American Indian Law Review

Volume 34 | Number 1

1-1-2009

# Biopiracy: The Struggle for Traditional Knowledge Rights

John Reid

## COMMENTS

# BIOPIRACY: THE STRUGGLE FOR TRADITIONAL KNOWLEDGE RIGHTS

*John Reid*[*]

### *I. Introduction*

Plants are complex chemical storehouses that hold many undiscovered biodiverse compounds with unrealized potential for use in modern medicine. Much of this potential is known by indigenous groups throughout the world. This knowledge has great value for pharmaceutical companies, as well as for many other industries. Researchers are constantly developing new technologies to assess the chemical makeup of plants, and they realize that using medicinal plants identified by native peoples makes research more efficient and less expensive. The problem is that the knowledge is neither protected nor organized. Instead, it is often passed down for generations and not recorded. The holders of this information are often located in developing countries that have limited bargaining power. No individual holds a property claim to the knowledge, and it cannot be determined who was the first to discover the beneficial properties. This wisdom is simply shared by a community and often protected by none.

Because there are no property rights assigned to it, and most of this understanding is located in developing regions of the world that cannot afford to fight for its protection, this knowledge about plants is often taken by researchers, leading to large profits for CEOs, stockholders, and academia. Sometimes this information forms a foundation for further discoveries by narrowing research efforts to plants which are particularly rich in biodiverse medical properties. The process of taking indigenous peoples' knowledge without compensation is referred to as biopiracy. For example, the natives of Madagascar knew rosy periwinkle had medical properties, leading pharmaceutical giant Eli Lilly to research it heavily, thereby finding treatments for Hodgkin's disease, childhood leukemia, and malaria.[1]

---

* Third-year student, University of Oklahoma College of Law.

1. Katie Bates, *A Penny for Your Thoughts: Private and Collective Contracting for Traditional Medicinal Knowledge Modeled on Bioprospecting Contracts in Costa Rica*, 41 GA. L. REV. 961, 970 (2007).

Additionally, as is often the case, traditional knowledge is merely taken and packaged into a patentable invention. Indigenous peoples feel this is theft of their property, arguing that they made the discovery but simply lacked the resources to patent the invention themselves.

This problem presents no easy solution. If the knowledge is overprotected, this will hinder potential future discoveries by limiting the base on which innovations can be built. Because the process of finding beneficial compounds within millions of varieties of plants can be incredibly expensive and time-consuming, any knowledge narrowing the search has the potential to lead to medical advances that can help the world. That is why the knowledge is of such great commercial value. But if the knowledge is unprotected, the original holders of the knowledge—and arguably the ones who would benefit the most from the compensation—do not receive any reward. Even a fraction of the potential profits could greatly improve the standard of living for indigenous peoples. A balance should, and can, be struck between the researchers and indigenous peoples so that both parties can benefit.

Monopoly rights granted by patent protection for drugs are designed to protect only those who invent or discover a new and useful composition of matter.[2] It defies patent law's fundamental purpose to award a patent for information that is already in the public domain. To ensure that patents are not awarded for widely known information, the knowledge must be recorded so that patent offices around the world will be able to show the invention already exists in the public domain.

Most traditional knowledge does not rise to a level where it can be patented. Further research is often required. Given that indigenous peoples do not generally have the means to conduct further research themselves, deep-pocketed companies could team with them to attempt new discoveries. Both indigenous peoples and research companies can benefit by contracting with each other to allow companies to enter a country, take samples, and obtain assistance from the native inhabitants. Indigenous peoples can greatly reduce the cost of these efforts by helping focus the scope of the research to material with possible benefits, while researchers can offer much-needed capital for conservation, education, and other community programs.

Part II of this comment provides an overview of traditional knowledge and biopiracy. Part III details ways in which knowledge and inventions of this type—along with the plants that contain the benefits themselves—can be protected under a traditional patent regime. The section goes on to discuss the

2. 35 U.S.C. § 101 (2006).

obstacles that indigenous peoples would face if they were to attempt to obtain property rights over the knowledge themselves and explains why this is not a viable option. Part IV begins the discussion on alternatives to patents for indigenous peoples. The section explores the relationship between databases and prospecting-agreement contracts. Part V offers a proposed solution.

### *II. Traditional Knowledge and Biopiracy*

Traditional knowledge encompasses indigenous and local community knowledge, innovations, and practices from around the world.[3] It includes a wide array of information passed from one generation to the next within indigenous communities. Currently, one of the most contested and valuable forms of traditional knowledge is traditional medicine. Traditional medicine refers to the "health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being."[4] A classic example of traditional medicine is the knowledge that a particular plant, used in a certain way, treats a particular ailment. Much of the controversy discussed in this comment refers to this type of situation.

Traditional medicine is still practiced heavily around the world. It has been estimated that up to eighty percent of Africa's population uses this type of medicine for its healthcare.[5] Even in many developed countries, seventy to eighty percent of the population has used some form of alternative or complementary medicine.[6] With so many consumers around the world, theft of this information is a growing problem. This is referred to as biopiracy.

