Using Patents to Protect Traditional Knowledge

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Abstract
The role that intellectual property can play in the protection of traditional knowledge (TK) has been on the international agenda for more than ten years, with little to show for it. For example, the World Intellectual Property Organization (WIPO) has provided a forum for international policy debate on the subject since 1998, and the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has held meetings on draft provisions for the protection of TK against misappropriation and misuse since 2001. Similarly, since 1999 the World Trade Organization (WTO) has been examining the most effective means to deal with the commercial use of TK when that knowledge is the subject of patent applications. Years of effort have produced few tangible results. While there has been little movement internationally, several nations, particularly developing ones, have attempted to provide a measure of protection for TK at the national or regional level. As international discussions drag on, pressure will likely increase for countries rich in TK to seek recourse in national or regional solutions. Prominent among those solutions will be the use of patent law. This article will review the benefits, shortcomings, and challenges of using patents to protect TK and survey some of the efforts that have been undertaken so far.

Keywords

Disciplines
Intellectual Property Law
USING PATENTS TO PROTECT TRADITIONAL KNOWLEDGE

Jay Erstling

INTRODUCTION

The role that intellectual property can play in the protection of traditional knowledge (TK) has been on the international agenda for more than ten years, with little to show for it. For example, the World Intellectual Property Organization (WIPO) has provided a forum for international policy debate on the subject since 1998, and the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has held meetings on draft provisions for the protection of TK against misappropriation and misuse since 2001. Similarly, since 1999 the World Trade Organization (WTO) has been examining the most effective means to deal with the commercial use of TK when that knowledge is the subject of patent applications. Years of effort have produced few tangible results.

While there has been little movement internationally, several nations, particularly developing ones, have attempted to provide a measure of protection for TK at the national or regional level. As international discussions drag on, pressure will likely increase for countries rich in TK to seek recourse in national or regional solutions. Prominent among those solutions will be the use of patent law. This article will review the benefits, shortcomings, and challenges of using

1. Professor of Law, William Mitchell College of Law, St. Paul, Minnesota. From 2002 to 2007, the author was the Director of the Office of the PCT at the World Intellectual Property Organization (WIPO). Any views expressed in this paper about either the PCT or WIPO are the author's own. The author would like to thank Brynn Bauer, a student at William Mitchell, for her contributions to the research that led to this article.

2. Because so much of a country's traditional knowledge focuses on the use and management of the country's genetic resources, discussions concerning the intellectual property protection of traditional knowledge are often linked to the protection of genetic resources. For the purpose of simplicity, this paper attempts to limit itself to traditional knowledge protection. It should nevertheless be understood that much of what is said about traditional knowledge applies also to the protection of genetic resources.


4. See World Trade Organization [WTO], TRIPS: Reviews, Article 27.3(B) and Related Issues, Background and the Current Situation (2008), http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm.

patents to protect TK and survey some of the efforts that have been undertaken so far.

What Is Traditional Knowledge?

There is no one standard definition of TK. The Convention on Biological Diversity, an important international agreement that will be discussed below, reflects the diverse nature of TK when it refers to it as "... knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles. ..." The WIPO IGC has suggested that TK could be characterized as referring:

... to the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.

What is apparent from both characterizations is that TK is far-ranging and, even more important for the purposes of this paper, TK need not be old, static, or lacking in a scientific or technological basis. The knowledge is traditional only in the sense that it is part of the customs and cultural traditions of the community that has developed and maintains it. Because the knowledge is often central to a community's cultural value system, the community generally holds and owns the knowledge collectively, although use of the knowledge may be restricted to certain community members. The knowledge may also be communicated orally or recorded in ways different from accepted Western scientific methodology, terminology or modes of expression.

6. Patents are by no means the only way to protect TK. Arguments have been made, in fact, that sui generis protection systems or remedies outside of traditional intellectual property rights, such as contract law and the law of misappropriation, may be more effective means of protecting TK. The purpose of this article is not to dispute those claims, but simply to discuss the benefits and challenges of looking to national patent systems for TK protection.


8. Id. art. 8(j).


11. Gervais, supra note 10, at 140–141. It should be noted that use of the knowledge may also be extensively practiced.
On the surface, therefore, TK bears resemblance to the sort of intellectual property protected by patents, but there may be significant differences in the way in which the knowledge is developed, held, or communicated.

**Why Patent Protection?**

Putting the differences in the above paragraph aside, a recent WIPO IGC consultation paper reported that “a significant number of patent applications concern inventions which are in some way related to traditional knowledge.”\(^\text{12}\) A community’s new and innovative advancements in TK may meet the requirements to qualify as patentable inventions, for example. In such cases, the holders of the TK need to ask whether they wish to take advantage of patent protection, whether it is in their best interests to do so, and assuming positive answers to both questions, whether they have the resources to file, prosecute, and enforce patent applications.

More typically, inventions claimed by others may make use of a community’s TK in that the others will derive their inventions from the TK or base their inventions on it.\(^\text{13}\) When inventions derived from TK become the subject of patent applications, the relationship between the inventions and their underlying TK may be key to the inventions’ patentability. For example, the TK may constitute prior art that destroys an invention’s novelty or non-obviousness. As prior art, failure to disclose the TK may result in a violation of the duty in United States patent law to disclose all known information material to patentability.\(^\text{14}\) The TK may also directly relate to the question of inventorship and entitlement to apply for a patent since the holders of the TK—and not the named inventor—may constitute the true inventors or co-inventors of the claimed invention.

It is clear, then, that there are critical links between TK and the patent system. The question is whether and if so, how, those links can be exploited to foster protection for TK. This question is not a new one and has been the subject of considerable scholarship.\(^\text{15}\) The answer, which may prove more difficult to achieve than to posit, seems to lie in the objectives of the patent system itself. While the primary objective of patent law is affirmative, i.e., to enable the grant of exclusive patent rights for qualifying inventions, a patent system also has an

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\(^{12}\) WIPO, *Recognition of Traditional Knowledge*, supra note 9 at ¶ 1.

\(^{13}\) Id.

\(^{14}\) *See* 37 C.F.R. § 1.56 (2000) (failure to disclose material information may result in a finding of inequitable conduct and in the consequential unenforceability of the patent).

important defensive objective, to ensure the denial of rights to inventions that are already known or lack a sufficient level of inventiveness. In addition, a patent system has a vital informational objective, to guarantee the disclosure to third parties of all relevant information concerning the invention as a quid pro quo for the grant of exclusive rights. Countries wishing to use patents to protect TK would do well to consider measures that reflect all three objectives. Such a three-pronged approach would focus on putting into place legislative or other mechanisms to provide for (1) defensive protection of TK, (2) disclosure of TK, with consequent provision for benefit sharing, and/or (3) affirmative protection of qualified TK through the grant of patent rights.

Defensive protection would ensure that none other than the holders of TK would be able to acquire intellectual property rights over that knowledge. Effective measures would include, on the one hand, the adoption of legislation that recognizes TK as prior art and the creation of information systems to make TK searchable by patent offices, and, on the other, the establishment of strong trade secret measures that allow the holders of TK to maintain the confidentiality of their knowledge should they choose to do so. At the heart of the second prong—disclosure and benefit sharing—is a community's right to maintain control over its TK. Inherent in that control are measures that would require applicants for patents for inventions derived from or based on TK to disclose in the patent application the geographic source of that knowledge and to provide assurance that there has been prior informed consent to make use of the knowledge. The third prong of affirmative protection would make available information, mechanisms, and resources to holders of patentable TK to make sure that those who wished to take advantage of patent protection were able to assert their rights.

**Why Protect Traditional Knowledge?**

Why should communities that hold TK choose to protect it? There is of course a moral rationale for protection, i.e., that communities should have the right to make use of their own TK pursuant to their own customs and policies, free from misappropriation or misuse by others. In addition, holders of TK may be motivated by economic, social, and environmental interests. Professor Graham Dutfield, a noted scholar on TK and intellectual property protection, has examined several of those interests. With respect to economic mo-
tivators, Professor Dutfield has found that "[s]ome indigenous and local communities depend on traditional knowledge for their livelihoods and well-being, as well as to sustainably manage and exploit their local ecosystems."  

For example, the World Health Organization (WHO) estimates that up to 80% of the world's population relies on traditional medicine for primary health care, and organizations such as the Food and Agriculture Organization (FAO), the World Bank, and the United Nations Environmental Programme (UNEP) now encourage the use of TK in sustainable rural development programs. Protecting TK could therefore "help local people to maintain livelihood security and physical well-being while providing opportunities for economic development."  

Protecting TK may also benefit national economies by giving countries greater control over the commercial use of their knowledge. TK-based products, including plant-based medicines, health products, cosmetics, and non-wood forest products, represent many developing countries’ value added and are a potentially lucrative source of export revenue, which sound use of TK protection could help realize. Because TK is often an essential element in the development of other products, such as pharmaceuticals, dietary supplements, personal care, pesticides, and even industrial enzymes, protecting TK could also give developing countries an economic edge in doing business with the industries that make those products and thereby promote domestic growth.  

Protecting TK can also provide significant environmental benefits. Contrary to the common stereotype that subsistence agriculture is environmentally unfriendly, traditional methods of farming and natural resource management often incorporate a conservation ethic that can enhance biodiversity. TK protection would not only contribute to the preservation of the world's plant and animal diversity, it could also foster the fair and efficient dissemination of environmentally sound agricultural methods while benefiting the traditional communities that created them. 

