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Biotechnology, Indigenous Peoples, and Intellectual Property Rights

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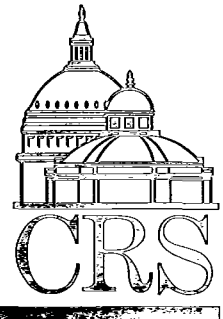

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BIOTECHNOLOGY, INDIGENOUS PEOPLES, AND INTELLECTUAL PROPERTY RIGHTS

SUMMARY

Plant and animal species are estimated to become extinct as a result of natural processes at a rate of one to ten species a year. But human activities and the destruction of habitat are calculated to increase the extinction rate to 10,000-150,000 species a year. This process threatens the gene pool base that is important for food crops, undermines ecological balance, raises moral concerns about humankind's relationship with other species, adversely affects the development of new products useful to the modern world, and causes the demise of indigenous peoples dependent upon their immediate habitat.

Several decades ago pharmaceutical companies and government research agencies devoted substantial efforts to screening plants and animals for useful medicinal properties. But the lack of widespread success and government budget cuts led to a decline in biodiversity screening in the 1970s in favor of efforts to synthesize new drugs in the laboratory. Now there has been a resurgence of interest in biodiversity screening. That resurgence has also been accompanied by a concern in some quarters to involve indigenous peoples in the screening process. The purposes of that concern have been to use the traditional knowledge of indigenous peoples about the medicinal properties of plants and animals to target the most promising species for screening and to develop economically viable arrangements that serve both to help indigenous peoples survive and to preserve biodiversity.

A number of arrangements have been forthcoming. The National Cancer Institute has formulated a Letter of Intent that attempts to ensure that indigenous peoples and/or developing countries benefit from biodiversity screening. Merck & Co., Inc., has entered into a contract with INBio, a Costa Rican biological research organization, under which INBio is providing samples of plants, animals, and microorganisms in exchange for an up-front payment and a portion of any royalties on products developed from the samples. At least one pharmaceutical company, Shaman Pharmaceuticals, is relying exclusively on the knowledge of indigenous peoples in its screening process. And there is growing interest in the feasibility of developing extractive reserves as a means both of providing economic sustenance to indigenous peoples and of preserving biodiversity.

An emerging issue in the debate about the rights of indigenous peoples has concerned whether their traditional knowledge might be entitled to protection under the national and international system of intellectual property law. That possibility seems doubtful, however. Developing countries that host most indigenous peoples have generally subordinated protection for intellectual property to concerns about rapid economic development. The rights of indigenous peoples are as yet ill-defined. Existing and proposed international agreements pertaining to intellectual property provide little support for the notion. And the requirements of U.S. patent law that an invention be novel, useful, non-obvious, and not be a product of nature appear to be insuperable obstacles to any domestic protection for such knowledge.

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BIOTECHNOLOGY, INDIGENOUS PEOPLES, AND INTELLECTUAL PROPERTY RIGHTS

OVERVIEW

Intellectual property law centers on the question of who has the right to exploit particular creations of the human mind. A patent gives an inventor the exclusive right to make, use, or sell an innovative product or process for a period of time. A copyright protects such works as writings, architectural drawings, motion pictures, and computer software from unauthorized duplication. Trade secrets afford protection to confidential information that gives a business a competitive advantage. And registerable marks (trademarks, service marks, certification marks, and collective marks) extend protection to names and insignia that have a particular identity in the economic marketplace.

All of these forms of intellectual property may be involved in the development, production, and marketing of pharmaceuticals. But patents may be the most important form, because a patent gives its owner the opportunity to control the production and marketing of a drug for a designated period of years and thus to reap economic benefit from it.

This report examines intellectual property rights in pharmaceuticals in a particular context, namely, medicinal products and processes derived from the biodiversity resources of areas inhabited by indigenous peoples. The subject has become of interest for a variety of reasons. First, there is increasing awareness that plant and animal species in the tropical rainforests and elsewhere are disappearing at an accelerating rate due to human activities that destroy or affect their habitat. Second, there has been a resurgence of interest among pharmaceutical companies and government research agencies in screening plant and animal species for medicinal properties useful in treating various diseases (biodiversity screening). Third, there is increasing awareness that the destruction of habitat has proven fatal not only to numerous plant and animal species but also to many indigenous peoples dependent upon that habitat, and continues to threaten many that still exist.

These factors have given rise to the question of whether the current interest in biodiversity screening might help preserve both biodiversity and indigenous peoples. More specifically, the question concerns whether some of the economic benefit that could result from biodiversity screening might accrue to the indigenous peoples of the areas screened. Indigenous peoples often have extensive knowledge about the possible medicinal uses of plants and animals in their habitat. That knowledge has been, or could be, exploited by pharmaceutical companies and others in screening local flora and fauna and in developing useful drugs. Does intellectual property law give indigenous peoples any claim to the economic benefit that may accrue from this process? Are there

alternative arrangements that have been, or could be, developed that provide some economic benefit?

Part I of this report provides background and context for this subject and examines selected developments that provide indigenous peoples some role in, and benefit from, biodiversity screening. It explores the meaning and importance of biodiversity generally and for indigenous peoples particularly, biodiversity's use in the development of pharmaceuticals, the role of the traditional knowledge of indigenous peoples in that process, and some of the arrangements that have been developed to provide indigenous peoples and less developed countries some economic benefit from that process. The latter discussion includes the National Cancer Institute's Letter of Intent regarding biodiversity screening, the recent screening agreement between Merck & Co., Inc., and INBio, a Costa Rican nonprofit biological research organization, and the feasibility of extractive reserves.

Part II of the report focuses more explicitly on the issue of intellectual property rights. It summarizes the ongoing debate about the definition of indigenous peoples, examines their rights under international law, and analyzes the complex issue of whether their traditional knowledge about the medicinal properties of plants might be protectable under the existing national and international system of intellectual property rights. It explores how the issue has been treated in the Biodiversity Convention concluded at the United Nations Conference on the Environment and Development held in Rio de Janeiro in June, 1992, in the ongoing Uruguay Round of the GATT negotiations, and in a draft patent harmonization treaty under consideration by the World Intellectual Property Organization. It analyzes as well whether such knowledge could qualify for protection under American law.

A final section summarizes the report's significant conclusions and speculates on additional possibilities. An Appendix sets forth the text of the National Cancer Institute's Letter of Intent.

PART ONE: BIODIVERSITY, THE DEVELOPMENT OF MEDICINAL PRODUCTS, AND INDIGENOUS PEOPLES[1]

A. Introduction

Biodiversity includes variety at the gene, species, and ecosystem level. Each species, or potentially interbreeding group of organisms, holds an immense amount of genetic information in its DNA and helps make up the many complex, interdependent communities which comprise different ecosystems. Although the level of global biodiversity has fluctuated throughout the ages, the current rate of loss, as measured by species, is thought to rival the mass extinctions that

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[1] This part of the report was written by Josephine R. Axt and M. Lynne Corn of the Environment and Natural Resources Policy Division.

occurred 65 million years ago with the decline of the dinosaurs.[2] Current scientific estimates of species loss range from 10,000 to 150,000 per year,[3] depending on the assumptions made for variables such as projected rates of deforestation and the overall number of species. In contrast, the natural, "background" rate of species extinction is believed to be about one to ten species a year.

The total number of species in the world is still unknown; approximately 1.4 million species have been identified. Scientists estimate the total number to be around 10 million species, but it could be as much as 80 million since there are still major habitats -- such as rainforests, coral reefs and the deep sea floor -- which are relatively unexplored.[4] Consequently, some species are lost before scientists have a chance to identify them. Most of the species yet to be identified are a broad assortment of invertebrates, fungi, algae, and microorganisms.[5] The major force behind the current rate of species loss is human activity, which -- fueled by a rapidly growing population -- places an ever-increasing demand on the world's natural resource base.[6]

Overall, in the past decade there has been a growing realization among developed countries that the Earth's biological diversity is: (1) disappearing at an unprecedented rate due to the impact of human activities, (2) integral to maintaining a properly functioning, global life-support system, and (3) a warehouse of valuable compounds which could aid in the development of useful new products. This part of the report focuses on (3), and examines both the history and prospects of biological contributions to the development of medicinal products useful to the modern world and the role of indigenous peoples in product development.

In this discussion two related types of products from natural sources are considered. Some products entering the market are "eco-derived", *i.e.*, derived from natural sources (often rainforests), with no particular claim that demand for the product is a result of its origin. Examples of such products include taxol, rubber, and Brazil nuts. A subset of these eco-derived products are also "eco-driven", *i.e.*, not only derived from natural sources but also with demand based largely on the source, usually rainforests, and usually indigenous (or at least poor) villagers. Examples of such products are "rainforest crunch" ice cream,

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[2] Wolf, E. C. (1987). "On the brink of extinction: conserving the diversity of life," Worldwatch Paper 78, Worldwatch Institute, p. 6.

[3] Ryan, J. C. (1992). "Life support: conserving biological diversity," Worldwatch Paper 108, Worldwatch Institute, p. 5.

[4] *Id.*

[5] Wilson, E. O. (1988). "The current state of biological diversity," *in* E.O. Wilson, ed., Biodiversity. National Academy Press, Washington, D.C., p. 3-4.

[6] U.S. Congress, Office of Technology Assessment, *Technologies To Maintain Biological Diversity*, OTA-F-300 (Washington, DC: U.S. Government Printing Office, March 1987).

and some cosmetics. Eco-driven products are also eco-derived, but the reverse is not true. Eco-driven and eco-derived products are not restricted to the field of medicine, but are also evident in other fields, such as agriculture and industry.

B. The Importance of Biodiversity

Continued loss of global biodiversity may have serious consequences for the modern world. First, the ability of today's principal food crops to adapt to changing climate conditions and novel pathogens has been threatened by the loss of their primitive and wild varieties. Today and in the past, agricultural productivity has been increased by selecting certain populations for domestication and then "improving" them by incorporating genetic information from wild varieties (*e.g.*, those known to have resistance to drought or a certain pest).[7] Botanists are currently searching for almost extinct varieties of wheat in the Ukraine and Turkey in an effort to procure genes that are resistant to a new type of aphid which kills wheat. Ultimately, they want to produce crop varieties which will be able to withstand the pest.[8]

The importance of maintaining wild gene pools has grown in the decades since the Green Revolution (when crop yields rose dramatically in response to energy intensive farming that used fertilizers, pesticides, mechanization, *etc.*) because the world's human population has increased its reliance on a relatively small number of food crops. Today, three plant species -- corn, wheat, and rice -- supply about 60% of the world's total food needs.[9] Because of this unstable reliance, plant biodiversity is also important as a source for new economic crops. It is estimated that nearly 80,000 species of plants possess food value for humans; only a tiny fraction of that number has been used.[10] In addition, crop improvement via genetically engineered plants, which some have called the new agricultural revolution, requires access to wild gene pools.[11]

Second, biological diversity plays an integral role in sustaining the Earth's life-support systems. Scientists are continuing to discover how the presence of life affects global processes, such as weather patterns and nutrient cycling. Rapid species loss may pose serious risks to the maintenance of proper ecosystem functioning. Ultimately, human beings rely on the performance of diverse ecosystems for their well-being. History has shown that the crucial roles

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[7] Oldfield, M. L. (1989). The Value of Conserving Genetic Resources. Sinauer Associates, Inc., Sunderland, MA, p. 12.

[8] Dolan, M. (1992). "Extinction of planet's species," *The Los Angeles Times*, May 22, p. A1.

[9] "Financing Ecological Destruction" (1987). World Bank and International Monetary Fund, for a WB/IMF meeting Sept. 29 - Oct. 1, 1987, p. 5.

[10] Oldfield, p. 13.

[11] Wrubel, R. P., Krimsky, S. & Wetzler, R. E. (1992). "Field testing transgenic plants," *Bioscience* 42 (4), p. 280.

played by "useless" species are all too evident upon their absence. For example, when predators are cleared from an area, pest populations may rise out of control.[12]

Third, although not amenable to precise quantification, the aesthetic and moral aspects involved with the issue of preserving biodiversity are worthy of note. A new field, bioethics, is just beginning to consider rigorously the relationships between *Homo sapiens* and other species. At the same time a conservation ethic appears to be emerging which questions the appropriateness of human actions when the result is a continuing erosion of the world's biological diversity.[13] Edward O. Wilson recognized the rising conservation ethic in his testimony on the Endangered Species Act before a congressional oversight committee in 1981 when he stated: "But the one process ongoing that will take millions of years to restore is the loss of genetic and species diversity by the destruction of natural habitats, careless misuse of parts of the environment that result in species extinction. That is the folly our descendants are least likely to forgive."[14]

Finally, the continued loss of global biodiversity will probably constrain the development of new products useful to the modern world. Rates of loss are highest in the tropics, which may house half of the world's biodiversity. Products tremendously important to the modern world, such as quinine, coffee and rubber, originated in the tropics.[15] In the past few years, and especially in the United States, pharmaceutical companies and other research institutions have markedly stepped up their allocation of funds for eco-derived products research. The driving force behind the growth in screening plants (and some animals) for new products is the recognition that nature provides many complex substances with numerous useful properties.[16]

C. Biodiversity and Medicine

Companies are screening samples from natural sources to isolate and identify compounds for use in fertilizers, pesticides, dyes, paints, and cleansers.[17] However, the most rigorous application of biodiversity screening is in the medical arena. Currently, over 200 companies and research

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[12] Ryan, p. 6.

[13] Wilson, E. O. (1984). Biophilia. Harvard University Press, Cambridge, MA, p. 119.

[14] U.S. Congress. Committee on Environment and Public Works. Subcommittee on Environmental Pollution. Endangered Species Act. Oversight Hearing, Dec. 10, 1981. 97th Congress, First Session. Washington, U.S. Govt. Print. Off., 1982. p. 289. Serial No. 97-H34.