Biopiracy occurs when genetic resources and traditional knowledge is taken from biodiverse developing countries without permission. This knowledge is then used to patent related inventions without sharing the resulting commercial profits.[7] The original holder of the knowledge receives no gains from the use and is likely barred from obtaining a patent. As one of the world's major

3. Bryan Bachner, *Facing the Music: Traditional Knowledge and Copyright*, HUM. RTS. BRIEF, Spring 2005, at 9, 9.

4. World Health Organization, Traditional Medicine, http://www.who.int/mediacentre/factsheets/fs134/en/index.html (last visited Oct. 13, 2008).

5. *Id.*

6. *Id.*

7. Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 436 (2006).

markets, United States companies have been involved in many of the current biopiracy disputes.

Biopiracy has become a growing problem due to the soaring sales of pharmaceuticals. The value of the world market for medicinal plants found by following leads given by indigenous and local communities has been estimated to be $43 billion.[8] Obtaining traditional knowledge increases the efficiency of the screening process for plants with medicinal properties by more than four hundred percent,[9] which is why indigenous peoples' knowledge is so valuable. Without formal legal protection for indigenous communities, biopiracy is often a shortcut to massive profits without having to provide fair compensation to the original sources of the information.

## *III. Hurdles to Patent Protection of Traditional Knowledge in the United States*

### *A. Introduction to the Problems Indigenous Peoples Face in Patenting Traditional Knowledge*

If researchers take information discovered by someone else and then patent it, why can the indigenous peoples not have some form of protection? If the invention is based on knowledge that has been around for generations, how can anyone patent it? Almost all drugs based on traditional knowledge are protected by the researcher when he or she obtains a patent. There are other forms of protection, however, such as plant patents and plant variety protection, which protect the plant species. These forms of protection are difficult, if not impossible, to obtain for those who have used the information for generations.

To understand the hurdles indigenous peoples face in gaining legal rights to their own knowledge, one must understand how patents work and the limitations that are intertwined within the system. The United States patent regime will be analyzed in answering these questions because the United States patent system is similar to those of most developed countries, and most of the pharmaceutical companies involved in biopiracy are located within the United States.

---

8. Vandana Shiva, *The Politics of Knowledge at the CBD*, THIRD WORLD NETWORK, http://www.twnside.org.sg/title/cbd-cn.htm (last visited Oct. 14, 2008).

9. *Id.*

### *B. Protecting the Traditional Knowledge as an Invention*

#### *1. Protection Under the United States' Patent System*

A United States patent allows the holder the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."[10] The holder is granted a twenty-year monopoly in exchange for a detailed disclosure of the invention.[11] This protection is available to anyone who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[12]

Different types of patents offer varying amounts of protection. Process patents are usually weak because they protect only the process of making the item.[13] Not surprisingly, most biopiracy involves medical uses. A process patent on a medical drug would only protect the patented process or procedure of making the drug. Therefore, if another company could make the same drug using a different process, it would not violate any law. In contrast, a composition-of-matter patent would offer far greater protection by protecting the drug itself.[14] No matter how the pharmaceutical is made, this latter type of patent ensures the end product is protected.

#### *2. Requirements for Obtaining a Patent*

To obtain a patent, the invention must be useful, non-obvious, and new.[15] The "useful" and "non-obvious" requirements are often easily met for pharmaceutical drugs. To meet the requirement of usefulness, the invention must have both a "useful purpose" and be operational.[16] For a medical drug, the drug must serve any beneficial purpose and actually accomplish the purpose it claims to perform. For an invention to be non-obvious, a person having ordinary skill in the field pertaining to the patent would not know how

---

10. 35 U.S.C. § 154(a)(1) (2006).

11. *Id.* § 154(a)(2).

12. *Id.* § 101.

13. *See, e.g.*, U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE 2100-51 (2008), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r6_2100.pdf.

14. 35 U.S.C. §§ 101-103.

15. *Id.* §§ 101, 103.

16. United States Patent and Trademark Office, General Information Concerning Patents, http://www.uspto.gov/web/offices/pac/doc/general/index.html#whatpat (last visited Oct. 13, 2009).

to solve the problem at which the invention is directed by using exactly the same method.[17] By their nature, medical drugs are rarely obvious because discovery requires much research and experimentation. The more difficult standard to overcome for traditional-knowledge cases is the novelty requirement.

The requirement that the product be novel sets a standard to make sure the patented invention is new. For an invention to be novel, it either could not have been known or used by others in the United States or have previously been patented or described in a printed publication in the United States or a foreign country.[18] This has a direct impact on Native Americans' traditional knowledge because when an invention is known or used in the United States, it does not have to be in a printed publication in order to bar a subsequent patent.[19] Traditional knowledge of Native Americans within the United States can destroy the novelty requirement and disallow future patents on the known substance if the knowledge is written or passed down orally. Because traditional knowledge is usually held by a group of indigenous people and passed down from one generation to the next, it should be easy to show that the knowledge is being used publicly. Therefore, traditional knowledge of Native Americans should prevent others from patenting this knowledge even if it has not been published. This is not the case for foreign indigenous peoples.

