



CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

## **Comments on Improving Identification of Prior Art**

### **Recommendations on Traditional Knowledge Relating to Biological Diversity Submitted to the United States Patent and Trademark Office**

**August 2, 1999**

These comments are submitted to the United States Patent and Trademark Office (PTO) in response to its May 27, 1999 Federal Register notice (64 Fed. Reg. 28803) requesting input from the public on the PTO's procedures and practices for identifying prior art during the examination of a patent application. They have been prepared by the Center for International Environmental Law (CIEL) on its own behalf, and also on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA), the Coalition for Amazonian Peoples and Their Environment (Amazon Coalition), and the Indigenous Environmental Network (IEN)'s North American Indigenous Peoples Biodiversity Project (NAIP-B).

CIEL is a non-profit organization based in Washington, D.C. that promotes sustainable and equitable development and environmental protection through the development and implementation of international law. COICA, based in Ecuador, is the coordinating body for more than 400 indigenous tribes that are members of nine national organizations of the countries in the Amazon region. The Amazon Coalition, based in Washington, D.C., is comprised of eighty non-governmental organizations dedicated to strengthening and broadening the alliance between indigenous peoples of the Amazon and groups who share their concerns for the future of the Amazon and its peoples. The Indigenous Environmental Network is an alliance of grassroots indigenous peoples groups whose mission is to protect the natural world by by maintaining and strengthening traditional Native American laws and teachings.

As explained in Part I below, traditional and informal knowledge developed and maintained by indigenous and local communities is a significant "prior art" resource for innovation, particularly in pharmaceutical and other technologies based upon biological diversity and biological resources. As Part II discusses, such prior art is relevant in determining whether patent applications in such fields of technology meet not only the statutory bar tests for printed publications, patents and known use provided by subsections 102 (a) and (b) of the Patent Act, 15 U.S.C. § 102, but also the test of subsection (f), for situations in which the applicant is not the inventor.

Part III explains how the PTO's current approach leads to problems in identifying such prior art, and in ensuring that the statutory bar is properly applied. Part IV recommends

improvements that the PTO could make to procedures and practices within the framework of existing law. These changes would significantly enhance the ability of patent examiners to assemble and review the prior art relevant to an application. At the same time, they would enhance recognition of the contributions of indigenous peoples and non-Western cultures to universal knowledge, enhance incentives for the conservation of traditional knowledge systems and associated biodiversity, and encourage equitable sharing of benefits between the users of traditional knowledge and those who have created and maintained it.

## **I. The Role of Traditional and Informal Knowledge in Technological Innovation**

A significant part of the intellectual base for innovation in certain fields of technology has come from outside the formal Western science-based research and development process. In particular, the informal and traditional knowledge developed, elaborated and maintained by indigenous and traditional societies has been an important resource in technologies based upon the manipulation, adaptation or use of biological resources.<sup>1</sup> Traditional knowledge is valuable in several ways. It informs resource management systems and practices of resource use that often have relatively low impacts upon biological resources. The existence of these systems and practices explains in part why these peoples are the custodians of much of the world's richest stores of biodiversity. Traditional knowledge also comprises extensive knowledge of the practical uses of these resources, as sources of medicines, foodstuffs, and other goods. As a result, traditional knowledge is itself a valuable resource not only for these communities but also for outsiders, including academic researchers, government agencies, and commercial firms.

Traditional knowledge has been used in a number of industries as a starting point for new product development in sectors such as specialty food and beverages, pharmaceuticals, agriculture, horticulture, and personal care and cosmetics. Relevant technology categories include—but are not necessarily limited to—fuels, sugars, cleaning, plant and animal husbandry, drugs and body treating compositions, foods, fabrics and textiles, perfumes, multicellular organisms and their unmodified parts, and chemistry, including carbon and organic compounds, natural resins, molecular biology, microbiology, and analytical and immunological testing.

The value of traditional knowledge is well demonstrated in the pharmaceutical sector. A recent analysis found that “57% of the top 150 brand names prescribed during [a six month period in 1993] contained at least one major active compound now or once derived or patterned after compounds derived from biological diversity.”<sup>2</sup> Of the 35 plant-derived drugs included in the top 150, 33—or 94%—contained at least one compound that “had or has a demonstrated use

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<sup>1</sup> These Comments use the shorthand term “traditional knowledge” to refer to the knowledge, practices, and innovations developed and held by indigenous and local communities. However, it is important to recognize that this “traditional” knowledge is not static but constantly evolving, and many “traditional” knowledge systems continue to produce significant innovation.

<sup>2</sup> See Francesca Grifo, et al., *The Origins of Prescription Drugs*, in BIODIVERSITY AND HUMAN HEALTH 131, 136 (Francesca Grifo & Joshua Rosenthal eds., Washington, D.C.: Island Press 1997). The analysis included compounds from all biological sources, including animals, plants, fungi, and microorganisms. *Id.* at 137. The top 150 compounds were identified according to the number of prescriptions filled. *Id.* at 136.

in traditional medicine related to the primary therapeutic use for which a physician might prescribe the drug.”<sup>3</sup>

For example, quinine was originally derived from cinchona bark, which Amazonian indigenous peoples used as a remedy for malaria. Quinine and its chemical analogs remain “the bulk of our antimalarial armamentarium.”<sup>4</sup> Herbal remedies currently being researched for pharmaceutical applications include qing hao su (artemisinin), a Chinese traditional medical preparation from the leaves of the plant *Artemisia annua*, which has antimalarial properties;<sup>5</sup> the bark of the rainforest tree *Alphitonia zizyphoides*, used by traditional Samoan healers as a tonic;<sup>6</sup> and *Homolanthus nutans*, from which Samoan healers prepare an infusion used to treat viral hepatitis.<sup>7</sup> A preliminary analysis of 74 plant species used medicinally by traditional Samoan healers revealed that “[o]ver 86% of the plants exhibited high levels of pharmacological activity.”<sup>8</sup> Researchers have catalogued 2,095 plant species used medicinally by Native Americans.<sup>9</sup>