[15] Caufield, C. (1985). "A reporter at large: the rain forests," *The New Yorker* 60, p. 58.

[16] Roberts, L. (1992). "The drug industry goes green," *Science* 256, p. 1143.

[17] Johnson, T. (1992). "From rain forest to medicine chest: natural riches up for grabs," *Miami Herald*, June 12, p. 1A.

organizations worldwide are screening compounds from plants and, to a lesser extent, animals for medicinal properties.[18]

All 120 pure chemical substances extracted from plants widely used in medicine today were isolated from less than 90 species of plants. Scientists estimate that there are at least 250,000 plant species on the Earth.[19] Although scientific attention began focusing on plants as a source of pharmaceuticals in the nineteenth century, most plants still have not been systematically evaluated as potential sources of drugs (*i.e.*, tested for a wide range of activity, not just a few specific effects). For example, in genetically rich tropical forest ecosystems, fewer than one percent of the native species have been investigated for potentially useful chemical compounds.[20] In the Pacific Northwest, the promising anticancer drug taxol was developed from a species long considered a "weed."

Two technological advancements have made increasing the percentage of investigated species more feasible. First, large-scale screening efforts now can use automated screening equipment, which both increases the speed of a single analysis and allows numerous analyses to be performed simultaneously. In addition, scientists now have a clearer understanding of the precise chemical pathways in humans which plant-derived compounds modulate when producing effects. This knowledge allows researchers to pinpoint crucial activity sites and design very accurate screening tests.[21]

D. Biodiversity and Indigenous People

Biological diversity is very important to indigenous groups. Throughout the world indigenous peoples use specific information about their local environment -- acquired through centuries of experience with plants and animals -- when managing natural resources, acquiring food, and providing health care. For example, indigenous peoples around the world still rely on traditional medicine (*i.e.* pre-modern health practices closely tied to cultural beliefs), and 85 percent of traditional medicine requires the use of plants.[22] According to World Health Organization estimates, 80 percent of the population in developing countries regularly uses traditional medicine for some basic health

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[18] New Pharmaceuticals Derived from Plants (1988). Technology Management Group, New Haven, CT, p. 4-1 through 4-37.

[19] Wilson (1988), p. 3.

[20] Caufield, p. 58.

[21] Stevens, W. K. (1992). "Shamans and scientists seek cures in plants," *New York Times*, January 28, p. C1.

[22] Farnsworth, N. R. (1988). "Screening plants for new medicines," *in* E. O. Wilson, ed., Biodiversity, National Academy Press, Washington, D. C.

care needs. In other words, several billion people regularly use plants for medical purposes.[23]

The knowledge indigenous groups possess about the species in their environments has proved valuable not only to themselves but to the modern world as well. Since the late 1980s there has been growing interest in the United States to expedite the process of identifying plants and animals with biologically active compounds by using the traditional knowledge of indigenous peoples. A small but expanding segment of the pharmaceutical industry is investigating the use of indigenous peoples to target the most promising plants and animals in areas with vast amounts of otherwise little-studied biodiversity. This is being done with the knowledge that of the 120 active compounds currently isolated from higher plants and used in medicine, 74 percent show a positive correlation between their modern therapeutic use and the traditional use of the plant from which they were derived.[24]

Without the input of indigenous knowledge, many valuable medicinal products used extensively throughout the modern world would not exist.[25] For example, alkaloids[26] extracted from roots of the serpent-wood species *Rauvolfia serpentina* are currently used as a treatment for a host of health problems, most notably hypertension. Although used for centuries in India for many of the same human ailments, it wasn't until the 1940s that the species came to the attention of Western scientists.[27] By 1967 root alkaloids derived from *R. serpentina* and two related temperate species comprised almost 90 percent of the U.S. market for antihypertensive drugs.[28] Because of the complication and expense involved with their artificial synthesis, the demand for the active alkaloids is still met largely from natural sources. The successful development of many useful drugs from species of *Rauvolfia* served to focus increased attention on the use of indigenous knowledge in finding new pharmaceuticals.

However, before the late 1980s the prevailing attitude in the developed world was still that technological, industrial countries had little to learn from indigenous people. Therefore, little effort was made to help indigenous groups preserve their unique knowledge and heritage. Now, the Western scientific

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[23] Farnsworth, N. R., Akerele O., Bingel, A. S., Soejarto, D. D. & Guo, Z. (1985). "Medicinal plants in therapy," *Bulletin of the World Health Organization* 63, p. 965-6.

[24] Farnsworth (1988), p. 95.

[25] Taylor, N. (1965). Plant Drugs that Changed the World. George Allen & Unwin LTD, London, p. 1-3.

[26] Alkaloids are alkaline organic compounds that contain nitrogen and are often the source for a plant's pharmaceutical activity (effect). They are often found in tropical plants and are referred to as secondary compounds since they are not explicitly required for growth.

[27] Taylor, p. 19 - 33.

[28] Oldfield, p. 106.

community is beginning to value traditional knowledge, but the groups themselves are facing habitat loss and the encroachment of modern civilization. Since 1900 it is estimated that an average of one indigenous group a year has gone extinct in the Amazon region alone.[29] If an indigenous group and/or its culture goes extinct, its accumulated learning usually goes with it. The loss of one indigenous group and its associated knowledge has been compared to the burning of a library.[30]

In response to this loss, organizations have developed to help indigenous groups maintain their cultural integrity while simultaneously developing products for sale in international markets. Although many of these nongovernmental organizations are not concerned with using indigenous knowledge to isolate and identify novel compounds for use in new products, their efforts might be important for securing the long-term survival of indigenous cultures. Organizations concerned with safeguarding indigenous culture help indigenous groups secure land rights and identify products that can be sustainably extracted. They also attempt to monitor the social and environmental impacts of the transition to a market economy to help ensure that the indigenous communities and their natural ecosystems are not injured.

Cultural Survival is one of the most prominent of these organizations. Its marketing arm, Cultural Survival Enterprises (CSE), works to help lessen the harm of the modern world to indigenous cultures while providing market opportunities for indigenous products. Through the development of products which can be sustainably harvested, CSE promotes both economic development and biodiversity conservation in forests which might otherwise be cut down for timber or farmland.[31] In 1989 CSE began importing hundreds of eco-driven products for sale to other companies in the manufacture of ice cream, cosmetics, cleansers, and other products. Cultural Survival supports autonomy and local decision making for the groups which sell it products, but some critics charge that native peoples are being turned into entrepreneurs and losing their identity.[32] CSE and its allies respond that the best way to protect indigenous cultures is to support their autonomy through projects which allow them to develop and manage their traditional lands responsibly.

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[29] Linden, E. (1991). "Lost tribes, lost knowledge," *Time*, September 23, p. 46.

[30] Plotkin, M. J. (1988). "The outlook for new agricultural and industrial products from the tropics," *in* E. O. Wilson, ed., Biodiversity, National Academy Press, Washington, D.C.

[31] Davis, W. A. (1992). "The rain forest's Cultural Survival," *The Boston Globe*, February 5, p. 1.

[32] *Id.*

E. Plant-Based Pharmaceutical Research

1. History

In the United States funding for plant-based[33] pharmaceutical research peaked between 1953 and 1960.[34] At that time pharmaceutical companies attempted to collect samples of species which showed promise of containing bioactive molecules. When positive results were not forthcoming, most pharmaceutical companies turned their attention to synthesizing new drugs in laboratories (for an exception, see box). Compared with high technology research, screening compounds from nature seemed tedious and old-fashioned.[35] However, the early difficulties with higher plant screening experienced by the pharmaceutical industry may have been a result of errors in sampling procedure by field botanists and misjudgments of biological activity in plant extracts by inexperienced lab technicians.[36] In addition, almost no effort was made to use the ecological knowledge of the indigenous peoples living near the sampling sites. By 1980 none of the U.S. pharmaceutical industry research budget was allocated towards research on higher plants.[37]

During the peak funding years one major player in the effort to screen plants and animals for biological activity was the National Cancer Institute (NCI) Developmental Therapeutics Program (DTP). Between 1956 and 1976 over 35,000 plant species, both tropical and temperate, were tested; preliminary tests showed roughly 10 percent with potential anticancer effects.[38] Seven anticancer compounds resulting from that study are now in the final stages of drug development.[39] One of the most important discoveries of the DTP program has been taxol, which is extracted from the bark of the Pacific yew, *Taxus brevifolia*. Clinical trials have shown taxol to be effective in combatting the advanced stages of several different types of cancers, but demand for the

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[33] Natural products research includes screening of both plants and animals. But, since the vast majority of early research centered on plants, large comparisons and generalizations of budget levels are often restricted to the information provided for plants.

[34] Farnsworth, N.R. & Soejarto, D.D. (1985). "Potential consequence of plant extinction in the United States on the current and future availability of prescription drugs," *Economic Botany*, 39 (3), p. 231.

[35] Stevens, p. C1.

[36] *Id.*

[37] Principe, P. P. (1991). "Valuing the biodiversity of medicinal plants," p. 89 *in* eds., O. Akerele, V. Heywood & H. Synge, The Conservation of Medicinal Plants, Cambridge University Press, Great Britain.

[38] Oldfield, p. 122.

[39] Given NCI's mandate, tests for activity against hypertension, colds, diabetes, etc. were not done. Consequently, NCI tests would clearly under-represent the potential medical utility of the tested species. See below for further discussion.

drug has exceeded its availability. The Pacific yew is primarily found in the shrinking, old-growth forests of the Pacific Northwest.[40] Although yew trees are not cut down when the bark is harvested, the process of removing all their bark is ultimately lethal. Environmental groups have expressed concern that demand for yew bark would endanger the species and harm the already stressed ancient forests. However, Bristol-Myers Squibb Co. (BMS), which applied to the U.S. Food and Drug Administration in 1991 for approval to market taxol, stated that by sometime in 1993 it will be able to synthesize the active compound from renewable parts of yew trees in Asia and Europe. While other scientists think the synthesis might be more difficult, according to BMS the need for Pacific yews should be much reduced by 1994, and by 1997 the Pacific yew will probably not be used as a source of taxol.[41]

The Rosy Periwinkle

Undoubtedly, the most famous example of successful drug development from natural products research is the rosy periwinkle. The isolation of alkaloids from this tropical ornamental, native to Madagascar, was an exception to the drift away from natural products research. First screened in 1954 by Eli Lilly & Co., the rosy periwinkle yielded two powerful drugs effective against Hodgkin's disease and childhood leukemia. Up to then, no plant alkaloids had been used in treating cancer. The rosy periwinkle was chosen for screening because it was reported to contain alkaloids and was used in traditional medicine. Eli Lilly's investment in drug development from natural products proved very profitable for the company, with yearly sales of the periwinkle alkaloids running into the tens of millions of dollars.

In addition to screening plant extracts, DTP also collected and tested tens of thousands of animal extracts and microbial cultures. As a result of these screening efforts, a handful of compounds with anticancer activity has been isolated and are in the later stages of clinical drug testing.[42] However, DTP's plant and animal screening program was terminated in 1981 during a budget cut, because some felt that natural sources were not leading to the identification of novel anticancer agents. Instead, the National Cancer Institute turned its attention to evaluating chemical substances which had already been isolated.[43]

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[40] Bylinsky, G. (1992). "The race for a rare cancer drug," *Fortune*, July 13, p. 100.

[41] Tanouye, E. (1992). "Bristol-Myers asks FDA to approve cancer drug taxol," *Wall Street Journal*, August 3, p. B4.

[42] Oldfield, p. 126.

[43] *Id.*

The discontinuation of the DTP program was viewed by segments of the pharmaceutical industry as evidence that extensive screening of biodiversity would not yield profitable results. Because it affected the perception of potential success in eco-derived products research, two points about the DTP program are worthy of note. First, although thousands of plant and animal extracts were tested, they were only tested for anticancer properties. A substance that does not show anticancer activity might be valuable in treating other diseases, such as hypertension or AIDS. In fact, very few plants have been systematically studied for a wide variety of effects.[44]

Second, although the DTP program did use indigenous knowledge of the local flora and fauna to help it recognize certain species which might display anticancer activity, it did not emphasize this information in its sampling methodology. A retrospective study done by researchers who were affiliated with the project in the 1960s concluded that the success rate in finding active species could have been doubled if medicinal folk knowledge had been the only information used to target species.[45]

2. Present Efforts

Today the National Cancer Institute is at the forefront of renewed interest in both eco-derived products screening and the use of indigenous peoples' knowledge to facilitate the identification of potentially useful species. After NCI de-emphasized screening of plants and animals in the early 1980s, the primary screening technique used in the DTP program was found to have generated some false positives (*i.e.*, the technique flagged compounds which were not effective against the desired tumors).[46] NCI's subsequent reevaluation of its antitumor screening strategy led to the establishment of the current eco-derived products program which uses a new *in vitro* human cancer cell screening procedure. Included in the current program are redesigned methods for extracting and isolating chemical compounds and a strong commitment to collecting plants known for their traditional medicinal properties.[47]

Most of the plant samples gathered in NCI's eco-derived products program are from developing countries. Through policies formulated in a letter of intent (see Appendix), NCI recognizes the value of screening a country's biodiversity and using its healers' traditional knowledge. The policies direct participating pharmaceutical companies in how to compensate countries which contain species that were used to develop a drug. For example, if an active bioagent isolated and patented by NCI were then licensed to a pharmaceutical company for drug

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[44] Farnsworth, p. 92.

[45] Principe, p. 92.

[46] Cragg, G. M. *et al.* (1992) (in press). *In* J. Janic & J. Simon, eds., Proceedings of the Second National Symposium on New Crops, John Wiley Publisher, New York.