Knowledge found in other countries prevents the novelty requirement from being met in the United States only if it is contained in published material.[20] Traditional knowledge that is handed down for generations outside the United States can be used and patented within the United States. As long as there is no public written record, a United States company can go into a foreign country and use knowledge handed down by indigenous peoples to obtain a patent. The company would be engaging in biopiracy, but would be breaking no law. Another problem is that once the company has published the traditional knowledge, it prevents indigenous peoples from patenting or profiting from the knowledge in the future. A researcher can also gather knowledge from indigenous peoples and publish it in an academic publication, preventing indigenous peoples from later patenting the knowledge.

---

17. *See* 35 U.S.C. § 103(a).

18. *Id.* § 102(a).

19. Murray Lee Eiland, *Patenting Traditional Medicine*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 45, 55-56 (2007).

20. *See id.* § 102(a).

*3. "First to Invent" and Joint Inventors*

Another hurdle that the United States Patent Office puts in the way of indigenous peoples' ability to patent their traditional knowledge is the "first to invent" requirement. Under this clause, one may not obtain a patent if "he did not himself invent the subject matter sought to be patented."[21] Because traditional knowledge is developed over generations, it is difficult to determine who is the first to discover the knowledge.

One solution to the problem of more than one person contributing to an invention is to obtain a patent via a joint invention. A joint invention allows two or more people to share a patent even if "(1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."[22] These three allowances, as well as case law, show that Native Americans and other indigenous peoples could file as joint inventors for drugs or other inventions if they contributed to at least one claim of the patent.[23] Case law suggests that there is no standard on the minimum contribution that is required to join in a patent as a joint inventor, putting forth a possible solution to sharing traditional knowledge while retaining certain rights for the holder(s) of this knowledge.[24]

The caveat is that the holders of the traditional knowledge will need to meet the other requirements of a patent. First, they would need to put forth more than mere knowledge that was already in the public domain. Second, they would need to "demonstrate some degree of conceptual connection between the information and invention."[25] This means they would need to go beyond simply understanding the knowledge. Third, the indigenous peoples would need to prove they were the first to come up with the traditional knowledge. Even with the possibility of providing protection to indigenous peoples by allowing them to share in the patent, there are still numerous obstacles to be overcome under the traditional patent regime.

---

21. *Id.* § 102(f).

22. *Id.* § 116.

23. Michael J. Huft, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U. L. REV. 1678, 1712-18 (1995).

24. *Id.*

25. Eiland, *supra* note 19, at 58.

### C. Protecting the Entire Plant to Which the Traditional Knowledge Pertains

Oftentimes, the pharmaceutical drug itself is not the sole patent granted. The United States allows one to receive patent rights to an entire plant.[26] This can be beneficial because the plant may result in future medical discoveries. This type of protection is also useful if the newly discovered plant is the invention, rather than a drug resulting from the plant. This could be the case if the plant has beneficial traits that other plants lack, such as higher yield or drought tolerance. This method of protection is relatively new, but rather than giving indigenous peoples another method to protect their knowledge, it more likely gives researchers additional tools to protect biopirated material.

In the United States, individuals can file for protection of a species of plant under three systems: Utility Patents,[27] the Plant Patent Act,[28] and the Plant Variety Protection Act.[29] Inventors are not limited to one form of protection and may choose to protect their plant variety under more than one system.[30] Because these are being utilized to protect entire species, it is important to understand how researchers are obtaining protection and why indigenous people are not.

#### 1. Utility Patents: Allowing Nature to Be Patented for the First Time

Natural laws, phenomena of nature, and abstract principles were not patentable in the past.[31] A general rule has always been that natural phenomena are not patentable.[32] This theory was challenged in *Diamond v. Chakrabarty*, where the Supreme Court allowed the first intact living organism to be patented.[33] The Court upheld a utility patent for a genetically altered bacterium that could break down oil.[34] Prior to this ruling, plants and other living organisms could not be protected under traditional patents because 35 U.S.C. § 101, which describes what is patentable, was held not to apply.[35]

---

26. *See* 7 U.S.C. § 2531 (2006); 35 U.S.C. § 161.

27. 35 U.S.C. § 101; *see* Diamond v. Chakrabarty, 450 U.S. 175 (1980) (allowing micro-organisms to be patented as a utility patent).

28. 35 U.S.C. § 161.

29. 7 U.S.C. §§ 2321-2582.

30. Nicholas J. Seay, *Protecting the Seeds of Innovation: Patenting Plants*, 16 AIPLA Q.J. 418, 429 (1989).

31. Diamond v. Diehr, 450 U.S. 175, 185 (1980).

32. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

33. 447 U.S. 303 (1980).

34. *Id.* at 318.

35. Mary Lynne Kupchella, *Agricultural Biotechnology: Why It Can Save the Environment*

After the Supreme Court allowed utility patents on living organisms, *Ex parte Hibberd* ruled plants, seeds, and plant tissue could be patentable under utility patents.[36] *Ex parte Hibberd* was the first major challenge after *Diamond v. Chakrabarty* upholding the theory that plants could be patented under 35 U.S.C. § 101.[37]

As with any other patent, a plant utility patent requires the invention to be new, useful, and non-obvious.[38] The requirement for usefulness is very easy to prove. Because plants are naturally occurring, in order to be new and distinct from one in nature, human intervention must have "altered the natural material from its natural state as to make it more useful, or useful in new ways, or cheaper, or available in greater quantity."[39] As for usefulness, the Federal Circuit held that "[t]o violate § 101, the claimed device must be totally incapable of achieving a useful result."[40] That court has also stated that substantial or practical utility for the invention must be discovered and disclosed where such utility would not be obvious.[41] A claim is non-obvious

> if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.[42]

These requirements are very similar to traditional patents.

