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TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY IN BRAZILIAN BIODIVERSITY LAW

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*132 Introduction

Brazil is a country of superlatives, and its ecological and biological diversity fit well with this conception. Covering almost half of the South American continent, Brazil is home to the world's largest tropical humid forest and largest inland wetland in addition to the uniquely Brazilian ecosystems of the caatinga and cerrado.[1] Brazil's coastal zone, covering 3.5 million square kilometers, contains coral reefs, dunes, mangroves, lagoons, estuaries, and wetlands.[2] The rich and varied ecosystems of Brazil harbor an astonishing variety of living organisms. With more than 20% of the world's known species found within its borders, Brazil is the planet's most biologically diverse country.[3] Many of these species are found nowhere else on earth and are in danger of extinction, and many have yet to be identified.[4]

With such a wealth of biological resources, Brazil is understandably concerned with how these resources are used. This concern extends beyond resource extraction and conservation efforts to the use of traditional knowledge. Since the arrival of the first humans in South America approximately 11,000 years ago,[5] the earliest Brazilians have interacted with, adapted to, and changed the surrounding environment. This interaction, as it continued through the centuries, has generated traditional knowledge in the fields of medicine, spiritualism, and customary practices. Not surprisingly, some of this traditional knowledge has commercial value in the 21st century. To utilize this value, Brazilians and foreigners engage in bioprospecting, which is an exploratory activity that aims to identify components of genetic heritage and information about associated traditional knowledge with the potential for commercial use.[6] Of greater concern is biopiracy, which is essentially theft of genetic resources or associated traditional knowledge from traditional communities, usually for commercial ends.

***133** This article explores the problems encountered in Brazil when modern intellectual property systems unlock the commercial value of traditional knowledge associated with biological resources. The article begins with a historical perspective of bioprospecting and biopiracy and then considers laws governing intellectual property and biodiversity. A discussion of the challenges traditional knowledge poses to the existing intellectual property systems follows. Barring the creation of a sui generis system to address traditional knowledge and intellectual property rights, relatively simple practices could be enacted to ensure better protection of traditional knowledge associated with genetic resources.

I. Bioprospecting and Biopiracy: A Historical Perspective

Although bioprospecting and biopiracy are defined in terms of modern-day genetics, neither is new to the world stage, and Brazil's experience with both dates back to the era of Portuguese exploration. The arrival of Pedro Alvares Cabral, the Portuguese explorer who encountered Brazil in 1500, foreshadowed what would become the nation of Brazil's first incident of bioprospecting. Pero Vaz de Caminha, one of Cabral's explorers, described an enormous grove of trees beneath which the Cabral's crew rested in a letter dated May 1, 1500.[7] These brazilwood trees (pau brasil) were used by the indigenous people of what later became the city of Porto Seguro to make a red dye. The Portuguese recognized the commercial value of the dye, and brazilwood became the principle export for more than a century from the American colony which later bore the tree's name.[8]

The most famous episode of biopiracy in Brazil's history does not involve traditional knowledge but must be mentioned because of its significance. In the mid-nineteenth century, natural rubber (Hevea brasiliensis) was produced primarily from wild trees in the Amazon basin.[9] As the demand for rubber grew during the Industrial Revolution in Europe and North America, so too did the value of raw rubber. Extraction of rubber expanded to large tracts of the Amazon rainforest and made use of forced indigenous labor.[10] The Amazon River cities of Manaus and Belém became the centers of an extremely lucrative, near-global monopoly. Displays of the so-called Rubber Barons' wealth are evident in the still existing Teatro ***134** Amazonas (Manaus) and Teatro da Paz (Belém) opera houses that, because of the gilt facilities and fabulous wealth of the patrons, were able to attract top European performers to the sweaty backwaters of the Amazon. Recognizing the profitability of rubber and that the growing demand could not be met by wild trees, The Royal Botanical Gardens, Kew commissioned the botanist Sir Henry Wickham to collect seeds from the Amazon. Wickham collected nearly 70,000 seeds from near Manaus and shipped them to London.[11] About 2,700 of these seeds germinated in the greenhouses at Kew, and the gardens then sent most of these seedlings to the British colony of Ceylon to establish the first rubber plantation. Within 30 years, the Ceylon operation exported rubber and the British established other plantations in South East Asia.[12] The British broke Brazil's lucrative monopoly on natural rubber, and the guides at the Teatro Amazonas have not forgotten this incident of biopiracy.

More recent incidents of biopiracy in the 1990's keep the issue alive and generate outrage among activists who pay attention to such things because the bioprospectors (or biopirates, depending on one's view) seek to profit from patent systems in developed countries. One of the most widely known patent controversy cases involving traditional knowledge and genetic resources is that of ayahuasca (Banisteriopsis caapi), a hallucinogenic vine found in the Amazon rainforest that is used in religious ceremonies. In 1986, the United States Patent and Trademark Office (USPTO) awarded a U.S. pharmacologist who visited Ecuador a plant patent on what he claimed was a unique variety of a plant used in sacred indigenous rituals.[13] Word of the patent trickled back to Ecuador almost a decade later and incensed indigenous groups, who in 1999 filed a request through the Center for International Environmental Law (CIEL) to re-examine the patent.[14] Because of this request, the USPTO rejected the ayahuasca patent in late 1999 on the grounds that descriptions of B. caapi in scientific specimen sheets constituted prior publication in the United States, which meant that the patent failed on the grounds of novelty.[15] On appeal, the USPTO reversed this decision and reinstated the original patent; lawyers from CIEL protested this reversal and said that the USPTO did not follow proper procedures.[16] While the reinstatement of the original patent was a defeat for ***135** CIEL and indigenous groups in Ecuador, the defeat was largely symbolic since the ayahuasca patent was only awarded for the supposedly unique physical attributes of the plant, such as leaf shape, and thus possessed little, if any, commercial value.[17] No attempts at commercialization were made by the patent holder,[18] and the patent expired in 2003 at the end of its seventeen-year term.

Turmeric is another case involving a patent based on traditional knowledge. Best known in the United States as a spice and food colorant, turmeric also is used as a component of traditional medicine in its native India.[19] In 1995, two Indian scientists working at the University of Mississippi Medical Center were granted U.S. Patent No. 5,401,504 for the medicinal use of turmeric in treating wounds.[20] The patent mentions that turmeric "has long been used in India as a traditional medicine for the

treatment of various sprains and inflammatory conditions" and then describes how the oral or topical administration of turmeric available from a grocery store assists in the treatment of wounds.[21] Presumably, the USPTO issued the patent because it described a new use of a known agent.[22] The '504 patent was not the first turmeric patent issued by the USPTO, nor was it the first for a medicinal use, but it was the first to spark an uproar.[23] Outrage at the issuance of this patent is palpable in an Indian book published at the time of the controversy:

The patent on turmeric is yet another example of biopiracy. The uses of turmeric in wound healing, inflammation, dietary, and cosmetics has been usurped from the collective wisdom of Indian people developed over centuries . . . . [T]he US Patent Office defends these patents arguing that while turmeric as a wound healing ointment has been in public use, its application in the powder form has not. This is absolutely incorrect as many elderly women in India would be able to vouch.

The fact that its use has been unknown to the US medical establishment, permits the piracy of the common knowledge of India by a medical centre of an American university.[24]

This book fails to mention that the holders of the '504 patent holders were Indian nationals.[25] In mid-1996, the Council of Scientific and Industrial Research of ***136** India (CSIR) spent approximately $14,000 to successfully challenge the turmeric patent, which was revoked in 1997.[26] CSIR cited ancient Sanskrit text and a medical journal article from 1953 to invalidate the patent for lack of novelty based on a printed publication.[27] The actions of the CSIR should not be construed to imply that India is opposed to using the USPTO to patent traditional knowledge: the CSIR currently holds a valid U.S. patent for a topical cream used to treat skin ailments in which turmeric is an active ingredient.[28]

The historical examples of the biopiracy of brazilwood and rubber give credence to the widely held impression that natural resources can be stolen by the developed world to the detriment of developing countries. Contemporary examples of biopiracy involving ayahuasca and turmeric illustrate that the value of natural resources and associated traditional knowledge can be monopolized through international patent law. Examples of biopiracy or wronged indigenous groups also stoke the concern that biopiracy is a real and serious threat, and reminders of this threat are not uncommon in the Brazilian press. For example, the December 1, 2004, edition of a Correio Brasiliense, a widely circulated daily in the federal capital, contained the story of a German man apprehended at the airport in Brasília with six spiders in his luggage and videos and digital photos of hundreds of Amazonian species.[29] The man claimed to be a tourist but police believed that he intended to conduct research on the spiders' venom, which, according to the police officer quoted in the article, retails for $1,000 per milliliter in Europe.[30] Stories such as these remind Brazilians of the value and attractiveness to outsiders of their natural resources and the risk that this value can be stolen and patented by someone else.