[47] *Id.*

development, the letter of intent recommends that the company pay a certain percentage of the royalties to the country where the species originated. The policies also direct pharmaceutical companies to try to obtain supplies of the necessary raw materials from the country of origin first, before investigating alternative sources. In this way, not only does the country of origin gain an export crop, but the local peoples can participate in the collection and/or cultivation of the plant. Through such policies covering royalty payments and raw material supplies, NCI is attempting to compensate countries for participation in NCI drug discovery efforts.[48]

In addition to NCI, some pharmaceutical companies are also enlarging their natural screening programs. The most recent example is the contract signed between Merck & Co., Inc., the largest pharmaceutical company in the world, and the National Biodiversity Institute (known as INBio), a nonprofit research center established by the government of Costa Rica. Under the two year agreement, which may be renewed, INBio will provide Merck with roughly 10,000 samples of plants, animals, and microorganisms. In exchange, Merck will pay INBio $1.3 million plus a percentage of any royalties on products developed from the 10,000 samples.[49] Although involvement of local people is encouraged, the agreement does not emphasize the use of indigenous knowledge.

Part of the $1.3 million will be used to train local people as parataxonomists. They will learn techniques of species identification and collection and provide INBio with samples to satisfy its agreement with Merck. They will also be contributing to INBio's goal of completely surveying Costa Rica's plants and animals. Although Costa Rica is very small in terms of land mass, it is estimated to hold 5 - 7 percent of the world's biodiversity.[50] INBio's goal reflects the Costa Rica's strong commitment to preservation; 25 percent of its land is set aside as forest preserves. To further this commitment, the government will receive 10 percent of the initial payment and 50 percent of any resulting royalties for use in its conservation programs.[51]

Some critics contend that the opportunity to search through Costa Rica's genetic resources should carry a bigger price tag than the initial $1.3 million prospecting fee, but the arrangement is potentially very profitable. The World Resources Institute has estimated that if ten successful drugs are developed, and Merck paid INBio 2 percent in royalties, the money Costa Rica could receive each year would be greater than the amount it makes from the sale of bananas and coffee, its two biggest exports. Not surprisingly, the agreement between INBio and Merck has caught the attention of many other developing, species-

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[48] *Id.*

[49] Preston, J. (1992). "Costa Rica's pact with Merck studied," *The Washington Post*, June 9, p. A16.

[50] Roberts, L. (1992). "Chemical prospecting: hope for vanishing ecosystems?" *Science* 256, p. 1142.

[51] Id.

rich nations. Nepal, Mexico, Indonesia, and Nicaragua, among others, have approached Costa Rica for advice in establishing their own non-profit research centers. In the United States other pharmaceutical companies and NCI have also expressed interest in discussing similar arrangements with Costa Rica.[52]

Although the relationship between Merck and INBio may provide a model for future partnerships between pharmaceutical companies and host governments, it is important to realize that many developing countries interested in such an arrangement might have to consider the roles and rights of indigenous peoples. In contrast, Costa Rica has almost no indigenous people. The agreement between Merck and INBio includes training individuals from the working class as parataxonomists, but they approach the forest as employees with institutional educations, not as traditional peoples with indigenous knowledge. As a result, there are no issues of patent rights or land ownership to consider. If traditional knowledge is used, pharmaceutical companies and host countries may be faced with the question of how to incorporate the rights of indigenous peoples into their agreements. In some countries they may also face conflicts where national governments are indifferent or even hostile to the interests of indigenous peoples.

The relative lack of success in early efforts at large-scale plant screening combined with the rapid development of biotechnology and molecular biology in the 1970s served to discourage U.S. pharmaceutical companies from using research funds for projects like the one between Merck and INBio. By the mid-1980s the industry's disinterest in eco-derived products screening had coalesced around three perceived problems. First, the same level of assurance that existed for patenting synthetic compounds did not appear to exist for patenting eco-derived products (see Part Two). Second, there was concern that biological variation might cause the percentage of active chemicals in the plant material to fluctuate from shipment to shipment. Third, because many promising plants were located in developing tropical countries,[53] many of which did not have stable governments, there was some question about the reliability of receiving steady shipments of the raw material.[54]

Although appropriations for eco-derived products research declined after the 1950s until very recently, the market for eco-derived drug products has remained relatively constant over the past three decades. There are two major reasons why demand remained steady in the face of decreased research for new products. First, although scientists could chemically synthesize almost all

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[52] *Id.*

[53] Tropical areas are considered excellent regions for biodiversity screening, because they contain an unrivaled concentration of species which are often rich in secondary compounds. However, although much deserved attention has been focused on their potential for harboring potentially useful compounds, it is important to remember that other ecosystems are also being investigated. Some American pharmaceutical companies are working extensively in desert regions, while others are examining U.S. forests.

[54] Farnsworth (1988), p. 95-6.

naturally occurring active compounds isolated to date, it was often much more cost-effective to extract the compound from natural sources directly. Second, researchers commonly used the chemical "blueprint" of active biological compounds in developing new synthetic drugs. In other words, by using the natural substances -- which generally have very complex chemical structures -- as building blocks, scientists were able to produce synthetic compounds with related uses.[55]

It is important here to distinguish between pharmaceutical discovery and pharmaceutical development. In terms of eco-derived products, pharmaceutical discovery involves the initial screening efforts which identify active compounds, while pharmaceutical development entails subsequent modification and testing of the compounds. As illustrated in the paragraph above, companies can help control costs by using a chemical compound identified through a discovery program as the starting point for several development efforts.

Today, the practice of "chemical prospecting," or looking for novel chemical structures in nature which can then be modified in the lab, is growing in popularity. As a result, research organizations are beginning to view natural extraction of compounds and artificial synthesis of compounds as complementary efforts.[56] Initially, the success of synthetic drugs in industrialized nations led to the phasing out of eco-derived products research. Now, companies are realizing the value of using both methods in combination; the Merck-INBio project is a prime example of this new drug development strategy. Although Merck and Co. would welcome the discovery in its extracts of an active drug which it could then collect and harvest from wild or cultivated plants, its main goal is to isolate promising substances which Merck chemists could then synthesize and/or modify in the laboratory.

3. Future Prospects

Renewed interest in eco-derived products research reflects the continuing market for eco-derived products. The latest available data indicate that over the past three decades roughly one quarter of prescriptions dispensed from U.S. pharmacies have contained chemicals isolated and generally still gathered from flowering plants.[57] Today it is reported that almost one half of all prescription drugs are derived from natural sources or have been synthesized to correspond to natural models.[58] In 1989 it was estimated that American consumers spent more than $8 billion on prescription drugs which contained active ingredients

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[55] Oldfield, pp. 91-3.

[56] Oldfield, p. 93-5.

[57] Farnsworth, N. R. (1988). "New medicines from plants," *The World and I* 3, p. 214.

[58] Heine, K. (1991). "Treasure in the jungle," *Monsanto Magazine* 1, p. 18.

still extracted from higher plants.[59] In January, 1991, there was enough interest by the pharmaceutical industry in plant-based drugs to hold a symposium on "Tropical Forest Medical Resources and the Conservation of Biodiversity." Among the sponsors and participants were Monsanto Co., Merck & Co., SmithKline Beecham Co., and Bristol-Myers Squibb Co.

Although most major pharmaceutical companies have eco-derived products research departments, many are still hesitant to employ indigenous knowledge to focus efforts on traditionally used species because the value of such a search strategy remains to be verified. So far a major exception to this hesitancy is Shaman Pharmaceuticals, Inc., a small California-based company which originated in May, 1990, and went public earlier this year. Shaman develops new pharmaceutical products based exclusively on the knowledge of indigenous peoples. Shaman also hopes to uncover new prototype pharmaceuticals (*i.e.*, drugs which have a heretofore unknown mode of action). Besides being committed to devoting 100 percent of its budget to working with indigenous groups, Shaman has formed a nonprofit conservation arm called the Healing Forest Conservancy. The goal of the Conservancy is to funnel part of the profits generated at Shaman to the people and countries where the research was performed. In this way Shaman hopes to strengthen the conservation of both biological diversity and traditional medicine.

Two of the company's drugs have started the human clinical trial process and reportedly may be on the market by 1995. Shaman is hoping that, with the use of traditional knowledge to pinpoint drug prospects, the time and expense associated with pharmaceutical development will be greatly reduced.[60]

F. Pharmaceutical Development

Unlike Shaman, when pharmaceutical companies have used foreign genetic resources or indigenous knowledge in the past to help identify promising new compounds, they often have not provided much compensation to the country of origin. Pharmaceutical companies argue that the process of drug development is very risky, expensive and time-consuming, and that if it weren't for their efforts, the active compounds would never result in widely available pharmaceuticals. In addition, they note that there is no guarantee their efforts will result in a successful drug. According to a study by the Center for the Study of Drug Development at Tufts University, companies invest an average

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[59] The 1989 - 1991 annual survey report of the Pharmaceutical Manufacturers Association did not delineate sales data by amount from plant-derived active ingredients, so the estimate was arrived at by taking 25 percent of their total domestic prescription sales. Eight billion dollars is a conservative estimate, since the number only includes sales of PMA members.

[60] Glater, J. & Barnum, A. (1992). "A walk in the woods for biotech," *San Francisco Chronicle*, June 17, p. B1.

of $231 million over 12 years to develop one novel, marketable medicine from initial laboratory investigations.[61]

New drugs must undergo rigorous testing before they are approved for sale in the United States. Once a company identifies a promising active compound, it is tested in the laboratory, often on animals, to gauge its biological activity and safety. According to the Pharmaceutical Manufacturers Association (PMA), on average such preclinical testing requires about three and a half years and has a low success rate, with only one of every 1,000 evaluated compounds advancing to the clinical trial stage.[62] In clinical trials, which are organized into three phases and usually take six years to complete, new drugs are tested in people. Each succeeding phase involves a larger test population receiving the drug for a longer time period. At all stages the drug's appropriate dosage, safety level, effectiveness, and side effects are monitored closely.

In its January 1993 bulletin entitled *New Drug Approvals in 1992*, PMA analyzed information from the Food and Drug Administration (FDA) about the approval process for new pharmaceuticals. After completion of clinical trials, a new drug application (NDA) is filed with the FDA. NDAs must contain all the scientific information gathered by the company, and as a result, they often exceed 100,000 pages. Although FDA is given six months by law to review an NDA, the average review time in 1992 for new drugs was nearly 2 1/2 years. According to PMA, the six biologics (drugs based on naturally occurring compounds) approved by the Center for Biologics Evaluation and Research at FDA in 1992 had an average approval period of almost 3 years. PMA's analysis further stated that of every one thousand compounds which advance to clinical trials, only one will obtain FDA approval for commercial marketing. Following approval, FDA is informed of the performance of new drugs by periodic reports from the company. In some cases a fourth phase of post-marketing testing is required to assess long-term effects.

PMA's January bulletin also reported that the U.S. pharmaceutical industry has allotted an increasing percentage of its total sales to the discovery and testing of new drugs, going from 11.7 percent in 1980 to an estimated 16.7 percent in 1993. PMA estimated that American pharmaceutical companies will spend approximately $12.6 billion for research and development in 1993.

G. Extractive Reserves

Extractive reserves are commonly defined as natural forest areas set aside for the sustainable extraction of products (such as nuts, fruits, and latex, but not the trees themselves), usually by native peoples. Theoretical studies have

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[61] DeMassi, J., Hansen, R. W., Grabowski, H.G. & Lasagna, L. (1991). "Cost of Innovation in the Pharmaceutical Industry," *Journal of Health Economics* 10, p. 107.

[62] As yet no rigorous data exist on the percentage of successful compounds found when traditional knowledge is incorporated into the sampling stategy, but companies working with indigenous peoples are assuming the percentage will be higher.

suggested that rural inhabitants can generate more income through practicing sustainable extraction of non-timber products than through activities such as farming and cattle ranching, which result in forest loss.[63] The economic viability of harvesting species for *medicinal* purposes had not been examined, until Michael Balick, Director of the Institute of Economic Botany at the New York Botanical Garden, published a paper in which he quantified the value of tropical pharmaceuticals.[64] In this study he calculated the worth of a tropical forest if it were harvested for medicinal plants and then compared that with its worth when cut down and converted to cropland. Although he acknowledged that his results might shift with changing market prices, he found that at current market prices the income of a person engaged in gathering medicinal plants for sale was two to ten times the income of a farmer. His results indicate that preserving some rainforest as extractive reserves for medicinal species might be economically justified, but to date these ideas have only been demonstrated on paper, not in the field.

But even as more and more conservation groups and donor organizations are electing to support the idea of extractive reserves, their sustainability and ability to preserve biodiversity are being questioned. First, forests with relatively few species are more likely to support financially successful extractive reserves. In other words, profits would be greater in an area where the valued species is common (*i.e.*, easy to find and harvest), but commonness is not typical of rainforests.[65] Second, there is concern about the long term maintenance of wild species' population levels. Careful resource management techniques would need to be followed to ensure a species' long term survival, since there are examples of both plant and animal species which have become depleted or endangered as a result of commercial demand.[66] Lastly, rural inhabitants who practice "extractivism," such as the rubber-tappers in Brazil, do not usually subsist wholly on their harvesting activities, but supplement their income with land clearing practices like farming. In addition to the resulting land degradation, studies have shown that over half of all rubber-tappers are in debt and remain in poverty regardless of how much they produce.[67]

Although the full impact of extractive reserves on indigenous peoples and biodiversity is unclear, the current interest in screening the biosphere for active chemical compounds has the potential to increase the number of extractive

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[63] Peters, C. M., Gentry, A. H. & Mendelsohn, R. O. (1989). "Valuation of an Amazonian rainforest," *Nature* 339, p. 656.

[64] Balick, J. M. & Mendelsohn, R. (1992). "Assessing the economic value of traditional medicines from tropical rain forests," *Conservation Biology* 6 (1), p. 128.