A utility patent makes it illegal to make, use, offer to sell, or sell a patented plant.[43] These patents are being used to protect discovered gene sequences and other useful aspects of discovered plants. Utility patents go beyond the protection of a single drug or other use for a plant, allowing researchers to claim protection on plant parts that may have a beneficial use in the future.

---

*and Developing Nations, but May Never Get a Chance*, 25 WM. & MARY ENVTL. L. & POL'Y REV. 721, 737 (2001).

36. 227 U.S.P.Q. (BNA) 443 (B.P.A.I. 1985).

37. Seay, *supra* note 30, at 428.

38. 35 U.S.C. §§ 101-103 (2006).

39. Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DENV. U. L. REV. 127, 130 (1991).

40. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992).

41. Cross v. Iizuka, 753 F.2d 1040, 1044 (Fed. Cir. 1985).

42. 35 U.S.C. § 103(a).

43. *Id.* § 271(a).

Indigenous peoples could potentially protect traditional knowledge by filing for a utility patent, but they would need to meet the requirements for this patent. The problem is, in order to do this they would have to go beyond mere knowledge of a plant and its properties. They would need to improve the plant in some way to make it unique through breeding. This is unlikely to occur, however, due to lack of funds and research capabilities.

*2. Plant Patent Act*

Utility patents provide the greatest protection for the holder, but the requirements to obtain the rights are the highest when compared to other forms of plant patents. To make it easier, the United States offers two alternatives with lower requirements, both of which are easier and cheaper to obtain but also offer the holder less of a monopoly. These alternatives are under the Plant Patent Act[44] and the Plant Variety Protection Act.[45]

The Plant Patent Act gives a breeder the right to obtain patent protection for an asexually reproduced plant variety that is distinct and new.[46] The Act's protection is limited only to a single plant that is propagated by asexual reproduction.[47] As with all plant-protection methods, to use this Act, Native Americans or other indigenous peoples would need to improve the plant in some way from its natural state.

There are several important differences that set the Plant Patent Act apart from traditional patents. First, the description has a lower standard than traditional patents and needs to be only "as complete as is reasonably possible."[48] Second, the Plant Patent Act grants only the "right to exclude others from asexually reproducing the plant, and from using . . . or selling the plant so reproduced."[49] A person may sell or use a plant protected under the Plant Patent Act as long as he or she reproduced it sexually. This effectively excludes patent protection from plants that can be reproduced from seeds.

*3. Plant Variety Protection Act*

The second type of alternative safeguard came in 1970, when Congress enacted the Plant Variety Protection Act to provide protection to the breeders

44. *Id.* § 161.
45. 7 U.S.C. §§ 2321-2582 (2006).
46. 35 U.S.C. § 161.
47. *Id.*
48. *Id.* § 162.
49. *Id.* § 163.

of sexually reproduced plants and tuber-produced plants.[50] The Department of Agriculture administers the Plant Variety Protection Act under the Plant Variety Protection Office.[51] To protect a plant under the Plant Variety Protection Act, the plant must be new, distinct, uniform, and stable.[52] A variety is considered new if, on the filing date, material from the variety has not been sold or given to others, by or with the consent of the rights-holder, for the purpose of utilizing the variety more than one year prior if in the United States or more than four years prior if outside the United States.[53] An exception to this rule is that for material outside the United States the time is extended to six years for trees or vines.[54]

To be distinct, the variety must be "clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application."[55] "Uniform" is defined as "describable, predictable, and commercially acceptable."[56] To meet the stability requirement, a variety, when reproduced, must remain unchanged with regard to "essential and distinctive characteristics" within a "reasonable degree of reliability" as compared to varieties of the same category with the same breeding method.[57]

Once the plant is registered, the Plant Variety Protection Act makes it illegal for others to sell or market, import or export, sexually multiply, use the variety to make new hybrids, dispense to others without notice of its protection, condition the variety for propagation, stock the variety for a prohibited purpose, or instigate another in the performance of a prohibited act.[58] This barrier lasts for twenty years from the date of issuance and twenty-five years for trees and vines.[59]

The Plant Variety Protection Act requires some improvement to the plant as a safeguard. This means that in order for indigenous peoples to use either of these Acts, they would need to change the variety in some way as to make it unique. Unfortunately, this would grant only a shield for the new plant, leaving the uncultivated variety for anyone's use. On the other hand, the Acts

50. 7 U.S.C. §§ 2321-2583 (2006).
51. *Id.* § 2323.
52. *Id.* § 2402.
53. *Id.* § 2402(a)(1)(A)-(B)(i).
54. *Id.* § 2402(a)(1)(B)(ii).
55. *Id.* § 2402(a)(2).
56. *Id.* § 2402(a)(3).
57. *Id.* § 2402(a)(4).
58. *Id.* § 2541.
59. *Id.* § 2483(b).

can benefit biopirates. If indigenous peoples tried to prevent others from patenting a plant based on lack of novelty because the traits of the plant were known prior to the patent application or because the plant was in its natural state, biopirates could simply modify the plant in one way and be secure in obtaining rights to it. The original plant would still be unprotected, but the biopirates could use a variety that is as good with minor modifications.