Bioprospecting and the use of traditional knowledge for commercial ends generate headlines, but it is important to place the two in context, especially as it concerns drug discovery. Natural products have contributed a great deal to the discovery and development of drugs, and one high-end estimate places the value of natural-product derived pharmaceuticals at $120 billion in global sales in 1997.[31] ***137** The portion of this value coming from the commercial use of traditional knowledge is smaller but still significant. Of the approximately 120 pharmaceuticals derived from plants in 1985, 75% were discovered through their use in traditional medicine.[32] The most common use of traditional knowledge in drug discovery efforts is as a guide to bioprospectors for initial plant selection for further analysis;[33] easily diagnosed diseases affecting traditional communities are the most frequently encountered leads.[34] Correlatively, traditional knowledge is less useful in blockbuster drug discovery programs for diseases such as cancer and Alzheimer's.[35] Despite the apparent value of using traditional knowledge as a means to identify biologically active compounds, its popularity as a method of drug discovery is declining due to cheaper and more efficient methods, such as the synthetic production of compounds and the use of existing genetic resource collections to identify promising leads.[36] While bioprospecting is most often associated with pharmaceuticals, the cosmetics industry also engages in the practice and makes use of traditional knowledge to develop new products. The use of traditional knowledge as part of a given product's history is sometimes even used to market the product.[37]

When traditional knowledge is used as a guide for further pharmaceutical or cosmetics research, it can shorten the time spent in the laboratory by years and thus save research companies millions of dollars. Because traditional knowledge used by bioprospectors can save time and money, the traditional knowledge itself has value and the holders of the knowledge deserve compensation. However, the value of any one piece of traditional knowledge is very difficult to ascertain before compounds are isolated and tested. Drug companies especially must expend significant amounts of time and money before realizing any returns on the research investment, yet many indigenous communities tend to overvalue their knowledge and genetic ***138** resources.[38] Though the number of blockbuster drugs derived from natural products and traditional knowledge is small and may be declining, natural products will remain a component of drug discovery programs and traditional knowledge has a

minor but important role to play.[39]

II. Intellectual Property in Brazil

If an inventor wanted to patent something such as the active ingredient in spider venom, the inventor would need to navigate Brazil's intellectual property laws, which are similar in many ways to the intellectual property laws of other countries. The Industrial Property Law is the principal Brazilian law governing patent, industrial design, and trademark.[40] Like most of the world, Brazil uses a first-to-file system, meaning that the first person to file for a patent has priority over other inventors regardless of date of discovery.[41] The Industrial Property Law applies in equal conditions to both individuals (pessoas físicas) and legal entities (pessoas jurídicas) of Brazilian nationality or domiciled in Brazil.[42] Thus, a legal entity can be both the inventor and the owner of a patent. The requirements for patentability in Brazilian law are described in Article 8 and include novelty, inventive activity, and industrial application.[43] These mirror the requirements of novelty, non-obviousness, and utility in other patent systems. Enablement is not expressly listed in Article 8 but is found in Article 24, the section detailing the patent application process. Article 24 requires the patent applicant to clearly and sufficiently describe the object, the method for a specialist in the subject to make the object possible, and, if necessary, the best form of execution.[44]

Brazil's patent system shares many similarities with that of the United States, but there are some notable differences. For the most part, these differences are traceable to the unique aspects of the United States system, which awards a patent to "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[45] The "first to invent" system requires more than the date of application to determine the owner of a disputed patent, which makes administration more difficult than the ***139** first-to-file system used almost everywhere else in the world. Another major difference between Brazil and the United States is who can apply for a patent. In the United States, the applicant for a patent must be the inventor,[46] and only natural persons can be inventors.[47] As previously noted, both individuals and legal entities can invent and own patents in Brazil.

The final major difference between the two patent systems is patentable subject matter. The Industrial Property Law does not expressly list patentable subject matter as a requirement for patentability although it is an obvious addition to the requirements mentioned in Article 8. Brazil, like most of the world, does not issue patents for organisms or biological material found in nature, including germplasm and genomes.[48] Brazil also expressly prohibits patenting substances derived from living organisms and transgenic microorganisms that do not meet the three requirements of patentability: novelty, inventive activity, and industrial application.[49] Brazil further restricts the patenting of transgenic microorganisms to those that possess a characteristic not normally attainable by the species in natural conditions.[50] Laws of nature, abstract ideas, physical phenomena, and naturally occurring substances are not patentable.[51] However, a refined natural substance, provided that it has a new use, is patentable.[52] The United States also issues patents for genes since the chemical structure of an isolated gene is distinct from the same gene found in a living organism and because purified substances are patentable.[53] Additionally, the requirements for patenting a transgenic microorganism are not as strict in the United States, requiring only that if it is humanly engineered, it is patentable.[54]

Plant patents are a lesser but still important component of the intellectual property regimes of Brazil and the United States. Since neither system permits the patenting of entire organisms except transgenic microorganisms, plant patents fill the void made necessary by valuable plant hybrids and transgenic plants by offering less than full patent protection. In the United States, both asexually and sexually reproducing distinct and new varieties of plants can receive protection.[55] Brazil ***140** governs plant protection through its Cultivar Protection Law.[56] Brazil defines a cultivar as any distinct, homogenous, and stable variety of a higher plant species or genus.[57] As with a patent, both individuals and legal entities can hold a plant patent.[58] Interestingly, the plant patent application requires the identification of the person who improved the variety (melhorista), who is defined as only being an individual.[59] Thus, while a legal entity could hold a plant patent, it could not apply for one unless the person who created the variety can be identified on the plant patent application. This mirrors patent application procedures in the United States.

Trade secrets are another aspect of intellectual property law present in both the United States and Brazil. In the United States, trade secrets are protected at the state level. Forty states have enacted the Uniform Trade Secrets Act, which defines a trade secret as:
information, including a formula, pattern, compilation, program, device, method, technique, or process that:

(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily

ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and

(ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.[60] Misappropriation of a trade secret is punishable by injunction, monetary damages, or both.[61] Trade secrets in Brazil are considered an aspect of unfair competition and are regulated at the federal level by the Industrial Property Law, the same law that regulates patents. The crime of unfair competition includes divulging, exploiting, or utilizing, without authorization, knowledge, information, or confidential information utilized in industry, commerce, or services, excluding those that are publicly known or evident to an expert in the field.[62] Current commercial use is not required since the same article extends unfair competition to the results of tests or other undisclosed data whose elaboration involved considerable effort and that has been presented to government entities for commercial approval.[63] In other words, ***141** the prospect of future commercialization can receive protection, although the law does not detail how far along in the approval process a product must be. The penalty for the crime of unfair competition is imprisonment (from three months to one year) or a fine.[64] While trade secrets exist in Brazil, they are not distinct from unfair competition and their legal definition is vague. Perhaps as a result, they are not commonly used to enforce intellectual property rights.

To summarize, an inventor seeking a patent in Brazil or the United States must fulfill many of the same requirements, such as demonstrating novelty, inventive activity, industrial application, and enablement. The two most significant differences are that a legal entity can apply for a patent in Brazil but not in the United States, and that the United States requires the identification of the inventor, who must be a natural person. Also, the United States is more permissive in the patenting of life forms. Outside of the laws governing utility patents, intellectual property laws governing plant patents and trade secrets in the United States and Brazil are similar.

III. Biodiversity Law

While intellectual property laws in Brazil and the United States are adaptable to various types of knowledge, wide-spread international awareness of the connection between intellectual property and biodiversity did not come until the 1992 United Nations Conference on Environment and Development held in Rio de Janeiro, Brazil. One of the principal documents to emerge from this conference was the Convention on Biological Diversity (CBD).[65] The three objectives of the CBD 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."[66] Sections of the CBD further explore the general principles of the three stated objectives and consider various aspects important to comprehensive strategies designed to protect biodiversity, including the protection of traditional knowledge associated with genetic resources.

Article 8(j) of the CBD recognizes the importance of traditional knowledge in the preservation of biodiversity. The article states that each Contracting Party shall:

> respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and ***142** 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.[67]

The proper interpretation of Article 8(j) is the subject of extensive and ongoing international debate. The CBD envisioned the use of existing national and international intellectual property regimes to promote and protect traditional knowledge as one way of addressing article 8(j) issues. Article 16 addresses the access to and transfer of technology and states that if traditional knowledge is subject to intellectual property rights, "access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights."[68] Contracting Parties are also required to ensure that intellectual property rights are "supportive of and do not run counter" to the CBD's objectives.[69] The CBD links traditional knowledge to existing intellectual property systems but also sets the two on a potential collision course by requiring both adequate and effective protection of intellectual property rights and that the intellectual property rights support the objectives of the CBD. Traditional knowledge and practices are viewed as more than a source of patentable inventions that generate revenue. The CBD lists traditional cultural practices as one method for the sustainable use of biological diversity. To the extent that traditional cultural practices are compatible with conservation or sustainable use requirements, these uses are to be protected and encouraged.[70] The importance of resolving Article 8(j) issues is underscored by the

existence of a dedicated working group of the Contracting Parties as well as listing Article 8(j) and related provisions as "issues for in-depth consideration" on the provisional agenda for the 8th Conference of the Parties of the CBD, which will take place in Curitiba, Brazil, from March 20- 31, 2006.[71]

The lack of specific language in the CBD means that conservation principles are defined only in vague terms. For example, parties are encouraged to develop strategies for the "fair and equitable" sharing of benefits, yet neither "fair" nor "equitable" is defined in the CBD. The same problem is encountered with "prior informed consent" required for access to genetic resources in Article 15. Article 3 recognizes that states have the "sovereign right to exploit their own resources pursuant to their own environmental policies," and Article 6 calls for contracting parties ***143** to "[d]evelop national strategies . . . which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned."[72] What constitutes consent is not specified, and the authority given in Articles 3 and 6 means that the state sets the terms of consent, whether the parties involved in the exchange of knowledge and biological resources actually gave their consent. The vagueness of the language in the Convention may have been intentional in that the loose terminology gives national governments maximum flexibility in implementing the terms of the CBD as they see fit. The lack of guidance in the text of the CBD has not been dismissed since meetings of the Conference of Parties following entry into force of the Convention have addressed themes of the CBD and clarified some areas of confusion. However, many countries passed legislation implementing the CBD into national law before benefiting from the ongoing meetings that clarify terminology. Thus, national legislation tends to use the same vague terms used in the Convention text, and this creates uncertainty when government officials attempt to translate national legislation into action.