[65] Peters, C. H., Balick, M. J., Kahn, F. & Anderson, A. B. (1989). "Oligarchic forests of economic plants in Amazonia: utilization and conservation of an important tropical resource," *Conservation Biology* 3, p. 341.

[66] Oldfield, p. 133 - 39.

[67] Browder, J. O. (1992). "The limits of extractivism," *BioScience* 42 (3), p. 176 - 80.

reserves. Since many products have been developed to species' detriment, the potential for sustainably managed extractive reserves may be worthy of investigation. Extractive reserves may also facilitate profit-sharing. Historically, the profits from product development have tended to accrue to the benefit of the pharmaceutical industry rather than to the country where the valuable species was found or to indigenous peoples (if their knowledge or labor were involved). While reserves may be less effective than natural rainforests in supporting the survival of indigenous peoples, they at least present an alternative to clear cutting and displacement of natives.

In conclusion, if active compounds successfully complete the drug development phase, drug companies may ultimately market novel pharmaceuticals and reap substantial profits. The development of novel chemical substances may also lead to new treatments for human ailments. If profit-sharing practices were adopted, host countries' conservation efforts could be strengthened. And by paying for the opportunity to screen a country's biodiversity and to utilize traditional knowledge, researchers could support indigenous peoples in their effort to retain traditional lands and maintain cultural identity. Furthermore, if indigenous peoples were employed to sustainably harvest valuable species, then they might be able to live in a way that does not destroy biologically rich ecosystems. Gradwohl and Greenberg claim: "Extractive reserves offer a mode of forest use that is both immediately economically competitive and sustainable in the long-run."[68]

PART TWO: INTELLECTUAL PROPERTY RIGHTS OF INDIGENOUS PEOPLES IN TRADITIONAL KNOWLEDGE AND BIOTECHNOLOGY DERIVED FROM SUCH KNOWLEDGE[69]

A. Introduction

The legal rights of indigenous peoples with regard to biotechnology and biodiversity are very complicated and unclear. Part of the problem arises from the fact that as yet there is no clear definition of "indigenous peoples" or "indigenous populations." There is also as yet no universally accepted or customary law of the human rights of indigenous peoples, although the International Labor Organization (ILO) and the United Nations Working Group on Indigenous Populations (Working Group) both have agreements or draft agreements on the rights of indigenous peoples.[70] Intellectual property rights

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[68] Gradwohl, J., and Greenberg, R. (1988). Saving the Tropical Forests, Earthscan Publishers, London, p. 150.

[69] This part of the report was written by Margaret Mikyung Lee of the American Law Division.

[70] ILO Convention 169, 28 I.L.M. 1384 (1989), was adopted by the International Labour Conference in June 1989. The United Nations Working Group on Indigenous Populations has been working on a Draft Universal Declaration on Indigenous Rights (Annex I of the Report of the Working Group on Indigenous Populations on its tenth session, E/CN.4/Sub.2/1992/33).

in traditional knowledge have not commonly been included in the dialogue on the human rights of indigenous peoples, although they sometimes have been subsumed in the larger issue of cultural preservation. But the rapid growth of the biotechnology industry and the growing concern over the preservation of biodiversity for commercial use, agricultural use, and environmental and ecological balance have moved the issue to the forefront. The U.N. Working Group will be conducting further studies on the subject.[71]

Two arguments have been made for recognizing the intellectual property rights of indigenous peoples. First, some environmentalists, anthropologists, and other scientists and biotechnological corporations assert that the developed world has a moral obligation to ensure that indigenous peoples receive a fair share of the profits and benefits derived from the use of their traditional knowledge about plants.[72] Aside from the economic benefit, this perspective suggests that the contributions of indigenous peoples should be publicly validated. The rosy periwinkle is generally cited by environmentalists and anthropologists as an example of developed societies' benefitting from pharmaceuticals developed from information given by indigenous people while the indigenous people received nothing in return (although some dispute the accuracy of this example).[73]

Secondly, aside from the ethical interest in compensating indigenous people, there is also the traditional interest of intellectual property laws in promoting the development and dissemination of scientific knowledge. The pharmaceutical, horticultural and agricultural industries have begun to realize what ethnobotanists and anthropologists have known for some time, that there are still many benefits to be derived from the traditional knowledge of

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[71] As part of the activities of the U.N. Working Group, the Chairman/Rapporteur Erica-Irene A. Daes has issued a working paper on the cultural property of indigenous peoples (E/CN.4/Sub.2/1991/34). At its tenth session in the summer of 1992, the Working Group discussed this working paper and the inclusion of a section on the intellectual property of indigenous peoples (¶¶ 150-154 of the Report of the Working Group on Indigenous Populations on its tenth session, E/CN.4/Sub.2/1992/33). The Secretary-General also issued Intellectual property of indigenous peoples: a concise report of the Secretary-General, E/CN.4/ Sub.2/1992/30.

[72] Intellectual property of indigenous peoples: a concise report of the Secretary-General, ¶ 10, E/CN.4/ Sub.2/1992/30. The draft Letter of Intent for the Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI), revision of Sept. 3, 1991, [hereinafter Letter of Intent] states in the preamble that the NCI "recognizes the need to compensate Source country organizations and *peoples* in the event of commercialization of a drug developed from an organism collected within their borders." The Letter of Intent provides for royalty compensation to those who provide information leading to the development of a drug (¶¶ 8-9 under the definition of the role of the DTP, DCT and NCI). Although the Biodiversity Convention, discussed below, does not provide for the intellectual property rights of indigenous peoples, it is meant to provide for the equitable distribution of the benefits of biotechnology to the countries that provide the genetic resources.

[73] Stone, *The Biodiversity Treaty: Pandora's Box or Fair Deal?*, 256 Science 1624 (14 June 1992). Johnson, *Letters: Drugs from Third World Plants*, 257 Science 860 (14 August 1992). *See infra* note 158 and accompanying text for further discussion of the debate about the rosy periwinkle.

indigenous peoples.[74] However, industrial exploitation of the lands traditionally inhabited by indigenous peoples and their gradual acculturation have already eroded biodiversity and cultural diversity. The loss of species has been well publicized. Less publicized but equally important has been the loss of traditional knowledge. As the younger generation of indigenous peoples become assimilated into the mainstream, they retain less of their people's traditional knowledge.[75] One observer notes that the older members of the Kamba people in Kathama, Kenya, could identify the uses of 100 trees while the younger people were only familiar with 14 trees.[76] Also, some indigenous farmers have abandoned the cultivation of certain traditional crops in favor of modern hybrids.[77] Although some of these traditional crops have been deposited in germplasm banks, they are otherwise unavailable to breeders, and other traditional crop breeds have become extinct. There may be a real advantage in encouraging farmers to continue to cultivate traditional crops to maintain biodiversity and breeding stock although these crops may not be as productive as modern hybrids. Indigenous peoples have also developed sustainable uses of the environment which developed cultures may learn.[78] The recognition of intellectual property rights in traditional knowledge, in short, could serve the goal of conserving the environment and maintaining biodiversity and useful medicinal and agricultural knowledge by giving indigenous peoples an incentive to maintain and disseminate traditional knowledge and practices in the face of attractive modern alternatives.

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[74] As discussed above in Part One, although pharmaceutical companies did explore plants as a source of new drugs, especially in the 1950s, the labor-intensive research did not yield many leads on new pharmaceutical compounds, and most companies and the U.S. industry largely abandoned such efforts by 1980. With the development of more sophisticated screening techniques and plant genetics, there has been renewed interest in the pharmaceutical industry in exploring plant-derived chemical compounds. *See Back to Nature for Chemicals and Drugs*, 13 Industrial Bioprocessing 3 (Oct. 1991)(News notes on current industry interest and activities in screening of plants and animals for useful compounds); Posey, *Ways and Means of Strengthening Sustainable and Environmentally Sound Self-Development of Indigenous Peoples*, U.N. Doc. E/CN.4/Sub.2/1992/31/Add.1 (describes some of the scientific traditional knowledge of the Kayapó Indians); Elisabetsky, *Pharmacopeia from the Forest*, 14 Garden 4 (No. 6, November/December 1990) (describing potential of the rainforest and traditional knowledge of it for yielding drugs); and McKiernan, *Preserving the Wisdom of the Ages*, 14 Garden 10, 15 (No. 5, September/October 1990) (describes the efforts of the Center for Indigenous Knowledge for Agriculture and Rural Development (CIKARD) to document traditional knowledge and disseminate it to development professionals; comments on possible utility for the "modern" world).

[75] P. Vestal and R. Schultes, The Economic Botany of the Kiowa Indians as It Relates to the History of the Tribe 68 (1939); Pope, *Wild Plants for the Hungry*, 13 Alternatives 17, 18 (Nov. 1986).

[76] Pope, *supra* note 75, at 18.

[77] Acharya, *Patenting of Biotechnology: GATT and the Erosion of the World's Biodiversity*, 25 J. of World Trade 71, 80-84 (1991) (discusses monoculture of high-yield crops as contributing to erosion of biodiversity).

[78] *See* articles by Posey, Elizabetsky and McKiernan, *supra* note 74.

Because the issue of intellectual property rights of indigenous peoples in traditional knowledge is relatively new, neither the government nor the pharmaceutical industry in the United States has formulated a position on it. The Patent and Trademark Office in the United States has taken no formal stance with regard to the remuneration of indigenous peoples for their contributions to scientific progress.[79] However, it is not opposed to any scheme for rewarding or providing incentives for persons for the advancement of the sciences. The pharmaceutical industry as a whole has not taken a formal position either, but some in the industry appear to be in favor of contractual arrangements between pharmaceutical companies and indigenous groups, such as the Merck -INBio agreement, or other arrangements, such as the National Cancer Institute's Letter of Intent and Shaman Pharmaceutical's Healing Forest Conservancy. It should be noted, however, that the National Cancer Institute's Letter of Intent is an agreement between the Institute and the "country organization," not between the Institute and an indigenous people directly. Moreover, the Merck-INBIo project does not emphasize the use of traditional knowledge in its screening process, and its provisions for training and employment apply to local, but not necessarily indigenous, people. Finally, it is also important to keep in mind that the governments of countries with significant indigenous populations may not necessarily favor the recognition of new rights for indigenous peoples, particularly if such rights interfere with foreign investment in such countries. In any case, the U.S. pharmaceutical industry seems to prefer the flexibility of using a broad spectrum of arrangements to deal with different situations, countries, and indigenous groups, rather than the possibly greater rigidity of statutorily mandated rights which may be difficult to define clearly.

A major problem in recognizing intellectual property rights in traditional knowledge is that there is no international standard for substantive intellectual property law. Although there has been some harmonization of procedural requirements and some effort to protect traditional knowledge about arts and crafts, there has been no true harmonization of substantive intellectual property standards, particularly with regard to patent standards for newer technologies. Intellectual property law differs from country to country. Developing countries tend to have looser laws and enforcement than industrialized states because they regard the protection of intellectual property rights as less important than, and even detrimental to, economic development.[80] Since their research and development is not yet equal to that of developed countries, they have a greater interest in the low-cost dissemination of industrial know-how. Moreover, even

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[79] Conversation on March 1, 1993, with Lee Skellington, attorney in the Office of Legislative and International Affairs, the Patent and Trademark Office, United States Department of Commerce.

[80] Dembo, Dias and Morehouse, *Biotechnology and the Third World: Some Social, Economic, Political and Legal Impacts and Concerns*, 11 Rutgers Computer & Tech. L.J. 431, 441 at note 62 and accompanying text, 450-452 (1985) (arguing that privatization of the biotechnology industry and the recognition of property rights in biotechnology hinder access by developing countries who most need the benefits of biotechnology). Leaffer, *Protecting United States Intellectual Property Abroad: Toward a New Multilateralism*, 16 Iowa L. Rev. 273, 275, 281-4 (1991).

within a country there can be disagreement over the direction of intellectual property laws. Within the United States, for instance, there is disagreement over what patent rights should be granted to new technologies and their products, *e.g.*, whether the human genome and multicellular animals should be patentable.[81] Without agreement on international standards for new technology, it may be difficult to discuss standards for rights in and protection of traditional knowledge.

An examination of intellectual property law in the United States reveals that traditional knowledge concerning arts and crafts is protected to some degree but that traditional scientific knowledge probably does not meet the federal statutory criteria for protection. Traditional scientific knowledge might be protectable under trade secret laws, however. But trade secret laws are a matter of state law, not federal law, so again, as in international law, there is a problem with lack of uniformity in the laws.

Intellectual property rights are addressed in part in the Biodiversity Convention[82] signed at the Earth Summit in Rio de Janeiro this past summer, in the ongoing negotiations about a new GATT agreement, and in a draft patent harmonization treaty proposed by the World Intellectual Property Organization. But none of these conventions or proposals would recognize any property rights in the use of traditional knowledge to screen living resources for useful medicines. Thus, at present any protections afforded the traditional knowledge of indigenous peoples would seem to depend on contractual agreements, mediating organizations, and ethical guidelines employed by public and private institutions in their dealings with such peoples.[83]

B. The Human Rights of Indigenous Peoples in General

1. The Definition of Indigenous Peoples

The first problem in any discussion of the rights of indigenous peoples or populations is a definitional one. There have been various attempts to define

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[81] The National Institutes of Health have patent applications on the human genome pending and there have been congressional hearings concerning the patenting of the human genome. *Ethics, Legality Of Gene Patenting Are Weighed In Senate Subcommittee Hearing*, 44 Pat. Trademark & Copyright J. (BNA) 534 (Sept. 24, 1992). Also, although the Patent and Trademark Office has granted patents on multicellular animals, such patents are still controversial and legislation to declare a moratorium on animal patents was introduced in the 102d Congress and has been reintroduced in the 103d Congress. S. 387 in the 103d Congress calls for a moratorium on patents on animals and human tissues and genes and an examination of the ethical, environmental and scientific issues involved.

[82] Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 (1992).