For example, *A* wants to sell a higher-yield corn used by indigenous peoples in country *X*. The indigenous peoples have used the corn for generations and cannot legally defend their exclusive rights to it, but neither can *A*. *A* can make any change, say breed for a darker color, and then obtain refuge under either Act, depending on whether it was reproduced sexually or asexually. Color is not the desired trait, but *A* still has made a change and can exclusively sell the seeds of *A*'s new variety in the United States. The original variety could still be sold, but it may not be available for sale because the indigenous peoples may not have the means to sell or protect it.

*4. Examples of Patented Traditional Knowledge*

In recent years there have been several examples of patented medicines rooted in traditional knowledge. Even with regulations laid out on the exact requirements for protection, United States companies have been able to protect pharmaceutical drugs even though they were considered to be biopirated. The following examples are some of the more famous drugs to be developed in this controversial fashion.

Eli Lilly was one of the first drug companies to be accused of biopiracy. Eli Lilly developed two drugs from rosy periwinkle, found on the island-nation of Madagascar. These drugs were *vinblastine* and *vincristine*, which are used in the treatment of Hodgkin's disease and childhood leukemia, respectively.[60] Eli Lilly earned $100 million from the sale of these drugs, and neither Madagascar nor the indigenous inhabitants obtained any royalties.[61] On top of this, a drug to treat malaria was recently being developed from the same plant.[62] There has been some question as to whether the prior learning could prevent the new malaria drug from being patented. The answer will depend on the relationship

60. Eiland, *supra* note 19, at 57 (quoting Liz Hanellin, *Protecting Plant-Derived Drugs: Patents and Beyond*, 10 CARDOZO ARTS & ENT. L.J. 169, 179 (1991)).

61. George Frisvold & Kelly Day-Rubenstein, *Bioprospecting and Biodiversity Conservation: What Happens When Discoveries Are Made?*, 50 ARIZ. L. REV. 545, 548 (2008) (citing Kelly Day-Rubenstein & George B. Frisvold, *Genetic Prospecting and Biodiversity Development Agreements*, 18 LAND USE POL'Y 205, 208 (2001)).

62. Eiland, *supra* note 19, at 57.

between the drug and the long-established familiarity with its benefits. If the historical information is not published, then the requirements for novelty will still be met within the United States because the knowledge is from a foreign source.[63]

Another famous example is the neem tree. Neem has been used in India by indigenous peoples in insect repellent, medicine, and cosmetics for years.[64] In 1993, AgriDyne (a United States company) filed a patent application for the use of neem in the United States and the European Union.[65] The patent application claimed an oil extract of the tree could be used as an insecticide and fungicide.[66] Once the patent prosecution was initiated, a clear distinction between United States and European Union law was shown. In the European Union, the patent was struck down for lack of novelty. To be novel in the European Union, the claim must not have been made available "to the public by means of a written or oral description, by use or in any other way, before the date of filing of the European Union patent application."[67] The European Union does not draw a distinction between knowledge that is foreign or domestic. As long as the knowledge is available anywhere, published or unpublished, the patent is not novel. In this instance, it was held that the information was available in India, and consequently the patent was not novel and was thus not granted.[68]

Patent law in the United States draws a distinction between foreign and domestic products in barring approval due to previous publication on grounds of novelty. The novelty requirement is not met if knowledge is available in any form within the United States, but knowledge outside the United States must be published to bar a patent for lack of novelty.[69] The lore regarding neem's characteristics in India was not published and therefore did not bar the

63. If the source of the facts were from Native Americans, the patent would be much harder to obtain since the knowledge does not have to be published if it is found within the United States.

64. Eiland, *supra* note 19, at 62.

65. Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 826 (2008).

66. Eiland, *supra* note 19, at 62.

67. Ladas & Parry EPO Practice Guide—Novelty, http://www.ladas.com/Patents/PatentPractice/EPOPractice/EPOPractGuide-4.html (last visited Oct. 15, 2009).

68. Chakravarthi Raghavan, *Neem Patent Revoked by European Union Patent Office*, THIRD WORLD NETWORK, http://www.twnside.org.sg/title/revoked.htm (last visited Oct. 28, 2009).

69. 35 U.S.C. § 102(a) (2006).

novelty requirement, and the patent was upheld in the United States.[70] On the other hand, had this been established learning of Native Americans, the patent would have been barred in the United States because knowledge within the United States does not have to be published to prevent patenting.

Probably the most famous example of biopiracy is the United States patent issued for turmeric.[71] The Indian Council for Scientific and Industrial Research opposed the patent based on lack of novelty because turmeric has been used in India for years.[72] The patent was eventually revoked, but not until the Indian government spent nearly $6 million fighting the patents for turmeric- and neem-based medicines.[73] This illustrates one of the largest problems with traditional knowledge. Most of it is not published, and the limited amount that is published is not compiled and is difficult to find. If the information regarding turmeric had been published and found by the United States Patent Office, then the patents would never have been granted, and India would not have needed to fight.