The CBD requires contracting parties to implement the convention into national law, but in Brazil, state governments were the first to act on the CBD's principles. The distinction of being the first to regulate access to genetic resources in Brazil belongs to the sparsely populated western Amazon state of Acre, which enacted its biodiversity law in July of 1997.[73] The Acre law codifies many of the principles of the CBD and created the template for the federal legislation enacted five years later. The most important contribution of the Acre law is that at the time it identified the absence of a national method to protect the traditional knowledge of indigenous and local communities.[74] The state law recognized the value of traditional knowledge associated with genetic resources and made special provisions for traditional knowledge and intellectual property. Article 41 says that local communities will benefit collectively from their traditional knowledge, including the sharing of intellectual property rights.[75] The law recognizes that some intellectual property relating to biodiversity can be attributed to an individual and requires that knowledge relating to biodiversity that cannot be attributed to an individual be treated as collective intellectual property.[76] The law also says that collective intellectual property rights are those that include ancestrally acquired knowledge.[77] This raises an important issue of whether the entire community can be considered ***144** the owner of knowledge possessed by a few. If segmented or restricted communal knowledge seems oxymoronic, consider an instance where only select members of a community have access to a certain practice, such as the knowledge possessed by a traditional healer. The healer may be the only person who has access to and knows how to use certain practices passed through generations. The healer is the holder of the knowledge but the community owns the knowledge. In other words, traditional knowledge is owned and transmitted collectively but can still be segmented or claimed based on social rank.[78] A glaring omission from the Acre law is the definition of traditional knowledge.[79] The law defines "local and indigenous community" and "provider of traditional knowledge" but never defines traditional knowledge itself. Another Amazon state, Amapá, passed its own biodiversity law in December of the same year.[80] The regulation of intellectual property and indigenous lands is the domain of the federal government,[81] so the passage of the biodiversity laws in Acre and Amapá can either be viewed as bold statements on the importance of traditional knowledge or futile exercises. In any case, these two state laws and federal representatives from the Amazon states spurred the federal government into action. One of the main supporters in the Congress of the federal legislation regulating access to genetic resources was then Senator from Acre and now Minister of the Environment, Marina Silva.[82]

The principal piece of Brazilian federal legislation dealing with access to and the commercial use of genetic resources and traditional knowledge is Medida Provisória 2186-16/2001 (M.P. 2186).[83] M.P. 2186 defines genetic resources as information ***145** of genetic origin from all or part of microbial, fungal, plant or animal species found in or coming from Brazilian territory, including the continental shelf and exclusive economic zone.[84] The definition lays claim to Brazilian specimens in ex situ collections, such as gene banks or zoos, wherever they may be; this draws on the principle espoused in the CBD that states have the sovereign right to exploit their own resources.[85] This claim also takes full advantage of the jurisdictional scope of Article 4 of the CBD in claiming sovereignty over processes and activities beyond the limits of national jurisdiction.[86] M.P. 2186 defines genetic resources in such a way as to include derivatives and extracts, an important area not addressed in the CBD. The omission of derivatives in the CBD is surprising since most commercial products use manipulated compounds and genes and not unmodified genetic resources.[87] However, the CBD's regulation of access to genetic resources enables the

consideration of derivatives, which is the interpretation selected by Brazil.[88]

In addition to an expansive reach for materials covered, M.P. 2186 adopts a broad definition of associated traditional knowledge and the rights belonging to ***146** holders of traditional knowledge. M.P. 2186 defines "associated traditional knowledge" as the information or individual or collective practice of an indigenous or local community with real or potential value associated with genetic resources.[89] "Local community" includes culturally distinct indigenous and quilombo populations that organize along traditional lines and conserve their social and economic institutions.[90] Indigenous and local communities have the right to decide how to use their traditional knowledge, including the right to refuse use of their knowledge.[91] M.P. 2186 reflects the precedent set by the Acre law in saying that traditional knowledge associated with genetic resources is communal, even if only possessed by an individual.[92] Notably absent from this provision is who has the power to make individual traditional knowledge into community knowledge. The definition of traditional knowledge appears suitable for M.P. 2186 even though it is restricted to knowledge "associated" with genetic resources since M.P. 2186 concerns only genetic resources. Traditional knowledge also extends into artistic expression, and in this situation M.P. 2186's definition is not suitable.

Parties wishing to access genetic resources and associated traditional knowledge in Brazilian territory must conform to stringent requirements.[93] Access to and collection of in situ resources, or those in their natural habitat, is only given to Brazilian entities.[94] If a foreign legal entity collects in situ samples or associated traditional knowledge, permission is granted only when the foreign entity partners with a Brazilian institution; the Brazilian institution must be the controlling partner.[95] When access occurs in situ, it must be with the prior informed consent (PIC) of the owner.[96] M.P. 2186 is vague on what exactly constitutes PIC and does not explicitly define the term, but it improves upon the CBD in that M.P. 2186 lists parties authorized to give consent. Those mentioned in what appears to be an exclusive list are: the indigenous community involved, after consulting the official indigenous ***147** body, when access occurs on indigenous land; the competent body, when access occurs in a protected area; the owner of a private area, when access occurs there; the National Defense Council, when the access occurs in an area deemed essential for national security; and the maritime authority, when access occurs in Brazilian jurisdictional waters, on the continental shelf, or in the exclusive economic zone.[97] The lack of a definition of PIC is particularly problematic when indigenous communities are involved since it is not always clear who can give effective consent.

Another vague term inherited from the CBD is the "fair and equitable" sharing of benefits required in access contracts when there is the prospect of commercial use of the genetic resources or traditional knowledge. Access is granted only with a signed contract of use and benefit sharing.[98] Again, M.P. 2186 improves upon the CBD in suggesting what might constitute a "benefit." Such items include: sharing of profits; payment of royalties; technology transfer; licensing of products and processes without cost; and capacity building.[99] While parties appear free to negotiate terms, there is no existing agency in Brazil to oversee the terms of individual contracts and to ensure that the terms are fair and equitable. More problematic is the lack of a mechanism to distribute benefits. South Africa answers both the questions of equitability and a distribution mechanism through legislation passed in June of 2004 implementing the CBD.[100] In South Africa, an access permit is granted only if the applicant and a stakeholder have entered into a benefit-sharing agreement that has been approved by the Environment Ministry.[101] Benefits can be whatever the parties decide, and the national government oversees contracts to ensure that they are reasonable.[102] The South African Act also establishes a Bioprospecting Trust Fund into which all payments are made and benefits are distributed.[103] South Africa's system appears simple and seems to minimize bureaucracy, but it has not been tested. South Africa's experience may assist Brazil, which has yet to designate an agency to oversee the fairness of individual contracts or establish a mechanism to receive and disburse monetary benefits.

With regards to intellectual property rights, M.P. 2186 follows the CBD. Protection of traditional knowledge associated with biodiversity does not affect, damage, ***148** or limit intellectual property rights as called for in Article 16 of the CBD.[104] Article 28 of M.P. 2186 states that the consideration of intellectual property rights is among the required clauses in the benefit sharing contract.[105] The award of intellectual property rights is conditional with following M.P. 2186, and penalties for not following the procedures set out by M.P. 2186 include the suspension and cancellation of any intellectual property rights.[106] A legislative decree elaborating Article 30 of M.P. 2186 establishes a schedule of fines and penalties for the misuse of genetic resources or traditional knowledge.[107] The range of fines for the illegal use of genetic resources or traditional knowledge is increased by one-third when the access involves an intellectual property right related to the illicitly obtained resource or knowledge.[108] When there is economic exploitation of the illicitly obtained resource or knowledge, fines are increased by one-half.[109]

M.P. 2186 establishes how Brazil deals with the commercial use of genetic resources and traditional knowledge, but it is not

the only piece of legislation regulating Brazilian biodiversity. Decree 3945/2001 establishes the rules and regulations of the Genetic Resources Management Council (Conselho de Gestão do Patrimônio Genético, or CGEN) as called for in Article 10 of M.P. 2186.[110] CGEN's duties include creating and maintaining databases on traditional knowledge relevant to the conservation of biodiversity as well as establishing the procedures and approval process for genetic access agreements.[111] CGEN has most of the authority regarding access to genetic resources and, after five years, is at the point where it is approving access for individual parties. CGEN does not oversee the equitability of access contracts, although it may do so in the future. CGEN is part of the Ministry of the Environment and is composed of representatives from federal ministries and foundations and institutes with interests in the use of traditional knowledge and biodiversity. Non-governmental organizations (NGOs) can attend CGEN's monthly meetings but are not allowed to participate. CGEN has been receptive to the criticisms of several NGOs that CGEN excludes civil society. Legislation developed by one of CGEN's working groups has been introduced in ***149** the Brazilian Congress to restructure the composition of CGEN to allow formal participation by civil society.[112] Although the legislation has the support of the Ministry of the Environment, it does not seem to have a high priority as it has languished in the Congress for more than two years.

Another central piece of legislation is the National Biodiversity Policy.[113] Despite the importance of a national biodiversity policy for a country as rich in biological resources as Brazil, the legislation expresses few new ideas and even less in the way of directing a comprehensive approach to managing Brazil's biodiversity in a sustainable manner. The overly broad goals of the legislation range from understanding biodiversity through scientific research and cataloging to the promotion of technology transfer. One notable contribution of the National Biodiversity Policy is the call for the establishment of a sui generis legal system for the protection of collective intellectual property rights associated with traditional knowledge and biodiversity.[114] The author of a noted environmental law text has gone so far as to call the National Biodiversity Policy "chaotic."[115] Subsequent legislation creates the National Biodiversity Commission, an entity charged with implementing the National Biodiversity Policy.[116] Presumably the National Biodiversity Commission will sort out some of the confusion created by the National Biodiversity Policy, although it is not clear how the National Biodiversity Commission will work with CGEN even though both are part of the Ministry of Environment.

Decree 5092/2004 identifies priority areas for the conservation, sustainable use and equitable benefit-sharing of biodiversity.[117] The decree authorizes the National System of Units of Conservation to research and inventory biodiversity and to distribute benefits derived from traditional knowledge associated with biodiversity.[118] The decree identifies priority biomes as the Amazon rainforest, the cerrado and pantanal, the caatinga, the Atlantic rainforest, the southern plains, and coastal and marine zones.[119] In other words, all the natural areas of Brazil are considered priorities.

***150** Brazilian laws implementing the CBD into national legislation created mechanisms and institutions to regulate the country's wealth of biological resources. M.P. 2186 and Decree 3945 create CGEN, a central authority to manage genetic resources, although uncertainty in the authorizing language resulted in implementation problems and the need for bureaucratic clarification. Two other laws, Decree 4339 and Decree 5092, give the appearance of a comprehensive national policy, but the contribution they make to Brazilian biodiversity law, particularly to the management of genetic resources, is questionable.