The underlying mission of United States intellectual property law is “[t]o promote the progress of science and useful arts.”<sup>10</sup> The award and enforcement of the patent right is one way that the law pursues its mission. But the financial rewards flowing from the award of exclusive rights are an incident of the mission rather than an end in themselves. The disclosure to the public of the basis for the invention, through publication of the application upon award of the patent, is another important mechanism—one which benefits a constituency beyond the patent owner alone. The proper acknowledgment of prior art in the application provides a complete and accurate history of the invention’s origin, which is valuable both as a resource for future innovators and as recognition accorded to the predecessors whose intellectual labors made the invention possible.

In this context, disclosure of traditional knowledge that forms part of the prior art “promotes the progress of science and useful arts” in at least two ways. First, by according recognition to knowledge created by cultures whose contributions have often been unrecognized and even denigrated, it provides a positive incentive for the maintenance of traditional knowledge systems. Positive incentives are vital to stem the rapid loss of these systems resulting from factors such as cultural assimilation and the continuing destruction of local biological resources and ecosystems with which they are intimately linked. Second, creating positive incentives to maintain these knowledge systems in turn can create an incentive for the knowledge holders to continue the traditional practices by which they have maintained high levels of biodiversity in their homelands over many generations. Indeed, this linkage led the drafters of the Convention on Biological Diversity to include a requirement that governments take steps to

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<sup>3</sup> *Id.* at 137, 139.

<sup>4</sup> See Catherine A. Laughlin and Alexandra S. Fairfield, *Natural Products for the Treatment of Infectious Diseases*, in BIODIVERSITY AND HUMAN HEALTH 164, 176.

<sup>5</sup> *Id.* at 177.

<sup>6</sup> See Paul Alan Cox, *Indigenous Peoples and Conservation*, in BIODIVERSITY AND HUMAN HEALTH 207, 215.

<sup>7</sup> *Id.* at 214.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at 216.

<sup>10</sup> U.S. Constitution, Art. 1, § 8, cl. 8. “The Congress shall have power. . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”

respect, preserve and maintain traditional knowledge of such peoples; to promote the wider application of such knowledge, contingent on the approval and involvement of its holders; and to encourage the equitable sharing of the benefits arising from utilization of traditional knowledge.<sup>11</sup>

## **II. Traditional Knowledge as Prior Art Relevant to the Statutory Bar of 35 U.S.C. § 102**

Section 102 of the Patent Act, 35 U.S.C. § 102, establishes a “statutory bar” against the grant of a patent in certain specified conditions. Several provisions of section 102 are particularly relevant to the treatment of traditional knowledge as prior art.

Subsections 102(a) and (b) provide that a patent shall not be granted if the invention was patented or described in a printed publication in either the United States or a foreign country, either before the date of the claimed invention or more than a year before the date of the patent application. These subsections also provide that a patent shall not be granted if the invention was “known or used by others in this country.” Unpublished or unpatented knowledge or use in a foreign country is not relevant to patentability under these subsections.

Subsection 102(f) precludes the award of a patent when the applicant did not invent the subject matter sought to be patented. Unlike subsections 102(a) and (b), subsection 102(f) contains no limitations as to geographic scope. Consequently, any information—published or unpublished, domestic or foreign—demonstrating that the applicant did not himself invent the subject matter claimed in the application will be material to patentability under subsection 102(f).

Patent applications whose claims merely duplicate processes known to indigenous and local communities will thus fail the statutory bar of subsection 102(f) and should be rejected. Similarly, traditional knowledge may be material in examining applications containing claims consisting in part of such knowledge. As described in Part III below, current PTO procedures and requirements relating to prior art do not adequately provide for examination of such applications.

Examiners must make a “thorough investigation of the *available* prior art relating to the subject matter” of the claimed invention.<sup>12</sup> Thus, the primary qualifying factor in an examiner’s consideration of section 102(f) prior art should be whether it is “available” to her. Prior art will be available when an examiner can access it on her own through written texts, data bases, published herbarium specimens or other sources, or when it is provided by the applicant under the applicant’s duty to disclose to the PTO all information known by that individual to be material to patentability.<sup>13</sup> Part IV, below, suggests several simple procedures for ensuring that

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<sup>11</sup> Convention on Biological Diversity, *entered into force* December 29, 1993, 31 I.L.M. 818 (1992) text available at URL <[www.biodiv.org](http://www.biodiv.org)>. Over 170 countries are Parties to the Convention; the United States has signed but not ratified it.

<sup>12</sup> 37 CFR § 1.104(a)(1) (emphasis added).

<sup>13</sup> See 37 CFR § 1.56.

such information is readily available to examiners, thus reducing the extent to which applications seeking to misappropriate traditional knowledge can slip through the examination process.

### **III. Problems With the Current Approach: Identifying Prior Art and Applying the Statutory Bar**

Recent controversies over United States patents based on traditional knowledge have raised concerns that the patent system as it is presently implemented does not adequately account for traditional knowledge as prior art. The PTO has issued patents that are neither novel nor non-obvious in the light of traditional knowledge. These patents allow those who have no right to claim traditional knowledge to wrongly take it out of the public domain, and they acknowledge fairly indigenous contributions to world culture and knowledge. Their issuance has provoked sharp protests by the peoples and countries from whom the knowledge or resources were acquired.