## *IV. Alternatives to Patents*

### *A. Introduction to Patent Alternatives*

The ability to protect traditional knowledge through the use of patents is unlikely because most indigenous peoples lack the funds and resources to obtain a patent. Other options, such as obtaining protection on the plant, are also likely impossible. To patent a plant successfully, it would need to be improved beyond its natural state. Although this would allow some protection, the plant in its natural state could still be used by others. The greatest advantage gained by patenting the improved variety would be that, once the plant is "published," it prevents others from patenting its beneficial use due to a lack of novelty. The downside is that patenting the plant is likely impossible. Although it would be hard for an indigenous group to obtain a patent, the benefit of preventing others from patenting could be accomplished in easier ways.

---

70. Eiland, *supra* note 19, at 63.

71. *See* Srividhya Ragavan, *Protection of Traditional Knowledge*, MINN. INTELL. PROP. REV., vol. 2, no. 2 (2001), at 1, 11.

72. *Id.*

73. *See* Soutik Biswas, *India Hits Back in 'Bio-Piracy' Battle*, BBC NEWS, Dec. 7, 2005, http://news.bbc.co.uk/2/hi/south_asia/4506382.stm.

*B. Databases*

*1. Advantages of a Database System*

An easy and less-costly solution to the publishing dilemma is to implement a database system. If traditional knowledge is put in a public database then it would be "published." Published work is not patentable.[74] After many battles over turmeric and neem, several countries, including India, have started a program to collect all traditional knowledge and catalogue it into a database.[75] India's project consists of nearly one hundred doctors examining a medical system that dates back thousands of years.[76] This project is estimated to cost $2 million, with the goal being to protect India's traditional knowledge by publishing it in a searchable format, allowing patent offices to differentiate between what is novel and what is already known.[77] India has already signed an agreement with the European Patent Office (EPO) to allow the EPO to search India's new database in order to prevent traditional knowledge from being patented.[78] India is currently in negotiations with the United States, United Kingdom, Sweden, and Japan to have each country's patent office search India's database to prevent further patents that are not truly novel from being granted.[79]

Even though knowledge within the United States does not have to be published in order to prevent others from patenting it as still being novel, the knowledge cannot be concealed or suppressed by the individuals possessing it.[80] If the information is not available because Native Americans are concealing the knowledge, then their knowledge may not be protected. Concealment and suppression usually take place within research settings and not within indigenous communities. Therefore, Native Americans' traditional knowledge should bar patent applications in almost all cases. The problem remains that, without publication, it may be difficult to prove they possessed the knowledge first. Proof is required to determine who invented first—without publication it may be difficult, and at the very least costly, to prove the knowledge was already in the public domain. Due to these limits of

74. 35 U.S.C. § 102(a).

75. Biswas, *supra* note 73.

76. *Id.*

77. *Id.*

78. *EPO Takes Step Toward Blocking Patents on Traditional Medicines; Obtains Access to Database of Indian Medicines*, 24 BIOTECH. L. REP. 445 (2005).

79. *Id.*

80. 35 U.S.C. § 102(g) (2006).

unpublished knowledge, a database of traditional knowledge would be helpful even within the United States. To be sure that Native Americans' traditional knowledge is protected, the United States Patent Office will need a method of searching their prior and existing knowledge.

*2. Problems with a Database System*

The database solution has critics who claim databases have the potential for increasing biopiracy.[81] It has been estimated that "nearly 4,000 patents or patent applications are based on the medicinal properties of plants that [are] already known."[82] For various reasons, many critics feel that implementing a database system will not disallow these patents, but will instead allow easier access to traditional knowledge that can be copied and then patented.[83]

First, any database will likely be difficult to search. Terms used by indigenous peoples are likely to be different than terms used by scientists. Term searches have the potential to be difficult given the possibility of a large number of possible phrases. For example, a United States patent was granted for a cure for dry eyes.[84] The solution contains a crushed mixture of leaves from the kumari plant (aloe vera) and water and was documented in Indian literature.[85] The United States patent was granted for a process that differed only in that it used chlorinated water.[86] This is a very simple example. There are currently pending patent applications that exceed one thousand pages and are full of scientific jargon.[87] The more complex the application, the harder it is to tell if the application is based on new innovations or centuries of traditional knowledge.

Second, the complexity of the application not only makes searching for a potential database more difficult, but also makes it easier for an inventor to take traditional knowledge and change it enough to pass the novelty test. As with the example of a remedy for dry eyes, when one takes a traditional cure, denotes an explicit type of water to be used, and then sets a temperature for the mixture, the original information seems different. If this is done on a larger, more complex scale, it will be even more difficult to recognize what is

81. *See* Devinder Sharma, Digital Library: Another Tool for Biopiracy (May 29, 2002), http://www.mindfully.org/GE/GE4/Traditional-Knowledge-Digital-Library-TKDL29may02.htm.

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

traditional knowledge and what is not. And all of this ignores the possibility that the inventor legitimately develops a new use, which is often the case.