[83] *Back to Nature for Chemicals and Drugs, supra* note 73. The article notes that a September, 1990, report of the Technology Management Group of New Haven, CT, identified more than 46 companies and 82 research organizations studying medicinal plants worldwide and lists a few of the organizations and describes the type of arrangements they have with local populations.

indigenous peoples or populations, but as yet there is no universally accepted definition. The problem has proven to be so thorny that the resolution of the definition issue has been deferred, while the energies of the various organizations involved in human rights issues remain focused on the more urgent issue of what rights should be recognized and how they may be enforced.[84]

Part of the dispute has concerned whether the term "peoples" or "populations" should be used.[85] Initially, the term "indigenous peoples" was used to refer to the pre-colonial inhabitants of a territory which had been colonized by Western Europeans. As a consequence, the term came to be associated with a right of self-determination.[86] Chapter XI of the United Nations Charter,[87] for instance, which concerns the administration of non-self-governing territories, uses the term "peoples" and is primarily applicable to former colonies. The wave of decolonization after World War II resulted in some places in the return of government and self-determination to the indigenous peoples who had been colonized, as in India. But in other cases decolonization did not mean the return of government to the indigenous peoples but instead meant the relinquishment of government from the imperial or "mother" country to the colonial or settler population, as in South Africa, New Zealand, and Australia. Because the term "indigenous peoples" seemed to connote a right of self-determination and because these governments had no intention of affording their internal indigenous groups such a right, they preferred to use the term "indigenous populations" in referring to such groups.[88]

Another reason why some prefer the term "indigenous populations" concerns multiple ethnic groups that occupy the same territory.[89] In various Eastern European countries, in India, in China and in the various republics of the former Soviet Union, there are multiple ethnic groups within the borders of one country, each of which may be considered indigenous to the same territory. If the rights of indigenous peoples attach only to the indigenous groups of former colonies, the question arises of what rights attach to such internal ethnic

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[84] Barsh, *Indigenous Peoples: An Emerging Object of International Law*, 80 Am. J. Int'l L. 369, 373 (1986); Torres; *Rights of Indigenous Populations: The Emerging International Norm*, 16 Yale J. Int'l L. 127, 129 (1991) (note 5 and accompanying text); Williams, *Encounters on the Frontiers of International Human Rights Law: Redefining the Terms of Indigenous Peoples' Survival in the World*, 1990 Duke L.J. 660, 663 (1990) (note 4).

[85] Barsh, *supra* note 84, at 369, 373, 376.

[86] *Id.*, at 369, 373. The article recounts the development of the definition of indigenous peoples or populations.

[87] 26 June 1945, 59 Stat. 1031, 1 U.N.T.S. xvi (1945).

[88] Mulgan, *Should Indigenous Peoples Have Special Rights?*, 33 Orbis 375, 376-8 (1989). This article discusses the origins of the indigenous peoples movement and the ramifications of the term "indigenous peoples".

[89] Barsh, *supra* note 84, at 375; Mulgan, *supra* note 88, at 378.

groups. Some urge that the rights of indigenous populations in any country are included in the rights of indigenous peoples. That is, one indigenous population in a given territory has rights which another indigenous population occupying the same territory must respect. Others say that the rights of such indigenous populations are subsumed in the discussion of the rights of minorities in general. China, India and Bangladesh, for instance, refuse to regard their ethnic minorities as indigenous peoples because they associate indigenous peoples with the post-colonial context.[90]

Although some United Nations documents still preserve the distinction that "indigenous peoples" have a right to self-determination which "indigenous populations" do not have, the terms now seem to be used interchangeably in most discussions of their rights. (This paper, it might be noted, uses the term "indigenous peoples" as an inclusive term.)

Along with this debate, other issues of the scope and meaning of the term remain unresolved. A few definitions have been articulated. The Study of the Problem of Discrimination Against Indigenous Populations[91] submitted to the Sub-Commission on Prevention of Discrimination and Protection of Minorities and called the Cobo Report after the Special Rapporteur José R. Martinez-Cobo, for instance, defines indigenous peoples as follows:

> 378. Indigenous communities, peoples and nations are those which, having a historical continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those territories, or parts of them. They form at present nondominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral territories, and their ethnic identity, as the basis of their continued existence as peoples, in accordance with their own cultural patterns, social institutions and legal systems.
>
> 379. This historical continuity may consist of the continuation, for an extended period reaching into the present, of one or more of the following factors:
>
> (*a*) Occupation of ancestral lands, or at least of part of them;
>
> (*b*) Common ancestry with the original occupants of these lands;
>
> (*c*) Culture in general, or in specific manifestations (such as religion, living under a tribal system, membership of an indigenous

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[90] Hannum, *New Developments in Indigenous Rights*, 28 Va. J. Int'l L. 649, 664 (1988).

[91] U.N. Doc. E/CN.4/Sub.2/1986/7 and Add. 1-4 (1986).

> community, dress, means of livelihood, life-style, etc.);
>
> (*d*) Language (whether used as the only language, as mother-tongue, as the habitual means of communication at home or in the family, or as the main, preferred, habitual, general or normal language);
>
> (*e*) Residence in certain parts of the country, or in certain regions of the world;
>
> (*f*) Other relevant factors.

International Labour Organization (ILO) Convention No. 169,[92] which revises ILO Convention No. 107, defines indigenous and tribal peoples as

> Art. 1, ¶ 1. (a) tribal peoples in independent countries whose social, cultural and economic conditions distinguish them from other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions or by special laws or regulations;
>
> (b) peoples in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonization or the establishment of present state boundaries and who irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions.
>
> ¶2. Self-identification as indigenous or tribal shall be regarded as a fundamental criterion for determining the groups to which the provisions of this Convention apply.

The U.N. Working Group also considered the definition of "indigenous" but ultimately chose not to adopt a formal definition in order to accommodate the widely disparate views of various governments.[93]

Indigenous groups themselves have stressed their right to define themselves and therefore have generally not accepted the definitions put forward by others.[94] In a 1977 resolution the World Council of Indigenous Peoples, an organization representing indigenous groups worldwide, stated that:

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[92] International Labour Organisation: Convention Concerning Indigenous and Tribal Peoples in Independent Countries, June 27, 1989, 28 I.L.M. 1384 (1989).

[93] Hannum, *supra* note 90, at 664.

[94] Hannum, *supra* note 90, at 663; Williams, *supra* note 84, at 663, note 4 and accompanying text.

> Indigenous peoples are such population groups as we are who from old-age time have inhabited the lands where we live, who are aware of having a character of our own, with social traditions and means of expression that are linked to the country inherited from our ancestors, with a language of our own, and having certain essential and unique characteristics which confer upon us the strong conviction of belonging to a people, who have an identity in ourselves and should be thus regarded by others.[95]

In 1980 the Indian Council of South America defined themselves thus:

> We, the Indian Peoples, are descendants of the first ethnic populations of this continent: we have common history, an ethnic personality of our own, a cosmic conception of life, and as inheritors of a thousand year old culture, after almost 500 years of separation, we are newly united in order to be the vanguard of our total liberation from western colonialism.[96]

In sum, in the discussion of the rights of indigenous peoples, it is not yet entirely clear who is deemed to be included.

2. Rights Sought by Indigenous Peoples

Formerly, integration and assimilation were thought to be the goals of relations with indigenous peoples, as exemplified by the ILO Convention No. 107.[97] Currently, the prevailing attitude seems to be that indigenous people should be supported in their efforts to preserve their distinctive society but that they should not be artificially maintained in a "primitive" state as curiosities. Rather, they should be supported in their efforts to integrate the best that modern society has to offer to the extent that they desire.[98] Concurrent with this change in attitude, there has developed an awareness that existing human rights agreements and declarations have not adequately addressed the problems of indigenous peoples. As a result, various organizations have been created to

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[95] 1 U.N. Special Rapporteur's Report 244, Annex III., as reprinted in Serafino et al., *Latin American Indigenous Peoples and Considerations for U.S. Assistance*, CRS Report 91-663 F (1991).

[96] *Id.* at Annex V, p. 255.

[97] Indigenous and Tribal Populations Convention, Jun. 26, 1957, 328 U.N.T.S. 247; Lawrey, *Contemporary Efforts to Guarantee Indigenous Rights Under International Law*, 23 Vand. J. Transnat'l L. 703, 717 (1990); Williams, *supra* note 84, at 663, note 4.

[98] Sources for this paragraph are Bunyard, *Guardians of the Forest: Indigenist Policies in the Columbian Amazon*, 19 The Ecologist 255, 257 (1989); Colchester, *Indian Development in Amazonia: Risks and Strategies*, 19 The Ecologist 249 (1989); Cunha, *Native Realpolitik*, 23 NACLA Report on the Americas 19, 20 (1989); Posey, *From Warclubs to Words*, 23 NACLA Report on the Americas 13, 18 (1989); Van Wageninen, *To Protect and To Prosper*, 7 The Environmental Forum 30, 31 (1990).

study their problems and to recommend solutions, and concepts of indigenous rights have begun to be formulated.[99]

Generally, the rights of indigenous peoples are said to include rights to land, natural resources, self-determination, and culture.[100] Inherent in each of these rights is the concept of collective rights.[101] Indigenous groups often do not have a concept of individual private ownership of property, for instance, so that it is difficult for an individual member of a group to claim and prove ownership of a particular plot of land and its natural resources.[102] The strongest claim that could be made would be the claim of the group to collective ownership of lands traditionally inhabited by the group and to the natural resources available from those lands.[103] Traditional knowledge may also be collectively owned. Traditional western legal concepts, however, do not generally include the notion of collective rights. The emphasis has been on individual rights *vis á vis* the state. This emphasis may limit the utility of Western concepts in helping indigenous peoples maintain their identity and rights in the face of pressure to assimilate and yield to the "modern" world.

Indigenous peoples in post-colonial societies lost lands to colonizing powers who took the lands under the western legal concepts of discovery or conquest.[104] Unless the indigenous group had attained a sophisticated level of social and legal development comparable to that of the aspiring colonizer, the western colonial powers deemed the land to be unoccupied by a legitimate sovereign power, *terra nullius*, and thus free for the taking.[105] The indigenous group may have lost the land by conquest and subsequent treaty or simply by the colonizing power's failure to honor contractual terms.[106] Indigenous peoples, however, emphasize the importance of the land to the preservation of their way of life, their strong bond to their traditional territories, and its

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[99] Torres, *supra* note 84, at 151ff.

[100] Barsh, *supra* note 84, at 379-383; Hannum, *supra* note 90, at 666ff.; Lawrey, *supra* note 97, at 722-726; Torres, *supra* note 84, at 127ff.; Williams, *supra* note 84, at 660.

[101] The following articles discuss collective or group rights--Clinton, *The Rights of Indigenous Peoples As Collective Group Rights*, 32 Ariz. L. Rev. 739 (1990); Note, *International Human Rights Law and the Earth: The Protection of Indigenous Peoples and the Environment*, 31 Va. J. Int'l L. 479 (1991) (discusses three generations of rights, the first including civil and political rights, the second including social, economic and cultural rights and the third including environmental and developmental rights); Williams, *supra* note 84, at 685-688.

[102] Hannum, *supra* note 90, at 668.

[103] Clinton, *supra* note 101, at 746.

[104] Hannum, *supra* note 90, at 667-668; Williams, *supra* note 84, at 688-689.

[105] *Id.*

[106] *Id.*

significance to their religion and culture.[107] Related to the land right is the right to the natural resources of the lands, which could provide a livelihood and income for the indigenous peoples. They may utilize the resources themselves or market them to those outside the group, enabling them to exist economically in the modern world.[108] Commentators, therefore, generally argue for a right to a return of the land or at least to compensation for its loss.[109]

In addition, there is a claimed right to self-determination, which is limited by the situation of certain groups.[110] Where the non-indigenous colonizing power does not constitute the majority and effectively withdrew upon returning power to the indigenous group(s), self-determination is more easily accomplished, as in India. However, where there is a non-indigenous group that constitutes the majority of the population, as in the U.S., it is effectively impossible to return government to the indigenous group. Nonetheless, a more limited degree of autonomy may be possible. In short, there is a broad spectrum of rights related to self-determination, ranging from very limited self-rule with regard to indigenous affairs, such as the right to administer special government programs, to secession from the state and full independence. In between there are varying degrees of economic and political autonomy over the community within a limited territorial area, or reservation.[111]

Finally, as mentioned above, cultural rights have become quite important. Cultural rights include the right to practice customs, traditional livelihoods and religions, to educate in the indigenous language, to keep cultural properties and artifacts in the hands of indigenous groups, and, perhaps, to receive protection and recognition of intellectual property.[112]

Among the many organizations and agreements which have developed, two of the most noted are the International Labour Organisation and its Convention 169, and the U.N. Working Group on Indigenous Populations and its Draft Declaration of the Rights of Indigenous Peoples.[113] In 1957 the ILO International Labour Conference adopted the Indigenous and Tribal Populations Convention, No. 107, which recognized collective and individual land rights of indigenous peoples and their right to compensation for confiscation of their

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[107] Hannum, *supra* note 9o, at 666; Torres, *supra* note 84, at 138; Williams, *supra* note 84, at 689.

[108] Williams, *supra* note 84, at 690.

[109] *Id.*

[110] Hannum, *supra* note 90, at 670ff; Lawrey, *supra* note 97, at 724-726; Mulgan, *supra* note 88, at 381-384; Torres, *supra* note 84, at 141-145, 161-163; Williams, *supra* note 84, at 691-695.

[111] *Id.*

[112] Torres, *supra* note 84, at 133-137, 159.