A recent patent on turmeric provides a well publicized example. In 1995, researchers at the University of Mississippi Medical Center obtained a United States patent for the use of turmeric as a healing agent.<sup>14</sup> This patent aroused considerable public controversy, because turmeric has been used to promote healing of wounds for generations by people in India.<sup>15</sup> Because the patent claims were for processes that were not new, but were part of traditional Indian knowledge in the public domain, the PTO canceled all six of the patent claims as a result of a reexamination requested by India's Council of Scientific and Industrial Research (CSIR).<sup>16</sup>

The turmeric case demonstrates that traditional knowledge constitutes prior art when a patent claim merely restates in whole or part processes that have long been held within the knowledge systems of indigenous and local communities. However, because the turmeric patent "slipped by" examiners who were not apprised of, and did not seek out, the available prior art, the burden was placed on the knowledge holders to protect their traditional knowledge, through the reexamination process. Yet developing countries and indigenous and local communities have limited means for discovering that their resources are being improperly claimed by United States commercial interests, and they have little chance of learning about an application until after the patent has been awarded. At that point, their least expensive and simplest recourse is to file and prosecute a reexamination at the PTO. Yet participation in such proceedings requires financial resources and access to legal expertise that are not readily available to developing countries and their inhabitants. Many indigenous and local communities in these countries are poor and isolated. Thousands upon thousands of villages have rich traditional knowledge systems attuned to local conditions, yet they lack communication facilities, access to information, and expertise.

Moreover, the basis for reexamination is limited: examiners may only consider newly discovered prior art patents and printed publications in a reexamination proceeding. As a result,

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<sup>14</sup> See Use of Turmeric in Wound Healing, U.S. Patent No. 5,401,504, issued March 28, 1995.

<sup>15</sup> See, e.g., *India Prevents Patenting of Turmeric*, The Statesman, Aug. 23, 1997; Sanjay Kumar, *India Wins Battle with USA Over Turmeric Patent*, The Lancet 350:724 (1997).

<sup>16</sup> See Use of Turmeric in Wound Healing, U.S. Patent and Trade Office Reexamination Certificate B1 (3500th), April 21, 1998.

indigenous and local communities in developing countries have no opportunity to bring attention to unwritten knowledge, practices, and innovations that demonstrate lack of novelty or non-obviousness. This is a significant drawback because—given that many of these traditions are oral and poorly documented in the extant scientific literature—published accounts may not have existed at the time the original patent application was filed.

In the turmeric case, a national scientific organization from a large developing country with a substantial scientific community intervened. The CSIR was able to produce a substantial body of publications that documented the long-standing use of turmeric by local communities in India. That fact demonstrated that (1) the examiner during the patent’s original prosecution failed to investigate all of the available prior art relating to the subject matter and (2) the applicant failed to disclose adequately all of the information that was material to patentability.

The growing sense in developing countries that patent systems are not fairly acknowledging contributions from their jurisdictions has led some developing countries to adopt restrictions on access to knowledge and biological resources. These restrictions could interfere with the very progress of science that patent law is supposed to encourage. The Philippines has enacted regulations strictly controlling access to biological specimens, which some critics complain has unnecessarily restricted scientific research and exchange. Two Brazilian states have adopted laws requiring foreign researchers to sign contracts requiring them to pay “bioroyalties” on any income they derive from local plants, and the Brazilian Congress is considering similar legislation.<sup>17</sup>

The controversy could affect international standards for intellectual property as well. For instance, an important policy goal of the United States is to promote multilateral agreement on the definition and enforcement of strong intellectual property rights systems worldwide. Major progress toward that goal is reflected in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which binds the 130-plus members of the World Trade Organization Agreement. However, the growing resistance on the part of many developing countries—based in part on perceptions among them that TRIPS standards facilitate the efforts of industrialized countries to misappropriate their traditional knowledge—has led to serious opposition to the implementation or strengthening of the Agreement.

#### **IV. Recommendations**

PTO examiners are obligated to access and evaluate prior art sufficient to ensure that applicants receive patents only for their inventions, and to prevent applicants from patenting subject matter that is broader than what they actually invented. This part suggests modifications to existing procedures that will respond to the problems identified in Part III and enable examiners to carry out their mandate more effectively.

Part IV.A relates to PTO requirements for disclosures in patent applications. It proposes a clarification of the disclosure rules in order to ensure that applicants are supplying all information regarding traditional knowledge that may be materially relevant to patentability.

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<sup>17</sup> See Anthony Faiolo, *Amazon Cash Crop*, The Washington Post, July 9, 1999, at A21.

Part IV.B specifies two routines that examiners can follow to gain access to traditional knowledge that may be relevant as prior art. First, as explained in Part IV.B.1, examiners should review all databases and other known registries of traditional knowledge to ensure that each aspect of an applicant's claims represents a truly inventive step. Second, as discussed in Part IV.B.2, examiners should more fully integrate the existing rules and guidelines governing international and international-type searches into the normal examination process for national applications.

Part IV.C proposes changes relating to plant patents. First, it proposes additional disclosure requirements for applicants. Second, it proposes an additional step in the examination procedure: where plant patents are based on specimens that originated in developing countries, examiners should routinely consult expert institutions to determine if herbarium specimens exist that may be materially relevant to whether the claimed plant is truly a new and distinct variety.

Part IV.D proposes that the PTO take the initiative to consider whether and how to define principles for taking moral concerns into account in patenting, particularly patenting of life forms.

## **A. Elaboration of Disclosure Requirements**

As part of their “duty of candor and good faith,” each individual associated with the filing and prosecution of a patent application has the duty to disclose to the PTO all information known by that individual to be material to patentability.<sup>18</sup> Among the categories of “material” information is information that establishes, alone or in combination with other information, a prima facie case of unpatentability. Information is also material if it refutes or is inconsistent with a position the applicant takes in asserting an argument of patentability.<sup>19</sup>

Such material information can include descriptions of traditional knowledge from sources outside the United States contained in printed publications available prior to the date of invention or more than one year prior to the application date.<sup>20</sup> It can also include any information relating to traditional knowledge from any source demonstrating that the applicant did not himself invent the subject matter sought to be patented.<sup>21</sup> And it can include information regarding traditional knowledge from a source within United States jurisdiction indicating that the invention was known or used more than one year prior to the date of application or prior to the claimed date of invention.