IV. Indigenous People

Although indigenous people comprise a tiny percentage of Brazil's population, they are a culturally distinct minority and an important component of Brazil's national identity. Brazil is home to at least 215 indigenous societies speaking 180 distinct languages.[120] Approximately 345,000 indigenous people, or about 0.2% of Brazil's total population, live in villages and indigenous territories occupying 12% of Brazil's territory.[121] About 200,000 indigenous people live in the nine Amazon states, and 100,000 to 190,000 people of indigenous descent live outside of indigenous lands in towns and cities throughout Brazil.[122] While many indigenous people are assimilating into modern life, the opposite end of the spectrum also still exists: an estimated additional 53 groups have not been contacted.[123]

Indigenous people have distinct legal rights. Article 231 of the federal constitution recognizes indigenous peoples' social organizations, customs, languages, beliefs, traditions and rights over traditionally occupied lands and says these rights are to be protected and respected.[124] Indigenous communities and organizations are recognized legal entities that can defend their rights and interests in court.[125] The legal rights of indigenous people are further detailed in the Statute of the Indian.[126] The Statute of the Indian extends the protection of Brazil's laws to all indigenous groups on the same terms that apply to all other Brazilians and offers specific protections ***151** and exemptions necessary to accommodate indigenous society.[127] One

important right recognized by the Statute of the Indian is that the natural resources in lands occupied by indigenous communities and in recognized indigenous territories are considered to be indigenous heritage collectively owned by the indigenous group.[128] Sovereignty over natural resources and the protection of biodiversity and associated traditional knowledge also factor into the Ministry of Justice's ongoing process of demarcating indigenous territory.[129]

Indigenous groups in Brazil have taken an active interest in the procedure regulating access to genetic resources and the use of associated traditional knowledge. Four entities representing the interests of indigenous people and local communities have official representation in CGEN; these are the Ministry of Justice, the Ministry of Culture, the National Indian Foundation (Fundação Nacional do Índio, or FUNAI), and the Palmares Cultural Foundation.[130] Some non-governmental organizations and indigenous groups do not feel that this representation is adequate since all of the official members of CGEN are government entities. Although CGEN's meetings are open to the public, the public can only observe. The introduced bill on access to genetic resources mentioned earlier would expand official representation on CGEN to civil society, although the method for determining which organizations would be granted official participant status is not specified in the bill.[131]

In addition to NGO's advocating for improved indigenous representation in CGEN, there has been a grass roots movement by indigenous groups regarding intellectual property, traditional knowledge, and biodiversity. On December 6, 2001, representatives from indigenous groups met in São Luís, the capital of the northeastern state of Maranhão, and wrote a letter known as the Carta de São Luís de Maranhão to the National Intellectual Property Institute (Instituto Nacional de Propriedade Industrial, or INPI), Brazil's patent office, on the subject.[132] The letter states that traditional knowledge is collective and cannot be commercialized like other products in the marketplace.[133] To address the unique challenges of traditional knowledge, the authors of the letter request official representation at CGEN ***152** and affirm their right to participate in global intellectual property forums such as the World Intellectual Property Organization (WIPO) and the World Trade Organization.[134] The letter also supports the creation of a sui generis system to regulate the intellectual property rights of traditional knowledge and favors the creation of databases and registries to record traditional knowledge.[135] None of these proposals is revolutionary since all have been discussed at the global level, but their inclusion in the letter indicates that some Brazilian indigenous groups support the proposals and would like to see Brazil implement changes at home and abroad to make the proposals realities.

V. Problems with Traditional Knowledge and Existing Intellectual Property Systems

In the bioprospecting examples involving brazilwood, ayahuasca, and turmeric, traditional knowledge played an important role in transforming natural products into something that some believed was valuable enough to exploit, even though only brazilwood resulted in a valuable product. Because traditional knowledge associated with biodiversity has potential value, holders of traditional knowledge seek to protect it using existing legal systems. Brazilian laws regulating biodiversity and intellectual property seem to accommodate the protection of traditional knowledge through existing structures, but significant practical obstacles remain to effective protection at both the national and international levels.

Even before the issuance of patents can be considered, special problems presented by the nature of indigenous communities and bioprospecting must be examined. The most significant of these is prior informed consent (PIC). The CBD states that PIC is subject to national law but provided no guidance for what constituted PIC in the Convention's text.[136] In April of 2002, the 6th Conference of Parties created a document known as the Bonn Guidelines that details the elements and procedures of attaining PIC.[137] Among the elements of a PIC system that follows these guidelines are competent authorities that grant or provide evidence of PIC.[138] National regulations of PIC should involve all relevant stakeholders, and in the case of indigenous and local communities, PIC should be obtained in accordance with traditional practices.[139] Additionally, PIC should be based on the specific uses for ***153** which the consent was granted.[140] In other words, a bioprospector could not contract for the medicinal use of a plant to treat X and then develop a product to treat Y. If a drug company uses traditional knowledge primarily as a way to identify genetic resources that may be of interest, problems could occur if the eventual use of the genetic resource and associated traditional knowledge is different from that specified in the access contract.

The Bonn approach is followed in Brazil. CGEN requires evidence of PIC before granting authorization for access to genetic resources or associated traditional knowledge.[141] Until very recently, CGEN did not specify what it considered to be PIC. This changed in March of 2004, when CGEN issued guidelines for obtaining PIC.[142] The CGEN resolution largely follows the Bonn guidelines, although it adds an important but overlooked requirement that PIC requires the use of language accessible to those giving consent.[143] This suggests that Portuguese may not be sufficient for a bioprospector seeking the consent of an indigenous community. The decree does not address the situation where some in the indigenous community speak Portuguese

or have a limited knowledge of Brazil's national language. PIC from an indigenous or local community adds two additional requirements to the Bonn Guidelines. The first is that the social organization and traditional political representation of the involved communities is respected.[144] The second is the clarification of the social and cultural impacts of the project.[145] If access is to occur in indigenous territory, the official indigenous organization will establish administrative procedures necessary to obtain the PIC of the involved indigenous community.[146] Given the cultural diversity of Brazil's indigenous population, the general procedures adopted by CGEN appear to avoid the difficulty of formulating a rule that works for every community and every issue.[147]

While the procedures for obtaining PIC in Brazil seem to empower indigenous communities by deferring to traditional social organizations and decision making procedures, the practical problem of who can give PIC remains. As an example, consider the case of the Krahô (Craô) Indians of Tocantins state. In 1999, ***154** Brazilian pharmacologists from the Federal University of São Paulo (Unifesp) sought and received the consent of three Krahô villages to engage in bioprospecting for commercial ends.[148] The contract established that the Krahô would have royalty rights to whatever drug developed from their traditional knowledge.[149] Unifesp did not seek permission from FUNAI because it already received what it believed to be the consent of Wyty-Cati, the legal entity representing three villages in the reserve.[150] In 2000, the Unifesp researchers learned of Kapey, another indigenous association that said it represented all seventeen villages of the Krahô nation.[151] When the fourteen villages learned of the agreement from which they were excluded, they protested. Unifesp said that it held another meeting involving representatives from all seventeen Krahô villages. In the meeting, the representatives agreed that three villages, two represented by Wyty-Cati and one represented by Kapey, would participate in the Unifesp study and that any benefits derived from the use of Krahô traditional knowledge would be shared by all seventeen Krahô villages.[152] Apparently this did not satisfy all parties involved because some Krahô complained to FUNAI and the Ministério Público and demanded twenty-five million reais (approximately $11.4 million), twenty million reais for an access charge, and five million reais for pain and suffering.[153] Unifesp refused to pay because it maintains that it had a valid contract entered into with the PIC of the Krahô nation.[154]

It is possible that the involvement of CGEN, which did not exist at the time Unifesp signed the first contract with the Krahô, could have prevented the confusion and resulting lawsuit. A government entity, such as FUNAI or CGEN, might have been able to coordinate the expectations of the seventeen Krahô villages to create what could have been a lucrative win-win situation involving Brazilian scientists, Brazilian research institutions, and a Brazilian indigenous group. But then again, the Krahô case could still have ended with the same result. CGEN's PIC guidelines only call for the bioprospector to seek consent using traditional decision-making organs. Unifesp apparently did that, at least in the second round of negotiations ***155** with representatives from all seventeen villages. Unifesp also dealt with competent legal entities, the Wyty-Cati and Kapey. The requirements for PIC treat indigenous groups as single entities and do not address what happens if there are multiple villages of the same indigenous group that may not be able to agree using traditional decision making processes. Also not addressed is what might happen if one village declares its independence from the traditional decision making processes. It is not clear whether a bioprospector would be stealing traditional knowledge if there is not unanimous consent. One could imagine a situation in which a bioprospector engages the traditional council of a multi-village indigenous group that grants its consent to access its traditional knowledge and genetic resources. It is not difficult to imagine the same situation involving a renegade village or villages that incorporate into a new legal entity and then sue the bioprospector for biopiracy. Some have criticized the PIC contract process as cumbersome in that it is unrealistic to ask companies to negotiate with all tribes that might possess the same knowledge.[155] As a solution, a government could impose licensing fees and distribute the revenue to all stakeholders.[156] However, the apportionment of revenues from a single fund is not likely to give any real benefits.[157] In one of the articles on the Krahô case, a Ministry of Environment official's quote could be translated as, "you can be certain there will be more cases. But these difficulties are going to facilitate the definition of the rules in the future."[158]

In addition to the difficulty of obtaining PIC even when following CGEN's regulations, other difficulties exist in integrating traditional knowledge into existing intellectual property protection regimes. One obstacle to protection of traditional knowledge is the nature of traditional knowledge itself. Many traditional medicine practices are infused with spiritualism.[159] Even the efficacy of such practices may be difficult to prove in a scientific manner. As a consequence, there may to be a tendency by the various patent offices to reject such patent applications for failing to meet the utility requirement.[160] Assuming that spiritual aspects can either be overlooked or are not essential to an application for a patent, the communal nature of traditional knowledge does not mesh easily with intellectual property systems designed to protect the works of individuals. In theory, if the link between the traditional knowledge and an invention is clear, the holder of the traditional knowledge could be identified as a co-inventor because of the inventive nature of the contribution. ***156** [161] Collective knowledge does not present a barrier to patentability in Brazil since legal entities, including indigenous groups, can apply for

and hold patents.[162] This is not the case in the United States since individual inventors must be listed on the patent application.[163] The European Patent Office also requires the application to designate an inventor.[164] In the case of traditional knowledge passed through generations, the "inventors" most likely are not known. If the inventor cannot be identified, a patent cannot be issued.

