people are confronted with the very complicated issues involving intellectual property, they should have access to expert advice and representation.

Public Interest Intellectual Property Advisors (PIIPA) was established as an independent international service and referral organization that can help fill the need for assistance by making the know-how of intellectual property professionals available to

* Michael A. Gollin is a partner in the Washington, DC, office of Venable LLP, www.venable.com. He is a patent attorney who obtained a bachelor's degree in biochemical sciences from Princeton University, a master's degree in zoology and molecular biology from the University of Zurich, and a law degree from Boston University (1984). Mr. Gollin is an adjunct professor at Georgetown University where he teaches Strategic Management of Intellectual Property. He has worked with public interest intellectual property issues for over fifteen years, and in 2002, with support from Venable and many others, he founded Public Interest Intellectual Property Advisors, www.piipa.org. David Farnum and Steven Price assisted in preparing this article and their help is gratefully acknowledged.

developing countries. PIIPA's services are practical, not policy-oriented. PIIPA's goal is to provide balance and information that may help harness the power of informed debate to solve problems, and combat the fear and ignorance that make solutions impossible and lead to protracted disputes. PIIPA's beneficiaries are finding new ways to solve problems in such contentious and difficult fields as traditional knowledge, biodiversity, health, and agriculture.

In recent years, the impacts of intellectual property laws and practices on developing countries have increased dramatically. Globalization has increased the contacts between developing countries and governments and organizations within countries with well-developed intellectual property legal regimes (mostly, the industrialized nations of the Northern Hemisphere, especially the European Union and the United States). Numerous international conventions and trade agreements that affect developing countries expand or involve intellectual property rights. These include the General Agreement on Tariffs and Trade's (GATT) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),¹ the United Nations Convention on Biological Diversity (CBD),² and the International Convention for the Protection of New Varieties of Plants.³ As these treaties have multiplied, their secretariats have dealt continuously with issues involving the impact of intellectual property on developing countries and other public organizations.⁴ In addition, international organizations, such as the World Intellectual Property Organization (WIPO), have begun to examine in-depth the role of intellectual property in issues of particular concern for developing

1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO]. Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND Vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

2. United Nations Convention on Biological Diversity, *opened for signature* June 5, 1992, 31 I.L.M. 818 (entered into force Dec. 29, 1993) [hereinafter CBD].

3. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, UPOV No. 221(e) (as revised at Geneva on Mar. 19, 1991) [hereinafter UPOV].

4. See Michael A. Gollin, *New Rules for Natural Products Research*, 17 NATURE BIOTECH. 921 (1999) (discussing how recent changes to the legal environment have profoundly affected the legalities associated with the collection of biological samples).

nations, such as traditional knowledge, cultural heritage and communal rights.⁵

Despite these rapid changes and their effects on developing countries, most developing countries do not have access to qualified intellectual property professionals who are willing and able to help them address the myriad issues they now face. Rather, most of the participants on the global and national stage have been economists, academics, anthropologists, scientists, and policy specialists, but not intellectual property professionals. In response to this need, in 2002, an international association of concerned individuals, including the author of this Article, decided to establish a new public interest organization. The new organization was named Public Interest Intellectual Property Advisors (PIIPA), and was incorporated as a non-profit, tax-exempt global pro bono initiative to provide intellectual-property-related services for governments, agencies and research institutions in developing countries and other public interest organizations.

This Article describes the genesis and development of PIIPA, focusing on the need for services of the type PIIPA offers and plans to offer as well as the logistical, legal, ethical and political hurdles that public interest organizations working in the area of intellectual property must overcome. Part I describes the growing need for intellectual-property-related legal and professional assistance for developing countries, and in the public interest. Part II discusses how PIIPA was founded and organized to address these needs. Part III addresses the on-going development of PIIPA, including illustrative cases, planned growth, and future directions.

5. See, e.g., WIPO Secretariat, *Review of Existing Intellectual Property Protection of Traditional Knowledge*, WIPO Doc. WIPO/GRTKF/IC/3/7 (May 6, 2002) [hereinafter WIPO Secretariat, *Review*]; WIPO Secretariat, *Certain Decisions of the Sixth Conference of the Parties to the Convention on Biological Diversity*, WIPO Doc. WIPO/GRTKF/IC/3/12 (May 24, 2002) [hereinafter WIPO Secretariat, *Sixth Conference*]; European Community and Its Member States, *Traditional Knowledge and Intellectual Property Rights*, WIPO Doc. WIPO/GRTKF/IC/3/16 (June 14, 2002) [hereinafter European Community, *Traditional Knowledge*], available at http://www.wipo.int/documents/en/meetings/2002/igc/index_3.htm (last visited Sept. 17, 2004).

I. THE NEED FOR INTELLECTUAL-PROPERTY-RELATED LEGAL ASSISTANCE IN DEVELOPING COUNTRIES

The expansion of international intellectual property law to date has been based on the argument that it brings benefits to innovators in all countries; but it has proceeded primarily at the insistence of industrialized, technology-exporting nations that have sought to obtain the same intellectual property protection for their inventions and creations in developing countries that they benefit from in industrialized countries.⁶ Opponents of intellectual property expansion include some non-industrialized, technology-importing countries⁷ which seek to retain access to the technologies of the wealthier countries, and discount the significance of incentives for innovation in their countries. Others oppose particular kinds of protection such as “life patents” and internet patents. At the same time, a movement has sought to assert new types of intellectual property rights, such as sovereign rights over genetic resources previously understood to be the common heritage of humankind,⁸ and rights to traditional knowledge.

So, the international laws relating to intellectual property developed in recent years have been met with wariness and basic opposition to the widespread implementation of Western-style intellectual property laws, as noted above. Is the current regime being applied fairly and equitably to people in developing countries? On at least one level the answer is no. Given that expertise in intellectual property laws, strategies, and management is currently limited primarily to professionals in industrialized countries and in the private sector, there exists a great gap in access to such expertise for developing countries.

Expertise in intellectual property can help advance the public interest in a wide range of endeavors. These include: health care (*e.g.*,

6. See generally Michelle Syverson, *Afterword, GATT, the Environment, and the Third World*, 23 ENVTL. L. 715, 716–17 (1992); Kirstin Peterson, *Recent Development, Recent Intellectual Trends in Developing Countries*, 33 HARV. INT’L L.J. 277, 277–78 (1992).

7. See Commission on Intellectual Property Rights Final Report, available at http://www.iprcommission.org/graphic/documents/final_report.htm (last visited Sept. 1, 2004).

8. See *id.*; Edgar J. Asebey & Jill D. Kempenaar, *Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention*, 28 VAND. J. TRANSNAT’L L. 703, 707 (1995).

obtaining access to patented medicines); agriculture (*e.g.*, licensing of improved crop varieties); biodiversity (*e.g.*, entering into biodiversity prospecting agreements and challenging misappropriation of biological resources); environmental protection (*e.g.*, entering into contracts for technology transfer for renewable energy sources); traditional/indigenous knowledge (*e.g.*, agricultural and health practices, and protecting traditional designs, handiwork, art, music, etc.); scientific research (*e.g.*, obtaining patents or other protection on inventions); and software and technology licensing (*e.g.*, dealing with internet access and related issues/disputes).

A consensus should support the benefits of providing intellectual property expertise to developing-country and public-interest organizations. Expansionists would recognize the need for expert assistance to realize the promise of intellectual property for innovation in health, agriculture, the environment, and industry. Opponents of expansion, or of particular intellectual property rights, should support access to intellectual property professionals who may mitigate or avoid negative impacts of intellectual property, balance the unfair advantage of wealthier organizations who may be collaborators or opponents, and find specific policy/legal initiatives that may be workable and therefore viable alternatives in international policy discussions.

A small, informal survey conducted in the summer of 2002 confirmed the need of developing countries for intellectual-property-related legal assistance.⁹ The survey polled professionals working in a variety of technical sectors (*e.g.*, biodiversity, environment, health) and geographical regions (*e.g.*, both industrialized and non-industrialized nations). In response to a question regarding how many potential clients would seek out professional assistance on intellectual-property-related legal issues, the majority of the respondents indicated that more than 100 such clients exist worldwide, with over one quarter indicating that more than 500 such clients may exist. In addition, the majority of the respondents indicated that such clients would have *continuing* needs. In response to a question regarding the fields in which such projects would arise,

9. Survey conducted by author. Results on file with author and with PIIPA, info@piipa.org.

the respondents listed a variety of fields, including health, agriculture, biodiversity, environmental technology, culture/art and information technology. Similarly, the survey responses suggest that developing nations may need assistance in many different areas of intellectual property law, including patents, copyright, trade secrets, licensing, litigation, and legislation.