[113] *Supra* note 70.

lands by governments.[114] However, Convention 107 was only ratified by a few states and has not proven effective in protecting indigenous rights even in the countries that have ratified it.[115] That fact plus criticism of the Convention's emphasis on assimilation rather than cultural preservation led to a revision.[116] In 1989 this revision, in the form of new Convention 169, was adopted by the International Labour Conference.[117] However, Convention 169 may not receive any more ratifications than the original. Some indigenous groups view the Convention as not going far enough in the protection of indigenous rights.[118] The indigenous preparatory meeting for the seventh session of the U.N. Working Group in 1989 submitted a resolution condemning the Convention, asking states not to ratify it, and demanding that the Convention be ignored in the development of the Draft Declaration. Among numerous objections, three are relevant to the present subject. First, the Convention only requires consultation with, and not the consent of, indigenous peoples on measures affecting them.[119] Second, the Convention provides that indigenous peoples shall have the right to retain their own customs and institutions but only to the extent that they are not incompatible with the fundamental rights under national laws.[120] Third, the indigenous groups opposed to the Convention were not satisfied with the provisions regarding land and natural resource rights.[121] However, other indigenous groups supported the Convention at the ninth session of the Working Group in 1989 and endorsed ratification by all states which have indigenous peoples in their territories.[122]

The Convention itself does not provide any protection for the intellectual property rights of indigenous peoples but it may provide a basis for other measures to do so. Article 2, paragraph 2(b), provides for action to protect the rights of indigenous peoples, including measures "promoting the full realisation of the social, economic and cultural rights of these peoples with respect for their social and cultural identity, their customs and traditions and their institutions." Article 4, paragraph 1, provides that "[s]pecial measures shall be adopted as appropriate for safeguarding the persons, institutions, property, labour, cultures and environment of the peoples concerned." Article 5(a) provides that "the

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[114] *Supra* note 97.

[115] Lawrey, *supra* note 97, at 717.

[116] Barsh, *supra* note 84, at 370; Lawrey, *supra* note 97, at 717.

[117] *Supra* note 92.

[118] Lawrey, *supra* note 97, at 718-720.

[119] Convention 169, Art. 6, 28 I.L.M. 1384, 1386 (1989); Lawrey, *supra* note 97, at 719.

[120] Convention 169, Art. 8, ¶ 2, 28 I.L.M. 1384, 1386 (1989); Lawrey, *supra* note 97, at 719.

[121] Lawrey, *supra* note 97, at 719.

[122] *Id.*, at 720.

social, cultural, religious and spiritual values and practices of these peoples shall be recognised and protected, and due account shall be taken of the nature of the problems which face them both as groups and as individuals." Protection and recognition of cultural practices, institutions and property might include the protection of rights in traditional knowledge. Advocates for the rights of indigenous peoples have noted that scientists from developed countries have generally regarded traditional knowledge as the common heritage of mankind and therefore not eligible for any protection.[123] While the advocates acknowledge that these scientists develop products and processes of great sophistication and quite different from those of the indigenous peoples, they argue that indigenous peoples should have rights in their traditional knowledge and some economic benefit, because their knowledge may provide the initial information that motivates a scientist to research the usefulness of a particular plant or animal.[124] Article 4 in particular could provide the basis for special measures to ensure that indigenous peoples are compensated for the use of traditional knowledge, even if this knowledge is not eligible for protection under the national intellectual property laws.

The United Nations Working Group on Indigenous Populations was created in 1982. In that year the Conference on Indigenous Peoples and the Land, a gathering of international non-governmental organizations, met at Geneva and called for the establishment of a United Nations working group on indigenous peoples to consider their grievances and demands.[125] The United Nations Sub-Commission on the Prevention of Discrimination and Protection of Minorities, in turn, recommended the creation of a Working Group on Indigenous Populations, and the U.N. Commission and the U.N. Economic and Social Council (ECOSOC) approved it. The Working Group is comprised of five international legal experts from the Sub-Commission and was given two tasks: (1) to review developments affecting the rights of indigenous peoples and (2) to develop standards concerning the rights of indigenous peoples.[126] In 1984 Australia, Canada, and several indigenous organizations indicated concern that the Working Group was simply collecting information on developments. So the Sub-Commission directed the Working Group to concentrate on its second task and to consider drafting principles on indigenous rights.[127] Since then, the

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[123] Kloppenburg, *No Hunting! Biodiversity, indigenous rights, and scientific poaching*, 15 Cultural Survival Quarterly 14, 16 (Summer 1991).

[124] Cunningham, *Indigenous Knowledge and Biodiversity: Global commons or regional heritage?*, 15 Cultural Survival Quarterly 4 (Summer 1991); Elisabetsky, *Folklore, Tradition, or Know-How? The ethnopharmacological approach to drug discovery depends on our ability to value non-western knowledge of medicinal plants*, 15 Cultural Survival Quarterly 9 (Summer 1991); Kloppenburg, *supra* note 123, at 14.

[125] Barsh, *supra* note 84, at 372-373; Lawrey, *supra* note 97, at 720-722; Williams, *supra* note 84, at 665.

[126] Barsh, *supra* note 84, at 372-373.

[127] *Id.*

Working Group, while continuing its data-gathering activities, has been working on a Draft Declaration on Indigenous Rights.[128]

The Draft Declaration, revised as agreed upon by the members of the Working Group at the first reading of its tenth session in 1992, contains a couple of provisions concerning the protection of intellectual property rights in traditional knowledge.[129] Operative paragraph 8 provides that "[i]ndigenous peoples have the right to revive and practise their cultural identity and traditions, including the right to maintain, develop and protect the past, present and future manifestations of their cultures, such as archeological and historical sites and structures, artifacts, designs, ceremonies, technology and works of art, as well as the right to the restitution of cultural, religious and spiritual property taken from them without their free and informed consent or in violation of their own laws." Operative paragraph 19 provides that "[i]ndigenous peoples have the right to special measures for protection, as intellectual property, of their traditional cultural manifestations, such literature, designs, visual and performing arts, seeds, genetic resources, medicine and knowledge of the useful properties of fauna and flora." Paragraph 19, thus, seems to acknowledge that traditional knowledge may not be eligible for protection under existing intellectual property laws and that, therefore, special measures may be necessary. Paragraph 8, on the other hand, could be a basis for the protection of traditional knowledge, since it provides for the protection of "present and future" manifestations of culture, including designs and technology.

In addition, as part of the activities of the Working Group, the Chairman/Rapporteur Erica-Irene A. Daes has issued a working paper on the cultural property of indigenous peoples.[130] At its tenth session in the summer of 1992, the Working Group discussed this working paper as well, and several representatives recommended the inclusion of a section on the intellectual property of indigenous peoples.[131] Moreover, the Secretary-General also issued a report in 1992 entitled Intellectual property of indigenous peoples: a concise report of the Secretary-General,[132] discussing some of the problems and issues involved in a consideration of indigenous intellectual property rights. The report contains the Conclusions and Recommendations on Indigenous Peoples and the Environment of the U.N. Technical Conference on Practical Experience in the Realization of Sustainable and Environmentally Sound Self-Development

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[128] Annex I of the Report of the Working Group on Indigenous Populations on its tenth session, E/CN.4/Sub.2/1992/33.

[129] *Report of the Working Group on Indigenous Populations on its tenth session*, Annex I, 20 Aug. 1992, E/CN.4/Sub.2/1992/33 [hereinafter *Report of the Working Group*].

[130] E/CN.4/Sub.2/1991/34.

[131] *Report of the Working Group, supra* note 129, at ¶¶ 150-154.

[132] 6 July 1992, E/CN.4/ Sub.2/1992/30.

of Indigenous Peoples, which met in Santiago, Chile, in May, 1992.[133] Those conclusions set out working principles and recommendations for sustainable and environmentally sound self-development of indigenous peoples.[134] Several of these principles and recommendations call for actions to protect the intellectual property rights and traditional knowledge of indigenous peoples, to be taken with their consent. The actions include special measures by the U.N., the promotion by the U.N. and other international bodies of research into and dissemination of indigenous knowledge, and provision of legal and technical assistance to indigenous people to help them promote their rights and sustainably manage their environment.

C. Intellectual Property Rights of Indigenous Peoples

1. The Nature of Traditional Knowledge

Darrell Posey identifies several types of traditional scientific knowledge from his study of the Mêbêngôkre/Kayapó Indians of northern Brazil and southern Venezuela, including ethnoecology (the understanding and cultivation of distinct ecosystems or ecological zones), ethnopedology (the understanding of soil composition and its use in agriculture), ethnozoology (the knowledge and use of animal phenomena, especially in pest control), ethnopharmacology and ethnomedicine (the use of plants and animals in traditional medicine), ethnobotany (the uses of plants by indigenous peoples), and ethnoagriculture and agroforestry (the knowledge of forest management techniques, natural pest repellent techniques, and other cultivation methods).[135] Of primary concern for this report is ethnopharmacology and ethnomedicine.

Indigenous peoples possess abundant knowledge of the usefulness of specific plants and animals as treatments for specific symptoms and diseases and as pesticides/pest repellents.[136] The Kayapó Indians in Brazil, for instance,

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[133] *Report of the U.N. Technical Conference on Practical Experience in the Realization of Sustainable and Environmentally Sound Self-Development of Indigenous Peoples*, 25 May 1992, E/CN.4/Sub.2/1992/31/Add.1. Although all the papers discuss traditional knowledge and its uses, the paper by Darrell Posey, *Ways and Means of Strengthening Sustainable and Environmentally Sound Self-Development of Indigenous Peoples*, specifically addresses the issue of just compensation on pp. 62-64, noting the commercial potential of traditional knowledge.

[134] *Report of the U.N. Technical Conference on Practical Experience in the Realization of Sustainable and Environmentally Sound Self-Development of Indigenous Peoples*, page 16, 23 June 1992, E/CN.4/Sub.2/1992/31.

[135] Posey, *supra* note 74, at 58-62; Posey, *Alternatives to Forest Destruction: Lessons from the Mebengokre Indians*, 19 The Ecologist 241, 243-4 (1989). The groups within the Kayapó nation call themselves the Mêbêngôkre. *See also* Ibarra, *Traditional Practices in Respect of the Sustainable and Environmentally Sound Self-Development of Indigenous People*, U.N. Doc. E/Cn.4/Sub.2/1992/31/Add.1, p. 27 (1992).

[136] In addition to the examples and citations following this footnote, *see also* Bird, *Medicines from the rainforest*, 131 New Scientist 34 (17 Aug. 1991); Jackson, *Searching for medicinal wealth in Amazonia*, 19 Smithsonian 95 (Feb. 1989).

place nests of "smelly ants" near gardens and fruit trees because their pheromones repel leaf-cutter ants, and inhale their highly aromatic scents to open up the sinuses.[137] Andiroba oil, extracted from the seeds of a species of *Carapa*, a tree in the mahogany family, is widely used in the Amazon region as an anti-inflammatory.[138] The Kamba people in Kenya prepare a drink from the bark of the tree *Pappea capensis* which is used to treat bruises.[139] Several tribes along the Rio Piraparana in the Amazon region use the ashes from the burned bark of the *Pouroma schultesii* to treat ulcers.[140] The Karijonas in the same region use a hot tea brewed from the stems and leaves of the *Piper schultesii* to treat tubercular coughs.

Some medicinal plants discovered by indigenous peoples have yielded drugs that enjoy widespread use in developed societies. Quinine, the antimalarial drug derived from the bark of several species of *Cinchona* trees, was originally called "Indian fever bark" after its initial users.[141] The amoebocide and emetic drug emetine, derived from the roots of *Cephalis ipecacuana*, was used by peoples in Brazil to treat dysentery.[142] The rosy periwinkle has yielded vinblastine and vincristine and other alkaloid derivatives useful in treating Hodgkin's Disease, juvenile leukemia, and rheumatoid arthritis.[143] The steroid diosgenin, a component of birth control pills, is extracted from a wild yam indigenous to Mexico and Guatemala.[144] The seed of the neem tree (*Azadirachta indica*), which yields azadirachtin, a compound that repels insects by interfering with the molting stage of the growth cycle, was used as a pesticide for centuries.[145] Indigenous people know how to detoxify certain wild poisonous plants and render them edible.[146]

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[137] Posey, *supra* note 74, at 60.

[138] Elisabetsky, *supra* note 74.

[139] Pope, *supra* note 75, at 17.

[140] Kahn, *Profiles: Jungle Botanist*, The New Yorker, June 1, 1992, at 35, 36. The article lists several examples, including the one following this footnote.

[141] King, *The Source of Our Cures*, 15 Cultural Survival Quarterly 19 (Summer 1991).

[142] *Id.*

[143] Kloppenburg, *supra* note 123, at 15; U.S. Pat. No. 4, 208, 414, Vinblastine in rheumatoid arthritis, Jun. 17, 1980.

[144] *Id.*

[145] Kloppenburg, *supra* note 123, at 16; McGowan, *Who is the Inventor?*, 15 Cultural Survival Quarterly 20 (Summer 1991); U.S. Pat. No. 5, 047, 242, Azadirachtin derivative insecticides, Sep. 10, 1991.

[146] Pope, *supra* note 75, at 18.