Another obstacle to protection of traditional knowledge in modern-day intellectual property systems is the shroud of secrecy.[165] With the exception of trade secrets, intellectual property protection requires disclosure. Disclosed patent applications become public knowledge freely usable by anyone upon the expiration of the patent. In the case of a traditional knowledge database, the disclosed information probably would be available before the issuance of a patent, depending on when the applicant files a patent and submits the information to the registry. No protection will be awarded if the holder of traditional knowledge is unwilling to disclose the knowledge for whatever reason, be it spiritual or the desire to prevent eventual use by members outside the community or even by other groups within the same community. As mentioned earlier, trade secrets do not require disclosure and many forms of traditional knowledge could be protected against infringers with trade secrets; trade secrets could be particularly useful if the traditional knowledge is held by a select few in an indigenous community.[166] However, trade secrets offer comparatively weak protection on a small scale; once a secret becomes widely known, it can no longer be protected as a trade secret. Holders of traditional knowledge may have to choose between strong protection and the potential for substantial profits on one hand and maintaining indigenous secrets for as long as possible on the other.

VI. Improving the Status Quo

The current situation regulating traditional knowledge and intellectual property associated with genetic resources suffers from a number of defects that seriously impede the goals laid out in Article 1 of the CBD. The ayahuasca and turmeric ***157** cases demonstrate that the most effective weapon to combat biopiracy is to challenge patents issued by the USPTO, but challenging patents after they have been issued is an expensive process, costing approximately $14,000 in the turmeric case.[167] Trade secret laws, if better defined and more widely used in Brazil, offer an alternative method for protecting traditional knowledge, but trade secrets will not protect traditional knowledge that is disclosed, for instance in a patent application. The ideal situation would be to develop a sui generis intellectual property regime for the protection of traditional knowledge that could accommodate the issues raised by short-comings of existing intellectual property systems. Given the effort required to combat entrenched interests and create a new system, a sui generis regime is not likely to be realized in the near or even distant future.

Fortunately, the current system can be substantially improved through a more thoughtful application of existing authorized powers and modest reform. The most promising step that could be taken to better protect traditional knowledge is the use of defensive disclosure, although such a step is not without risks or trade-offs. Defensive disclosure is "information or documentation intentionally made available to the public as prior art in order to render any subsequent claims of invention or discovery ineligible for a patent."[168] Defensive disclosure negates any claim of novelty. In the United States, there is a statutory bar against an invention patented or described in a printed publication for one year prior to the application date.[169] The USPTO considers a printed publication to be a document that "has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it."[170] Printed publications include scientific and technical journals as well as electronic publications, including on-line databases or internet publications, provided they are accessible.[171] Electronic publications are considered to be publicly available as of the date posted; if there is no date, the publication cannot be relied on as prior art.[172] Documents distributed only within an organization or those which are intended to remain confidential are not considered printed publications.[173]

***158** Defensive disclosure has two significant drawbacks relevant to traditional knowledge. The first is that knowledge must be disclosed. For indigenous groups or individual members of such groups valuing secrecy above all other considerations, defensive disclosure is not a viable option. Some governments have not recognized the incompatibility of secrecy and defensive disclosure. For example, Peru established registers of traditional knowledge to provide defensive protection against patents and to maintain the collective knowledge of indigenous peoples.[174] The law creates two types of national registers: a common National Register and a parallel National Confidential Register that is not accessible to third parties.[175] Indigenous groups in Peru proposed the National Confidential Register as a way to protect traditional knowledge that the holders prefer to keep secret.[176] A holder of traditional knowledge in Peru has the option of submitting the information to either register, both of which contribute to the preservation of traditional knowledge. While the option to include the information in the National Confidential Register respects the desire for secrecy, it serves no role in defensive protection since it is not

accessible and thus cannot constitute prior art; only the accessible National Register would provide defensive protection.

The second and more significant drawback of defensive disclosure is that if the knowledge is available on the register for one year before the date of a patent application, the knowledge holder is prevented from seeking a patent on his own invention. The statutory bar applies to third parties as well as the original inventor, or in this case, the holder of traditional knowledge. Thus, assuming that inventors can even be identified as required for the patent application, traditional knowledge holders would have to choose between (1) seeking a patent with the risk that someone might appropriate the knowledge before the knowledge holder receives a patent and (2) preventing others from profiting from the traditional knowledge by negating patentability. A possible resolution to this conundrum is for the holder of traditional knowledge to register the knowledge and then file patent applications on promising inventions within one year. It may be desirable for INPI, Brazil's patent office, to establish some sort of expedited review process for patent applications involving traditional knowledge to overcome the statutory bar of the USPTO.

If Brazil decides to pursue a policy of defensive disclosure, several agencies involved in the protection of traditional knowledge already are authorized to create and maintain databases of traditional knowledge. CGEN can establish criteria for the creation of databases to register information related to traditional knowledge as ***159** well as create and maintain its own database of information obtained during the collection of genetic resources.[177] The type of information, whether it be descriptive, scientific, or anthropological, is not specified, but since CGEN can create its own criteria, presumably the database could contain information to establish prior art, such as species, enablement, and result. The National Biodiversity Policy gives an extensive description of permitted objectives and actions to create, catalog, and promote knowledge of Brazil's biodiversity.[178] Most of the specific authorizations deal with scientific research and cataloging, although several biodiversity objectives involve the sustainable use, development of economic potential, and promotion of traditional knowledge.[179] The National Biodiversity Policy also promotes the distribution of information regarding biodiversity through databases and scientific publications.[180] Divulging traditional knowledge is also expressly encouraged when there is consent from the traditional knowledge holders.[181] The activities of the National Biodiversity Policy are much more expansive than CGEN's, but the portions regarding authority to create and maintain databases on traditional knowledge overlap. The subsequent Decree 4703 created the National Biodiversity Commission to implement the National Biodiversity Policy, thus both the National Biodiversity Commission and CGEN have authority over the creation of databases of traditional knowledge and genetic resources.[182] There is a third entity within the Ministry of Environment with the authority to create and maintain databases on biodiversity and traditional knowledge: the National System of Units of Conservation established by Decree 5092.[183] As if three agencies with authority over traditional knowledge databases were not enough, the National Artistic and Historical Heritage Institute (Instituto do Patrimônio Histórico e Artístico Nacional, or IPHAN), an organ of the Ministry of Culture, catalogs Brazil's cultural heritage into four "books."[184] Both the Book of Knowledge, which records knowledge and ways of doing things rooted in the daily life of communities, and the Book of Celebrations, which records ways of life, religious practices, and other celebrations, are conducive to accommodating traditional knowledge.[185] Neither of these books is ***160** mentioned in M.P. 2186, and the creation of a book specific to traditional knowledge may better suit the purposes of defensive disclosure.[186] However, the creation of a new book specific to traditional knowledge may need congressional authorization and does not seem necessary given the authority of CGEN to create and maintain its own databases.

The multiple agencies with authority to create a database on traditional knowledge seem to set up a situation of mass confusion. None of the described databases in their existing authorization would meet the requirements for defensive disclosure. Worse, agencies are not required to work together and there is certain to be a turf battle between the National Biodiversity Commission, with authority to implement Brazil's chaotic National Biodiversity Policy, and CGEN, with expertise in traditional knowledge and genetic resources. While the National Biodiversity Commission is composed of numerous ministries and representatives from NGOs, academia, and civil society, the Secretary of Biodiversity and Forests of the Ministry of Environment presides over the commission.[187] The same Secretary presides over CGEN. The best resolution would be for CGEN to take the lead in coordinating the creation of a database of traditional knowledge and genetic resources for the purpose of defensive disclosure. CGEN already has the expertise, and the Ministry of Culture and several of the ministries participating in the National Biodiversity Commission are represented in CGEN. Thus, CGEN is the nexus for the authorized databases and has the explicit authority to establish criteria for any database of traditional knowledge and genetic resources. The potential exists for either mass confusion or highly integrated coordination. CGEN is studying the idea of a database of traditional knowledge but is mired in how best to proceed. The latest action of CGEN's sub-group dedicated to associated traditional knowledge was to emphasize the difficulty of creating an operational database.[188] No concrete proposal has since been developed.

If one of the purposes of a database of traditional knowledge in Brazil is defensive disclosure, CGEN must craft the database

to meet international standards for prior art. In the eyes of the USPTO, such a database would be a publicly accessible printed publication sufficient to enable a person having ordinary skill in the art to recreate the invention without undue experimentation. An online database with the date of availability posted regularly constitutes a published document. To make such a database accessible, a link should be posted on a centralized location, such as CGEN's homepage, or even better, on the WIPO's website. Information should ***161** be available at least in one of the publication languages in which most patent applications are filed.[189] The information contained in the database must enable the invention; the minimum necessary would be the genus and species of the organism, the part of the organism or method of extraction, the mode of preparation and administration, and the intended effect. Additional information, such as a more detailed description of the process or the indigenous group responsible for the traditional knowledge, may also be desired. Another requirement for the database is that it be searchable. Existing databases of traditional knowledge are criticized for not being conducive to searching for prior art.[190] Search functions also make the database more accessible and user-friendly. Finally, the information contained in the database must be obtained with the prior informed consent of the relevant indigenous group. CGEN could create and maintain a searchable online database, and indigenous groups could elect to have their traditional knowledge included in the database. CGEN should not follow Peru's lead and create a parallel confidential database since such a database would not constitute prior art, would complicate the registration process, and might mislead traditional knowledge-holders into believing they have defensive protection. If CGEN ever establishes a benefit-sharing mechanism, registration of traditional knowledge in the online database could be a condition of receiving benefits.