The PTO should establish the following four specific requirements to help ensure that examiners have access to such material information.

### **1. Applicants Must Disclose Traditional Knowledge Used in Invention**

Any traditional knowledge that the applicant used in the process of discovering or creating the applied-for subject matter should presumptively be considered material to

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<sup>18</sup> 37 CFR § 1.56 (a).

<sup>19</sup> *Id.* § 1.56(b).

<sup>20</sup> 35 USC § 102(a)-(b)

<sup>21</sup> *Id.* § 102(f).

patentability and therefore should be subject to the requirement of disclosure. The disclosure should not be limited to printed publications or patents. Instead, it should also disclose other sources of material information—particularly, unpublished traditional knowledge that may qualify as section 102(f) prior art, as discussed in Part II above.

## **2. Applicants Must Conduct Prior Art Searches of Traditional Knowledge**

Because applicants will likely have conducted extensive research in the country and communities where the knowledge is held, they will often have more ready access to traditional knowledge prior art than will examiners. Accordingly, it will generally be most cost-effective for applicants themselves to conduct prior art searches concerning any traditional knowledge or resources they utilize in their subject matter. Such searches should include all relevant publications, including databases, herbarium specimens, etc., that pertain to the traditional knowledge, especially those publications prepared in the source country. Searches should also review any orally transmitted traditional knowledge, practices, or innovations of indigenous peoples relevant to the subject matter, again consistent with section 102(f). The results of these searches should be fully reported along with the patent application.

## **3. Applicants Must Disclose Country and Geographical Location of Knowledge and Related Resources**

Applicants should disclose the country and exact geographical location from which the knowledge or related resources (e.g. plants identified as medicinal on the basis of traditional knowledge) were obtained. This will help guide the examiner in his search for section 102(a) or (b) prior art printed publications, including database searches.

Disclosure of the exact geographical source of living resources can also be useful for evaluating the patentability as well as enablement with respect to naturally based products, because the specific chemistry of plants may depend on the local environment (especially the soil) from which they originated. Additionally, such disclosures could assist the examiner in the event it becomes necessary to corroborate or obtain more information about non-published section 102(f) prior art that documents traditional knowledge.

## **4. Applicants Must Certify Their Compliance with Applicable Laws**

Applicants who utilize traditional knowledge or resources in their inventions should certify that the knowledge or resources were acquired in full compliance with the local laws of the source jurisdiction. The certification should include contact information for any local authorities from whom authorization for exploitation of the knowledge was obtained. In situations in which they believe it necessary to corroborate a certification, examiners should also be able to request the texts of any agreements the applicant entered into with local authorities or communities that provided for benefits sharing or acknowledgment of the contribution of indigenous and local communities to development of the subject matter.<sup>22</sup>

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<sup>22</sup> Any invention based on biological material or traditional knowledge obtained in violation of applicable laws may also be subject to attack under the “tainted research doctrine.” *See* Michael A. Gollin, Venable, Baetjer, Howard & Civiletti, LLP, “New Rules for Natural Products Research” (publication forthcoming).



Such certification would assist examiners in evaluating whether the applied-for subject matter was truly novel and nonobvious. Moreover, it would provide examiners with the means to seek further information and clarification from the local peoples and authorities from whom traditional knowledge was acquired, should the examiner believe such further information would assist him in the prosecution of the application. This latter benefit would also comport with the enablement requirements of 35 U.S.C. § 112. Because certification would serve to assure those practiced in the art that they could learn where and how to access the traditional knowledge or resources, the provision of certified information by an applicant would be analogous to a biotechnology applicant fulfilling the deposit requirements for biological material pursuant to 37 C.F.R. § 1.801 *et seq.* and the Budapest Treaty.<sup>23</sup>

## **B. Elaboration of Examiner Search Procedures**

In addition to changes in disclosure requirements, the examination procedure could also be modified through several specific steps that would more effectively screen patents that misappropriate traditional knowledge. These include reviewing accessible databases and other reference sources, integrating the guidelines for international and international-type searches into normal examination procedure, and consulting with expert institutions regarding plant patent applications.

### **1. Examiners Should Review All Accessible Databases, Registries and Other Sources of Information on Traditional Knowledge**

When prosecuting a patent application, examiners are required to make a “thorough investigation of the available prior art relating to the subject matter of the claimed invention.”<sup>24</sup> The examination must be complete with respect to the patentability of the invention as claimed.<sup>25</sup> A “complete” examination will thus include a review of all traditional knowledge that may have contributed to the invention of the subject matter, to ascertain whether all the claims for the subject matter are truly novel and nonobvious.

Important gateways to such prior art are found in electronic databases and registries containing data regarding traditional knowledge, ethnobotany, ethnopharmacology, and the commercial use of biological resources from developing countries.<sup>26</sup> Database searches can

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<sup>23</sup> See Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

<sup>24</sup> 37 CFR § 1.104(a)(1).