Ritual, magic, and the shaman or medicine man play important roles in the concept of intellectual property and of medicine in lesser developed, "primitive" indigenous societies. One commentator has argued that "far from being non-existent, intellectual property rights actually pervade preliterate societies and figure prominently in the complex of magical beliefs surrounding numerous aspects of daily life."[147] Basically, the shaman controls the use of the intellectual property by connecting the use of a particular treatment with rituals and magic which the shaman alone has the power to perform.[148] An ordinary member of the indigenous group would believe that a treatment would not be effective unless applied in conjunction with the shamanistic magic. Another expert, who has made a study of the use of wild animals and their parts in the rituals and traditional medicine of Nigeria, observes that most of those he studied "believe that there are some magical powers which are attached to special healing acts when wild animals' by-products are used as directed by a traditional healer."[149] The traditional knowledge is disseminated within the indigenous community when the shaman exchanges the knowledge for goods and services or according to other social relationships, and the knowledge exists within a strong spiritual context.[150] However, the authority of some shamans apparently is fading. According to Plotkin, the Tirió medicine men in Suriname with whom he works are regarded as old-fashioned and have no apprentices. Plotkin planned to get the tribal elders to assign young apprentices to the shamans to record their knowledge before it was lost.[151]

Another characteristic of traditional scientific knowledge that bears on its patentability is that it is often freely shared with outsiders. One ethnobotanist/activist, Mark Plotkin, notes that when asking shamans about the uses of a plant, he followed Richard Schultes' premise that "an Indian will seldom say no to a white man."[152] Schultes himself recalled an experience that facilitated such openness by demonstrating respect for the role of ritual magic and the authority of the shaman.[153] He used western serum to treat a native girl but made sure that the local medicine man was present and conducted his ritual simultaneously. Thus, Schultes ensured that no matter what happened, he would remain in the good graces of the people and their shaman.

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[147] Suchman, *Invention and Ritual: Notes on the Interrelation of Magic and Intellectual Property in Preliterate Societies*, 89 Colum. L. Rev. 1264 (1989).

[148] *Id.*

[149] Adeola, *Importance of Wild Animals and Their Parts in the Culture, Religious Festivals, and Traditional Medicine, of Nigeria*, 19 Environmental Conservation 125 (Summer 1992).

[150] Gray, International Work Group for Indigenous Affairs (IWGIA) Document 70, Between the Spice of Life and the Melting Pot: Biodiversity conservation and its impact on Indigenous Peoples 44-45 (1991).

[151] Jackson, *supra* note 136, at 98.

[152] *Id.*, at 100.

[153] Kahn, *supra* note 140, at 47.

The collective nature of ownership within indigenous peoples is also critically important. Indigenous peoples have collectively maintained and contributed to the development of folkloric arts. Similarly, any property right in scientific folklore may necessarily be a collective right. Among indigenous peoples traditional knowledge or folklore generally cannot be traced to a specific inventor and to a particular point in time. Its essential characteristic is that it has been handed down for generations within the indigenous community.[154]

Moreover, folklore and traditional knowledge evolved as distinct indigenous peoples acquired knowledge from each other and developed that knowledge differently. Vestal and Schultes, in their study of the economic botany of the Kiowa Indians, note that the Kiowa borrowed the uses of some of the plants from other tribes.[155] Vestal and Schultes classified the plants used by the Kiowa into five groups according to the four migratory stages in the recent history of the Kiowa.[156] The first group of plants occurred in the original region or homeland in Montana which the Kiowa inhabited. The other groups were plants with which the Kiowa became familiar as they migrated to the Black Hills of South Dakota and then to Oklahoma. As the Kiowa migrated and came into contact with other tribes and with white settlers, they learned about new plants and their uses and learned about new uses for plants they already were using. Vestal and Schultes found that the Kiowa used some plants in a manner identical to that of other tribes, used some plants in the same way plus in some additional ways, used some plants differently from the way other tribes used them, and used some plants that no other tribes used.[157] It may be difficult, in other words, to determine which tribe would merit the intellectual property rights for a particular use of a plant where more than one tribe uses a plant, sometimes in different ways.

In another example, concerning the rosy periwinkle, Irving S. Johnson, former vice-president of research at Eli Lilly and Co., states that "two different groups were investigating the plant because of folklore suggesting the use of a tea of the leaves for diabetes. These reports were from the Philippine Islands and Jamaica. The plant, however, grows wild or is cultivated in most temperate

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[154] One folklore expert, Alan Jabbour, has noted that certain issues regarding protection for artistic folklore must be resolved, issues that concern scientific folklore as well. Internationally, copyright and patent laws share the characteristic of granting property rights to individuals as a reward for individual creativity and an incentive for future creativity. Jabbour argues that some intermediate concept of intellectual property rights, between the public domain and individual property rights, must be recognized, a sort of group intellectual property right. Jabbour, *Folklore protection and national patrimony: developments and dilemmas in the legal protection of folklore*, 17 Copyright Bull. 10, 13-14 (1983); telephone interview with Alan Jabbour, Director of the American Folklife Center, Library of Congress, on October 26, 1992. Jabbour served as the United States delegate to the Working Group on the Intellectual Property Aspects of Folklore Protection which drafted a model law for the protection of folklore in 1981.

[155] Vestal and Schultes, *supra* note 75, at 81-82.

[156] *Id.*, at 70.

[157] *Id.*, at 81-82.

and semi-tropical parts of the world. At the time it could be harvested because of its rampant growth in India and Madagascar, and it was grown commercially in Texas."[158] Johnson points out that the folklore and genetic resources leading to the discovery of the vinca alkaloids and their use in the treatment of cancer came from many sources, not just Madagascar, and that if one argues that Madagascar's contribution merits compensation, then all the other countries involved merit compensation also. Also, the folkloric use was a remedy for diabetes, but Lilly ultimately developed a treatment for cancer.

These examples and the characteristics of traditional knowledge noted above illustrate some of the difficulties that attend the issue of intellectual property rights for indigenous peoples. Would such rights have to be collective in nature? Should an indigenous people receive intellectual property rights that entitle them to compensation from the ultimate developer of a drug which has a use different from their original folkloric use? If two peoples use the same plant in different ways and that plant eventually yields a pharmaceutical product which has a quite different use from either folkloric use, should both peoples receive compensation and recognition? If the pharmaceutical use is similar to the use of one group, does that group alone merit compensation? As the following sections show, these questions are not resolved or, in most cases, even addressed by existing international and American law concerning intellectual property rights.

2. International Law Regarding Intellectual Property Rights in Traditional Knowledge

a. Patent Law

The intellectual property rights of indigenous peoples basically depend on the laws of the country in which they or their lands are located. Intellectual property laws are not extraterritorial, nor is there any internationally uniform definition of intellectual property and accruing legal rights. Intellectual property which is protected in one country may not be protected or even recognized as intellectual property in another country. Despite the existing agreements that attempt to achieve international harmonization of the intellectual property laws concerning patents,[159] there are still significant substantive differences among national laws, especially those regarding

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[158] Johnson, *supra* note 73.

[159] The major conventions concerning intellectual property include, *inter alia*, the Patent Cooperation Treaty (PCT), June 19, 1970, 28 U.S.T. 7645, T.I.A.S. 8733, 9 I.L.M. 978; the International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 23 U.S.T. 2767, 815 U.N.T.S. 89; the Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, ___ U.S.T. ___, T.I.A.S. ____, 168 Parry's T.S. 185; and the Paris Convention for the Protection of Industrial Property, March 20, 1883, U.S.T.S. 379, 25 Stat. 1372, 161 S.T.S. 409.

patentable subject matter.[160] The U.S., for instance, is in the forefront of the biotechnology industry and its regulation. The U.S. courts have recognized the patentability of genetically altered organisms,[161] and Congress has recognized a public interest in encouraging the growth of this industry by providing for the patent protection of plant varieties.[162] Other countries, both developed and developing, differ on extending patents to such subject matter and some do not extend patent protection to pharmaceutical products or medical treatments.[163] Currently, there is no concluded international agreement addressing these issues.[164]

Moreover, some developing countries have enacted various intellectual property laws in response to pressure from the developed countries because of concern in the latter about the negative impact of intellectual-property piracy on their industries and because they would otherwise be reluctant to encourage technology transfer.[165] However, some observers contend that the primary beneficiaries of the enactment of such patent laws have been foreign multinational corporations.[166] Because of these experiences, many developing countries either have not enacted strong intellectual property laws or have not enforced them vigorously in order to permit their domestic industries to develop without having the burden of paying foreign corporations for the use of their

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[160] Butler, *The Trade-Related Aspects of Intellectual Property Rights: What Is At Stake?*, 72 Fed. Reserve Bank of St. Louis Rev. 34 (1990) (Tables 2 and 3); Fuller, *Intellectual Property Rights Associated with Biotechnology--An International Trade Perspective*, 16 AIPLA Q.J. 529, 533-6 (1988-89) (summary of property protection granted to microorganism, plants and novel organisms in the U.S. and Europe).

[161] Dembo, Dias and Morehouse, *supra* note 80, 11 Rutgers Computer & Tech. L.J. 431, 441 at note 62 and accompanying text, 450-452.

[162] 35 U.S.C.A. §§ 101, 161-5 (1984 & Supp. 1992) (patent protection for hybrids and for asexually reproduced plants, respectively) and the Plant Variety Protection Act, codified generally at 7 U.S.C.A. §§ 2321-2582 (1988) (protecting sexually reproduced plants, but not by patent coverage).

[163] Butler, *supra* note 160.

[164] There is no agreement recognizing the patentability of genetically altered organisms. However, for those countries that grant intellectual property rights in a microorganism or a process using a microorganism, there is the Budapest Treaty on the International Recognition of the Deposit of Microorganism for the Purposes of Patent Procedure, April 28, 1977, T.I.A.S. 9768, 17 I.L.M. 285, providing that one deposit shall suffice to satisfy the depositary requirements of patent procedure in all parties to the treaty. Also, there is the International Convention for the Protection of New Varieties of Plants, *supra* note 159, which was concluded before the development of genetic engineering, but now covers genetically altered varieties. However, the Convention does not offer protection under *patent* law, but offers protection outside the context of patent law to plant varieties generally not protected by patent law. The Plant Variety Protection Act, codified at 7 U.S.C.A. §§ 2321-2582 (1988) is the U.S. implementation.

[165] Dembo, Dias and Morehouse, *supra* note 80, at 441.

[166] *Id.*, at 451.

intellectual property.[167] This lack of strong intellectual property protection in some developing countries may limit the intellectual property rights that indigenous peoples could obtain in traditional knowledge.

As mentioned above, there have been several efforts to harmonize the intellectual property laws concerning patents. The Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty primarily represent efforts to harmonize the *procedures* in the patent offices of the contracting parties, while the on-going efforts to conclude a World Intellectual Property Organization (WIPO) patent harmonization treaty and a GATT Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) are intended to harmonize some *substantive* standards in the laws. The Biodiversity Convention signed at the Rio summit in 1992 also addresses the subject of intellectual property rights. But none of these existing or proposed agreements provide explicit legal protection for the traditional knowledge of indigenous peoples.

(1) The Paris Convention. The principal concluded agreement concerning intellectual property rights for patents, industrial design and trademarks is the Paris Convention for the Protection of Industrial Property, which created the Paris Union.[168] The Paris Convention was concluded in 1883; the United States ratified it in 1887; and the Convention currently has 101 members.[169] The Paris Convention was the first of its kind and its objectives were relatively limited. The most recent revision of the Convention was signed in Stockholm in 1967.[170] This revision divided the Convention into two parts, administrative and substantive, and allowed the member nations to join either or both parts. The U.S. joined both parts as of 1973.

The Convention most significantly provides for national treatment, that is, each Contracting Party must grant the same intellectual property protection to nationals of other Contracting Parties that it grants to its own nationals.[171] The Convention also provides that if a citizen of any member nation files a patent application in the patent office of another member nation within twelve months from the date of the original filing in the home country, then the foreign filing date will date back to the original filing date for the purposes of priority.[172] However, once the application is filed, it is subject to the

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[167] Leaffer, *supra* note 80, at 275, 281-4.

[168] *Supra* note 159.

[169] Treaties Affairs Staff, Office of the Legal Advisor, U.S. Dept. of State, Treaties in Force: A List of Treaties and other International Agreements of the United States in Force on Jan. 1, 1992 335 (1992) [hereinafter Treaties in Force].

[170] 1967 Stockholm Revision, 21 U.S.T. 1583, T.I.A.S. 6923, 828 U.N.T.S. 305.

[171] Paris Convention, *supra* note 159, at Article 2.

[172] *Id.*, at Article 4.

individual patent procedures in each country of filing; and after a patent is granted, it still is governed separately by the pertinent laws in each country.[173] Therefore, depending on the substantive laws governing validity and patentability in each member nation, an application may succeed in one member but not in another. Likewise, the post-grant invalidation of a patent during infringement or opposition proceedings in one country does not have a similar effect in other members. Thus, the Paris Convention merely gives an applicant some breathing space in which to consider the desirability and efficacy of seeking patent protection outside his home country, but it does not harmonize or unify the laws of the member states.

The Convention also has a compulsory licensing provision which should be noted. Article 5, subsection A--(2-4), permits Contracting Parties to legislate the granting of compulsory licenses in order to prevent abuses resulting from the exercise of exclusive rights, such as failure to work a patent (to work a patent means to use, manufacture and sell the patented invention). Forfeiture of the patent is not to occur except in cases where the grant of a compulsory license would not have been sufficient to prevent the abuses. A certain time period must elapse before a compulsory license may be sought on the ground of failure to work or insufficient working, and a compulsory license application shall be refused if the patent holder justifies his inaction by legitimate reasons. In countries that have a working requirement, even if indigenous peoples could obtain a patent in traditional knowledge, they may find it difficult to work it themselves. The U.S. has no requirement to work a patent.[174]

(2) Patent Cooperation Treaty. In 1970 the Patent Cooperation Treaty (PCT)[175] was concluded. The United States ratified it in 1978, and the PCT currently has 47 members.[176] The PCT aimed to achieve some simplification of procedures under the international patent laws beyond the retroactive priority date set by the Paris Convention by offering a more uniform route for applications for patents in more than one country. These provisions do not supplant the Paris Convention but complement it and are optional. Following PCT procedures the applicant need prepare only one international application form for filing, designate the PCT nations in which he intends to seek patents, and file it with a receiving office.[177] This office transmits copies to the

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[173] *Id.*, at Article 4*bis*.

[174] The right to not work a patent was upheld by the United States Supreme Court in an infringement case, *Paper Bag Patent Case*, 210 U.S. 405 (1908). A manufacturer bought patent rights to an invention that would have been competitive with its product. A competing manufacturer infringed the patents and defended its action by saying that a patent holder who failed to work its patent should not permitted to enjoin the working of the patent by others. But the Court rejected this defense and affirmed the right of the patent holder to not work the patent.