Existing online databases for indigenous knowledge illustrate the potential for web-based defensive disclosure but still present problems. The World Bank's Indigenous Knowledge Database has very few entries, none of which is sufficiently detailed to constitute prior art.[191] Among other defects, the listings do not properly disclose the invention and do not provide a date of publication. The World Bank database appears to be more of a reference source for published articles about the use of traditional knowledge. A much more promising example of an online database is India's Traditional Knowledge Digital Library (TKDL). The TKDL is being developed for the purposes of establishing prior art and has improved substantially in the past year.[192] The National Institute for Science Communication and Information Resources (NISCAIR) leads the collaborative project. The digital library will document the knowledge of Ayurveda, India's 5,000 year-old system of traditional medicine, and present it in a digitized, searchable format in five international ***162** languages.[193] NISCAIR intends to expand the TKDL to include all of India's traditional knowledge. The impetus for the development of the TKDL was the commercial exploitation of India's traditional knowledge, such as patented or copyrighted yoga postures and the turmeric patent case.[194] The TKDL is still in the demonstration phase and thus does not presently meet the requirements for prior art, but it does show that web-based defensive publication is possible.

Another strategy with more limited promise is for Brazil to make better use of the Patent Cooperation Treaty (PCT). The chief advantage of the PCT is that an applicant can file an "international" patent application in her own country and seek patent protection simultaneously in each of the contracting states.[195] There are currently over 100 contracting states, including the United States, Japan and the member states of the European Union. Filing an international patent application establishes a priority date for all countries in which protection will eventually be sought and enables the applicant to claim a priority date from an earlier application in a contracting state.[196] Another advantage of the PCT is that applicants receive up to eighteen additional months from the priority date to meet the formalities of filing an application in the patent office of a contracting state.[197] An international patent application must still meet the requisites for patentability in a foreign country for the application to receive patent protection in that country.[198] For example, if a Brazilian applicant filed an international patent application in Brazil and wanted patent protection in the United States, the applicant must be able to identify the inventor. Thus, an application involving traditional knowledge would not receive protection in the United States, but the applicant would hold a valid patent in Brazil and any country that does not require the inventor to be listed. While not an ideal situation since the patent protection is not global, patent protection in some countries is better than nothing. Furthermore, the patent would be considered prior art in the United States, thus preventing the appropriation of traditional knowledge.

Brazil is actively pursuing reform at the international level that has encountered significant opposition from the United States. In a WIPO document, Brazil argues that "[d]isclosure of origin, prior informed consent and fair and equitable benefit sharing . . . should be a mandatory requirement, to be imposed on patent applicants ***163** in all jurisdictions, preferably through an amendment to relevant international intellectual property treaties, such as the WTO TRIPS Agreement."[199] Disclosing the source of biological material automatically alerts a patent examiner to conduct a search for prior art in a particular region, a task that would be facilitated if searchable online databases were available. Brazil's position for the positive obligation imposed on a patent applicant proposes that insufficient, wrongful, or lack of disclosure of source and country of origin could lead to revocation of the patent, full or partial transfer of the intellectual property rights, narrowing the scope of claims, criminal sanctions, and civil sanctions.[200] The United States is the most vigorous opponent of the Brazilian position and

asserts that new disclosure requirements in the patent system are not an effective means of achieving prior informed consent or the equitable sharing of benefits.[201] The United States believes that new disclosure would increase uncertainty, increase administrative burdens, and exacerbate ineffectual monitoring systems.[202] Essentially, the United States favors national solutions whereas Brazil favors internationally binding rules. The most recent WIPO documents show the parties becoming entrenched in their positions.[203] The debate over disclosure of origin also raises the issue of databases of traditional knowledge.[204] Brazil and India argue that databases cannot serve as a ***164** substitute for a disclosure requirement since there is no guarantee that patent examiners will search the databases prior to granting a patent.[205] The two countries also express concerns about the confidentiality of traditional knowledge.[206] The documents relating to the disclosure of origin played a small role in the Ministerial Conference of the World Trade Organization in Hong Kong, China in December 2005 and will play a larger role in the 8th Conference of Parties of the Convention on Biological Diversity in Curitiba, Brazil in March of 2006. Given the opposition of the United States and the slow progress of international negotiations, Brazil likely will have the most success from measures taken at the national level.

Conclusion

The subject of biopiracy generates considerable headlines when it occurs. Unfortunately, coverage of incidents of biopiracy tends to gloss over important details such as the highly variable value of any one patent, as in the case of ayahuasca with its negligible value, or that patents can be challenged successfully, as in the case of turmeric. Nevertheless, fears of biopiracy coupled with the objectives of the CBD spurred considerable effort in Brazil and elsewhere for the establishment of a fair and equitable system for regulating traditional knowledge associated with genetic resources. Brazil created a reasonably just system in theory, but vague terms and the establishment of multiple agencies with authorization to implement biodiversity policy creates conflict and confusion. Fortunately, CGEN is the coordinating agency and can incorporate objectives of existing agencies to protect traditional knowledge more effectively through existing intellectual property systems. CGEN also appears to be creating better guidelines for legislative phrases such as "prior informed consent," although the guidelines need to be tested in the real world and further refined, as the case of the Krahô demonstrates.

The fundamental problem with traditional knowledge and current intellectual property systems is that patent protection in the United States requires an inventor to be listed. For traditional knowledge the inventor is usually unknown and unknowable. A sui generis system of intellectual property protection of traditional knowledge is the ideal, but creating such a system may be impossible at worst and will take substantial time and effort at best. Brazil and other countries rich in both genetic resources and traditional knowledge can work within the existing intellectual property system until one more accommodating to traditional knowledge is established. The most effective means to prevent the appropriation of traditional knowledge is through the use of defensive disclosure, which would establish prior ***165** art and negate patentability. While the negation of patentability seems to destroy a mechanism for the creation of wealth, if traditional knowledge is stolen, traditional knowledge holders would not benefit anyway. Searchable, accessible databases have the added benefit of recording traditional knowledge before it disappears as indigenous people assimilate into modern society. Brazil can also make better use of other existing aspects of intellectual property protection, such as a more extensive use of trade secrets and a more thoughtful engagement with the Patent Cooperation Treaty.

Footnotes

a1 J.D. candidate, The University of Texas School of Law. I conducted much of the research for this paper as a Latin American Democracy Fellow in the Office of the Legal Advisor in the Ministry of Environment in Brasilia, Brazil during the summer of 2004. I would like to thank Professors Antonio Benjamin and Sarah Cleveland of the University of Texas and Daniela Guimarães Goulart and Gustavo Trindade at the Ministry of Environment for their support during the fellowship. I would also like to thank Sidley Austin LLP for sponsoring the Best Note Competition at the Texas Intellectual Property Law Journal.

1 The caatinga is a semi-arid scrubland in the northeast. The cerrado is a tropical savannah and forest that covers much of the central high plains of the country. Brazilian Ministry of the Environment, Secretary of Biodiversity and Forests, http://www.mma.gov.br/port/sbf/chm (follow 'Biodiversidade brasileira' link; then follow 'Riqueza de espécies' link) (last visited Dec. 8, 2005).

2 Id.

[3] Id.

[4] Id.

[5] Fundação Nacional do Índio, http://www.funai.gov.br (follow 'Índios do Brasil' link; then follow 'A Origem dos Povos Americanos' link) (last visited Dec. 8, 2005).

[6] Medida Provisória No. 2186-16 art. 7(VII), de 23 de agosto de 2001, 1 D.O.U. de 24.08.2001, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action, also available in English at http://www.mma.gov.br/port/cgen/doc/mp2186i.pdf (Brazil).

[7] Letter from Pero Vaz de Caminha, Portuguese explorer, to Dom Manuel, King of Portugal (May 1, 1500), http://www.correios.com.br/institucional/conheca_correios/historia_correios/carta_ pero_vaz.cfm (last visited Feb. 18, 2006).

[8] Rafael Gomez & Babeth Bettencourt, História Pode Revelar um Novo Brasil [History Can Reveal a New Brazil], Brit. Broad. Corp. Braz. Apr. 21, 2000, http://www.bbc.co.uk/portuguese/esp_bra_historia.htm (last visited Dec. 8, 2005).

[9] International Rubber Research and Development Board, History of Natural Rubber (Part I), http://www.irrdb.com/IRRDB/NaturalRubber/History/History1.htm (last visited Dec. 8, 2005).

[10] Amazonlink.org, First Immigrants, http:// www.amazonlink.org/ACRE/amazonas/rubber-tappers/rubber.htm (last visited Dec. 8, 2005).

[11] International Rubber Research and Development Board, History of Natural Rubber: Henry Wickham, http://www.irrdb.com/IRRDB/NaturalRubber/History/HenryWickham.htm (last visited Dec. 8, 2005).

[12] Id.

[13] Philip Schuler, Biopiracy and Commercialization of Ethnobotanical Knowledge, in Poor People's Knowledge 159, 169 (J. Michael Finger & Philip Schuler eds., 2004).

[14] Id. at 170.

[15] Id. Use of ayahuasca by indigenous people in Ecuador did not count as prior art since foreign sources of prior art must be published. 35 U.S.C. § 102(a) (2000).

[16] Center for International Environmental Law, The Ayahuasca Patent Case, http://www.ciel.org/Biodiversity/ayahuascapatentcase.html (last visited Dec. 8, 2005).

[17] Schuler, supra note 13, at 170.

[18] Telephone Interview with Glenn Wiser, Senior Attorney, Center for International Environmental Law, in Washington, D.C. (February 7, 2005).

[19] Schuler, supra note 13, at 166.

[20] Id. at 167.

[21] U.S. Patent No. 5,401,504 (filed Dec. 28, 1993).

[22] See 35 U.S.C. § 100 (2003).

[23] Schuler, supra note 13, at 167.