As the survey suggests, there is an acute need for public-interest intellectual-property-related legal assistance. However, as noted above, many people and organizations in developing countries are either unaware of, or unable to deal with, the impact of intellectual property rights. In addition, in most of these countries, there are few qualified legal professionals who can represent the rights and interests of such people or organizations—even for those who could afford such services. Further, most of the non-industrialized countries in the world have very limited resources to expend on acquiring knowledge, training or professional assistance. Existing organizations focus on policy formation, or generalized training and capacity building, not practical case-by-case representation. Thus, there is a gap to fill for many developing countries and public interest organizations that need access to pro bono publico intellectual property services.

Conversely, among intellectual property professionals in industrialized nations (including lawyers, agents, and licensing specialists), there is a need for information regarding the types of public interest projects for which their education, skills and experience are uniquely suited. While many organizations admirably perform this service in other areas of the law, such as criminal defense, asylum, and formation of small non-profit corporations by artists, few organizations attempt to inform legal professionals about intellectual-property-related public interest work. Many intellectual property professionals in industrialized countries, especially law students and recent graduates, have expressed a desire to use their skills and experience to improve the role that intellectual property plays in the developing world and would relish the chance to share their expertise with disadvantaged public interest clients. If developing countries are to gain access to useful intellectual property expertise, the information deficiency must be remedied.

With this basic sketch in mind, the following Parts discuss specific examples of intellectual-property-related issues that affect developing nations and the need for professional legal assistance to address such issues.

A. Agricultural Technology

The protection of agricultural technology, and biotechnology in particular, is an important and contentious area of intellectual property. Agricultural biotechnology, in its broadest interpretation, refers to the application of biotechnology to agricultural problems in order to increase crop yields, open up new growing environments, use fewer chemical pesticides, improve nutritional content and decrease energy consumption in growing and processing.¹⁰ Generally, these activities involve research and breeding to produce improved crops, and the innovators charge a premium price for such improved varieties in order to recover the investment in making the improvements. A key component of commercial innovative breeding is the ability to ensure that farmers must buy the improved seed each year, and not keep and replant seed from the past season.

The highly touted benefits of agricultural biotechnology are not readily accepted by everyone, and many have concerns ranging from possible increased use of herbicides to unintended effects stemming from the planting, use, and consumption of genetically modified organisms. Along with the rapid pace of technology innovation, a host of legal mechanisms for protecting the intellectual property rights in these agricultural biotechnology advances have developed.¹¹

Major changes in the legal regime surrounding agricultural biotechnology have occurred in recent decades, ranging from a requirement of the International Union for the Protection of New Varieties of Plants (UPOV) that “[e]ach Contracting Party shall grant

10. See Michael A. Gollin, *At the Crossroads: Intellectual Property Rights and Agricultural Biotechnology 1*, Third Asia-Pacific Conference on Agricultural Biotechnology: Issues and Choices, Thailand (1996) (on file with author).

11. For a discussion of these various mechanisms in the United States and elsewhere in the world, see Neil D. Hamilton, *Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources*, 28 TULSA L.J. 587, 594 (1993).

and protect breeders' rights,"¹² to the United States Supreme Court's decision in *Diamond v. Chakrabarty* that genetically modified bacteria are "compositions of matter" or "manufacture" subject to patenting.¹³ This legal regime continues to evolve. For example, the Canadian Supreme Court recently held that a genetically modified mouse, the so-called Harvard mouse or oncomouse, is not patentable subject matter; and in so holding noted that "[t]he patenting of all plants and animals, and not just human beings, raises several concerns that are not appropriately dealt with in the [Canadian] *Patent Act*."¹⁴ The impact of this decision on the Canadian agriculture market, on the international legal regime, and on other countries' laws remains to be seen, but it illustrates that determining how intellectual property laws apply to agricultural biotechnology innovations relating to plants and animals presents high-impact issues whose resolution requires significant professional expertise.

Also, the enforcement of intellectual property licensing strategies by agricultural biotechnology companies has led to high-profile court challenges against farmers, for example in the Canadian case of *Monsanto v. Percy Schmeiser*.¹⁵ Intellectual property concerns pervade even technical, non-legal measures to prevent farmers from re-using seed from past growing seasons, such as the so-called genetic-use restriction ("Terminator") technology. Recently, a body of the CBD (described in the following section) notified WIPO and UPOV that there is a need to examine "the specific intellectual property implications of genetic use restriction technologies, particularly in respect of indigenous and local communities."¹⁶ This communication notes that the potential impact of genetic use restrictions on smallholder farmers, indigenous and local communities, and on farmers' rights needs to be explored with an emphasis on the development of new legal mechanisms to cope with such restrictions.¹⁷ In addition, the World Trade Organization's

12. UPOV, *supra* note 3, art. 2.

13. 447 U.S. 303, 310 (1980).

14. *Harvard Coll. v. Canada (Comm'r of Patents)*, 219 D.L.R. (4th) 577, 659 (2002).

15. [2001] F.C. 256, available at <http://decisions.fct-cf.gc.ca/fct/2001/2001fct256.html>; see also *Monsanto vs [sic] Schmeiser*, at <http://percyschmeiser.com> (last visited Feb. 21, 2005).

16. See WIPO Secretariat, *Sixth Conference*, *supra* note 5, at Annex, p. 7.

17. *Id.*

(WTO) TRIPS Council is reviewing Article 27.3(b), regarding patent protection for plant and animal inventions.¹⁸

New intellectual property management strategies have been developed recently. The case of golden rice¹⁹ involved the negotiation of a complex web of licenses to provide freedom to use the technology for humanitarian purposes. The Collaborative Crop Research Program of the McKnight Foundation requires grantees to adopt intellectual property terms facilitating technology transfer to poor countries.²⁰

The rapid changes in agricultural biotechnology in recent years are likely to continue as genetic manipulation techniques open up new avenues for scientific research and new corporate business strategies confront farmers with the need to understand intellectual property rights. Developing countries and farmers, therefore, have a need to understand how these new technologies will impact them and how the decisions regarding the management of intellectual property rights in these new technologies will affect them.

B. Biodiversity

In 1992, the United Nations Conference on Environment and Development convened in Rio de Janeiro and created two international agreements—the climate-change framework, and the CBD.²¹ Generally, the CBD “established sovereign national rights over biological resources and committed member countries to conserve them, develop them sustainably, and share the benefits resulting from their use.”²² Although the CBD has now been signed

18. See WTO Secretariat, *Review of the Provisions of Article 27.3(b) Illustrative List of Questions*, WTO Doc. No. IP/C/W/273/Rev.1 (Feb. 18, 2003) (last visited Aug. 25, 2004).

19. Rice was engineered to include genetic material from daffodils causing vitamin A production. The resulting varieties have been as heavily praised by the biotechnology industry, see <http://www.isaaa.org/kc> (last visited Aug. 25, 2004), as they have been criticized by the anti-genetic engineering movement, see <http://www.grain.org/publications/delusion-en.cfm> (last visited Aug. 25, 2004).

20. See <http://www.mcknight.org/science/cropresearch.asp>.

21. United Nations Conference on Environment and Development: Rio Declaration on Environment and Development, Principle 22, June 14, 1992, 31 I.L.M. 874, 880 [hereinafter Rio Declaration].

22. See Gollin, *supra* note 4.

by at least 168 countries,²³ significant debate surrounded its passage and still plagues the implementation of the CBD today.²⁴

Over the centuries, many samples of unique genetic resources have been taken from their original country of origin to collections in industrialized nations. Many unique biological resources have yet to be catalogued or even discovered. These resources, which are concentrated in developing countries of high biodiversity, remain in demand as sources of leads for new products, or for scientific collections.²⁵ This demand has led many biodiversity-rich developing countries to exercise their rights over biological resources established by the CBD by enacting national laws and rules to protect their resources.²⁶ The extension of developing countries' laws to require informed consent and benefit-sharing as preconditions to access to biological resources has resulted in contractual arrangements between biodiversity source countries and biotechnology and pharmaceutical corporations seeking access to the biological resources. These agreements are variously referred to as either biodiversity prospecting agreements or access and benefit sharing agreements.