<sup>25</sup> *Id.*

<sup>26</sup> The data contained in computerized databases qualify as prior art publications under § 102(a) and (b). When evaluating whether a printed publication constitutes prior art under § 102, courts do not recognize a “dichotomy” between “printing” and “publication.” See *In re Wyer*, 210 U.S.P.Q. 790, 793; 655 F.2d 221, 226 (C.C.P.A. 1981) (citing *Philips Electronics & Pharmaceutical Indus., Inc. v. Thermal & Electronic Indus., Inc.*, 171 U.S.P.Q. 641, 646; 450 F.2d 1164, 1170 (3d Cir. 1971)). Instead, they identify the “probability of dissemination” and the “public accessibility” of the item taken as a whole as the relevant questions. *Id.* Dissemination by printing or other mechanical reproduction is not in itself necessary. Rather, there must be a showing that the item in some way has “been available and accessible to persons concerned with the art to which the document relates.” *Philips*, 171 U.S.P.Q. at 647, 450 F. 2d at 1171, *quoted in Wyer*, 210 U.S.P.Q at 794, 655 F.2d at 227. Thus, the court in *Wyer* focused on whether the item had been “properly classified, indexed or abstracted” in a publicly accessible repository of information. Under these principles, databases comprise prior art publications under § 102. Because they are generally available over the World Wide Web, they are both widely disseminated and readily accessible to the

serve to alert patent examiners that prior art in the form of traditional knowledge may exist that is material to the patentability of an applied-for invention. Where necessary, examiners can then make further inquiries of the applicant and/or governments and other entities in the source countries.

The most comprehensive of the databases currently available to on-line researchers is NAPRALERT, produced by the Program for Collaborative Research in the Pharmaceutical Sciences, College of Pharmacy, University of Illinois at Chicago. NAPRALERT contains a broad range of information about natural products derived from plants. The database can be searched to access information about plant pharmacology, biological activity, ethno-medicine, plant chemistry, and microbial and animal extracts. It is available on the worldwide web from STN Easy at <<http://stneasy.cas.org/>>. One limitation of NAPRALERT as a source of traditional knowledge prior art is that it is compiled from written sources. Consequently, traditional knowledge that has been transmitted solely in oral form will not be contained in the database.

Another relevant database is operated by Dr. James Duke of the USDA's Agricultural Research Service. "Dr. Duke's Phytochemical and Ethnobotanical Databases" provides search capabilities by plant, chemical, activity, and ethnobotany categories. It is available at <[www.ars-grin.gov/duke](http://www.ars-grin.gov/duke)>. Other phytochemical databases may be accessed through the Phytochemical Society of North America's "Links to Phytochemical Resources on the Web" site, located at <[www.fin.edu/orgs/psna/links.html](http://www.fin.edu/orgs/psna/links.html)>.

Databases that list traditional knowledge from specific geographical regions are also becoming available. The "Prelude" database of traditional veterinary medicine, part of the "Tropical Diseases Webring," focuses on traditional knowledge of Africa. The website is located at <[http://pc4.sisc.ucl.ac.be/prelude/prelude\\_HomePage.html](http://pc4.sisc.ucl.ac.be/prelude/prelude_HomePage.html)>. Similarly, the World Bank hosts a searchable "Database of Indigenous Knowledge and Practices" in Sub-Saharan Africa. The database can be accessed at <[www.worldbank.org/afr/ik/datab.htm](http://www.worldbank.org/afr/ik/datab.htm)>. Researchers can find both of these databases through links contained in the Nuffic/CIRAN International Indigenous Knowledge (IK) Network. The IK Network includes databases listing numerous reference sources for international indigenous knowledge, organized by broad subject matter. It is located at <[www.nuffic.nl/ciran/ik.html](http://www.nuffic.nl/ciran/ik.html)>. In addition, the Bioresources Development and Conservation Program (BDCP) in Washington, D.C. has developed a database that catalogues the medicinal use of plants by indigenous peoples in Africa. BDCP expects to place its AFRICMED database on-line in the near future.

The People's Biodiversity Registers (PBRs) program sponsored by World Wildlife Fund India is endeavoring to create a system of databases that will provide a record of local knowledge for the use of present and future generations of Indian village community peoples, and to protect local biodiversity and knowledge from misappropriation by outsiders. The completed program is envisioned as a network of decentralized databases, all linked to a consolidated national database.

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public. They are usually easily searchable through search engines available at the websites or provided by the searchers themselves.

The Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI) is another non-governmental organization from India. For several years, SRISTI has been documenting information on the innovations and creative practices of rural farmers. These have been published in SRISTI's "Honey Bee" database, which SRISTI is considering posting at least in part on the worldwide web. SRISTI's website is located at <<http://csf.Colorado.EDU/sristi/>>.

The extent to which the SRISTI "Honey Bee" database and the PBRs are publicly accessible is yet to be determined. Because of their concerns about "pirating" of traditional knowledge, the managers of these databases may be hesitant to make data freely available. However, it is possible that the PTO could make arrangements so that the managers could conduct prior art searches in response to PTO inquiries and then disclose information sufficient to demonstrate the lack of patentability of a given claim. The PTO should also explore ways of reciprocating by making the information available in the patent files more readily available to informal innovators, perhaps through expanded use of Internet gateways.

As countries implement their obligations under the Convention on Biological Diversity (CBD), it is anticipated that they will increasingly rely upon databases as a means of identifying, preserving and maintaining the knowledge, innovations and practices of indigenous and local communities. More databases will thus likely become available that will be useful to patent examiners conducting prior art searches of patent claims relying in whole or part upon traditional knowledge. The international Clearinghouse Mechanism of scientific and technical information established under the Convention may provide a single gateway to these various databases as well as the non-governmental databases described above. It could therefore be useful for the PTO to follow the implementation of the provisions of the Convention on Biological Diversity regarding protection of traditional knowledge and sharing of scientific and technical information, so that it can track and link to CBD-related databases as they become operational.

The websites described above are listed in the Appendix attached to these Comments.

## **2. The Rules and Guidelines Governing "International-Type" Searches Should Be Integrated into the Examination Process for National Applications.**

Examination procedures should be revised to integrate more effectively the guidelines for international-type searches into the examination process for patent applications. Those rules and guidelines treat traditional knowledge prior art more flexibly than do PTO examiners under their current practices.