Finally, while the patent system has been accused of facilitating biopiracy by tolerating third-party patenting of TK, using the patent sys-
tem appropriately to protect TK can serve more to prevent biopiracy than to permit it. Biopiracy generally refers to the exploitation of traditional knowledge or genetic resources—typically by multinational companies—without the authorization of the holders of that knowledge, and/or the patenting of inventions based on traditional knowledge without the consent of the knowledge holders or payment of compensation. Several cases of alleged biopiracy, including patents granted for neem, turmeric, the enola bean, and quinoa, have aroused controversy and focused attention on how patenting can lead to unjust results. Although it is extremely difficult to estimate the extent to which biopiracy actually takes place in any particular country, protecting TK could provide some assurance against misappropriation by clarifying the duty that third parties owe to the holders of the knowledge when the knowledge has contributed to an invention that is the subject of a patent application.

Thus there are convincing reasons for turning to the patent system to protect TK. The view is far from unanimous, however, that doing so makes sound policy. Many traditional communities are reluctant to embrace the patent system. The high cost of prosecuting and enforcing patents may be one cause for caution on the part of TK holders. Another may be the structure of the patent system itself. At a recent seminar on intellectual property, biotechnology, traditional knowledge, and social issues co-hosted by L’Institution Sciences Po and McGill University, Professor Tania Bubela expressed the commonly held view that:

There is a mismatch between the IP rights framework and TK. The main problem is that IP rights are time limited. Patenting of TK also requires public disclosure but most TK is based on cultural and spiritual beliefs that do not always agree with disclosure. It is also very difficult to know who holds the traditional knowledge. An appropriate balance needs to be struck between national economic interests and the needs of the communities to which TK owes its existence.

Based on the same reasoning, the majority of “Indigenous Groups in Attendance” at a 2000 UNCTAD Expert Meeting on Systems and National Experiences for the Protection of TK, Innovations and Prac-

24. Id. at 52.
ties recommended that "[t]he current IPR system is inappropriate for the recognition and protection of traditional knowledge systems because of the inherent conflicts between these two systems. . . ."\(^27\)

If patents are to be used effectively to protect TK, therefore, the concerns of the holders of TK will have to be addressed and measures adopted that are compatible with their communities' values, norms, and objectives. To the extent that some of the concerns may be based on lack of confidence in, or misconceptions about, the patent system, clarification and education will be essential to provide TK holders with both the self-assurance and the wherewithal to make appropriate use of patents.

**The International Framework**

Another critical ingredient in using patents to protect TK is the international framework within which patent systems in general, and TK protection in particular, has to operate. There are a number of international agreements that touch upon the rights of TK holders,\(^28\) but three have a particular bearing on the relationship between TK and the patent system: the Convention on Biological Diversity (CBD);\(^29\) the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS);\(^30\) and the Patent Cooperation Treaty (PCT).\(^31\) This section will attempt to provide an overview of the requirements, restrictions, and opportunities created by the international framework.

**The CBD**

The CBD provides particular support for the middle prong of TK protection: disclosure of the origin of inventions derived from TK,

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28. Those agreements include the ILO Convention No. 169 Concerning Indigenous and Tribal Peoples in Independent Countries, the UPOV Convention for the Protection of New Varieties of Plants; and the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture.

29. CBD, supra note 7.


especially when the traditional knowledge relates to the conservation and sustainable use of biological diversity. The CBD was adopted in 1992 in response to growing concern over the loss of the world’s biological diversity. Currently 191 countries are party to the CBD, although the United States is not one of them. The objectives of the CBD, as stated in Article 1, are “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, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.” It is the CBD’s goal of achieving fair and equitable benefit sharing that is the most relevant to the issue of patent protection and TK.

Although the thrust of the CBD is on appropriate access to and benefit sharing of a country’s genetic resources, the preamble to the Convention and Article 8(j) refer expressly to the role of TK in the access and benefit-sharing process. In its preamble, the CBD recognizes “the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components. . . .” In aspiring to realize the goal of benefit sharing, Article 8(j) states:

Each contracting party shall, as far as possible and as appropriate:

(j) Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

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32. The United States signed the convention on June 4, 1993, but it never ratified it. The other countries that participated in the deliberations leading to the adoption of the convention, but that are not party to it are Andorra, the Holy See, Iraq, and Somalia.

33. CBD, supra note 7, art. 1.

34. For example, Article 15.4 of the CBD requires that access to genetic resources “shall be on mutually agreed terms . . .,” and, in accordance with Article 15.5, “subject to the prior informed consent of the Contracting Party providing such resources . . ..” To ensure fair and equitable benefit sharing, Article 15.7 requires Contracting Parties to “take legislative, administrative or policy measures . . . with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.” CBD, supra note 7, art. 15.

35. Id. at Preamble para. 12.

36. Id. at art. 8(j).
The Conference of Parties (COP) of the CBD, the convention's governing body, has focused considerable attention on effective ways for member countries—called Contracting Parties in the Convention—to implement Article 8(j). Among the recommended measures, the COP has urged countries to require disclosure in patent applications of the source of TK. For example, at its sixth meeting in 2002, the COP adopted Decision VI/24 containing the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization" (Bonn Guidelines) as well as recommendations concerning the "[r]ole of intellectual property rights in the implementation of access and benefit-sharing arrangements." The Bonn Guidelines counsel Contracting Parties to consider measures that would "encourage the disclosure of the country of origin . . . of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights . . . ." In implementing mutually agreed terms for benefit sharing, the Bonn Guidelines further call on member countries to contemplate "[t]he possibility of joint ownership of intellectual property rights according to the degree of contribution."

The recommendations of Decision VI/24 echo the urgings of the Bonn Guidelines. While the recommendations do not mandate any particular action on the part of member countries, they invite:

Parties and Governments to encourage the disclosure of the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual

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39. Id. ¶¶ 2–3.
40. Id. ¶ 16(d)(ii).
41. Id. ¶ 43(d).
property rights, where the subject matter of the application concerns or makes use of such knowledge in its development.\textsuperscript{42}

That the COP has devoted attention to the link between benefit sharing and intellectual property rights should not be viewed as surprising since the CBD itself makes that link. Article 16.5 of the CBD recognizes that “patents and other intellectual rights may have an influence on the implementation of this Convention,” and directs member countries to “cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to [the Convention’s] objectives.”\textsuperscript{43} Member countries are entrusted, therefore, to exercise patent rights in support of the objectives of the CBD.

\section*{Recent Developments}

Most recently the COP has expanded its focus to elaborate “Considerations for guidelines for documenting traditional knowledge,” which are directly related to the question of defensive protection, and it has engaged in preparatory discussions on the Draft Elements of a Code of Ethical Conduct, which could have an important impact on TK protection.\textsuperscript{44} At the ninth session of the COP in May 2008, the countries expressed concern that recording and documenting TK\textsuperscript{45} posed potential threats to the holders of the knowledge if the exercise were carried out without the full and effective participation of the communities concerned. As a result, the COP in Decision IX/13 asserted that the documentation “should primarily benefit indigenous and local communities and . . . their participation in such schemes should be voluntary and not a prerequisite for the protection of traditional knowledge.”\textsuperscript{46} To meet that objective, the COP urged Parties, Governments, and international organizations:

[T]o support and assist indigenous and local communities to retain control and ownership of their traditional knowledge, innovations and practices including through:

(a) The repatriation of traditional knowledge, innovations and practices, in databases, as appropriate; and

(b) Supporting capacity-building and the development of necessary infrastructure and resources;

\textit{With the aim of ensuring that:}

\begin{itemize}
\item \textsuperscript{42} Id. \S 2.
\item \textsuperscript{43} CBD, supra note 7, art. 16.5.
\item \textsuperscript{44} Conference of the Parties to the Convention on Biological Diversity [CBD], Article 8(j) and related provisions, C, Decision IX/13, UNEP/CBD/COP/DEC/IX/13 (May 19–30, 2008), available at http://www.ciesin.columbia.edu/repository/entri/docs/cop/CBD_COP009_dec13.pdf [hereinafter Article 8(j) and Related Provisions].
\item \textsuperscript{45} See infra pp. 30–32 for a brief discussion on the establishment of TK databases.
\item \textsuperscript{46} CBD COP 9, Decisions IX/13, supra note 44, C.
\end{itemize}
(c) Documentation of traditional knowledge, innovations and practices, is subject to the prior informed consent of indigenous and local communities; and
(d) Indigenous and local communities can make informed decisions regarding the documentation of their traditional knowledge, innovations and practices. . . .

The recommendation will prove particularly relevant in the elaboration of TK databases to provide defensive protection against the inappropriate claiming of TK-based inventions by third parties.

Among the COP's more ambitious charges is the development of a code of ethical conduct on respect for the cultural and intellectual heritage of indigenous and local communities relevant to the conservation and sustainable use of biological diversity. The code is intended to be voluntary, and its aim is to promote respect for and the preservation and maintenance of TK. The draft text last discussed at the ninth session of the COP in May 2008 was still tentative and preliminary, reflecting considerable disagreement among the parties over the scope of the code. It is thus too early to predict whether, and if so when, a final text will be approved, or what shape such a text might take. Many provisions of the current draft have several different options for discussion and the code's text is replete with alternative language within square brackets. Nevertheless, the draft code contains several worthy statements concerning the contours of acceptable conduct with respect to TK.