While national legislation relating to biological resources and biodiversity prospecting agreements is intended to protect countries' rights to their biological resources, it has also added new legal complexities. Intellectual property experts have not been extensively involved in the establishment of such rules, with the result that they are of limited practicality.²⁷ Developing countries, therefore, have a need for professional legal advice regarding the passage and implementation of effective laws, the formation and execution of appropriate biodiversity prospecting agreements, and also their enforcement in the event of a breach. Countries may also require

23. See Parties to the Convention on Biological Diversity / Catagona Protocol on Biosafety, at <http://www.biodiv.org/world/parties.asp> (last update May 25, 2004).

24. See Sarah A. Laird & Kerry ten Kate, *Biodiversity Prospecting: The Commercial Use of Genetic Resources and Best Practice in Benefit Sharing*, in *BIODIVERSITY AND TRADITIONAL KNOWLEDGE* 241, 243 (Sarah A. Laird ed., 2002).

25. *Id.* at 241-42.

26. See Gollin, *supra* note 4.

27. For example, anecdotal evidence suggests that the extremely restrictive model of regulation enacted in the Philippines in Executive Order 247, available at <http://www.elaw.org/resources/text.asp?ID=257>, has resulted in widespread bypassing of the procedures by plant researchers.

assistance in the event that a company engages in biopiracy—the taking of biological resources without the requisite permissions and agreements.

While some biodiversity prospecting agreements may be fairly straightforward, many provide negotiated royalty payments in exchange for access and sample collection, and other agreements involve complex negotiations regarding the sharing and value of locally acquired and/or pre-existing indigenous knowledge regarding a developing country's biological resources.²⁸ Source countries may place a high value on these contracts in monetary, environmental, and political terms. Thus, legal representation that can adequately and appropriately handle the intellectual property issues that arise in the context of biodiversity prospecting agreements is crucial.

C. Traditional Knowledge

For several years, WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO Committee) has been both examining the existing intellectual property mechanisms that could be used to protect traditional knowledge and debating the development of a sui generis system for protection of traditional knowledge.²⁹ WIPO Members have indicated that, depending on the country involved, a wide range of intellectual property laws may be available to protect traditional knowledge, ranging from patent to trademark to copyright to trade secret.³⁰ For instance, both Australia and Canada can cite to examples where existing copyright laws were used to protect

28. Perhaps the most famous example of a developing country providing more than just access to biological resources is Costa Rica's National Institute of Biodiversity (InBio), which conducts its own commercial collections in protected areas and possesses a reliable information system on those collections. *See, e.g.*, Charles V. Barber et al., *Developing and Implementing National Measures for Genetic Resources Access Regulation and Benefit-Sharing, in BIODIVERSITY AND TRADITIONAL KNOWLEDGE* 363, 371–74 (Sarah A. Laird ed., 2002).

29. *See* WIPO Secretariat, *Review, supra* note 5; WIPO Secretariat, *Elements, supra* note 5.

30. *See* WIPO Secretariat, *Review, supra* note 5, at 3–6; WIPO Secretariat, *Report of Existing Intellectual Property Protection of Traditional Knowledge*, WIPO Doc. WIPO/GRTKF/IC/4/7 (Nov. 5, 2002) (reporting further responses to questionnaire on existing protection for traditional knowledge from the Fourth Session of the Committee).

traditional knowledge and creations of aboriginal peoples.³¹ On the other hand, several Members either had adopted or intended to adopt sui generis systems to protect traditional knowledge.³² Significantly, the vast majority of Members “stated that there are no special measures in place to assist traditional knowledge holders handling their intellectual property matters.”³³ Moreover, a number of Committee Members have expressed concerns that traditional knowledge does not always easily qualify for protection under existing intellectual property laws.³⁴ Thus, the European Community and its Member States, for example, have expressed their support for continued study of whether patent applications should disclose the origin of traditional knowledge where appropriate, and for the development of an international sui generis model for the legal protection of traditional knowledge.³⁵ This issue is just now coming under discussion in the European Community but not yet extensively in the United States.

Given the WIPO Committee’s findings, it is clear that developing countries desiring to help protect traditional knowledge face a daunting challenge. In recognition of this fact, the Committee has designed a series of workshops and consultations with local and indigenous communities in developing countries.³⁶ In order either to determine whether and how traditional knowledge may be protected by existing intellectual property laws or to develop a sui generis system of protection, a substantial amount of work must be done. For either of these endeavors, there is a need for the expertise of an intellectual property professional who has significant experience finding, interpreting, and applying, for example, copyright and trademark laws to practical, real-life situations. Developing countries

31. See WIPO Secretariat, *Review*, *supra* note 5, at 4–5.

32. *Id.* at 6 (noting that Brazil, Costa Rica, Guatemala, Panama, the Philippines, Samoa, Sweden and Venezuela all indicated that had some type of special protection for traditional knowledge, and that Ecuador, New Zealand, Papua New Guinea, Peru, the Solomon Islands, Tanzania, Tonga, Trinidad and Tobago and Viet Nam all indicated they intended to adopt such a system in the future).

33. *Id.* at 9.

34. *Id.* at 10–11.

35. See European Community, *Traditional Knowledge*, *supra* note 5, at 4–5.

36. See WIPO Secretariat, *Participation of Local and Indigenous Communities in the Work of the Committee*, WIPO Doc. WIPO/GRTKF/IC/4/12, at 3–4 (Oct. 20, 2002).

could gain valuable insights from these professionals, who could also be of great assistance in shaping existing or developing new laws to protect traditional knowledge. This need may be particularly great, for example, in developing countries that export crafts and natural products, and those where tourism plays a significant role in the country's economy.

D. Health Care

AIDS is an especially great challenge for the developing countries of Sub-Saharan Africa.³⁷ The challenges go well beyond the scientific problem of devising a treatment to the formidable task of obtaining affordable versions of any treatments.³⁸ Many have argued that the absence of affordable treatments can be traced to the deadly combination of Sub-Saharan Africa's poverty, poor infrastructure, lack of ability to administer and monitor a pharmaceutical treatment regime and, more controversially, strong patents under the intellectual property laws required by the TRIPS agreement. The counter-argument is that the innovations arising under a strong patent regime are the only hope, over the long run, for new cures for AIDS and other diseases. One way to resolve this debate between populist and economic views involves the practical use of intellectual property strategies on a case-by-case basis.³⁹

TRIPS requires its members to award "patents . . . for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."⁴⁰ Article 70(8) of TRIPS sets forth procedures for establishing "patent protection for pharmaceutical and

37. In 2000, it was estimated that since the AIDS epidemic began, over fifteen million Africans have died from AIDS and almost twenty-five million Sub-Saharan Africans are infected with HIV/AIDS. Press Release, The World Bank Group, World Bank Steps Up Fight Against AIDS in Africa (Sept. 14, 2000).

38. See World Health Organization Essential Drugs and Medicines Policy (noting that fifty percent of the population in developing countries lack access to essential drugs and that fifty to ninety percent of drugs in developing countries are paid for out-of-pocket, which places the heaviest burden on the poor), available at <http://www.who.int/medicines/rationale.shtml> (last updated July 28, 2004).

39. Michael A. Gollin, *Sustainable Innovation for Public Health*, FDLI UPDATE MAG., Jan. 2002, available at <http://www.venable.com/docs/publication/816.pdf>.

40. TRIPS, *supra* note 1, art. 27(1), at 332.

agricultural chemical products.”⁴¹ Developing countries have attempted to avoid the drug-restrictive effects of patents in developed countries and their own by relying on the TRIPS parallel importation and compulsory licensing measures,⁴² but these strategies have met with only limited success. In November 2001, WTO members concluded the Doha Development Agenda (Doha Declaration), an agreement on patents and access to medicines. Unfortunately, the Doha Declaration did not fully resolve the problem of developing countries’ access to medicines.⁴³

In December 2002, in the face of disagreement over the extent to which the Doha Declaration would give developing countries flexibility to override patent rights in the importation of essential medicines for health crises, the United States announced its own pledge “to permit [developing] countries to override patents on drugs produced outside their countries in order to fight HIV/AIDS, malaria, tuberculosis, and other types of infectious epidemics.”⁴⁴ The United States also stated that it “will implement the Doha Declaration by pledging not to challenge any WTO Member that breaks WTO rules to export drugs produced under compulsory license to a country in need.”⁴⁵ The announcement concluded that: “[U]nder current WTO rules, products produced under compulsory license generally cannot be exported to other WTO Members. The U.S. solution is intended to eliminate this export restriction so medicine can be supplied to countries most in need that cannot manufacture their own pharmaceuticals.”⁴⁶

Developing countries need professional assistance to cope with the restrictions of TRIPS and the Doha Declaration. For example,

41. TRIPS, *supra* note 1, art. 70(8), at 351.

42. See CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 42–44 (2000).

43. For an overview and access to the relevant legal documents involved in the debate over TRIPS and the provision of pharmaceuticals to developing countries, including the latest materials relating to the Doha Declaration, see http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm (last visited Aug. 25, 2004).