[24] Vandana Shiva et al., The Enclosure and Recovery of the Commons 42 (1997).

[25] The book also fails to mention that public use will only defeat patentability in the United States if the invention was known or used by others in the United States. 35 U.S.C. § 102(a) (2002).

[26] CSIR reportedly spent 500,000 Rupees (Rs) challenging the patent. Schuler, supra note 13 at 167. On June 1, 1996, Rs 1 = US $0.028510.

[27] Siddhartha Prakash, Nurturing Traditional Knowledge Systems for Development, IK Notes No. 61, Oct. 2003, available at http://siteresources.worldbank.org/EXTINDKNOWLEDGE/Resources/iknt61.pdf, 4.

[28] U.S. Patent No. 6,200,570 (filed Nov. 25, 1998).

[29] Renato Alves, Alemão É Preso Acusado de Contrabandear Aranhas Brasileiras [German is Caught, Accused of Smuggling Brazilian Spiders], Correio Braziliense, Dec. 1, 2004.

[30] Id.

[31] Kerry ten Kate & Sarah A. Laird, The Commercial Use of Biodiversity 43 (2000).

[32] Id. at 61.

[33] Nuno Pires de Carvalho, From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent, 17 Wash. U. J.L. & Pol'y 111, 120 (2005).

[34] Kerry ten Kate & Sarah A. Laird, Bioprospecting Agreements and Benefit Sharing with Local Communities, in Poor People's Knowledge 133, 143 (J. Michael Finger & Philip Schuler eds., 2004).

[35] Id.

[36] ten Kate, supra note 31, at 56.

[37] One example from the Brazilian cosmetics company Natura is its Ekos Product, whose promotional material begins with the

sentence "[h]á séculos, os povos nativos que viviam nas florestas do Brasil já possuíam um precioso acervo de conhecimentos sobre a flora como fonte de alimento, saúde e beleza.' This can be translated as, "[f]or centuries, the native peoples that live in the forests of Brazil already possessed a precious archive of knowledge about flora as a source of food, health, and beauty." Produtos/Banho/Natura Ekos/Ativos e Tradições Populares, http://www.natura.com.br (last visited Feb. 20, 2005).

[38] ten Kate, supra note 31, at 318.

[39] Id. at 57.

[40] Lei No. 9.279, de 14 de maio de 1996, 1 D.O.U. de 15.05.1996, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action (Brazil).

[41] Id. at art. 7.

[42] Id. at art. 4.

[43] Id. at art. 8.

[44] Id. at art. 24.

[45] 35 U.S.C. § 101 (2000).

[46] 37 C.F.R. § 1.41(a) (2004).

[47] Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993).

[48] Lei No. 9.279, supra note 40, at art. 10(IX).

[49] Id. at art. 18(II)-(III).

[50] Id. at art. 18, Parágrafo único.

[51] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[52] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.N.Y. 1911).

[53] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991).

[54] Diamond, 447 U.S. at 309.

[55] 35 U.S.C. § 161 (2000) (asexual reproduction); 7 U.S.C. § 2402 (2000) (sexual reproduction).

[56] Lei No. 9.456, de 25 de abril de 1997, 1 D.O.U. de 25.09.1997, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action (Brazil).

[57] Id. at art. 3(IV).

[58] Id. at art. 5.

[59] Id. at arts. 14(VI) & 3(I).

[60] Unif. Trade Secrets Act § 1.4 (1985).

[61] Id. at §§ 2-3.

[62] Lei No. 9.279, supra note 40, at art. 195(XI).

[63] Id. at art. 195(XIV).

[64] Id. at art. 195.

[65] Convention on Biological Diversity, Jun. 5, 1992, 1760 U.N.T.S. 79, available at http://www.biodiv.org/doc/legal/cbd-un-en.pdf. The U.S. is a signatory but not a party to the CBD. The CBD entered into force on December 29, 1993, after the thirty parties necessary ratified it; the convention currently has 188 parties.

[66] Id. at art. 1. Art. 2 of the CBD defines "genetic resources" as "genetic material of actual or potential value," and "genetic material" is "any material of plant, animal, microbial or other origin containing functional units of heredity." Id. at art. 2.

[67] Id. at art. 8.

[68] Id. at art. 16(2).

[69] Id. at art. 16(5).

[70] Id. at art. 10(c).

[71] Conference of the Parties to the Convention on Biological Diversity, Eighth Meeting, Provisional Agenda, Item18. UNEP/CBD/COP/8/1 (Sept. 20, 2005), available at http://www.biodiv.org/doc/documents.aspx.

[72] Convention on Biological Diversity, supra note 65 at arts. 3 & 6.

[73] Lei No. 1.235, de 9 de julho de 1997, D.O.E. (AC) (Brazil) (on file with author).

[74] Paulo de Bessa Antunes, Direito Ambiental [Environmental Law] 491 (7th ed. 2004).

[75] Lei No. 1.235, supra note 73, at art. 41.

[76] Id. at art. 41, Parágrafo único.

[77] Id. at art. 42.

[78] Matthias Leistner, Analysis of Different Areas of Indigenous Resources, in Indigenous Heritage and Intellectual Property 49, 57 (Silke von Lewinski, ed., 2004).

[79] Lei No. 1.235, supra note 73, at art. 5(iii).

[80] Lei No. 388, de 10 de dezembro de 1997, D.O.E. (AP) No. 1708, de 12.12.1997, available at http://www.al.ap.gov.br/lei0388.htm (Brazil).

[81] Antunes, supra note 74, at 491.

[82] Notice for a public session entitled "Dialog on Access to Biodiversity," Nov. 14, 2001, http://www.sbq.org.br/PN-NET/pn-net00/msg00024.html (last visited Dec. 8, 2005).

[83] Medida Provisória No. 2186-16, supra note 6. The legislation regulating access to genetic resources is not a law but a medida provisória, which is analogous to an executive order submitted for congressional approval. Medidas provisórias are described in Art. 62 of the Brazilian Constitution, which reads:
Em caso de relevância e urgência, o Presidente da República poderá adotar medidas provisórias, com força de lei, devendo submetê-las de imediato ao Congresso Nacional ...
§ 3 As medidas provisórias ... perderão eficácia... se não forem convertidas em lei no prazo de sessenta dias, prorrogável ... uma vez por igual período ...
This can be translated as follows:

> "In relevant and urgent cases, the President of the Republic may adopt provisional measures with the force of law and shall submit such measures to Congress immediately ...

§ 3 Provisional measures ... shall lose their effect ... if not converted into law within sixty days, renewable...once for an equal period ...
cf. art. 62, available at http://www.senado.gov.br/sf/legislacao/const/. Whether a medida provisória is approved or not, the President is able to initiate debate on an issue in the Congress.
Although medidas provisórias have the force of law, some commentators do not view them with the same respect as a piece of legislation originating within the legislative branch (Antunes, supra note 74 at 472). Medidas provisórias are relics of the dictatorship and are convenient ways for the executive to enact a favored law without passing through the cumbersome but more democratic legislative process through which a law passes. A bill re-writing M.P. 2186 and correcting its deficiencies has been introduced into Congress (Ante projeto de Lei de Acesso ao Material Genético e seus Produtos, de Proteção aos Conhecimentos Tradicionais Associados e de Repartição de Benefícios Derivados do seu Uso) [Bill of Access to Genetic Material and Its Products, of Protection of Traditional Knowledge and of Benefit Sharing Derived from Its Use], http://www.mma.gov.br/port/cgen/index.cfm (follow "Câmaras Temáticas" hyperlink; then follow "Câmara Temática de Legislação" hyperlink; then follow "Textos" hyperlink) (submitted to the Minister of Environment on Sept. 29, 2003) (last visited Dec. 8, 2005). This new bill also would correct the perception that Brazil's principle piece of legislation governing access to genetic resources is not really a law even though the medida provisória has the force of law.

[84] Medida Provisória No. 2186-16, supra note 6, at art. 7(I).

[85] Convention on Biological Diversity, supra note 65, at art. 3.

[86] Id. at art. 4.

[87] ten Kate, supra note 31, at 17.

[88] Id.

[89] Medida Provisória No. 2186-16, supra note 6, at art. 7(II).

[90] Id. at art. 7(III). Quilombos are communities formed by runaway slaves.

[91] Id. at arts. 8-9.

[92] Id. at art. 9, Parágrafo único.

[93] Some of the conditions of access to genetic resources and associated traditional knowledge have been summarized in a helpful publication by the Genetic Resources Management Council (Conselho de Gestão do Patrimônio Genético, or CGEN). See Ministério Do Meio Ambiente Departamento do Patrimônio Genético, Regras para o Acesso Legal ao Patrimônio Genético e Conhecimento Tradicional Associado [Ministry of the Environment Department of Genetic Resources, Rules for the Legal Access of Genetic Resources and Associated Traditional Knowledge] (2005), available at http:// www.mma.gov.br/port/cgen/doc/cartilha.pdf.

[94] Medida Provisória No. 2186-16, supra note 6, at art. 16.

[95] Id. at art. 16 § 6.

[96] Id. at art. 14(I)(a).

[97] Id. at art. 16 § 9.

[98] Id. at art. 16 § 4

[99] Id. at art. 25.

[100] National Environmental Management: Biodiversity Act, 2004 (Jun. 7, 2004), available at http://www.info.gov.za/acts/2004/a10-04/index.html.

[101] Id.

[102] Id.

[103] Id.

[104] Medida Provisória No. 2186-16, supra note 6 at art. 8 § 4.

[105] Id. at art. 28(V).

[106] Id. at arts. 30-31.

[107] Decreto No. 5.459, de 7 de junho de 2005, 3 D.O.U. de 08.06.2005, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action (Brazil).

[108] Id. at arts. 16(2), 21(1).

[109] Id. at arts. 16(3), 21(2).

[110] Decreto No. 3.945, de 28 de setembro de 2001, 3 D.O.U. de 03.10.2001, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action (Brazil).

[111] Id. at art. 3.

[112] Anteprojeto de Lei, supra note 83 at art. 60.