A foundational principle of the code, which has apparently found acceptance, is the preamble's recognition that "respect for traditional knowledge requires that it is valued equally with and complementary to Western scientific knowledge, and that this is fundamental in order to promote full respect for the cultural and intellectual heritage of indigenous and local communities relevant to the conservation and sustainable use of biological diversity." The code also recognizes that TK can be collectively or individually owned, and it states that "those interacting with indigenous and local communities should seek

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47. Id. C ¶ 1.
49. Id. Annex ¶ 1.
50. Even the draft title of the code contains alternative texts. The title is presented as "DRAFT Elements of a code of ethical CONDUCT TO [promote][ensure] RESPECT FOR THE CULTURAL AND INTELLECTUAL HERITAGE OF INDIGENOUS AND LOCAL COMMUNITIES RELEVANT TO THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY" (emphasis added). The differing texts concern apparent differences in opinion about the breadth of the code; for example, whether the code should apply to all uses of traditional knowledge "related to the conservation and sustainable use of biodiversity," or only to those uses "occurring on or likely to impact on, sacred sites and on lands and waters traditionally occupied or used by indigenous and local communities." Id. ¶ 10.
51. Id. ¶ 5. In G, Annex section paragraph 12, the code states that "Traditional knowledge must be respected as a legitimate expression of the culture, traditions, and of relevant indigenous and local communities."
to understand the balance of collective and individual rights and obligations."  

With those statements in mind, one of the focuses of the code is transparency in relations between TK holders and third parties in addressing intellectual property issues:

Community and individual concerns over, and claims to, intellectual property relevant to traditional knowledge, innovations and practices related to the conservation and sustainable use of biodiversity should be acknowledged and addressed in the negotiation with traditional knowledge holders and/or indigenous and local communities, as appropriate, prior to starting activities/interactions. [Knowledge holders should be allowed to retain existing rights, including the determination of intellectual property rights, over their traditional knowledge.]

In a later paragraph that is still especially tentative and unclear, third parties are called upon to fully disclose and inform indigenous and local communities "about the nature, scope and purpose of any proposed activities/interactions" they propose to undertake.

One of the areas of greatest disagreement in the draft seems to be the extent to which approval or prior informed consent should be sought before TK can be used by others. The current draft presents three options, which range from a blanket statement that "[t]raditional knowledge should only be used with the approval of the knowledge holders" to statements filled with lots of qualifiers. For example, a variation of one option would limit the ethical obligation for approval or prior informed consent (both of which are presented within square brackets) to "[a]ny activities/interactions related to biological diversity, conservation and sustainable use occurring on or likely to impact on [sacred sites and on lands and waters traditionally occupied or used by] indigenous and local communities and impacting upon specific groups. . . ."

52. id. ¶ 13. The paragraph goes on to say, in square brackets, that, "[The right of indigenous and local communities to protect, collectively or otherwise, their cultural and intellectual heritage should be respected.]" Agreement has not yet been reached on this last sentence.

53. id. ¶ 8. The sentence in square brackets has not been agreed to by the COP.

54. id. ¶ 10 ("Indigenous and local communities should be [fully] informed [to the fullest extent possible] about the nature, scope and purpose of any proposed activities/interactions carried out by others [that may involve the use of their traditional knowledge, innovations and practices related to the conservation and sustainable use of biodiversity] [occurring on or likely to impact on, sacred sites and on lands and waters traditionally occupied or used by indigenous and local communities]. [Subject to national law,] this information should be provided in a manner that takes into consideration and activity engages with the body of knowledge and cultural practices of indigenous and local communities.").

55. id. ¶ 11.

56. id. Option B.

57. id. Option A.
The deliberations concerning the code of ethical conduct point to strong international acceptance that users of TK should treat TK, and the holders of the knowledge, with transparency and respect. Whether such behavior encompasses an international ethical obligation to disclose the source of the TK and obtain the consent or approval of the TK holders is still the subject of disagreement, however. The absence of a harmonized international perspective adds compelling weight to the argument that countries wishing to establish a TK protection system may need to act on their own without the benefit of a firm international framework.

The TRIPS Agreement

While the CBD loosely supports using patents to protect TK, the TRIPS Agreement imposes constraints on the actions member countries may take. The TRIPS Agreement, which was elaborated during the 1986-1994 Uruguay Round of multilateral trade negotiations, introduced enforceable intellectual property rules into the multilateral trading system for the first time. The agreement was signed on April 15, 1994, and its membership is made up of all WTO member countries.

Although the TRIPS Agreement does not expressly cover patent protection for TK, it contains several provisions, including Articles 7 and 8, 27, 29, 32, and 62.1, which are especially relevant to the issue of disclosure of the source of TK in patent applications. In light of the CBD’s access and benefit sharing provisions, a number of studies have examined the conformity of the CBD’s obligations with the TRIPS Agreement, but those studies have reached inconsistent results. As the studies and deliberations continue with little progress toward consensus, it is unlikely that an international approach will emerge soon.

Basic Principles

Articles 7 and 8 state the objectives and underlying principles of the TRIPS Agreement. Article 7 emphasizes that intellectual property rights “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a bal-

ance of rights and obligations.” 59 Article 8 states as TRIPS principles that “[m]embers may . . . adopt measures necessary to . . . promote the public interest in sectors of vital importance to their socio-economic and technological development . . . .” and that “[a]ppropriate measures . . . may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which . . . adversely affect the international transfer of technology.” 60 Since using patents to protect TK would seem to promote social and economic welfare in a manner consistent with Articles 7 and 8, it may be assumed that TK protection furthers the objectives of, and has place within, the TRIPS Agreement.

Article 27 broadly regulates the scope of patentability under the agreement. It provides that WTO member countries must make patents available “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.” 61 The article further provides that countries may not discriminate “as to the place of invention, the field of technology and whether products are imported or produced locally.” 62 These statements clarify that member countries are not free to impose additional substantive conditions of patentability on the grant of patents, nor may they single out particular categories of inventions for arbitrary treatment. 63 Countries may nevertheless impose administrative requirements or additional substantive requirements concerning the entitlement to apply for a patent, for example, 64 without seemingly violating the Agreement.

Article 27 goes on to permit several exceptions to patentability, generally covering fields of technology that most countries have long deemed off limits to patent protection. According to Article 27.3, countries may exclude:

(a) diagnostic, therapeutic and surgical methods for the treatment of human or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Mem-

59. TRIPS Agreement, supra note 30, art. 7.
60. Id. art. 8.1-.2.
61. Id. art. 27.1.
62. Id.
63. Countries are free, however, to adopt different rules for particular technologies, provided that the differences in the rules can be supported by bona fide reasons. In holding that “discrimination” is not the same as “differentiation,” the WTO dispute resolution panel held in Canada – Patent Protection for Pharmaceutical Products, WT/DS 114/R, ¶ 7.92, (Mar. 17, 2000), available at http://docsonline.wto.org-WT/DS114/R, that “Article 27.3 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.”
64. See Sarnoff, supra note 58, ¶¶ 2.1.11–2.3.2, at 37–43 for a compelling argument that disclosure of TK obligations constitute a permissible substantive requirement concerning the entitlement to apply for a patent.
bers shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any effective combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.  

The review of Article 27.3(b) began in 1999, and in 2001 the adoption of the Doha Declaration added an extra focus of analysis. Paragraph 19 of the Doha Declaration instructs the member countries to examine the relationship between the TRIPS Agreement and the CBD, looking in particular at the protection of TK. As a result of the Doha Declaration, the protection of TK and the relationship between the CBD and the TRIPS Agreement have become integral parts of the WTO discussions.

**TRIPS and Disclosure of Origin**

Of primary concern in those discussions is the place of a disclosure obligation within the TRIPS Agreement. Responses vary greatly. On the one hand, a group of WTO member countries represented by Brazil and India has proposed an amendment to the TRIPS Agreement that would make disclosure an international requirement. Under the proposal, to remain in conformity with the TRIPS Agreement, WTO member countries would have to require patent applicants to disclose the country of origin of any TK used in inventions, to show evidence that they received prior informed consent, and to provide evidence of fair and equitable benefit sharing. On the other hand, the United States and several other countries have argued that contractual and other non-patent-law-based remedies are more appropriate mechanisms to prevent the misappropriation of TK. Until such time as member countries reach a common understanding with respect to TK disclosure, countries remain free to devise and implement their own TRIPS-compliant measures.