44. Press Release, Office of the United States Trade Representative, U.S. Announces Interim Plan to Help Poor Countries Fight HIV/AIDS and other Health Crises (Dec. 20, 2002).

45. *Id.* (noting that under the WTO rules countries are free to resort to compulsory licensing to override a patent, in certain situations, to allow for production of the item in the domestic market).

46. *Id.*

invoking compulsory licensing laws might require input from intellectual property professionals.

Developing countries have many other needs relating to health care for which intellectual property is relevant. For example, another organization has identified “the need for good management of IP in health R&D” as part of a broad-based plan to improve public health in developing countries.⁴⁷ In addition, complex intellectual property issues limit the ability of public-private partnerships to address the existing health research funding imbalance (the so-called “10/90 gap”).⁴⁸ These sophisticated strategic alliances for research, production, and delivery of health products and services involve licensing and ownership of patents, trade secrets, and trademarks. In sum, expanded intellectual property assistance should help to resolve the immediate need for access to affordable medicines, and the longer term need for sustainable management of innovation in public health, as global society seeks to find an equitable balance between the public health needs of today and of tomorrow.⁴⁹

47. See Centre for the Management of IP in Health R&D (MIHR) (last visited Aug. 25, 2004). In its mission statement MIHR defines its goals as:

- To define effective licensing practices for public sector management of IP so that new and improved products can become more readily available to the poor in developing countries.
- To promote the development of new norms for licensing and other management of IP.
- To become an international mechanism for effective exchange of information in the rapidly evolving field of IP management in health research.
- To deliver training to increase capacity in IP management for health technology R&D in developed and developing countries.
- To promote coordination and synergy in public sector product R&D.

Id.

48. See Press Release, Global Forum for Health Research, 10/90 Report on Health Research 2000: Narrowing the 10/90 Gap in Health Research (May 2, 2000), available at http://www.globalforumhealth.org/non_compliant_pages/report00/presserelease.htm (“Less than 10% of the estimated US\$56 billion spent annually on health research by the public and private sectors is devoted to diseases or conditions that account for 90% of the global burden of disease.”); see also Initiative on Public-Private Partnerships for Health, Mission Statement, available at http://www.ippph.org/presentation/affich_mission.cfm?chap=4&sous_chap=0 (last visited Aug. 25, 2004).

49. See Gollin, *supra* note 39.

E. Technology Transfer and the Environment

Developing countries are essential players in environmental conservation. It has been recognized that transfer of technologies between countries should emphasize the transfer of environmentally sound technologies. For example, the Intergovernmental Panel on Climate Change (IPCC) has identified national governments and certain international agreements as key elements of an effective, environmentally sound technology transfer system.⁵⁰ Transfer of renewable energy sources and low greenhouse gas emitting engines and generators are initiatives promoted by the Global Environment Facility under the auspices of the IPCC.⁵¹ Transfer of these and other technologies that reduce pollution to land and water or reduce consumption of natural resources may require skilled intellectual property negotiators to effectuate.

As efforts to ensure environmentally sound technology transfer continue to grow, developing countries will increasingly be called upon to navigate thickets of intellectual property rights in order to license and access the relevant technologies. Countries may need to conform their policies and regulations accordingly. As such, developing countries could benefit greatly from intellectual property professionals experienced in technology transfer.

F. Open-Source, Internet Access, and Information Technologies

As access to and reliance on internet resources increases worldwide, including in developing countries, concerns about fair and equal access to these resources are also increasing. Organizations such as Open Source,⁵² IP Justice,⁵³ the Electronic Frontier Foundation,⁵⁴ the Global Internet Liberty Campaign,⁵⁵ and The Digital Divide Network⁵⁶ have highlighted the public interest need

50. See IPCC Special Report on Methodological and Technological Issues in Technology Transfer, available at <http://www.ipcc.ch/activity/srft-out.htm> (last visited Mar. 6, 2003).

51. Global Environment Facility (2004), at <http://gefweb.org>.

52. See Open Source Initiative (2005), at <http://opensource.org>.

53. See <http://ipjustice.org> (2003).

54. See <http://eff.org> (last visited Jan. 6, 2005).

55. See <http://gilc.org> (last visited Jan. 6, 2005).

56. See <http://www.digitaldividenetwork.org> (last visited Jan. 6, 2005).

for legal advice and representation in this evolving arena. Current concerns include building a global public domain of open source materials, copyright law, and privacy, to name just a few. The focus of these efforts has naturally followed the growth pattern of the internet, with the primary historical focus being on the United States, Europe, and parts of Asia.

As access to the internet becomes more globalized, so do concerns about access and fair use. Attempts to analogize internet issues to locally relevant statutes or norms can lead to complicated and unpredictable legal scenarios for people in areas where the law of the internet is still in a nascent stage or when those same people are confronted with international treaties or laws of foreign nations regarding open source materials, access, privacy, and censorship. Professionals experienced in these intellectual property issues can help address the public interest needs for information access.

II. THE FOUNDING AND ORGANIZATION OF PIIPA

In order to address the impacts of intellectual property on developing countries and others as described in Part I, PIIPA was founded in July 2002, by a global association of individuals, with a variety of backgrounds, who perceived a growing need for an organization that facilitated the actual provision of public interest legal and professional assistance.⁵⁷ Individuals involved with the founding of PIIPA include lawyers and other professionals affiliated with a diverse group of organizations from throughout the world.⁵⁸

57. PIIPA was accepted as a Type 2 partnership during the Johannesburg Worldwide Summit on Sustainable Development in August 2002.

58. These organizations include: AstraZeneca Research Foundation (India), Capetown University (South Africa), Foundation for International Environmental Law and Development (United Kingdom), Global Bioscience Development Institute (U.S.), Initiative on Public-Private Partnerships for Health (Switzerland), the Central Advisory Service of the Consultative Group on International Agricultural Research (the Netherlands), Liu, Shen & Associates (China), National Institutes of Health (U.S.), National Law School (India), Natural Science Collections Alliance (U.S.), Sidley Austin Brown & Wood LLP (U.S.), Smithsonian Tropical Research Institution (Panama), Southern Africa Research & Innovation Management Association (South Africa), The Concept Foundation (Thailand), Venable LLP (U.S.), Washington University School of Law (U.S.), and World Bank Global Environment Facility. This list of organizations is provided for identification purposes only in order to illustrate the diverse array of groups that deal with developing country issues relating to intellectual property. The inclusion of an

PIIPA began with a volunteer founding committee.⁵⁹ PIIPA then incorporated as a tax-exempt non-profit corporation with a small initial board of directors. An International Advisory Committee was established in 2003 and currently has twenty-five members.⁶⁰

A principal goal of PIIPA is to improve the ability of developing countries to manage, protect, or challenge intellectual property in the public interest. To this end, PIIPA was formed to help governments, government agencies and non-government public service organizations acquire intellectual property expertise on a pro bono basis, in order to meet the health, agricultural, environmental, and cultural needs of poor and underprivileged people in developing countries and worldwide.

PIIPA seeks to promote volunteerism among private sector intellectual property professionals worldwide to serve developing country public interest needs. PIIPA serves as a mechanism for networking between intellectual property legal professionals in different countries, and as outreach to such professionals.

As outlined in more detail in the next section, PIIPA intends to achieve these goals, in part, by operating a web-based referral service. Through this service, PIIPA helps those who need assistance identify whether they have intellectual-property-related needs and, if so, helps them frame the issues they need to resolve. In addition, the service helps persons requesting assistance find suitable professional representation from an intellectual property professional or team who will be experienced and trained to deal with public interest issues. By dynamic management of the referral process, PIIPA is able to assemble teams including expert specialists and professionals

organization on this list does not necessarily imply that the organization endorses PIIPA's goals or adheres to a particular viewpoint regarding the role of intellectual property in developing countries.