Examiners must already perform an "international-type" search as part of every examination of a national application.<sup>27</sup> In practice, examiners perform international-type searches only for applications that enter the national stage from international applications. However, 37 C.F.R. § 1.9 defines a "national application" to include any U.S. application for patent filed under 35 U.S.C. § 111, not only applications entering the national stage from international applications. Consequently, the international-type search must be performed on *all*

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<sup>27</sup> See 37 CFR § 1.104(a)(3).

U.S. patents filed on and after June 1, 1978.<sup>28</sup> Failure of examiners to perform such searches constitutes a failure to perform a statutory duty.

An “international-type” search is an international search as defined under the Patent Cooperation Treaty (PCT).<sup>29</sup> Carried out on a national application, it is similar to an international search.<sup>30</sup> Such a search is required as part of the United States’ implementation of the PCT.<sup>31</sup> Like other international treaties ratified by the United States, the PCT is the “supreme law of the land,” on a par with U.S. statutes.<sup>32</sup> Consequently, the Rules of Practice in Patent Cases incorporates by reference the relevant provisions of the PCT and PCT Rules when discussing the terms of international and international-type searches.<sup>33</sup> Patent examiners prosecuting national applications are thus obligated to use PCT-stipulated rules when fulfilling the international-type search requirement.

According to Article 15.2 of the PCT, the objective of the international search is to discover relevant prior art. For the purposes of Article 15.2, relevant prior art is everything that has been made available to the public anywhere in the world by means of written disclosure, and which can be of assistance in determining that a claimed invention is novel or nonobvious.<sup>34</sup> Oral disclosure, use, exhibition or other means of disclosure are not relevant prior art for the purposes of an international search unless substantiated by a written disclosure.<sup>35</sup> However, “[t]he date on which the written disclosure was made available to the public may have been *after* the filing date of the international application.”<sup>36</sup>

In the context of a domestic patent application claim based wholly or partly upon traditional knowledge, this latter provision means that the traditional knowledge qualifies as prior art when it has been published in some form, even if that publication occurs after the application date. Orally transmitted traditional knowledge in itself would not qualify as prior art. However, it would qualify if it was collected in a database or printed in a publication, even if the data did not become available in that form until after the patent application had been filed. In a sense, this feature of the PCT international-type search rules helps put into effect the statutory bar of sub-section 102(f), insofar as it is not subject to the same publication date restrictions as is prior art under subsections 102(a) or (b).

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<sup>28</sup> See *id.*; 37 C.F.R. § 1.9(a)(1).

<sup>29</sup> Patent Cooperation Treaty (PCT) of June 19, 1970, as amended and modified, to which the United States became a party on January 24, 1978. Available at World Intellectual Property Organization web site, <[www.wipo.org/eng/main.htm](http://www.wipo.org/eng/main.htm)>.

<sup>30</sup> See *id.* art. 15.5(a).

<sup>31</sup> See *id.* art. 15.5(b).

<sup>32</sup> See U.S. Constitution art. 6 § 2; Restatement of Foreign Relations Law § 111 (1) (1986).

<sup>33</sup> See, e.g., 37 CFR 1.413(c)(3).

<sup>34</sup> PCT Regulations rule 33.1(a) (WOPCR 1/40, Jan. 1, 1999), available at <[www.wipo.org/eng/main.htm](http://www.wipo.org/eng/main.htm)>.

<sup>35</sup> *Id.* rule. 31.1(b); PCT International Search Guidelines, PCT Gazette, chptr. VI § 1.2 (Special Issue No. 06/1998, Oct. 8, 1998), available in [www.wipo.org/eng/main.htm](http://www.wipo.org/eng/main.htm).

<sup>36</sup> PCT International Search Guidelines, chptr. VI § 1.2 (emphasis added).

## C. Modification of Disclosure Requirements and Examination Procedures for Plant Patents

While they form a very small proportion of patents granted in the United States, plant patents continue to provide some companies with an avenue for acquiring rights relating to botanical resources, including those belonging to indigenous and local communities. The Plant Patent Act, 35 USC § 161 *et seq.*, was intended to recognize and protect inventions of the plant breeder who has worked “in aid of nature.”<sup>37</sup> Consequently, when a plant patent applicant attempts to patent a newly found plant, he must “particularly point out the location and character of the area where the plant was discovered.”<sup>38</sup> The strict implementation of this requirement is an important means for ensuring compliance with the provision of the Plant Patent Act that prevents the award of a patent to one who discovers a previously unknown variety that already exists in the wild.<sup>39</sup>

### 1. The “Ayahuasca” Patent Controversy

The failure to implement this requirement adequately contributed to the award of one of the most controversial United States plant patents in recent memory. In 1986, an American entrepreneur obtained a U.S. plant patent on a purported variety of the “ayahuasca” vine, *Banisteriopsis caapi*, which he dubbed “Da Vine.”<sup>40</sup> In his application, he stated merely that “[t]his plant was discovered growing in a domestic garden in the Amazon rain-forest of South America.” That vague disclosure provided the patent examiner with no useful information whatsoever for evaluating or verifying whether “Da Vine” originated from cultivated or uncultivated stock, and whether it thus satisfied the prohibition against patenting wild plants.

In fact, *B. caapi* grows wild throughout the Amazon basin, and is also cultivated by dozens of indigenous tribes who inhabit the rainforest there. Because the plant has been widely dispersed by generations of indigenous peoples, it is not possible to pinpoint exactly where the species originated, or whether individual plants that are growing in an uncultivated state are descended from naturally occurring stock or stock that was once propagated by humans. As a result, identical forms of the plant can be found growing both wild and in or near the villages of indigenous peoples. This phenomenon makes it extremely difficult or impossible to ascertain whether a given form of *B. caapi* represents cultivated or uncultivated stock.