Article 29 of the TRIPS Agreement may help countries discern the contours of TRIPS compliance, especially with respect to TK disclo-

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65. TRIPS Agreement, *supra* note 30, art. 27.3(a)–(b).
69. The group includes Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, and Thailand, and is supported by the African group and other developing countries. *See Council for Trade-Related Aspects of Intellectual Property Rights, Note by the Secretariat: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, ¶ 71 & n.135, IP/C/W/368/Rev.1 (Feb. 8, 2006).*
70. Id. ¶ 71.
Echoing most national patent legislation, Article 29 requires "that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. . . ."72 With respect to inventions derived from TK, a cogent argument can be made that disclosure of the TK and the origin thereof is necessary to describe fully the background of the invention, how the invention came about, and how it is novel over the prior art.73 Since such a disclosure would seem to fall within the permissible scope of Article 29, there is little likelihood that it would be deemed to constitute an additional substantive condition of patentability prohibited by Article 27.74

Article 62.1 of the TRIPS Agreement, which gives member countries the right to establish reasonable procedures, would seem to support such an interpretation. The article provides that "[m]embers may require, as a condition of the acquisition or maintenance of [patent] rights . . . compliance with reasonable procedures and formalities . . . consistent with the provisions of this Agreement."75 Compelling disclosure and even requiring the submission of supporting evidence, such as a certificate of origin or benefit-sharing agreement, arguably fall within the confines of reasonable procedures that do not create an undue burden on patent applicants in much the same way that the inventor's oath and other requirements under US law are considered TRIPS compliant.76

What seem somewhat less clear are the consequences that may follow if a TK disclosure requirement is violated. At issue, in particular, is whether the TRIPS Agreement would permit a country to refuse to grant or to revoke a patent if an applicant did not comply with the disclosure requirement, or whether failure to comply would simply render a patent unenforceable. The answer seems to depend largely upon how that requirement is categorized. If, as Professor Joshua Sar- noff has argued, a requirement to disclose the source of TK is adopted expressly as a substantive condition of entitlement to apply for and own a patent, there is nothing in the TRIPS Agreement to prohibit a

72. TRIPS Agreement, supra note 30, art. 29.
73. See, e.g., DUTFIELD, supra note 19, at 112.
74. For a contrary view, see Carvalho, supra note 58, at 121.
75. TRIPS Agreement, supra note 30, art. 62.1.
76. See 35 U.S.C. § 115 (2006), which provides, "The applicant shall make oath that he believes himself to be the original and first inventor of the process, machine, manufacture, or composition of matter, or improvement thereof, for which he solicits a patent; and shall state of what country he is a citizen." Similarly, 35 U.S.C. § 202(c)(1) (2006) requires small business firms or non-profit organizations that receive Federal Government funding to mention in the patent application that the invention was made under Federal financial assistance.
country from coupling the requirement with reasonable remedies, including rejection of the application or revocation of patent rights.\textsuperscript{77}

Professor Sarnoff's argument can find support in Article 32 of the TRIPS Agreement, which provides for the right of judicial review. Under Article 32, member countries must make available "[a]n opportunity for judicial review of any decision to revoke or forfeit a patent..."\textsuperscript{78} This provision is noteworthy in that it does not limit the grounds on which a patent may be invalidated; in fact, the TRIPS negotiators specifically rejected a proposal to limit the grounds for revocation or forfeiture to the substantive criteria for patentability.\textsuperscript{79} Provided applicants or patentees had recourse to judicial review flowing from their failure to comply with TK disclosure requirements, Article 32 would not be a stumbling block to TRIPS compliance, but rather would tend to support it.

Even if disclosure of the source of TK were not considered a substantive condition of entitlement to apply for a patent, compliance with the TRIPS Agreement would still be achievable, provided that failure to disclose the TK did not render the invention unpatentable but rather made the patent unenforceable, especially if an opportunity to correct the failure were available. Such an approach would treat disclosure as a simple administrative requirement in compliance with the TRIPS Agreement.

While conformity of TK protection with the TRIPS Agreement has given rise to considerable discussion and debate, careful crafting of TK protection provisions at the national or regional level, especially concerning disclosure of origin requirements, should allow national or regional legislation to escape any potential TRIPS pitfall.

\textit{The PCT}

The PCT, a treaty that was concluded in 1970, entered into force in 1978, and is administered by WIPO, creates a unified procedure to facilitate the filing of patent applications worldwide. Under the PCT framework, applicants can acquire patent rights in any number of PCT member countries\textsuperscript{80} by filing a single "international" application instead of having to file separate applications in every country in which they seek protection. All applications receive a non-binding search of the prior art by a major patent office and are published by the International Bureau of WIPO, which gives PCT applicants provisional

\textsuperscript{77} See Sarnoff, \textit{supra} note 58, 3, \textit{\underline{\underline{\text{2.2.8-2.2.10.}}}}. Sarnoff cautions, however, that it would be prudent to give applicants or patentees the opportunity to cure failures to disclose the source of the TK, even intentional ones, with permanent loss of rights.

\textsuperscript{78} TRIPS Agreement, \textit{supra} note 30, art. 32.

\textsuperscript{79} See Sarnoff, \textit{supra} note 58, at 42.

\textsuperscript{80} At the time of drafting this article, the number of PCT member countries was 139.
rights. The PCT has become today's standard means of obtaining international patent protection.

The PCT process is divided into two phases: a first international phase, during which the provisions of the treaty and its accompanying regulations govern the prosecution and processing of applications; and a national phase, when international applications are converted into bundles of national applications and national law and practice generally prevail. The PCT raises issues regarding TK protection in at least two respects, and while both directly concern the international phase, they have national phase implications. The first issue concerns the extent to which countries are free to create rules, in particular relating to the disclosure of origin of TK, that have an impact on the international phase. The second concerns the extent to which the non-binding prior art search that occurs during the international phase is likely to identify and properly search inventions based on TK.

National Rulemaking

With respect to national rulemaking, Article 27(1) of the PCT provides that "[n]o national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations." Rules 4 and 51bis.1 of the Regulations generally govern the permissible contents of an inter-

81. Article 6(1) of the Patent Law Treaty (PLT) – a treaty aimed at harmonizing national patent law procedure – contains an analogous provision:

6(1) [Form or Contents of Application] Except where otherwise provided for by this Treaty, no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to:

(i) the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty;
(ii) the requirements relating to form or contents compliance with which, under the Patent Cooperation Treaty, may be required by the Office of, or acting for, any State party to that Treaty once the processing or examination of an international application, as referred to in Article 23 or 40 of the said Treaty, has started;
(iii) any further requirements prescribed in the Regulations.

Patent Law Treaty, art. 6(1), June 1, 2000, 39 I.L.M. 1049 (2000), available at http://www.wipo.int/treaties/en/ip/plt/trtdocs_wo038.html#P105_12369. The PLT entered into force on April 28, 2005, but, at the time of drafting this article, had only 18 member countries. The United States is a signatory but has not yet ratified the treaty. Although the PLT is not covered separately in this article, wherever relevant, anything said about the PCT should be considered to apply analogously to the PLT.

82. PCT, supra note 31, art. 27(1).

83. Regulations under the Patent Cooperation Treaty, Rule 4, 51bis.1, June 19, 1970 (as in force from July 1, 2008), available at http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct_regs2008.pdf [hereinafter PCT Regulations], Rules 4 and 51bis.1. With regard to Rule 4, which is quite lengthy, the provisions that are particularly relevant to the question of the declaration of the source of TK are 4.1(c)(iii), 4.17, and 4.18(a).
national application. Although the rules permit applicants to include certain declarations\(^8\) in the international application form concerning which national patent offices may require evidence or documentation, a declaration concerning the source of TK used in the invention is not one of the declarations mentioned.\(^9\) To remedy this gap, in May 2003 the Government of Switzerland proposed an amendment to the PCT Regulations that would explicitly enable national patent laws to require the declaration of the source of traditional knowledge in international patent applications.\(^10\) Despite repeated discussion at PCT meetings, the proposal failed to achieve consensus among the PCT member countries and has not been adopted.\(^11\)

Nevertheless, the PCT should not be viewed as preventing national laws from addressing the issue of disclosure and benefit sharing in the national phase, particularly if the penalty for failure to disclose or share benefits is linked to the enforceability of patent rights. Countries are free to treat patents granted on the basis of PCT applications just as they would treat patents granted from national applications. Nothing in the PCT, therefore, prevents countries from holding patents unenforceable if the patent holders fail to meet a disclosure obligation.

An argument can also be made that the PCT tacitly permits patent offices to invalidate national phase applications or revoke the resulting patents if they do not disclose the source of TK. Article 27(3) of the PCT provides that "[w]here the applicant, for the purposes of any designated State, is not qualified according to the national law of that State to file a national application because he is not the inventor, the

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84. See id. Rule 4.17, which permits declarations that correspond to the matters set out in Rule 51bis.1(a)(i) to (v), including declarations as to the identity of the inventor, the applicant's entitlement to apply for and be granted a patent, the applicant's entitlement to claim priority, inventorship, and non-prejudicial disclosures. Rule 4.18(a), PCT Regulations, prohibits national laws from requiring applicants to furnish more information at the international phase than is required under the regulations.

85. It is worthwhile noting that the rules apply only to the contents of the application form, not to the body (the description of the invention) of the application. Therefore, applicants would be expected to declare the TK as well as the source thereof in the description if doing so were essential to meeting the enablement requirement.