59. In addition to the author, the founding committee included Shyamkrishna Balganes, Todd Capson, Beatrice Chaytor, Elliot Eder, Mark Epstein, Roberta Faul-Zeitler, Robert Frank, James Gollin, A.D. Heher, Victoria Henson-Apollonio, Gerald Keusch, John Kilama, S. Anand Kumar, Charles McManis, Alan Miller, Tina Kuklenski Miller, Kent Nnadozie, Joachim Oehler, Gerard Treanor, Roy Widdus, Richard Wilder, Rosemary Wolson, and Jianyang Yu. The founding board included the author, John Kilama and Richard Wilder. The founding president was Tina Kuklenski-Miller. See <http://piipa.org/founding.asp> (last visited Feb. 21, 2005).

60. The members are listed at http://piipa.org/advisory_committee_04.asp (last visited Feb. 21, 2005).

knowledgeable about local laws and situations in particular developing countries.

PIIPA envisions servicing assistance seekers from a broad range of areas, including: intergovernmental organizations (*e.g.*, WHO, Joint United Nations Program on HIV/AIDS, Food and Agriculture Organization of the United Nations, South Centre); non-industrialized countries' governments and government agencies; certain research institutions (*e.g.*, universities and government funded public laboratories in developing countries); international research consortia (*e.g.*, Consultative Group on International Agricultural Research, disease specific public-private partnerships); non-governmental organizations and non-profit entities (*e.g.*, MIHR, Oxfam); and certain qualified small-to-medium enterprises and individual innovators.

A. The Primary Operations of PIIPA

PIIPA pursues its principal goal of improving access to intellectual property services through two basic activities:

1. Matching Applicants with Professionals Able to Provide Intellectual Property Services, Including Counseling, Negotiating, Protecting Intellectual Property, and Challenging Intellectual Property Rights

The purpose of PIIPA's service is to meet the need for advice and assistance from qualified intellectual property professionals including attorneys, patent agents, and licensing specialists (IP professionals). PIIPA's role is (a) to identify assistance seekers and help them articulate their needs in particular cases, and (b) to introduce the assistance seekers to the IP professionals and help them establish a case-specific engagement. The IP professionals commit to provide services to their clients on a pro bono basis. The pro bono commitment is for a set number of hours or completion of a particular matter, whichever comes first.

PIIPA is developing a worldwide corps of IP professionals (IP Corps) able and willing to provide pro bono representation to developing country clients. By the beginning of 2005, over 150 IP professionals had agreed to do pro bono work through PIIPA's IP

Corps.⁶¹ Members of the IP corps are solicited via professional associations, direct solicitations, and professional firm networking. PIIPA screens interested volunteers for the IP Corps as to their public interest experience and commitment, their level of expertise with the various types of IP (patent, trade secrets, trademark, copyright, plant protection), kinds of matters (licensing, counseling, prosecution, litigation), professional and ethical qualifications, and language skills. PIIPA is prepared to train candidates for the IP Corps in special issues arising in representing developing country clients, and will provide forms, guidelines, and materials useful to the IP Corps in carrying out their work in cases referred by PIIPA.

Professional outreach is done by PIIPA's CEO, Board, and International Advisory Committee. Outreach involves attendance at various international IP organizations, internet-based contacts, and personal networking. Public awareness of the need for intellectual property services in developing countries is increasing due to activities of PIIPA staff, directors, and volunteers by participation in conferences and panel discussions attended by members of the IP Corps. PIIPA is promoting training of professionals in developing countries by arranging for them to work side-by-side with members of the IP Corps from industrialized nations who are experienced in particular matters, so they can learn skills and handle such matters in the future.

Services have been initiated as PIIPA receives case inquiries from people requesting assistance, and expands its directory of IP professionals. People in need of assistance are being directed to PIIPA by international agencies such as the World Intellectual Property Organization, government agencies such as national patent offices, and non-profit organizations. Inquiries also come through PIIPA's website and from publicity regarding PIIPA's services.

PIIPA matches applicants with members of the IP Corps. This work is currently coordinated by the CEO and will expand as a worldwide network of PIIPA offices is established and case management coordinators are able to work under supervision of corporate officers and according to guidelines established by PIIPA's

61. E-mail from Steven Price to author (Dec. 30, 2004).

Board of Directors. Although PIIPA's headquarters are in Washington, DC, in Smithsonian Institution facilities, it is planned that PIIPA will have field offices strategically located worldwide (*e.g.*, in Geneva, Switzerland, China, India, various Central American countries, Thailand, and various African countries). Each field office will serve as an increasingly autonomous focal point for providing assistance in the areas of translations, local laws and issues, identifying organizations in need of intellectual property assistance, recruiting IP professionals who are willing to assist as part of PIIPA's membership, and identifying local sponsors for funding PIIPA activities. Members of the International Advisory Committee are already fulfilling some of these functions on a volunteer basis. PIIPA's activities also rely on an interactive website that allows assistance seekers and professionals to submit and obtain information via the internet.

By helping assistance seekers find qualified IP professionals to represent them in specific matters PIIPA provides a unique and desperately needed service that is not met by existing commercial services or non-profit organizations.

2. Strengthening Intellectual Property Counseling and Management Resources in Developing Countries Through Training, Monitoring, and Collaborative Arrangements

In addition to helping applicants find IP professionals for particular matters, PIIPA provides educational and general training materials and programs on how intellectual property rights may be applied (or challenged) to further the interests of poor and underprivileged people worldwide, particularly in developing countries.⁶² This work augments current initiatives by other organizations conducting research on the impact of various intellectual property policies. PIIPA and its volunteer IP Corps will continue to produce the media, which can include web-based discussion groups, lectures, forums, panel discussions, conferences, and the like. The audience includes officials of governmental and

62. See, for example, the Bioprospecting Resource Manual and the Designation of Origin memo, *available at* <http://piipa.org/library.asp> (last visited Feb. 21, 2005).

international agencies, non-governmental organizations, and research institutes. This activity will be expanded into different sectors as funding becomes available. PIIPA delivers such materials and assistance on its website, in one-on-one consultations with staff in PIIPA offices and, in collaboration with other organizations, in training sessions. PIIPA's website includes a growing set of links to current intellectual property cases, laws, and other pertinent reference information.⁶³

As funding becomes available, PIIPA will also assist organizations with obtaining financial support from government agencies, non-government organizations, and research institutes working in or with developing countries to defray expenses associated with intellectual property management and implementation. These include, for example, paying government fees for registering patents, copyrights, or other intellectual property assets, travel costs for professionals, and other costs.

B. Legal, Ethical and Political Issues

As a public interest organization seeking to provide generalized information and a matching service between developing country organizations and IP professionals, PIIPA must comply with a number of legal and ethical regulations and good practices relating to referral ethics, conflicts of interest, attorney-client privilege, and so on. In addition, given the strong debates regarding the role of intellectual property in developing countries, PIIPA will undoubtedly face questions regarding its political agenda. These issues are addressed below.

1. Legal and Ethical Issues⁶⁴

Although each country has its own legal and ethical rules, many features of professional practice are shared. In the United States, state legal ethics rules govern the manner and extent to which lawyers may accept referrals of clients. These rules vary widely. For example, in

63. http://piipa.org/resource_sites.asp (last visited Feb. 21, 2005).

64. Acknowledgments are due to Elliot Eder for outlining the relevant issues in this Part.

New York “[A] lawyer may request referrals from a lawyer referral service operated, sponsored or approved by a bar association and may pay its fees incident thereto.’ Permitting lawyers to contribute to the administrative expenses of a nonprofit lawyer referral service is consistent with the spirit of Canon 2.”⁶⁵ In contrast, the State Bar of South Dakota appears to take the view that all internet-based referral services for which an attorney pays a fee to participate are prohibited cost-sharing arrangements.⁶⁶ However, other jurisdictions permit an attorney to sign up for a referral for pro bono or non-profit organizations meeting certain criteria.⁶⁷

Other countries have different rules, and PIIPA recognizes that special referral rules may have to be devised to address requirements that are applicable to the professionals from particular countries. The rules in China apparently permit referrals of the type PIIPA contemplates.⁶⁸ In India, there is an absolute bar on attorney advertising that would preclude Indian attorneys from being listed on a referral website.⁶⁹ PIIPA can avoid such restrictions simply by not listing all IP Corps members, but instead screening and selecting suitable IP Corps candidates to meet an applicant’s needs. Again, the rules for lawyers, patent agents, and licensing specialists may vary.