Third, construction of these databases is difficult and expensive. India's attempt is budgeted for $2 million.[88] Even at this cost, it is unlikely that all traditional knowledge will be included. Tracking down centuries of knowledge is practically impossible, and many groups are reluctant to share their traditions, especially if they receive no benefit. Furthermore, it is difficult to take oral traditions and put them in writing. All traditional knowledge needs to be recorded in order fully to prevent biopiracy. A partial database will be of limited use and may also pose additional problems. If patent offices rely on these databases as their only search, then they may not consider other previously existing knowledge. Once a patent is granted it is considered valid, and the burden of proof shifts to the challenging party to prove the patent does not meet the novelty requirement.

If there is a dispute that the patent is not based on new knowledge, it can lead to costly litigation. As previously mentioned, the neem and turmeric patent disputes cost the Indian government $6 million.[89] There have also been other potential disputes that countries did not litigate due to the large cost. For example, Pakistan planned to join a suit fighting the United States patent for basmati rice.[90] The litigation costs were estimated to be $300,000,[91] and Pakistan withdrew.[92] Databases strengthen these claims as a definitive source of published prior work, but they will not automatically negate the patents. Costs may be reduced, but they will not be eliminated.

Conversely, databases could still be a source to help along an invention. Many plants have multiple benefits, and because some are known, these could help scientists narrow their search and find further uses for the plants. A database could be used to find plants that have a multitude of medical properties, therefore limiting researchers to a few varieties. This use might be a net benefit to the world, but the indigenous peoples who developed the uses would still not receive any compensation.

Finally, even if the database system works as planned, the indigenous groups will still receive only limited benefits. The purpose of the databases

88. Biswas, *supra* note 73.

89. *Id.*

90. Sharma, *supra* note 81.

91. *Id.* The author states the cost to be "US $ 3,00,000." The number 3,00,000 is the method used to express three lakhs in the Indian numbering system. One lakh is the equivalent of one hundred thousand in the Western numbering system. Therefore, "US $ 3,00,000" is equal to $300,000.

92. *Id.*

is to prevent others from claiming knowledge and subsequently patenting that knowledge as their own. In essence, the databases still provide the knowledge for free. The only benefit the indigenous peoples receive is that the database system prevents others from selling them back their own knowledge. The databases help credit the knowledge to their country, but as far as monetary rewards go, there likely are not any.

*C. Contracts and Prospecting Agreements*

Because a database system can be costly and can lead to limited results, prospecting agreements are becoming a more-widely-used alternative. This type of agreement occurs when a research company contracts with a country for rights to biological material and traditional knowledge.[93] Usually, an initial fee is paid, and royalties are negotiated. The countries involved in these contracts are typically developing countries, and the payments go for a variety of causes, from conservation to schools and roads.[94]

One of the most famous examples of a prospecting agreement was between the Costa Rican government and the United States pharmaceutical firm Merck, who paid a government-created entity $1 million, furnished $130,000 worth of equipment, provided training and technology transfer, and agreed to pay a royalty for any drug that was discovered.[95] The initial fee and any royalties went to conservation efforts, among other things.[96] In return, the Costa Rican entity agreed to provide Merck with ten-thousand samples of plant and animal germplasm,[97] with help from both the government and native population.[98]

This type of agreement creates a contractual relationship and gives the government a cause of action if Merck were to breach its contract. Because the knowledge and biological germplasm are not protected, any other company can still use the resources Merck gathered. This means that if another company acquired any of the samples and developed a drug from them, the Costa Rican government would have no legal recourse. For this reason it is important to note that these types of contractual agreements do not offer protection beyond the contracting parties.

---

93. *See* Michael A. Gollin, *Answering the Call: Public Interest Intellectual Property Advisors,* 17 WASH. U. J.L. & POL'Y 187, 196 (2005).

94. *See, e.g.*, Eiland, *supra* note 19, at 70.

95. Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 143 (1996).

96. *Id.*

97. *Id.*

98. Eiland, *supra* note 19, at 70.

Further, most of these agreements are between the researcher and a government. They do not include the people whose ancestors made the original discoveries. Although in the Merck example there was no mention of indigenous peoples' rights, there is a possibility they will receive an indirect benefit as a result of the conservation or other government uses of the money—but there is no direct benefit.[99]

Other agreements have paid more attention to indigenous needs. A California company called Shaman Pharmaceuticals provided payments for potable water, roads, and healthcare, as well as technology transfers.[100] Royalties on any patents were paid to both the indigenous communities and the local governments.[101] But even with agreements that seemingly meet the local population's needs, there are still complaints. Indeed, Shaman has itself been accused of biopiracy.[102] The company has patented two drugs from a plant called sangre de drago, one for a child respiratory disease and one for herpes.[103] The plant grows in South America, where it was claimed it had been used by the original inhabitants for years.[104] If this is the case, the patent should not have been granted because it was not novel. Even if Shaman were sharing royalties, it had no right to the monopoly power a patent provides.