87. The principal opponents of the proposal were a group of industrialized countries led by the United States that opposed in principle any requirement of disclosure, and a group of developing countries led by Brazil and India that preferred to see a broader resolution of the issue within the context of the TRIPS Agreement.
international application may be rejected by the designated Office."\textsuperscript{88}

Since disclosure of the source of TK may be critical in determining whether the named inventor in the international application has legitimate inventorship rights in accordance with national law, it would make sense to view Article 27(3) as tolerating a disclosure requirement for the purpose of assessing inventorship rights. This type of approach, which is based on treating disclosure as a substantive condition of entitlement to apply for a patent,\textsuperscript{89} would likely meet with opposition from a substantial number of countries, including the United States.\textsuperscript{90}

**PCT International Search**

The second issue—the extent to which the PCT international search is likely to identify inventions that are derived from and anticipated by TK—is most closely related to the defensive protection of TK. The issue is governed largely by PCT Article 15 on The International Search and Rule 34 of the PCT Regulations on Minimum Documentation. Article 15(1) states that "[e]ach international application shall be the subject of international search."\textsuperscript{91} That search is carried out by one of fifteen designated International Searching Authorities, all of which are major patent offices.\textsuperscript{92} Although the international search is preliminary and non-binding, countries, especially developing ones, tend to rely on it for patenting decisions in the national phase, and applicants look to it as an early predictor of the likelihood that their patent applications will achieve success.

The objective of the search, according to Article 15(4) is to "discover as much of the relevant prior art as [the searching authority's] facilities permit," but the authority "shall, in any case, consult the documentation specified in the Regulations."\textsuperscript{93} Rule 34 specifies that the required documentation, referred to as "Minimum Documentation," should consist of patents granted by designated countries, published PCT applications, and "such other published items of non-patent literature as the International Searching Authorities shall agree

\textsuperscript{88.} PCT, *supra* note 31, art. 27(3).

\textsuperscript{89.} See Sarnoff, *supra* note 58, ¶ 2.4.5–2.4.8.

\textsuperscript{90.} As was mentioned above (*supra* note 76), the United States Patent Act itself contains a substantive condition of entitlement to apply for a patent. Section 115 of the Act, 35 U.S.C. § 115, requires that all applications filed in the United States be accompanied by an oath or declaration from the claimed inventors that they believe themselves to be the original and first inventors of their claimed inventions.

\textsuperscript{91.} PCT, *supra* note 31, art. 15(1).

\textsuperscript{92.} The current International Searching Authorities are the patent offices from the following countries and organizations: Australia, Austria, Brazil, Canada, China, European Patent Office, Finland, India, Japan, Korea, Nordic Patent Institute, Russia, Spain, Sweden, and the United States. U.S. applicants are authorized to use the United States Patent and Trademark Office, the European Patent Office, the Korean Intellectual Property Office, and the Australian Patent Office.

\textsuperscript{93.} PCT, *supra* note 31, art. 15(4).
The non-patent literature consists primarily of technical journals and, until 2005, included no literature related to TK. As a result, even if a claimed invention had been directly derived from TK, an examiner carrying out an international search would have had virtually no chance of locating prior art relating to that knowledge. Inventions not worthy of patent protection would accordingly receive "clean" international search reports.

Beginning in 2004, the PCT International Searching Authorities began adding journals of TK to the list of non-patent literature included in the PCT minimum documentation. Currently the list contains fourteen journals. While it is too early to determine whether this exercise has had any impact, it is at least a start. For the PCT minimum documentation to have an impact on the protection of TK, it will be essential that more TK journals are added to the list and that patent examiners, particularly those who work in relevant technical fields such as life sciences and environmental technology, receive training and awareness in TK and TK systems.

The international framework created by the CBD, the TRIPS Agreement, and the PCT thus provides support for, but also imposes some limitations on, using patents to protect TK. The three agreements allow the adoption of legislation and other measures that would permit countries to implement all three prongs of TK protection, but they also set parameters that may restrict the options countries have. The following sections will look in greater depth at the characteristics of the three prongs of TK protection and will highlight a few of the efforts of countries that have attempted to put protection systems into place.

DEFENSIVE PROTECTION OF TK

The purpose of defensive protection is to prevent anyone other than the holders of TK from acquiring patent rights over their knowledge. The protection is defensive in that it serves to preserve the TK holders' right to use the TK they created against any third party who may later seek to patent inventions derived from it. Defensive protection

94. PCT Regulations, supra note 83, Rule 34.1(b)(iii).
97. For example, it is not known to what extent, if any, international search examiners are aware of TK and TK systems, and include TK journals in their search processes.
entails intentionally disclosing information about the invention, knowledge, or technology so that the information may count as prior art and defeat any third-party patent application which claims the TK and which, if granted, could interfere with the TK holders’ right to use their knowledge.

Defensive protection is thus directly linked to the patent law notion of prior art, which can loosely be defined as information made available to the public prior to the filing, priority, or invention date of the patent application. An invention is deemed worthy of patent protection if it is both novel and non-obvious.98 Determining whether an invention meets those requirements requires a patent examiner to compare and analyze the claimed invention in relation to the relevant prior art. An examiner will find in favor of patentability if the invention is neither anticipated by the prior art nor rendered obvious by it. Because examiners assess patentability in light of the prior art, defensive protection can succeed as a strategy only if TK is effectively included in the prior art, which, in turn, depends upon two critical factors: that the holders of TK document or disclose information about the knowledge in such a way as to meet national patent law requirements to be counted as prior art; and that the information is available to patent examiners in a readily accessible manner so that it is likely to be found in a prior art search.99

Challenges to Defensive Protection

A challenge to the protection of TK is that national and regional requirements vary as to what standards prior art must meet in order to count in the assessment of patentability. Laws differ, for example, on whether prior art may include oral disclosures or use of the technology, or whether the disclosure must occur in written form. Even if oral disclosures or use are included within the prior art, legislation often requires that the disclosure or use must have occurred locally. As a result, orally disclosed TK or TK used in another country may constitute prior art in some countries or regions, but not in others. As much TK is communicated orally and used locally, this limitation is problematic.

98. To be patentable, an invention must also fulfill a utility requirement (i.e., it must be useful or industrially applicable), but that requirement is not directly relevant to the issue of prior art. See, however, the discussion on affirmative patent protection, infra, where the utility requirement is briefly discussed.

The European Patent Convention\textsuperscript{100} and the Japan Patent Act,\textsuperscript{101} which both define prior art as including oral disclosures and use without geographical limitation, are examples of legislation most favorable to successful defensive protection. Article 54(2) of the Convention provides that prior art "shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application."\textsuperscript{102} Similarly, under Article 29 of the Japanese act:

(1) An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention, except for the following:
(i) inventions that were publicly known in Japan or a foreign country, prior to the filing of the patent application;
(ii) inventions that were publicly worked in Japan or a foreign country, prior to the filing of the patent application; or
(iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country, prior to the filing of the patent application.\textsuperscript{103}

In contrast, the PCT definition restricts the scope of prior art to written disclosures only. Rule 33.1 of the PCT Regulations provides as follows:

[R]elevant prior art shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (i.e., that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date.\textsuperscript{104}

Another example of legislation that poses a challenge to defensive protection for TK is the United States Patent Act. Section 102(a) of the Act\textsuperscript{105} defines prior art as encompassing oral disclosures or use

\textsuperscript{100} Conference of the Parties to the Convention on Biological Diversity [CBD], \textit{Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization}, Decision VI/24/A, UNEP/CBD/COP/6/20 (Apr. 7–9, 2002), \textit{available at} http://www.cbd.int/decisions/?m=cop-06&d=24 [hereinafter Bonn Guidelines].


\textsuperscript{102} Bonn Guidelines, supra note 100 (using the term "state of the art" synonymously with prior art).

\textsuperscript{103} Patent Act No. 121 of 1959 art. 29(1).

\textsuperscript{104} PCT Regulations, supra note 83, Rule 33.1(a). Although this definition governs only the non-binding international search carried out during the international phase of the PCT, the results of that search, especially if they are positive, carry persuasive weight in national patent grant procedures in many countries.

only if the acts occurred in the United States; written disclosures, how-

ever, are included regardless of where they occurred. The section
states, “A person shall be entitled to a patent unless (a) the invention
was known or used by others in this country, or patented or described
in a printed publication in this or a foreign country, before the inven-
tion thereof by the applicant for patent.”106

The difficulty that narrow definitions of prior art pose is that they
shift the burden to the holders of TK to ensure that the knowledge is
disclosed in a manner sufficient to be included in the prior art. Meet-
ing this burden is not only onerous and inconsistent with the manner
in which TK is typically held and managed, but at times it may prove
counterproductive to the best interests of TK holders. Defensive pro-
tection alone—without the assertion of affirmative patent rights—en-
tails placing in the public domain TK that may otherwise be
undisclosed, secret, or inaccessible and giving access to it to the public.
Such a move could mean that TK holders would forego the possibility
of acquiring patent rights over the disclosed knowledge, or they could
lose whatever trade secret protection they had previously secured. By
making undisclosed information easily accessible, moreover, defensive
protection could contribute to enabling the unauthorized use of the
very TK that the holders wish to protect.107 Communities that em-

bark on strategies of defensive protection therefore need to make cer-
tain that the TK they disclose is knowledge they wish to make publicly
available. For that reason, defensive protection against third-party
misappropriation is perhaps most effective in protecting TK that is
already in the public domain.

**Keys to Defensive Protection**

With that caution in mind, TK holders who choose to make use of
defensive protection also need to ensure that the strategies they em-
ploy are effective. The WIPO IGC has drafted several practical
guidelines that should be considered whenever TK-related informa-
tion is published.108 The following summarizes some of those
guidelines.