Intellectual property practitioners obtaining cases with PIIPA’s assistance would need to clear any representation according to the

65. See New York State Bar Assoc. Comm. on Prof’l Ethics, Op. 651 (1993), available at http://www.nysba.org/Content/NavigationMenu/Attorney_Resources/Ethics_Opinions/Committee_on_Professional_Ethics_Opinion_651.htm (last visited Aug. 25, 2004) (quoting NYSBA CODE OF PROF’L RESPONSIBILITY DR 2-103(C)(1) (2000)).

66. See State Bar of South Dakota, Ethics Op. 98-10 (1998), available at <http://www.sdbar.org/members/ethics/default.htm> (last visited Aug. 25, 2004) (noting that Ethics Opinion 90-3 advised that a lawyer could not make payments to a referral service that would run television commercials listing an toll-free number and that while “the medium may have changed, the internet has not changed a lawyer’s professional obligations”). For further information on the views of other state bars see the listing and links to other state bar ethics opinions at the end of Ethics Opinion 98-10. *Id.*

67. See, e.g., Iowa Sup. Ct. Bd. of Prof’l Ethics Op. 97-11 (1997) (noting that Iowa lawyers can participate in pro bono referral service as long as the referral service qualifies under applicable provision of the code of professional responsibility); Nebraska State Bar Assoc. Ethics Op. 95-3, available at <http://www.nebar.com/ethics/opinions/05-3.htm> (noting that it is “clear that a lawyer may pay the ‘usual charges’ of a not-for-profit lawyer referral service or other legal service organization”) (last visited Aug. 25, 2004).

68. Email from Jianyang Yu to author (Feb. 13, 2003).

69. Email from Shyamkrishna Balganes to author (Feb. 2003).

conflict of interest rules applicable to their profession and country. As those rules may vary from country to country, at a minimum, PIIPA asks the IP practitioners to notify their prospective clients of any adverse or potentially adverse clients being represented by the practitioner. PIIPA itself does not currently plan to represent clients directly and therefore should not be subject to conflict of interest rules. PIIPA refers to the organizations as assistance seekers or applicants, and notifies them that they are not clients of PIIPA.⁷⁰

In regard to attorney-client privilege, PIIPA avoids having applicants provide privileged information to PIIPA. The intake process is “filtered” by making clear that applicants should not provide sensitive information, and by controlling the flow of such information, *e.g.*, by limiting information provided by applicants, using prescribed database entry fields. PIIPA recognizes that privileges might apply to communications between clients and their selected professionals according to the rules of various countries and professional groups, and intends to work with representatives of those countries and professional groups to try to ensure compliance with any applicable rules.

A final concern for PIIPA is to avoid making negligent referrals. Although it seems clear that some United States courts would not hold a non-profit organization offering a legal referral service liable for a claim of negligent referral,⁷¹ other courts have held that a referring *attorney* has “a duty to exercise care in retaining [the successor lawyer] to ensure that he was competent and trustworthy.”⁷² PIIPA intends to minimize the risk of negligent

70. See Applicant Consent Form, available at http://piipa.org/consent_applicant.asp (last visited Feb. 21, 2005).

71. See generally *Bourke v. Kazaras*, 746 A.2d 642, 643–45 (Pa. Super. Ct. 2000) (holding that no cause of action exists under Pennsylvania law against bar association’s lawyer referral service for allegedly negligent referral to lawyer who committed malpractice); *Weisblatt v. Chicago Bar Assoc.*, 684 N.E.2d 984, 990 (Ill. Ct. App. 1997) (holding that no cause of action for “negligent referral” exists under Illinois law against not-for-profit organization that provides a lawyer referral service even though organization collects referral fee because organization is not a “lawyer” and therefore has no duty of care to monitor or maintain responsibility for legal services ultimately rendered).

72. *Tormo v. Yormack*, 398 F. Supp. 1159, 1170 (D.N.J. 1975). For a discussion of the various factual and theoretical bases upon which negligent referral claims have been predicated, and suggestions for minimizing potential liability for such claims, see Emily S. Lassiter, *Liability for Referral of Attorneys*, 24 J. LEGAL PROF. 465 (2000).

referral by several practices. First, PIIPA could require professionals to certify their level and area of expertise, as well as whether they have ever been subject to any professional disciplinary action. Second, PIIPA's referral forms and information disclosure include appropriate disclaimers regarding the referral process and PIIPA's obligations.⁷³ Third, to the extent consistent with the rules in a given country, PIIPA can provide a list of professionals from which prospective clients are able to vet and choose their own intellectual property professional, as opposed to having a particular individual appointed by PIIPA itself. Fourth, PIIPA is instituting a program to ask applicants for feedback regarding their level of satisfaction with the professionals with whom they have worked and could de-list any professionals whom PIIPA determines provide unsatisfactory service. These measures should help applicants find the right professional(s) to meet their particular needs.

2. Political Issues

As discussed above, intellectual property has become a topic of great controversy in national and international public policy debates. "Stronger patents are crucial to progress" says one side. "Patents on drugs and living organisms are unfair and immoral" say others. Because PIIPA provides intellectual property legal services to developing countries, many people may assume that PIIPA, as an organization, takes a side in this polarized debate. However, PIIPA has no political agenda to promote in the sense of favoring any one regime of intellectual property rights over any other. Rather, PIIPA conceives its mission as growing out of the proposition that all people, regardless of their wealth or home or beliefs, are entitled to legal and professional assistance, especially when dealing with the authority of the state. This principle of fair access to counsel leading to just results also underlies free criminal defense legal aid services.

Indeed, the American Bar Association's Model Rule of Professional Conduct Rule 6.1 exhorts lawyers to provide pro bono

73. See Professional Consent Form, available at http://piipa.org/consent_volunteer.asp (last visited Feb. 21, 2005).

publico service. Although Rule 6.1 is not mandatory,⁷⁴ Maryland has instituted mandatory annual reporting of pro bono activities under its version of Rule 6.1. PIIPA believes that many lawyers feel obliged to extend assistance to persons in need. This is particularly true where parties have unequal bargaining positions due to a lack of expertise, a common occurrence in cases involving the highly specialized area of intellectual property.

Intellectual property assets, laws, and policies impact developing countries every day regardless of the role those countries or others believe intellectual property should play. To improve beneficial impacts and diminish harms, developing countries and public interest organizations should have access to expertise about how particular aspects of intellectual property affect them—whether or not they endorse the adoption of strong Western style intellectual property legal regimes.

Intellectual property laws have existed for at least five centuries and will surely continue to impact people and society for the foreseeable future. Even in the unlikely event that all future intellectual property rights were abolished, as the most extreme organizations may advocate, it would still be decades before the current assets expire, and there would be a long lasting need to deal with these assets.

Giving access to intellectual property expertise will help developing countries deal fairly with technology-rich countries and will thereby improve their ability to obtain the best medicines, seeds, and environmental technology while also negotiating favorable benefit sharing agreements that regulate access to, and protection of, these countries' genetic resources, traditional knowledge, and cultural creations. In addition, access to intellectual property expertise may enable developing countries to use, challenge or reform existing intellectual property laws according to local requirements and

74. For a discussion of the current status of efforts to mandate pro bono publico service, including the experiences of jurisdictions with mandatory requirements and the arguments and reactions against mandatory requirements, see Kellie Isbell & Sarah Sawle, *Pro Bono Publico: Voluntary Service and Mandatory Reporting*, 15 *GEO. J. LEGAL ETHICS* 845 (2002); James Baillie, *Fulfilling the Promise of Business Law Pro Bono*, 28 *WM. MITCHELL L. REV.* 1543 (2002); Deborah L. Rhode, Essay: *The Pro Bono Responsibilities of Lawyers and Law Students*, 27 *WM. MITCHELL L. REV.* 1201 (2000).

conditions. These results should advance the goals of sustainable development, health, agriculture, and cultural diversity. Helping developing countries access intellectual property expertise will improve their ability to acquire, research, and independently develop medicines, agricultural products (including biotechnology and conventional crops and pesticides), conserve biodiversity and environmental technology, and protect their cultural heritage, traditional knowledge, and folklore.

Combating ignorance and lack of know-how about intellectual property in developing countries helps level the playing field in debates, disputes, and opportunities for developing countries and public interest groups. Thus, PIIPA's political stance is that informed attention to and debate about individual matters can help solve problems on a case-by-case basis in pragmatic ways.

III. THE CURRENT DEVELOPMENT OF PIIPA AND FUTURE DIRECTIONS

This Part addresses the ongoing development of PIIPA, including cases that have already been submitted for assistance, relationships being formed with other organizations, remaining challenges, and planned growth and future directions.