[113] Decreto No. 4.339, de 22 de agosto de 2002, 3 D.O.U. de 23.08.2002, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action (Brazil).

[114] Id. at art. 14.2.5.

[115] Antunes, supra note 74 at 472.

[116] Decreto No. 4.703, de 21 de maio de 2003, 3 D.O.U. de 22.05.2003, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action (Brazil).

[117] Decreto No. 5.092, de 21 de maio de 2004, 2 D.O.U. de 24.05.2004, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action (Brazil).

[118] Id. at art. 4.

[119] Id. at art. 2.

[120] Fundação Nacional do Índio, http://www.funai.gov.br (follow ‘Índios do Brasil‘ link, then follow ‘O Índio Hoje‘ link) (last visited Dec. 8, 2005).

[121] Id.

[122] Povos Indígenas no Brasil [Indigenous Peoples in Brazil], http://

www.socioambiental.org/pib/portugues/quonqua/ondeestao/indexon.shtm (follow ‘Quem, onde, quantos‘ link, then follow ‘Onde estão‘ link) (last visited Dec. 8, 2005).

123 Id.

124 Constituição Federal [C.F.] art. 231 (Brazil).

125 See C.F. art. 232.

126 Lei No. 6.001, de 19 de dezembro de 1973, 1 D.O.U. 21.12.1973, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action.

127 Id. art. 1, Parágrafo único.

128 Id. arts. 39-40.

129 Fundação Nacional do Índios, http://www.funai.gov.br (follow ‘Os Índios‘ link; then follow ‘As Terras‘ link) (last visited Dec. 8, 2005).

130 Decreto No. 3.945, supra note 110, at art. 2.

131 Anteprojeto de Lei, supra note 83, at art. 60 § 2.

132 Carta de São Luís de Maranhão, letter from indigenous representatives to the National Industrial Property Institute (Dec. 6, 2001) (on file with author).

133 Id. at art. 2.

134 Id. at arts. 3, 5.

135 Id. at arts. 15-16.

136 Convention on Biological Diversity, supra note 65 at art. 15.

137 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable sharing of the Benefits Arising out of their Utilization, UNEP/CBD/COP/6/24 (Apr. 2002), available at http:// www.biodiv.org/decisions/default.aspx?m=cop-06&d=24.

138 Id. at art. 14.

139 Id. at art. 31.

140 Id. at art. 34.

[141] Decreto No. 3.945, supra note 110 at arts. 8(V), 9(V).

[142] CGEN/MMA Res. 12, 1 D.O.U. 05.04.2004, available at http:// www.mma.gov.br/port/cgen/doc/res12.pdf (Brazil).

[143] Id. at art. 2.

[144] Id. at art. 2, Parágrafo único (I).

[145] Id. at art. 2, Parágrafo único (II).

[146] Id. at art 3.

[147] See Laurel A. Firestone, You Say Yes, I Say No; Defining Community Prior Informed Consent Under the Convention on Biological Diversity, 16 Geo. Int'l. Envtl. L. Rev. 171, 178 (2003).

[148] Reinaldo José Lopes, Tribo Quer R$ 25 mi por Ervas Medicinais [Tribe Wants R$25 Million for Medicinal Herbs], Folha de São Paulo, Jun. 19, 2002 [hereinafter Tribe Wants].

[149] Reinaldo José Lopes, Universidade Diz que Não Pagará Indenização a Tribo Indígena Craô [University Says it Will Not Pay Damages to Krahó Indigenous Tribe], Folha de São Paulo, Jun. 28, 2002 [hereinafter University Says].

[150] Tribe Wants, supra note 148.

[151] University Says, supra note 149.

[152] Id.

[153] Id. The Ministério Público is a powerful independent fourth branch of the government that functions like the Inspector General offices in U.S. Executive Agencies and like the Attorney General.

[154] Id.

[155] Michael F. Brown, Who Owns Native Culture? 241 (2003).

[156] Id.

[157] Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity 81 (2001).

[158] Tribe Wants, supra note 148.

[159] Brown, supra note 155, at 207.

[160] See 35 U.S.C. § 101 (2006).

[161] Pires de Carvalho, supra note 33, at 120.

[162] C.F. art. 232; Lei No. 9.279, supra note 40, at art. 4.

[163] Rules of Practice in Patent Cases, 37 C.F.R. § 1.51(c)(1)(ii) (2004).

[164] Convention on the Grant of European Patents art. 81 Oct. 5, 1973, http://www.european-patent-office.org/legal/epc/e/ar81.html (last visited Feb. 3, 2006).

[165] Daniel Wüger, Prevention of Misappropriation of Intangible Cultural Heritage Through Intellectual Property Laws, in Poor People's Knowledge 183, 190 (J. Michael Finger & Philip Schuler eds., 2004).

[166] Dutfield, supra note 157, at 86.

[167] Schuler, supra note 13, at 167.

[168] Stephen A. Hansen & Justin W. VanFleet, Traditional Knowledge and Intellectual Property: A Handbook on Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property and Managing Their Biodiversity 34, (2003), available at http:// shr.aaas.org/tek/handbook/handbook.pdf.

[169] 35 U.S.C. § 102(b) (2000).

[170] United States Patent and Trademark Office, Manual of Patent Examining Procedure § 2128 (2004) (quoting In re Wyer, 665 F.2d 221, 226 (C.C.P.A. 1981)).

[171] Id.

[172] Id.

[173] Id. at § 2128.01(III).

[174] Manuel Ruiz, Isabel Lapeña & Susanna E. Clark, The Protection of Traditional Knowledge in Peru: A Comparative Perspective, 3 Wash. U.Global Stud. L. Rev. 755, 782 (2004).

[175] Ley 27811, Jornal Oficial del Peru, Aug. 10, 2002, available at http://www.congreso.gob.pe/ntley/Imagenes/Leyes/27811.pdf.

[176] Ruiz, supra note 174, at 783.

[177] Decreto No. 3.945, supra note 110, at arts. 3(II)(d) and 7(XII)(b).

[178] Decreto No. 4.339, supra note 113, at Anexo (10)

[179] Id. at 10.1.6, 10.3.2, 10.4.7.

[180] Id. at 15.1.11 and 15.1.12.

[181] Id. at 15.2.7.

[182] Decreto No. 3.945, supra note 110, at arts. 3(II)(d) and 7(XII)(b); Decreto No. 4.339, supra note 113, at Anexo 15.1.3- 15.1.5.

[183] Decreto No. 5.092, supra note 117, at art. 4.

[184] Decreto No. 3.551, de 4 de agosto de 2000, 1 D.O.U. 07.08.2000, available at http://www6.senado.gov.br/sicon/PreparaPesquisaLegislacao.action (Brazil).

[185] Antunes, supra note 74, at 537.

[186] Id. at 536, 539.

[187] Decreto No. 4.703, supra note 116, at art. 7.

[188] Minutes of the 23rd meeting of the Associated Traditional Knowledge study group, Nov. 24, 2004, available at http:// www.mma.gov.br/port/cgen/index.cfm (follow 'Câmaras Temáticas' link; then follow 'Conhecimento Tradicional' link; then follow 'Atas' link).

[189] The most common languages are English, French, and German, and in certain cases Chinese, Japanese, Russian, and Spanish. World Intellectual Property Organization, Basic Facts About the Patent Cooperation Treaty, art. 7, http://wipo.int/freepublications/en/patents/433/wipo_pub_433.pdf.

[190] Leistner, supra note 78, at 60.

[191] See World Bank Indigenous Knowledge Database, http:// www4.worldbank.org/afr/ikdb/search.cfm (last visited Dec. 8, 2005).

[192] Traditional Knowledge Digital Library of Ayurveda, http:// tkdl.res.in/ (last visited Dec. 8, 2005).

[193] NISCAIR, http://tkdl.res.in (follow 'Activities and Services' link; then follow 'Major Projects' link). The five languages are English, French, German, Japanese, and Spanish.

[194] David Orr, India Adopts Fighting Position to Hold on to Ancient Yoga Poses: New Database to Stop Western Gurus 'Stealing' Intellectual Property, Sunday Telegraph (London), Sept. 18, 2005.

[195] Patent Cooperation Treaty art. 3, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

196 Id. at art. 8.

197 Id. at art. 29, § 3.

198 Id. at art. 27.

199 Proposal of Brazil to the WIPO Process Regarding an Invitation by the Convention on Biological Diversity on Access to Genetic Resources and Disclosure Requirements in IP Rights Applications, at 2, Dec. 16, 2004, http:// www.wipo.int/tk/en/genetic/proposals/brazil.pdf.

200 Id. at 4-5.

201 Proposal of the United States of America to the WIPO Process Regarding an Invitation by the Convention on Biological Diversity on Access to Genetic Resources and Disclosure Requirements in IP Rights Applications, 1 (Dec. 17, 2004), available at http:// www.wipo.int/tk/en/genetic/proposals/usa.pdf. Japan is skeptical of the imposition of a mandatory disclosure requirement.

202 Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, IP/C/W/434 (Nov. 26, 2004), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_ e.htm.

203 See The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge: Technical Observations on Issues Raised in a Communication by the United States (IP/C/W/434), Submission from Brazil and India. IP/C/W/443 (Mar. 18, 2005), available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_ e.htm. See also Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge, Communication by the United States. IP/C/W/449 (June 10, 2005), available at http:// www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

204 The WIPO does not promote the establishment or use of databases, but it does promote discussion on how such databases can advance the intellectual property interests of traditional knowledge holders. World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources Traditional Knowledge and Folklore, Update on Technical Standards and Issues Concerning Recorded or Registered Traditional Knowledge, at II(3) WIPO/GRTKF/IC/7/7 (Oct. 4, 2004). Some commentators argue that the discussion of access to genetic resources is not appropriate to intellectual property forums such as WIPO. Dominic Keating, Access to Genetic Resources and Equitable Benefit Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum, 87 J. Pat. & Trademark Off. Soc'y 525, 545 (2005).

205 Submission from Brazil and India, supra note 203, at 8 (Mar. 18, 2005).

206 Id. at 9.