106. *Id.* A comparison of the description of what constitutes prior art in the Euro-

on which disclosures constitute prior art for the purpose of assessing patentability.
The European Patent Convention – as well as the legislation of all other countries –
provides that the effective date is the date of filing of the patent application; the U.S.
Patent Act, however, provides that it is the date on which the claimed invention was
reduced to practice. See generally Margo Bagley, *Patently Unconstitutional: The Geo-


107. See WIPO, *Recognition of Traditional Knowledge*, supra note 9, ¶ 14, in this
regard.

One of the most important is that the disclosure should be publicly available and contain an unambiguous publication date. For prior art to be considered relevant in the examination of a patent application, the prior art must have been made available to the public (not simply written down and set aside) before the filing, priority, or invention date of the application. If the date cannot be determined, the information will be ignored. A clear and unambiguous publication date is especially important in the case of internet-based prior art disclosures. Because the date of posting of internet-based content is often unclear, and internet databases and websites can be easily amended, it is critical that prior art information posted on the internet remain consistently available and the date of posting of the information (as well as the dates of posting of any subsequent or supplementary information) be readily determinable.

The content of the disclosure is also of prime importance. The publication should ideally contain a complete and comprehensive description of the innovative or technological concept behind the TK. Incomplete disclosures leave open the possibility that patent claims on undisclosed aspects of the TK will be considered valid. The publication should also strive to include descriptions of uses of the TK, both those that have already been demonstrated and other more speculative ones, and it should aim to describe the technological concept behind the TK in a sufficient enough manner to meet the patent law requirement of enabling a person skilled in the art to carry out the invention. Although the content should therefore be as complete as possible, there is at least one element that it should avoid including. The disclosure should steer clear of statements about the TK's limitations or about what the TK cannot do, since such statements may result in strengthening the patent applications of inventions that claim to overcome the TK's shortcomings.

**TK Databases**

As mentioned above, unless the information is available to the public, it cannot constitute prior art. From the perspective of defensive protection, the requirement of public availability means ensuring that information about TK can be found easily by both researchers and patent examiners. One of the most effective ways to achieve the objective of public availability, in addition to publication in TK technical journals, is by including information about the TK in an accepted TK database.

109. *Id.* ¶ 24(b). When TK is being cited as prior art because it was publicly used, the ability to pinpoint the date upon which the use first occurred is as crucial as being able to establish a clear publication date.
110. *Id.* ¶ 24(c).
111. *Id.* ¶ 24(d).
112. *Id.*
While the number of TK databases worldwide is still limited, a few stand out as having amassed a considerable collection of reliable data. Principal among those is the Indian Traditional Knowledge Digital Library (TKDL). Begun in 2001, the TKDL is a collaborative project of a number of Indian Government institutes and ministries, the objective of which is to document the body of knowledge that is available in the public domain on the traditional Indian systems of medicine and to protect that knowledge from misuse by third parties attempting to obtain patents on non-novel and obvious innovations. The staff of the TKDL consists of traditional medicine experts, patent examiners, IT experts, scientists, and technical officers, whose job it is to compile and reference centuries-old TK that has been described in ancient texts in Sanskrit, Urdu, Persian, or other generally inaccessible languages and passed down by word of mouth. The TKDL also provides the contemporary names for the medicinal plants, diseases, and processes described in the texts, establishes the relationship between that TK and modern concepts, and presents its data on the Internet in English, French, German, Japanese, and Spanish in patent application format easily understandable by patent examiners. The database currently contains more than 200,000 formulations from the principal traditional Indian medicine systems, including Ayurveda, Unani, and Siddha. Typical of patent databases, it is important to note that the TKDL does not itself constitute the prior art; the TKDL serves as the reference tool that points examiners to the texts that constitute it. Consequently, the prior art dates of the references included in the TKDL are generally vastly older and bear no relation to the dates on which the references were added to the database.

An additional important contribution of the TKDL was the creation of the Traditional Knowledge Resource Classification (TKRC), which is a structured classification system based on the International Patent
Classification (IPC)\textsuperscript{118} that facilitates the arrangement, dissemination, and retrieval of the information included in the TKDL.\textsuperscript{119} The TKRC has greatly expanded the system of classifying traditional medicine by adding about 25,000 subgroups relating to medicinal plants, minerals, animal resources, and methods of medicinal preparation and administration as compared to the very few subgroups that had been included in the IPC. The success of the TKRC has also led to a substantial increase in the IPC’s coverage of TK, in particular, to the inclusion of more than 200 subgroups covering different categories of medicinal plants, and to the establishment of linkages between both classification systems.\textsuperscript{120}

Two additional models of TK databases come from China and focus on Traditional Chinese Medicine: the China TCM Patent Database,\textsuperscript{121} and the Chinese Medical Literature Analysis and Retrieval System (TCMLARS).\textsuperscript{122} The TCM Patent Database was developed within the State Intellectual Property Office of China initially to assist patent examiners. It now exists also in English and is fully accessible to the public. The database includes over 22,000 patent records dating from 1985 to the present and 40,000 Traditional Chinese Medical formulations. It also possesses a sophisticated classification system and easy-to-use search tools. TCMLARS,\textsuperscript{123} which is administered by the Academy of Traditional Medicine, is a database of information contained in more than 800 biomedical journals published in China since 1984, and it currently contains about 68,000 records, which are all extensively indexed. A portion of TCMLARS exists in English.

The Indian and Chinese databases are models for other countries to emulate.\textsuperscript{124} They call attention to the importance of TK and make it feasible for patent examiners to discover TK-related prior art. The addition of a broad range of TK databases would have the dual bene-

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{118} For background about the IPC, see http://www.wipo.int/classifications/ipc/en/ (last visited on Feb. 23, 2009).
\item \textsuperscript{120} See About TKDL, http://www.tkdl.res.in/tkdl/langdefault/common/AboutTKDL.asp (last visited Feb. 27, 2009).
\item \textsuperscript{123} An excellent description of TCMLARS can be found in Weiyu Fan, \textit{The Traditional Chinese Medical Literature Analysis and Retrieval System (TCMLARS) and Its Application}, 35 \textit{Int’l J. Special Libr.} 147 (2001).
\item \textsuperscript{124} For a list of other online databases containing TK documentation, see Manuel Ruiz, \textit{Ctr. For Int’l Envtl. Law, The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries} 22–23 (2002), available at http://www.ciel.org/Publications/PriorArt_ManuelRuiz_Oct02.pdf.
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fit of making it easier for the holders of TK to engage in defensive protection while increasing the integrity of the patent system by preventing the grant of invalid patents.

**Patent Monitoring**

There is yet an additional element to effective defensive protection: monitoring patent applications and patent grants to take action against those who inappropriately claim TK. While patent monitoring is a fairly costly and burdensome task, it would be rendered much more practicable if patent applicants were required to disclose the source of any TK from which the claimed invention was derived or upon which it was based. The following section will discuss mandatory disclosure of the source of TK and provision for benefit sharing, which is the middle prong of TK protection.

**Disclosure of the Source of TK and Benefit Sharing**

Requiring the disclosure of the source of TK in patent applications has multiple benefits. Disclosure calls attention to whether the TK holders have claims of inventorship or ownership rights in the invention, and it signals the need to include TK within the scope of the prior art search. It also aids in ensuring that the patent applicant has obtained the prior informed consent of the TK holders, and it monitors enforcement of access and benefit-sharing obligations in conformity with CBD Article 8(j) obligations.¹²⁵

**Inventorship**

The issue of whether an applicant or inventor is entitled to apply for a patent or claim inventorship rights is distinct from the question of whether an invention is patentable. With respect to inventions derived from TK, the question of inventorship and entitlement becomes particularly relevant when the holder of the TK is not acknowledged in the patent application. Since the TK holder may be entitled to claim inventorship or ownership rights in the TK-based invention, determining the TK holders’ status may have an important impact on the validity of the application or any ensuing rights.

It is a firmly established principle that “[t]he inventor shall have the right to be mentioned as such in the patent”¹²⁶ even if the inventor has no rights in the patent itself. According to the secretariat of WIPO:

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Identifying the inventor or inventors is fundamental as the patent right is derived, directly or indirectly, from the act of invention. An applicant who does not have the required relationship with the actual inventor or inventors (e.g., as the inventor, as the inventor's relevant employer, or otherwise as successor in title) is not entitled to a patent right, even if the patent is otherwise fully valid on substantive grounds (novel, inventive, and industrially applicable). . . .

Failure to declare an inventor or joint inventor may therefore prejudice the patent right.

An inventor or patent applicant whose claimed invention is derived from the TK of others may not have any entitlement to a patent. The patent law and practice of most countries requires that an invention be the original work of the person named as the inventor in the patent application. If that person did not conceive the invention but rather based it in whole or in part on the conception of another, the patent application may be rejected or the patent deemed invalid in the absence of naming the other person as the inventor or co-inventor.

In the United States, inventorship is governed generally by Section 102(f) of the Patent Act, 35 U.S.C. § 102(f). The section provides that a person is not entitled to a patent if "he did not himself invent the subject matter sought to be patented." In interpreting the provision, courts have held that it is proper to reject patent applications under Section 102(f) when it can be shown that the applicant derived the invention from another. Applying this principle, which can be found in most patent laws worldwide, the secretariat of WIPO has suggested the following scenario:

A patent application claims a combination of known traditional ingredients, with the claim that it has a surprising therapeutic effect. This surprising effect may have been disclosed by a traditional medical practitioner, who had discovered it during the course of their own experimentation and adaptation of traditional healing methods. In this case, the traditional healer may be the actual inventor, and the title to apply for a patent may need to be legally derived from that person.