A. Representative Requests for Assistance

PIIPA has received a growing number of specific requests for assistance,⁷⁵ and has been able to assist in providing representation for most of the assistance seekers. Arranging representation has turned out to be surprisingly complex and time consuming in some cases, and surprisingly simple and quick in others. The following list is not exhaustive, but is sufficient to demonstrate the breadth and depth of the demand for public interest IP services in developing countries, and confirms the importance of PIIPA's central mission of making such services available. It is important to note that virtually

75. These summaries are provided for information purposes only. PIIPA has not represented that any of the descriptions precisely characterizes the actual assistance involved.

all of the effort involved in PIIPA's activities and those of the IP Corps have been on a volunteer, unpaid basis.

- The *Peruvian Working Group* (headed by INDECOPI, the Peruvian patent office), seeking to satisfy local concerns of biopiracy, asked PIIPA to find U.S. patent counsel to challenge the validity of U.S. patents on a Peruvian medicinal root, Maca (*Lepidium meyenii*). PIIPA arranged pro bono representation and the matter is proceeding.⁷⁶
- The *Kenyan Wildlife Service (KWS)* asked PIIPA to recruit IP professionals to assert claims for misappropriation against a multinational company that is commercializing an enzyme product based on bacteria taken from a soda lake in Kenya without compliance, and to seek equitable benefit sharing. PIIPA helped identify and coordinate a team of professionals in Nairobi, the U.S., and the United Kingdom, who are representing the KWS.⁷⁷
- The *Fogarty Center of the U.S. National Institutes of Health (NIH)* requested that PIIPA assist its International Cooperative Biodiversity Groups (ICBGs) with training, including: sample agreements, templates, lists of frequently asked questions, "do's and don't's," and links to other relevant sources. PIIPA provided a training session for ICBGs in Bethesda, Maryland, in December 2003. PIIPA posted training materials including an exhaustive *Bioprospecting Resource Manual* with over 150 links to web resources on biodiversity prospecting, including sections on the Business of Bioprospecting, the Legal Framework, Ethical Codes and Institutional Policies and Guidelines for Bioprospecting, Negotiation Issues, Bioprospecting/Access and Benefit-Sharing Case Studies, Types of Access and

76. Alicia Upano, *D.C. Team Gets to the Root of the Problem*, LEGAL TIMES (Jan. 12, 2004), available at <http://piipa.org/upano1-12-04.pdf>.

77. Cormac Sheridan, *Kenyan Dispute Illuminates Bioprospecting Difficulties*, NATURE BIOTECHNOLOGY, Nov. 2004, at 1337, available at <http://www.nature.com/cgi-taf/dynapage.taf?file=/nbt/journal/v22/n11/full/nbt1104-1337.html>.

Benefit Sharing Agreements, and Important Contractual Terms to Consider.⁷⁸

- The *Fogarty Center* also requested that PIIPA assist its International Cooperative Biodiversity Groups (ICBGs) by arranging representation for negotiations on behalf of developing country organizations. PIIPA has arranged for representation for the following developing country entities in their negotiations within the ICBG program:
 - Madagascar—University of Antananarivo, University of Fianarantsoa
 - Vietnam—Vietnamese Academy of Science and Technology, Cuc Phong National Park
 - Laos—Traditional Medicine Research Center
 - Panama—Smithsonian Tropical Research Center
- The *Peruvian Working Group* and other groups inquired about whether disclosure of biological origin laws are consistent with international treaties. PIIPA arranged for a report on Disclosure of Origin requirements from the IP clinic at American University's Washington College of Law. The report was delivered to the Peruvian Working Group and was made available to the public on PIIPAs website.⁷⁹
- *Amazon Alliance* and *Amazonlink* asked for assistance with challenging U.S. trademark applications filed by a Japanese company on Cupuacu (*Theobroma grandiflorum*). PIIPA identified U.S. counsel to represent the organizations in this dispute.
- The *Public Intellectual Property Resource for Agriculture* (PIPRA), a non-profit organization based at the University of California, Davis, asked PIIPA to identify patent attorneys to assess freedom to operate issues raised by agricultural patents. PIIPA has identified several pro bono attorneys who are representing PIPRA.
- The *Sierra Leone Ministry of Trade and Industry* asked PIIPA for assistance in developing national legislation to

78. See <http://piipa.org/library.asp> (last visited Feb. 21, 2005).

79. *Id.*

satisfy TRIPS requirements. PIIPA has identified lawyers in practice and at a law school clinic to assist Sierra Leone and possibly similarly situated countries.

- The *International Alpaca Association* in Peru asked PIIPA to identify counsel to challenge a Certification Mark in the U.S. PIIPA arranged legal representation and an opposition was filed in the USPTO.
- The *Smithsonian Institution* seeks professional assistance with negotiating biodiversity access agreements in various countries for importing specimens of plants and insects for its collection.
- The *University of Capetown* is seeking counsel for drafting, filing and prosecution of patent applications worldwide, particularly in the life sciences, there being few experienced African patent attorneys in the field. Counsel would also advise regarding patent inventorship/ownership in international collaborations.

B. Potential Referral Sources

PIIPA, consistent with its network model of providing services, has made arrangements with several organizations that can serve as referral sources for new inquiries. The following list illustrates the types of collaborations that PIIPA is entering into as it expands its matching services.

- The *World Intellectual Property Organization (WIPO)* is in discussions with PIIPA about handling developing country organizations who approach WIPO needing referrals to advisors to assist in handling individual intellectual property matters such as disputes, preserving rights in traditional knowledge, prosecuting patents, and technology transfer strategies.
- The *Global Bioresources Development Institute* conducts generalized training, including intellectual property, for professionals in developing countries and has agreed to collaborate in referring specific requests for assistance that may arise.

- The *International Intellectual Property Institute* conducts intellectual property training worldwide and has also agreed to collaborate as to referrals on a case-by-case basis.
- The *Center for the Management of IP in Health R&D (MIHR)* is collaborating with PIIPA to refer professionals who can help draft training materials and assist MIHR's developing country constituents. MIHR promotes access to health technologies for the poor through improved management of intellectual property in research and development. PIIPA will provide assistance to MIHR in creating effective licensing practices for public sector management of IP, improving exchange of information, and providing training.
- *Millennium Ecosystem Assessment (MEA)*, initiated by various United Nations agencies, the World Bank, the World Resources Institute, the Convention to Combat Desertification, the Convention on Biological Diversity, and international scientific organizations and individuals, to "improve the management of the world's natural and managed ecosystems" by providing "the scientific underpinning to a wide range of national and international efforts" including "climate, biodiversity, freshwater, marine and forest issues."⁸⁰ MEA approached PIIPA about providing intellectual property counseling, licensing, and negotiating relating to collection and world-wide publication and dissemination of environmental data.
- The *African Agricultural Technology Foundation*⁸¹ has discussed with PIIPA how to address the needs of AATF's African collaborators for professional assistance with multiple projects involving licensing existing proprietary agriculture technologies, know-how, and materials from corporations and public research institutes to African institutions, and counseling regarding management of innovations developed in these projects. Technologies include, for example, existing and new crop varieties, tissue

80. See generally <http://www.millenniumassessment.org/en/about.overview.aspx>.

81. Justin Gillis, *To Feed Hungry Africans, Firms Plant Seeds of Science*, WASH. POST, Mar. 11, 2003, at A1.

culture marker-aided selection, databases, and crop management methods.

- Finally, developing country grantees of the Global Fund for AIDS, Tuberculosis and Other Diseases can be expected to require professional assistance relating to counseling on the impact of patents and technology transfer strategies for medicines to combat these diseases in developing countries.

B. Remaining Challenges for the Launch of PIIPA

This Part describes three of the primary challenges that PIIPA is currently confronting. In particular, this subpart discusses issues involving the screening of developing country applicants, the screening of IP professionals, and securing adequate funding.

1. Criteria for Screening Applicants for PIIPA Services

A question fundamental to PIIPA's charitable purpose is: What criteria should PIIPA employ to screen applicants in order to ensure adherence to PIIPA's public interest mandate? The criteria must reflect PIIPA's basic operations as a referral service to match needy applicants with professionals of the IP Corps who will provide pro bono services. At present, PIIPA is refining three different criteria for screening applicants.