After Shaman filed for the patents, it went bankrupt.[105] As a result, the patents are in the name of a company that no longer exists and will likely fall into the public domain without benefiting anyone. This has the same result as a database in preventing others from patenting, and there are still no benefits flowing to the indigenous peoples. This situation is a direct result of not presenting the patent jointly between the company and a representative for the native population.[106]

---

99. *Id.*
100. *Id.*
101. *Id.*
102. *Id.*
103. *Id.* at 70-71.
104. *Id.* at 71.
105. *Id.*
106. There are a few examples of the United States government forcing companies to provide contract rights for indigenous products. Congress passed the Indian Arts and Crafts Act of 1990, requiring retailers to identify crafts that appeared to be made—but were not actually made—by Native Americans. Pub. L. No. 101-644, 104 Stat. 4662 (codified as amended at 25 U.S.C. § 305(a) (2006)). The goal is to preserve the culture and identity of the Native American tribes. *Id.* In essence, the Act grants a trademark to the Native American tribes and protects the name rather than the knowledge, which in this case tends to be the product of value. This type of agreement would not work in most situations involving medical information, but it serves as an example of where a government has stepped in to safeguard indigenous residents.

Even considering the possible negative outcomes, prospecting agreements can offer protection and benefits to indigenous communities. The contracts do not always benefit the historical inhabitants directly, and the researchers often stand to gain more than the locals. The contracts usually do not protect those who originally developed the information in all circumstances, such as in the case of Shaman going bankrupt or third parties using the gathered knowledge. On the other hand, the local community benefits more than they would absent an agreement. Sharing traditional knowledge has little cost to the indigenous peoples, and even limited benefits for sharing it are better than nothing.

## *V. Proposal*

As technology advances, natural resources will become more valuable. Much of the untapped diversity lies within the control of indigenous groups. It is incredibly costly to sift through the massive amounts of resources to find a benefit. Traditional knowledge greatly reduces this effort. One pharmaceutical company claims that with traditional knowledge, the search can be reduced from one benefit in ten thousand samples to one in every two samples.[107] This knowledge can be of great value. Unfortunately, the people who could use the benefits the most are the ones who are least protected.

The only way to gain full control over the knowledge would be to obtain a patent to it. This is often very difficult for an indigenous group due to a lack of resources. It is unlikely that an indigenous community would have the funds or research abilities to meet the necessary requirements. And even with the funds, many potential hurdles remain.

The problem with the entire system is that, in general, indigenous peoples have very limited bargaining power. They are usually in developing countries with limited funds. The developed countries, which have economic power, need to be the ones to set up a system to protect native citizens' rights. Developed countries' governments are generally against creating such a system because they currently benefit from this knowledge at the expense of indigenous groups.

If we change the system to strengthen protection for indigenous peoples, we risk losing new drugs. It is extremely expensive to develop new medicine; if the sources of these medicines are protected, it is unlikely that anything would be developed from them. Many of the countries with the largest amount of genetic diversity do not have the means to develop drugs from these resources. They would likely still need outside help in development. This would take

107. Eiland, *supra* note 19, at 71.

them back to contracting out their rights. Because they can, and have, started doing this, offering further protection would accomplish little.

Offering greater protection may force companies to contract and give indigenous peoples further bargaining power during contract negotiations. Anything that limits pharmaceutical companies' rights to resources, however, has the potential to limit drug development. With past contracts, availability of resources did not always mean results. Merck's contract with Costa Rica did not yield any new drugs.[108] Shaman's contracts did yield a few medical developments, but they did so at such a cost that Shaman ended up in bankruptcy.[109] The more control indigenous peoples have over these resources, the more expensive access to them will become, leading to a decrease in development.

A balance needs to be struck that can provide benefits to both developing and developed countries. To do this, both databases and prospecting agreements should be utilized. Due to lack of capital, it is untenable for many countries to utilize the resources available to them. Unfortunately, many of the most biologically diverse countries are also some of the poorest. Even if we could protect their traditional knowledge, they would not be able to utilize it effectively.

Instituting a database system to supply the world with the existing traditional knowledge would supply a base on which new breakthroughs in medicine could be built. Research companies could narrow their searches, potentially reducing cost and increasing new advances. This would also prevent companies from usurping existing inventions, packaging them, and selling them back to the ones who first discovered them. Databases would promote innovation and reduce theft.

Although databases do not benefit indigenous peoples directly, if used in conjunction with prospecting agreements they can provide income in exchange for traditional knowledge and native materials. Databases only offer clues to future breakthroughs. They do not provide all of the knowledge and materials needed for these new inventions. Databases have the potential to bring in customers with deep pockets, eager to take advantage of the clues in these compilations. Countries could also contract with researchers for the rights to biological samples of native plants and animals. This has been done in the past without databases.[110] The researchers had to sift through huge amounts

108. *Id.* at 70.
109. *Id.* at 71.
110. Bosselmann, *supra* note 95, at 142-43.

of material and found nothing of substantial use.[111] Significant fees have been paid in the past for these rights. If the search could be limited, and the chance of positive results increased, then the fees charged could be increased, providing more money to the indigenous peoples while reducing the overall cost. Databases can do this by identifying plants rich with medical marvels.

Even if the initial database is not bringing in income, indigenous peoples could profit by increasing the potential contract fees for prospecting agreements. As long as indigenous peoples do not have the financial means necessary to profit from direct use of their traditional knowledge, the next best thing is to ensure others are not stealing it for their own use and to attract researchers to pay for this knowledge.

111. *Id.* at 144.