127. WIPO, Recognition of Traditional Knowledge, supra note 9, ¶ 42.
130. WIPO, Recognition of Traditional Knowledge, supra note 9, ¶ 47. The example goes on to raise an issue that will be discussed under the section on affirmative protection for TK: "If the effect, claimed to be surprising, apparently seems to be consistent with an established traditional medicine system then it may be necessary to consider whether it would be obvious to a person skilled in the art, a test which may include practitioners of this form of traditional medical knowledge." Id.
Even if the traditional medical practitioner were not entitled to full inventorship rights under the law of a particular country, it is likely that the practitioner would be declared a co-inventor. In the United States, Section 116 of the Patent Act, 35 U.S.C. § 116, sets the standard for joint inventorship by providing that it is not necessary for a co-inventor to "make a contribution to the subject matter of every claim of the patent." Therefore, it would be proper to name a TK holder as an inventor on a patent application containing 10 claims, for example, even if the TK holder contributed to the conception of just one of them.

The United Kingdom seems to have adopted a similar approach. At least one case has held that the person who generated the idea for an invention but did little else had made a significant enough inventive contribution to be treated as a co-inventor. Analogizing to TK, where an applicant or inventor would not have developed an invention without the knowledge and prompting of the TK holder, the holder would be entitled to co-inventor status, which might also include ownership rights. Requiring disclosure is therefore a valuable mechanism to assure that rights of inventorship and ownership go to those who deserve them.

Approaches to Disclosure

Disclosure is also a direct and effective means of ensuring compliance with the prior informed consent and fair and equitable benefit-sharing obligations of Article 8(j) of the CBD. Countries that have disclosure provisions in place have adopted various approaches. While some countries or regions have introduced legislation directly into their patent law, others have adopted separate legislative mechanisms, and still others have combined both. India and the

132. See, e.g., Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998) ("[a] contribution to one claim is enough.").
134. See, for example, Law on the Protection of Intellectual Property Rights (2003) (Egypt), available at http://www.egypo.gov.eg/inner/english/PDFs/law2002e.pdf. Article 13 of the Law provides in part that “[w]here the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner,” and Article 14 states that “[t]he Patent Office may, as stipulated in the Regulations, require the applicant to make any amendments or complements which it shall deem necessary to comply with the provisions of Article 13. If the applicant fails to comply within three months of notification, he shall be considered as having withdrawn his application.”
Andean Community are two that have followed a combined and comprehensive approach.

In 2002, the Indian Parliament adopted the Patents (Amendment) Act (No. 38 of 2002). An important objective of the amendments was to prevent the misappropriation of TK associated with genetic resources. To accomplish this goal, the act not only makes it obligatory to disclose the source and geographical origin of any biological material used in an invention, it also punishes the failure to do so by adding two new grounds for opposition or revocation of a patent: “that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;” and “that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.” Furthermore, the Act adds TK to the list of things that are not considered to be inventions within the meaning of the Act and thereby prohibits the patenting of TK per se. Nevertheless, inventions based on TK remain eligible for patent protection.

The Indian Patents Act does not oblige the patent applicant to obtain the prior informed consent of the TK holder or to enter into a benefit-sharing agreement concerning the use of the TK. However, an associated act, entitled the Biological Diversity Act, 2002, requires patent applicants for inventions based on genetic materials of Indian origin to obtain the prior informed consent of the National Biodiversity Authority, and it permits the Authority to impose benefit-sharing fees or royalties on the commercial use of the invention. Sections 6(1) and (2) of the Act provide in part as follows:

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137. The Patents (Amended) Act of 2002 § 8(a), amending section 10(4)(d) of the principal act, The Patents Act, No. 39 of 1970 (as amended by The Patents (Amendment) Act, 1999) (requiring the applicant to “disclose the source and geographical origin of the biological material in the specification, when used in an invention.”). The Patents Act has since been amended by The Patents (Amendment) Act, No. 15 of 2005, India Code (2005); however, these latest changes did not modify the 2002 amendments regarding disclosure.

138. The Patents (Amended) Act of 2002 §§ 18(a), 31(a)(v) (amending §§ 25(1) and 64(1) of the principal Act).

139. The Patents (Amended) Act of 2002 § 4(e) (amending § 3 of the principal Act). The amendment provides that “an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components” is not an invention within the meaning of the Act, § 4(e).

140. See Gopalakrishnan, supra note 58, at 17.


142. Id. cl. 6(1)–(2).
(1) No person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:
Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned.

(2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.\footnote{Failure to obtain prior informed consent or to comply with benefit sharing arrangements is punishable under the Act with imprisonment or a fine,\footnote{but violations of the Biological Diversity Act are not actionable under the Patents Act. Therefore, there is no authority under the Patents Act to oppose or revoke patents on the ground that the National Biodiversity Authority failed to grant approval, a gap that has been criticized by at least one commentator.\footnote{The National Biodiversity Authority is a government agency established by the 2002 Act to help India realize the objectives of the CBD.\footnote{The Authority is headed by a chairperson "who shall be an eminent person having adequate knowledge and experience in the conservation and sustainable use of biological diversity and in matters relating to equitable sharing of benefits," and by members representing all government ministries with interests in tribal affairs and science and technology.\footnote{In addition to the Authority's mandate to grant prior informed consent and impose benefit sharing arrangements, the Authority has jurisdiction to regulate activities related to biodiversity and to grant foreigners permission to obtain and use biological and genetic resources.\footnote{Because the Biological Diversity Act is distinct from the Patents Act, the Indian Patents Office is not represented on the National Biodiversity Authority.\footnote{The Andean Community has also implemented a mandatory disclosure regime. The Andean Community is an economic community consisting of Bolivia, Colombia, Ecuador, and Peru "that decided voluntarily to join together for the purpose of achieving more rapid, better balanced and more autonomous development through Andean,}}}}}}
South American and Latin American integration.\textsuperscript{150} Decision 391 of the Andean Community, which establishes a Common Regime on Access to Genetic Resources,\textsuperscript{151} and Decision 486 establishing a Common Intellectual Property Regime\textsuperscript{152} together provide that patent applications must contain a copy of the contract or authorization for access if the claimed invention was obtained or developed from genetic resources or TK originating in one of the member countries. They further provide that patent rights are not valid if they were obtained or used in violation of the terms of the contract or authorization for access.

An objective of Decision 391 is "to recognize the historic contribution made by the native, Afro-American, and local communities . . . "\textsuperscript{153} each of which it defines as "a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them."\textsuperscript{154} In keeping with its objective, as well as with the CBD, Article 7 of Decision 391\textsuperscript{155} directs the member countries to "recognize and value the rights and the authority of the native, Afro-American and local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products." The Decision therefore establishes a multi-layered access to biological or genetic resources application and authorization procedure that requires the execution of an access contract containing fair and equitable benefit sharing provisions.\textsuperscript{156} Persons violating the Decision are subject to punishment, including "administrative sanctions, such as fines, preventive or definitive confiscation, temporary or definitive closing-down of establishments and disqualification of the violator from applying for new accesses in cases of violation of this regime."\textsuperscript{157} In addition, member countries are directed not to acknowledge, as well as to request or bring nullification actions against, patents "that were obtained or de-

\begin{footnotesize}
\textsuperscript{153} Decision 391, supra note 151, para. 5.
\textsuperscript{154} Id. art. 1.
\textsuperscript{155} Id. art. 7.
\textsuperscript{156} Id. tit. V.
\textsuperscript{157} Id., arts. 46, 47.
\end{footnotesize}
veloped through an access activity that does not comply with the provisions of this Decision."\(^{158}\)

Decision 486, which creates a common intellectual property law for the Andean Community member countries, reinforces the principles established in Decision 391. Article 26(i) of the Decision not only requires that a patent application disclose the source of any TK used in an invention, it also mandates that the application be accompanied by evidence of authorization to use the TK:

Applications for patents shall be filed with the competent national office and shall contain:

... if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391. ...\(^ {159}\)

Moreover, the Decision gives the national patent offices the authority to declare invalid any patent in the event the applicant failed to submit the requisite documentation:

The competent national authority may, either ex officio or at the request of a party, and at any time, declare a patent null and void, where:

... when pertinent, the products or processes whose protection is being requested have been obtained or developed on the basis of traditional knowledge belonging to indigenous, African American, or local communities in the Member Countries, if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the Member Countries. ...\(^ {160}\)

The Andean Community legislation provides a relatively strong level of TK protection. Because the Decisions directly link disclosure and benefit sharing to the patent application process and permit the invalidation of patents that fall short of the disclosure requirements, the Andean Community provisions are particularly far reaching. Nevertheless, Decisions 391 and 486 have no effect when misappropriation of TK occurs outside the Andean Community in countries that do not have similar regimes in place. This weakness is unfortunately inherent in all national TK protection systems.

\(^{158}\) Id., Complementary Provisions, 2d.
\(^{159}\) Decision 486, supra note 152, art. 26(i).
\(^{160}\) Id. art. 75(h).
USING PATENTS

AFFIRMATIVE PATENT PROTECTION

The view has been expressed that patent protection is not appropriate for TK. A few of the reasons given are that TK is generally collective, it is developed over time, and TK holders do not often employ Western scientific method. While those assertions may be true for certain categories of TK, much of TK, in particular traditional medicine, contains technical solutions that may meet the requirements for, and benefit from, patentability. This section will look at the possibilities, limitations, and challenges of patenting TK.