If the examiner had required a sufficiently detailed disclosure, he might have learned before the patent was granted that “Da Vine” was identical to varieties of *B. caapi* that grow wild throughout the region. With a basis for denying the application, the PTO could have avoided the intense controversy that this patent aroused when Amazonian indigenous peoples learned that a plant that is sacred and central to the religions of many Amazonian tribes was the subject of a private property claim in the United States.

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<sup>37</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 312 (1980) (citing S. Rep. No. 315, 71st Cong., 2d Sess., at 6-8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., at 7-9 (1930)).

<sup>38</sup> 37 CFR § 1.163(a).

<sup>39</sup> *Id.*; see also 35 USC § 161 (patent cannot be issued for a plant found in an uncultivated state).

<sup>40</sup> See U.S. Plant Patent No. 5,751 (issued June 17, 1986).

## **2. Applicants Should Provide a Full Accounting**

To avoid future mishaps of this kind, applicants seeking plant patents for putative new varieties of tropical species such as *B. caapi* must provide detailed, specific accounts of the precise location where the original specimen or parent stock of the plant was found, including the circumstances under which it was discovered, consistent with 37 CFR § 1.163(a). The account should also include the date and full name of the person or group from whom the specimen was acquired, and the detailed circumstances surrounding its acquisition. This will aid examiners in corroborating whether the subject matter is a wild plant. It will also lessen the possibility that specimens were fraudulently or illegally obtained. To that end, an applicant should attach to his disclosure an affirmation or written statement from the source person that contains the person's prior informed consent. Applicants should also provide a certification that they complied with all laws of the source country, and obtained all required permits or licenses, when they collected the specimen and removed it from the source country. Additionally, they should provide contact information for the relevant government authorities in the source country who have jurisdiction over the collecting and exporting of the subject plant, to make it easier for the examiner to validate the information provided or obtain additional information as needed.

Applications that do not fully disclose all information necessary to evaluate whether the subject matter is truly new and distinct fail to fulfill the applicant's legal "duty of candor and good faith."<sup>41</sup> Such applications should automatically be rejected, because if they are approved, prior art in the form of printed publications may not be available to support a reexamination request, leaving affected indigenous peoples with no avenue for challenging a wrongly issued patent.

## **3. Prior Art Searches Must Include Herbarium Specimen Sheets**

Although full disclosure of the above information by applicants will help preclude granting some patents on tropical plants that do not satisfy the Plant Patent Act's terms, examiners will still be faced with the task of determining whether available prior art demonstrates that the applied-for subject matter is truly a new and distinct variety of plant. The claimed differences may be subtle and difficult to confirm. For many Amazonian species, few or no scientific monographs have been published that fully and accurately describe the species. In the case of the "Da Vine" patent application, the most important claimed difference was that the "new" variety had flowers of slightly different color than typical forms. That claim was based on a comparison of the subject plant to the only scientific monograph of *B. caapi* that existed at the time of the application. But because neither the examiner nor the applicant searched prior art in the form of specimen sheets of *B. caapi* housed in the collections of major U.S. herbaria, the examiner did not discover that identically colored specimens had been collected and reported by scientists in the United States and South America well before the application for "Da Vine" was filed.

In all instances where an applicant is attempting to obtain a plant patent on a species that originated in a developing country, or that occurs in both wild and cultivated states, the applicant should be required to perform a prior art search of major herbaria in the United States and the

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<sup>41</sup> See 37 CFR § 1.56(a).

source country. The applicant should supply photocopies of all specimen sheets that contain specimens or descriptions that are similar to the claimed subject matter. Similarly, the examiner should perform her own search of these sources to confirm the integrity of the applicant's efforts and to discover any prior art sheets that the applicant may have omitted or overlooked.

Herbarium sheets were recently accepted by the PTO as prior art publications when it granted the reexamination of the "Da Vine" patent.<sup>42</sup> These sheets satisfy the criteria for prior art publications because they are readily and routinely available for consultation by scientists and lay people with a legitimate need, including inspection for patent purposes, and they are housed in collections that are cataloged by easily used systems.

Patent examiners can easily determine where sheets of a particular specimen of tropical plant can be found by telephoning the Botany Division of the Smithsonian Institution's Museum of Natural History and asking the curators there which herbaria have the best collections of the subject species. Specialists in plant taxonomy are a fairly small community, and the people at the major herbaria know very well who works on what and where the best collections for particular groups are. Regarding the "Da Vine" patent, Dr. William R. Anderson, curator of the University of Michigan Herbarium, has said,

If the Patent Office had called the Smithsonian Botany Department and asked who could advise them about an Amazonian member of the Malpighiaceae [the family to which *B. caapi* belongs], they would have had my name and phone number in five minutes. If they had asked which herbaria in the United States have the best collections of South American Malpighiaceae, they would have gotten several suggestions: Michigan, the U.S. National Herbarium, New York Botanical Garden, Field Museum of Natural History, and Missouri Botanical Garden.<sup>43</sup>

Although Dr. Anderson says that the best way to identify which herbaria are relevant is still through "word-of-mouth," he adds that web sites exist that can also guide researchers to the best contact persons at major herbaria. These include Index Herbariorum, administered by the New York Botanical Garden, at <[www.nybg.org/bsci/ih/searchih.html](http://www.nybg.org/bsci/ih/searchih.html)>; and the membership directory of the American Society of Plant Taxonomists, at <[www.sysbot.org/members](http://www.sysbot.org/members)>.