One, a purpose-based test focuses on determining whether the activity for which PIIPA assistance is sought is one which is in the "public interest" and/or in furtherance of developing country interests. One of the problems with applying a purpose-based test involves how to define in operational terms what is meant by "public interest." This is a particularly difficult issue where intellectual property is involved as opinions vary widely over the extent to which intellectual property laws act in or against the public interest.

Two, a financial, need-based test focuses on assessing whether the entity/individual is financially able to pay for professional assistance in the absence of pro bono assistance provided through PIIPA. The primary difficulty with this approach is determining the threshold amount to use. This is a particularly thorny problem where professional intellectual property services for developing countries

are involved because (a) the initial presentation of the problem may not accurately reflect the full extent of the issues and concomitant need for professional assistance, and (b) the disparities in wealth and cost of legal services are so great, with attorneys in New York charging twenty times the hourly rate of an attorney in New Delhi.

Three, an organizational test makes certain types of applicants automatically eligible, such as, for example, developing country governments and agencies. Other organizations, such as nonprofit organizations and developing country individuals or business entities, would have to satisfy one or both of the purpose test and the financial test. This screen also raises issues regarding the appropriate distinguishing characteristics to use in the threshold determination.

2. Criteria for Screening Intellectual Property Professionals

PIIPA requires that IP Corps members provide an initial consultation or certain number of hours to clients they obtain through PIIPA, without charge (*e.g.*, fifty hours, which is about the bar-recommended three percent of the busy professional's 1800 billable hours). However, PIIPA's purpose will be served only if the donated services are of a competent level. Thus, PIIPA screens the IP professionals forming PIIPA's IP Corps.

PIIPA is reviewing criteria to use in enlisting individual IP professionals to provide client assistance. This task is greatly complicated by the differences between countries and between professions, which in effect negate the possibility of using a "one-size-fits-all" approach. Thus, PIIPA is presently evaluating a number of different criteria that will most likely have to be applied flexibly to accommodate these differences.

PIIPA currently selects IP Professionals for the IP Corps based on their self-designated level of experience with particular types of intellectual property, and different types of matters. In other words, professionals can be screened and categorized based on whether they have experience with (*e.g.*, patent, trade secrets, trademark, copyright, or plant protection issues). Few people have experience in all these areas. An expert patent attorney may be a beginner for copyright. A trademark expert may know nothing about patents. In addition, factors such as experience in particular geographical regions

and language skills are also important in matching IP professionals to applicant's needs. Similarly, PIIPA is screening professionals based on their experience with particular kinds of actions, such as licensing, counseling, prosecution or litigation.⁸²

Among other possible mechanisms PIIPA is evaluating is a system that ranks intellectual property professionals based on their level of expertise. For example, a system could differentiate between experts, who are qualified as trainers and could be selected for high-profile, precedent-setting cases; certified professionals, who display basic competence to handle routine cases; and trainees or beginners.

The extent of prior public interest involvement is also a relevant screen for intellectual property professionals. Those with a record of providing pro bono assistance may be better attuned to the types of matters PIIPA's constituents have. In applying this screen, PIIPA examines the past experience and personal goals of the professionals.⁸³

Lastly, the ability of the intellectual property professionals to conform to ethical requirements is of paramount importance. For the reasons set forth in Part II.B above, PIIPA requires IP Corps volunteers to certify that assistance can be provided consistent with an individual's professional standards, specifically in accordance with the rules of conduct of all professional organizations, associations, and bars of which I am a member."⁸⁴ This may involve issues that differ among jurisdictions and professional categories, such as conflicts of interest, confidentiality, competence, and, where appropriate, insurance. In addition, PIIPA is developing plans for intellectual property professionals to adhere to requirements such as that they advise clients about the terms and limitations of their representation and obtain informed consent, ensure no conflicts, describe any limitations on confidentiality, etc.

82. See Volunteer Form, <http://piipa.org/memberregister.asp> (last visited Feb. 21, 2005).

83. *Id.*

84. *Id.*

3. Funding Strategy

PIIPA has been, to date, primarily a voluntary venture. Initial efforts involved a pro bono incubation at Venable LLP, which contributed time and effort and in-kind contributions of infrastructure (office facilities, postage, telephones, and so on) as well as some initial expenses. Private donors added to Venable's contributions. PIIPA then received funds from the Fogarty Center of the NIH which supported the resources on biodiversity prospecting, and some additional funds from the Venable Foundation. The Rockefeller Foundation has promised substantial funding for 2005 to fund ongoing activities, and PIIPA's grant applications are being favorably reviewed by other philanthropic and development organizations. This funding will allow PIIPA to conduct a methodical assessment of needs in different regions, and to expand its activities in all sectors (health, agriculture, traditional knowledge, environment, science, and information technology).

As with most start-up ventures, PIIPA now faces significant challenges in obtaining sufficient funding for large-scale and sustained operations. Following advice from PIIPA's founding committee, advisory board, and other counselors, PIIPA is forging ahead to provide benefits as quickly as possible. PIIPA seeks funding from the following: law firms, philanthropic foundations, corporate foundations, government grants, and service fees. Financial support is leveraged by a much higher return on investment measured by the time value of the pro bono contributions of the IP Corps. PIIPA is able to account for the leveraged value of services by polling its members as to their billing rates and the number of hours contributed, thereby defining a value for in-kind contributions of time.

D. Future Directions

One of the main areas of growth for PIIPA is the formation of affiliated regional offices around the world. These offices are intended to serve as focal points for particular countries, where developing country representatives can gain information about PIIPA and its activities. Currently, PIIPA volunteers are active in China, India, Central Africa, Southern Africa, South and Central America,

and Europe. These volunteer affiliations should ultimately result in establishing regional offices. In either case, a number of practical and legal issues may arise.

Among the issues that must be resolved is overcoming language barriers for volunteers and participating IP professionals. Unless regional offices have very narrow spheres of activity, major differences in the languages encountered will exist. PIIPA anticipates operating to some extent in English, French, Spanish, and Chinese, but even this will not be sufficient for communication with all representatives in all countries. To date, PIIPA has provided translations of its website into Spanish and Chinese. The international network model simplifies the translation barrier because PIIPA need not be extensively involved with less common languages in order to complete a referral. Once a Spanish-speaking applicant finds a Spanish-speaking member of the IP Corps, for example, no further language barrier will exist.

Beyond the obvious language concerns, the regional volunteers and affiliates can help identify local legal and policy issues. PIIPA's International Advisory Committee is directing regional outreach. Effective outreach informs both developing countries and intellectual property professionals about potential issues and opportunities relating to intellectual property law in a way that communicates the substance of the matters to them in terms they can understand. Eventually, regional offices can play a critical role in framing and translating problems of assistance seekers into legal issues that can be addressed. In addition, outreach involves facilitating communication between the volunteers already in place in China, India, Central Africa, Southern Africa, South and Central America, and Europe so that they may learn from each other's experience.

The regional offices will help PIIPA's core activities of handling requests for assistance for projects related to developing countries and identifying qualified IP professionals to assist on a pro bono and/or reduced rate basis. In particular, PIIPA seeks professionals with experience in negotiating and drafting IP licensing agreements, including material transfer agreements, biodiversity prospecting agreements, and agreements relating to the licensing of traditional knowledge. PIIPA also seeks individuals who have experience with

obtaining IP protection for traditional knowledge. In addition, IP professionals with patent and other litigation experience are sought.

CONCLUSION

International, multi-national, and national intellectual property laws and practices increasingly affect life in developing countries and bring about a great need for experienced professional assistance in the public interest. Currently, organizations that provide such assistance tend to be limited to policy initiatives or generalized training, not specific projects. Public interest applicants seeking professional assistance generally do not have access to information about intellectual property professionals or the ability to retain a suitable representative. Conversely, intellectual property professionals who are interested in providing public interest assistance, on a pro bono or reduced-fee basis, do not have access to a source of information on such opportunities. PIIPA is filling this void by providing a referral and matching service for assistance seekers and intellectual property professionals, and by providing appropriate education and training for both of them.

Developments in the laws regarding patents, copyrights, and traditional knowledge will increasingly affect developing country and other public interest concerns such as agricultural development, biodiversity protection, and health care. We can anticipate further efforts to strengthen, weaken, or revise these laws and how they are applied, so there is a great opportunity for individuals to adopt practices in specific cases that best reflect their and their society's goals and values. Promoting relationships between developing country organizations and volunteer intellectual property professionals will advance the public interest in this crucial period of globalization. Fair access to IP expertise will promote just results worldwide.