Challenges to Affirmative Protection

One of the asserted challenges concerns the community nature of TK ownership. If TK is held by the community as a whole, one may question whether the community, and not an individual, may be the holder of a patent. Professor Daniel Gervais has contended, correctly so in the opinion of this author, that “[t]o recognize a community as owner of a patent is not a particularly difficult conceptual jump... [and] does not threaten the foundations of intellectual property as it currently exists.” Neither TRIPS nor the PCT imposes rules on ownership, and community ownership is little more than an extension of joint ownership, which is quite common. Assuming the traditional community itself is not culturally averse to asserting ownership rights, that an inventor or inventors can be identified, and that some mechanism exists, including customary law, to transfer the rights from the inventor or inventors to the community, community ownership is perhaps the least of the challenges that TK patenting faces.

In addition to the patent law requirement of novelty, discussed above, the requirements of non-obviousness and utility raise particular issues with respect to TK. A patent examiner’s determination of whether or not an invention is obvious generally depends upon how that invention would be viewed by a “person skilled in the art,” in other words, a person possessing ordinary knowledge and skill in the technical area of the invention. As Professor Gervais has noted, however, “there is an inherent difficulty stemming from the fact that a determination of who is ‘skilled’ and what constitutes the relevant


162. The World Health Organization (WHO) defines traditional medicine as “the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses.” WHO, Fact Sheet on Traditional Medicine No. 134 (Dec. 2008), http://www.who.int/mediacentre/factsheets/fs134/en/index.html.

163. Gervais, supra note 10, at 149. There are theoretically few differences between ownership by a traditional community and ownership by a university or corporate entity.
‘art’ may not be culturally neutral terms.” If the claimed invention draws in whole or even in part on TK, logic would dictate that the person skilled in the art would be a person skilled in the relevant TK system, for example, a traditional medical practitioner, healer, or shaman. But if the knowledge is confidential to the holders of the TK, or the patent examiner has no familiarity with it and is unable to assess the invention fully on that basis, the skills of the TK holders may not be sufficiently taken into account in examining the patentability of the invention. To overcome this problem, TK holder patent applicants may have to assume the burden of describing the invention in terms more readily understood and appreciated by patent examiners.

A similar challenge exists with respect to the patent requirement of utility. In most countries, the requirement is gauged by the capacity to apply the invention industrially or commercially, which is evaluated by patent examiners on the basis of accepted scientific evidence. Such evidence, in the minds of most patent examiners, is that with which they are familiar. In the absence of evidence, the invention is deemed too speculative for patenting. While TK holders might justifiably prefer to describe their TK innovations in terms familiar to them, for example employing traditional descriptions of chemical formulations rather than “Western” ones, their patent applications will best overcome the utility hurdle only if they incorporate the sort of scientific terminology that patent examiners are trained to assess.

Again looking at this problem in cultural terms, Professor Gervais has stated, “In the current patent law environment, the scientific method itself may seem culturally discriminatory to some holders of traditional medicinal knowledge for example, but there is scant hope of avoiding the filter of accepted scientific canons to gauge the actual utility of an invention . . . .”

The greatest limitation posed by patenting TK, however, concerns the term of protection. While the hurdles created by the requirements

164. Id. at 154.
165. Id. Professor Gervais suggests providing patent examiners with training in TK systems “to build cross-cultural bridges,” in the same manner as patent offices have done with instructing examiners on new areas of technology. Id.; WIPO, Recognition of Traditional Knowledge, supra note 9, ¶ 40. The International Bureau of WIPO recently posed the following question to member countries of the IGC: “If an element of TK . . . is considered available to or accessible by the public outside the original community that holds the TK, but skills to interpret or practice the art of TK are limited to the community only, how would the person skilled in the art be assessed for the determination of inventive step?” See id. for a selection of answers from China, EPO, Azerbaijan, Australia, Finland, and Trinidad and Tobago.
of novelty, non-obviousness and utility can be overcome with relative ease, the term of patent protection cannot. It is a bedrock principle of patent law that protection does not last forever; in most cases, it expires 20 years from the filing date of the application, following which the invention enters the public domain. Moreover, since most patent applications are published at about eighteen months following the filing of the application, the ability to maintain the confidentiality of TK vastly diminishes and may vanish entirely early in the application process. As with all inventions, therefore, the decision to seek patent protection for TK needs to be based on a careful weighing of the benefits the TK holder will derive from the grant of exclusive rights for a limited period of time balanced against the potential drawbacks of permanently divulging the TK.\textsuperscript{168}

\textit{Advantages of Affirmative Protection}

Despite the above-mentioned limitations and challenges, patents have a place in a TK protection system. A prime example is the use of patents to protect Traditional Chinese Medicine. The practice of Traditional Chinese Medicine dates back to the beginning of Chinese history. At its most basic, it is "a systematic practice of distinguishing among various illness-causing imbalances of qi. [It] achieves health by restoring a patient’s internal yin-yang equilibrium via herbal remedies and physical manipulation."\textsuperscript{169} Traditional Chinese Medicine is of enormous importance not only to the Chinese—and the world’s—healthcare systems, but also to the Chinese economy.\textsuperscript{170} It is no surprise, therefore, that the Chinese Government has made it a policy to encourage the patenting of innovative Traditional Chinese Medicinal products.

Although most developing countries tend to find disfavor with the TRIPS Agreement, the Agreement has proven to be a boon to the protection of Traditional Chinese Medicine. Prior to the adoption of Article 27.1 of the TRIPS Agreement, which required China to make patents available “for any inventions, whether products or processes, in all fields of technology . . . ,” the Chinese Patent Law\textsuperscript{171} did not

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\textsuperscript{168} Professor Anil Gupta has maintained, for example, that while the basic “recipes” for traditional Indian health systems, such as Ayurvedic, Unani, or Siddha, are not appropriate for patenting, “modifications of these recipes should be permissible for patenting” under certain circumstances. WIPO & UNEP, Study on the Role of Intellectual Property Rights, supra note 166, at 161.


\textsuperscript{170} According to the WHO Traditional Medicine Fact Sheet, supra note 162, “[i]n some Asian and African countries, 80% of the population depend on traditional medicine for primary health care,” and “[h]erbal medicines are the most lucrative form of traditional medicine, generating billions of dollars in revenue.”

\textsuperscript{171} Patent Law of the People’s Republic of China (adopted at the 4th Meeting of the Standing Committee of the Sixth National People’s Congress on Mar. 12, 1984,
protect Traditional Chinese Medicine. Since the Law's amendment, there has been a significant uptake in patent activity, particularly related to Traditional Chinese Medicine-based pharmaceuticals, and many supporters of Traditional Chinese Medicine believe that this activity has served to incentivize investment in Traditional Chinese Medicine, increase the Traditional Chinese Medicine knowledge base, and transform Traditional Chinese Medicine into a major global export asset.\textsuperscript{172} Since 1992, when the Patent Law was amended, applicants have filed patent applications with the State Intellectual Property Office of China (SIPO) at a rate of 1,400 cases a year,\textsuperscript{173} but they have not limited their activity to China alone; they have also filed applications in countries such as Germany, Japan, the United Kingdom, and the United States. Moreover, patent holders have begun to enforce the rights they have been granted. For example, in February 2007, China Business News reported that a Chinese patentee Traditional Chinese Medicine manufacturer won the first Traditional Chinese Medicine infringement case against another Chinese company. The patentee was awarded an injunction prohibiting the infringing company from selling the infringing products as well as damages.\textsuperscript{174}

The promotion of Traditional Chinese Medicine has led to the establishment of organizations such as the Shanghai Innovative Research Center of Traditional Chinese Medicine (SIRC),\textsuperscript{175} which in turn has further encouraged patent protection for TK. Founded in 2000 with support from the Chinese Ministry of Science and Technology and the Shanghai Municipal Government, SIRC seeks to modernize Traditional Chinese Medicine and innovate drug discovery "by integrating modern life science, chemistry, and information technology with [Traditional Chinese Medicine]"\textsuperscript{176}—just the right formula to maximize patenting potential.\textsuperscript{177}

Although the patent system may not be suited to all types of TK, using patents to protect Traditional Chinese Medicine seems to have achieved some success in encouraging new innovation and invention.

\textsuperscript{172} Liu, supra note 169, at 81–82.
\textsuperscript{173} Murray Lee Eiland, Patenting Traditional Medicine, 89 J. PAT. & TRADEMARK OFF. SOC’Y 45, 78 (2007).
\textsuperscript{176} Id.
Communities working to advance other areas of innovative TK may do well to follow China’s example.

**Conclusion**

TK is often rich, innovative, and complex, and it deserves protection. Using patents to secure TK protection can serve to prevent misappropriation and misuse, enforce prior informed consent and benefit sharing mechanisms, and permit TK holders to enjoy the benefits of exclusive patent rights. Until such time as a meaningful international protection system can be devised that fully respects the needs of TK holders, national and regional measures to protect TK need to be adopted. As more countries embrace national or regional TK protection systems, international norms are certain to emerge that will ultimately make international protection a reality.