#### **4. Avoiding Abuse of the System is Good Policy**

The rules and interpretations proposed here would increase the burden on applicants who seek to patent the botanical resources of developing countries. However, any increased burden would be offset by the benefits derived from reducing the opportunity for abuse of the system, which is presently significant. Such abuses interfere with the achievement of the mission of the patent law—to encourage progress in science and useful arts. The result of such abuses is the improper removal of information from the public domain and the failure to recognize the contributions to beneficial universal knowledge made by excluded groups that sorely lack incentives to continue conserving and adding to their knowledge.

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<sup>42</sup> See Order Granting Request for Reexamination, No. 90/005,307 at 3 (May 28, 1999) (deciding that two herbarium sheets of *B. caapi* raise a substantial new question of patentability).

<sup>43</sup> Communication from Dr. William R. Anderson, July 15, 1999.

The political ramifications from these abuses can thwart policy initiatives that are important to the United States government. The ayahuasca case provides a useful illustration. The ayahuasca vine that was the subject of the “Da Vine” patent is revered as a sacred plant by indigenous peoples throughout the Amazon region. It has been likened by them to the Christian cross or the Eucharist, and has been an essential ingredient in their religious and healing ceremonies for generations. When indigenous groups learned of the “Da Vine” patent’s existence in 1994, they were insulted and outraged that their sacred symbol could be commodified and privatized by a foreigner. Disinformation and confusion about the legal implications of the patent were rife, and the controversy eventually took on international proportions, involving the U.S. Embassy in Ecuador, the Inter-American Foundation, and numerous national and international environmental and human rights groups, amid charges and counter charges of deceit, “bio-piracy” and terrorism. Ultimately, the patent led to a setback for a significant United States trade initiative, when the Ecuadorian legislature—influenced by indigenous groups who feared the implications of a U.S. patent on their domestic use of ayahuasca—voted to reject a proposed bilateral intellectual property rights agreement with the United States. Had the original examination of the “Da Vine” patent been prosecuted under procedures such as those recommended here, these negative developments could likely have been avoided.

#### **D. Consideration of Moral Concerns**

The ayahuasca case raises additional concerns that go beyond the PTO’s treatment of prior art. As just noted, the “Da Vine” patent purported to award private, exclusive rights over a plant that is sacred to indigenous peoples throughout the Amazon region. Where the appropriation and commodification of an important element of a widely held religious system is inherently offensive to that system’s adherents, the award of a patent raises special moral concerns that cannot be readily addressed under PTO procedures as they are currently defined.

Analogous problems with trademarks that are offensive on moral or religious grounds have been addressed through statutory language and specific decisions. At the international level, Article 27.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) specifically provides that governments may make exclusions from patenting on grounds of morality. As the PTO itself has noted, the utility requirement of 15 USC § 101 permits it to deny patentability to inventions deemed “injurious to the well being, good policy, or good morals of society.”<sup>44</sup> In support of the principle that factors outside the patent law itself can affect patentability, the PTO recently rejected an application for a patent on a human-animal chimera on the grounds that it impermissibly embraced a human being.<sup>45</sup>

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<sup>44</sup> United States Patent and Trademark Office, *Facts on Patenting Life Forms Having a Relationship to Humans*, Media Advisory 98-6, April 1, 1998. The Advisory cited *Lowell v. Lewis*, Fed. Cas. No. 8568 (C.C. Mass. 1817), as quoted in *Tol-O-Matic, Inc. v. Proma Product-und Marketing Gesellschaft, M.B.H.*, 20 U.S.P.Q.2d 1332, 1338; 945 F.2d 1546, 1552 (Fed. Cir. 1991). Based upon *Lowell*, the PTO concluded that “inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.”

<sup>45</sup> See Rick Weiss, *US Ruling Aids Opponent of Patents for Life Forms*, The Washington Post, June 17, 1999, at A2.



Rather than waiting for case-by-case controversies to arise, the PTO should initiate consideration of how to design principles and procedures that would better protect moral values in the context of patenting living organisms. Such a review could be carried out through a process analogous to the exercise underway regarding the treatment under trademark law of official insignia of Native American tribes.<sup>46</sup> Such a review could help the PTO ensure that the United States' intellectual property system maintains the proper balance between exclusive rights and the public domain.

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<sup>46</sup> See 46 Fed. Reg. 13,004 (Mar. 16, 1999); Pub. Law 105-330, § 302 (1998). Similarly, the World Intellectual Property Organization has recently launched a program to study and evaluate similar issues at the global level, including extensive consultation with various constituencies. See World Intellectual Property Organization, *Main Program 11: Global Intellectual Property Issues*, Doc. No. A/32/WO/BC/18/2 at 105 (1998), available at <[www.wipo.org](http://www.wipo.org)>.

## Appendix: List of Database Websites

1. Dr. Duke's Phytochemical and Ethnobotanical Databases, <[www.ars-grin.gov/duke](http://www.ars-grin.gov/duke)>
2. NAPRALERT, <<http://stneasy.cas.org/>>
3. Nuffic/CIRAN International Indigenous Knowledge (IK) Network, <[www.nuffic.nl/ciran/ik.html](http://www.nuffic.nl/ciran/ik.html)>
4. Phytochemical Society of North America's "Links to Phytochemical Resources on the Web," <[www.fin.edu/orgs/psna/links.html](http://www.fin.edu/orgs/psna/links.html)>
5. "Prelude" database of traditional veterinary medicine, Tropical Diseases Webring, <[http://pc4.sisc.ucl.ac.be/prelude/prelude\\_HomePage.html](http://pc4.sisc.ucl.ac.be/prelude/prelude_HomePage.html)>
6. Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), <<http://csf.Colorado.EDU/sristi/>>
7. World Bank, "Database of Indigenous Knowledge and Practices" in Sub-Saharan Africa, <[www.worldbank.org/afr/ik/datab.htm](http://www.worldbank.org/afr/ik/datab.htm)>