[175] *Supra* note 159.

[176] Treaties in Force, *supra* note 169, at 368.

[177] PCT, *supra* note 159, at Articles 3 and 4.

International Searching Authority and to the International Bureau that performs administrative duties for the PCT, as well as the Paris Union and other special intellectual property bodies.[178] If the form is filed in a national office or offices before filing in the receiving office, then the date of the earliest filing applies to the international filing as the priority date.[179] If the international filing is the first filing, then that date is the priority date.[180] The International Search Authority conducts an international search of the prior art, *i.e.*, existing inventions and knowledge, and submits a report to the International Bureau and the applicant.[181] The applicant can then amend the application accordingly and submit the amendments to the Bureau.[182] The Bureau then transmits the amended application and the search report to each designated national office and publishes it, normally eighteen months after the priority date.[183] No later than twenty months after the filing date, the applicant must furnish to each designated national office a copy of the international application if one has not already been received from the Bureau, a translation into the language required by the national office, and the payment of any national fees.[184] This twenty-month deadline is extended to thirty months if the applicant chooses to request an International Preliminary Examination.[185] An International Preliminary Examining Authority issues a report containing a preliminary, non-binding opinion on the patentability of the invention.[186] Each member of the International Patent Cooperation Union has agreed that the format, specifications, and language(s) prescribed by the PCT are acceptable to its patent office. Because English is one of the prescribed languages and the need for translation is eliminated in many countries of the PCT, the preparation of international applications has been greatly simplified for American applicants. Under the Paris Union a separate application form had to be prepared for each country according to its laws.

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[178] *Id.*, at Article 12, and WIPO, General Information 67 (1990).

[179] *Id.*, at Article 2(xi).

[180] *Id.*

[181] *Id.*, at Articles 16-18. The International Search Authority is one of the major patent offices, that is, the Patent Offices of Australia, Austria, Japan, Sweden, the U.S. and the European Patent Office. WIPO, General Information 27 (1990).

[182] PCT, *supra* note 159, at Article 19.

[183] *Id.*, at Articles 20 and 21.

[184] *Id.*, at Article 22.

[185] *Id.*, at Articles 31 and 39.

[186] *Id.*, at Articles 31-35. The International Preliminary Examining Authority is one of the major patent offices, that is, the Patent Offices of Australia, Austria, Japan, Sweden, the U.S. and the European Patent Office. WIPO, General Information 27 (1990).

(3) GATT TRIPS. If a GATT Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS)[187] is successfully concluded and if a significant number of GATT parties become parties to the TRIPS, the establishment of an international standard for intellectual property protection would get a big boost.[188] In provisions pertinent to biotechnology, Article 27 of the Dunkel Draft TRIPS[189] apparently would provide that microorganisms shall be patentable if they meet the other substantive requirements but would permit countries to deny patents on plants and animals other than microorganisms.[190] Article 30 of the Dunkel Draft TRIPS states that "[p]arties may provide limited exceptions to the exclusive rights conferred, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties,"[191] thus apparently permitting compulsory licensing. Articles 65, 66, and 67 of the Dunkel Draft TRIPS provide for some flexibility with transitional provisions for developing countries and special consideration for least developed countries. Consequently, in some countries without strong intellectual property protections, indigenous people probably would still not be able to obtain protection for traditional knowledge because their countries could continue to

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[187] Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex III, Agreement on Trade-Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods, MTN.TNC/W/FA, 20 December 1991 [hereinafter Dunkel Draft TRIPS].

[188] For an overview of the role of the GATT in international intellectual property rights and its role with regard to biotechnology specifically, see respectively Leaffer, *supra* note 80, and Acharya, *supra* note 77.

[189] *Supra* note 187.

[190] The relevant language of the Dunkel Draft TRIPS is:

> 1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial applications.[footnote omitted] Subject to paragraph 4 of Article 65 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
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> 3. Parties may also exclude from patentability:
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> (b) Plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Parties shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. This provision shall be reviewed four years after the entry into force of this Agreement.

[191] Articles 13 and 17 provide similarly for copyrights and trademarks respectively, although Article 13 uses stronger language stating that "[p]arties shall confine limitations or exceptions" to exclusive rights "to certain special cases . . . ."

give preference to the rapid and cheap dissemination of all inventions useful to the economic development of the country.

(4) WIPO Draft Patent Harmonization Treaty. A draft patent harmonization treaty was considered in June, 1990, by the Committee of Experts at the World Intellectual Property Organization (WIPO) and is expected to be given final consideration at the Paris Union Assembly's diplomatic conference in July, 1993.[192] Articles 10 and X in the draft treaty could affect traditional knowledge and biotechnology. Article 10 provides that patent protection shall be available for inventions, whether they concern products or processes, in all fields of technology. Some developing countries circulated an alternative text, however, which would permit Contracting Parties to make broad exceptions to the covered fields of technology. The permitted exceptions would include "plant or animal varieties or essentially biological processes for the production of plants or animals" and "methods of medical treatment for humans or animals."[193] Additionally, the alternative text provided that "(c)ontracting States may, on grounds of public interest, national security, public health, nutrition, national development and social security, exclude from patent protection, either in respect of products or processes for the manufacture of those products, certain fields of technology, by national law."[194] These broad exceptions would permit Contracting Parties to refuse patent protection to virtually anything. As result, the U.S. delegation stated that the suggested alternative text would be unacceptable and would discourage investment in countries enacting such exclusions.[195] The GATT TRIPS would permit a few exclusions, but does not provide for the liberal exceptions permitted by the broad language of the alternative Article 10.

Article X of the draft treaty establishes the obligations of the patent holder, including the obligation "to work the patented invention in the territory of the Contracting State for which it is granted within the time limits as provided by national law."[196] The United States and many other developed country delegations objected to the inclusion of Article X.[197] The laws of the United States contain no working requirement, and the United States stated that the working requirement in the WIPO draft patent treaty did not accord

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[192] 44 Pat. Trademark & Copyright J. (BNA) 3 (May 7, 1992); 41 Pat. Trademark & Copyright J. (BNA) 231 (Jan. 10, 1991) provides a summary of the treaty's provisions with comments.

[193] 41 Pat. Trademark & Copyright J. (BNA) at 233 (Jan. 10, 1991).

[194] *Id.*

[195] *Id.*

[196] *Id.*, at 240.

[197] *Id.*

with the Paris Convention, which also does not require the working of a patent (although it does permit compulsory licensing where there is no working).[198]

For the present both the GATT TRIPS and the WIPO draft patent harmonization treaty remain under consideration but not concluded.

(5) Biodiversity Convention. The Biodiversity Convention, which was concluded at the Earth Summit in Rio de Janeiro on June 5, 1992,[199] mentions the rights of indigenous peoples but only to *encourage* parties to the Convention to respect their cultures and traditions and to equitably share the benefits from biodiversity. For example, the preamble states that the Contracting Parties recognize "the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components." Article 1 states that "the objectives of this Convention ... are ... the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies." Article 8(j) provides that each Contracting Party shall, as far as possible and as appropriate, "[s]ubject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." Article 10(c) provides that each Contracting Party shall "[p]rotect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements." And Article 18, ¶ 4, provides that "(t)he Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention." There is no language that unequivocally guarantees the indigenous peoples any rights in traditional knowledge. The Contracting Parties are to preserve and respect such knowledge and promote its application with the approval and involvement of the indigenous peoples, but the Parties are only obligated to encourage the equitable sharing of benefits from the use of such knowledge.

In sum, then, from a legal standpoint there is no current obligation in either existing or proposed international law to recognize any property rights of indigenous peoples in their traditional scientific knowledge.

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[198] *Id.*

[199] *Supra* note 82.

b. Traditional Arts and Crafts

The growing market for traditional arts and crafts inspired a movement in the early 1970s to protect developing countries from a drain of their tangible and intangible cultural property.[200] Not only were highly valuable cultural artifacts being exported from those countries,[201] but the designs of traditional arts and crafts were being copied and cheaply mass-produced in other countries.[202] This movement led ultimately to the creation of the Working Group on the Intellectual Property Aspects of Folklore Protection under the auspices of the United Nations, which drafted a model law for the protection of folklore in 1981.[203] However, this model law concerned the extension of copyright protection to traditional arts and crafts and was not intended to be an international agreement but a model for domestic laws that might be enacted in each country individually. The draft model law provided for the use of artistic folklore upon authorization by a "competent authority," which was left undefined.[204] This competent authority could collect fees on behalf of the community whose folklore was being utilized.[205] The participation of this community in the decisions of the competent authority was not defined or specifically established by the draft model law.

Subsequently, the Group of Experts on the International Protection of Expressions of Folklore by Intellectual Property produced a draft Treaty for the Protection of Expressions of Folklore against Illicit Exploitation and Other Prejudicial Actions.[206] The draft treaty also leaves open the question of who would constitute the competent authority that could authorize the use of

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[200] Jabbour, *supra* note 154, at 12.

[201] Lobo, *The Fabric of Life: Repatriating the sacred Coroma textiles*, 15 Cultural Survival Quarterly 36 (No. 3, 1991) (problem of returning sacred textile artifacts).

[202] Telephone conversation with Geoffrey Stamm, Assistant General Manager of the Indian Arts and Crafts Board, Department of the Interior (Oct. 12, 1992) (Conversation concerned some of the problems with obtaining intellectual property protection for traditional Indian crafts, music and dance; trademark and Board certification mark are aimed at providing some protection for authentic Indian designs).

[203] Jabbour, *supra* note 154, at 13; Working Group on the Intellectual Property Aspects of Folklore Protection, *Report (Second Meeting)*, Annex I, *Model Provisions for National Laws on the Protection of Expressions of Folklore*, 31 March 1981, UNESCO/WIPO/WG.II/FOLK/4 [hereinafter *Model Law*].

[204] *Model Law*, *supra* note 203, at Articles 10 and 11.

[205] *Id.*

[206] Group of Experts on the International Protection of Expressions of Folklore by Intellectual Property, *On the International Regulation of the "Intellectual Property Aspects" of Folklore*, part III, 19 October 1984, UNESCO/WIPO/FOLD/GEI.1/2 [hereinafter Group of Experts].

protected folklore as well as the question of whether any remuneration would be paid to the community originating the folklore.[207]

Finally, the General Conference of the United Nations Educational, Scientific, and Cultural Organization (UNESCO) adopted a Recommendation on the Safeguarding of Traditional Culture and Folklore at its twenty-fifth session in Paris on November 15, 1989.[208] Subsection E(g) states that member states should "encourage the international scientific community to adopt a code of ethics ensuring a proper approach to and respect for traditional cultures." Subsection F(a) recognizes that the Recommendation only recommends protection of artistic folklore and that there is an urgent need for separate action in other areas of folklore. Thus, while there have been several efforts to produce concrete protection for folklore internationally, no widely effective agreement exists, and the efforts that have been made focus only on artistic folklore.

3. American Laws Regarding Traditional Knowledge

There has been limited recognition of intellectual property rights of Native Americans in their artistic works in American law but no recognition of rights in traditional scientific knowledge. Also, there has been no recognition of any intellectual property rights of foreign indigenous groups in traditional knowledge. There has been recognition of rights in cultural property[209] as concrete, tangible manifestations (such as traditional art work that was unlawfully removed from another country), but not as intangible property (*e.g.*, the design of the art work which might be copied).

a. Traditional Arts and Crafts

Most of the efforts regarding the intellectual property rights of indigenous peoples have concerned the protection of traditional arts and their reproduction. The U.S. has had laws protecting the authenticity of Indian arts and crafts since 1935; these laws were strengthened in 1990.[210] The Indian Arts and Craft Board was established to help protect the rights of Native Americans in their art and craft works. Before the revision of the Copyright Act in 1976[211], under the common law there was a presumption that the copyright to a work of art

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[207] *Id.* at Articles 3 and 4.

[208] United Nations Educational, Scientific and Cultural Organization, Recommendation on the Safeguarding of Traditional Culture and Folklore adopted by the General Conference at its twenty-fifth session, Paris on November 15, 1989.

[209] 19 U.S.C.A. §§ 2601-2613 (Supp. 1992).

[210] Act of Aug. 27, 1935, c. 748, 49 Stat. 891, and Act of Nov. 29, 1990, Pub. L. 101-644, Title I, 104 Stat. 4664, codified as amended at 25 U.S.C.A. § 305 *et seq.* (1983 & Supp. 1992).

[211] Pub. L. 94-553, title I, §101, Oct. 19, 1976, 90 Stat. 2568, is codified at 17 U.S.C.A. §§ 201 *et seq.* (1977).

was sold together with the object itself, unless the copyright was specifically reserved.[212] Since probably most traditional designs, dances and songs have been sold or performed without any copyright notice and obviously predate more recent laws that are more favorable to the artist, Native Americans probably have no copyright in most of their traditional designs. In any case, even if a design had been copyrighted, a minor alteration in the design would produce a design that technically would be a new design and thus not an infringement of the copyrighted design.[213]

However, a Native American individual or a Native American group, such as a business owned primarily by Native Americans, can register a trademark, just as any other person doing business in the U.S. can, and sell their craft work under their trademark. Moreover, the Indian Arts and Crafts Board has a certification mark which is designed to encompass the trademark and which certifies that the article so marked is a genuine Native American craft work.[214] Consequently, although there may be no copyright in the articles, the articles are protectable through the use of the trademark and certification mark. Additionally, there are civil causes of action[215] and criminal penalties for misrepresentation of Indian produced goods[216] and criminal penalties for counterfeiting the Indian Arts and Crafts Board trademark.[217] The regulations of the Customs Service provide for the indelible marking of the country of origin on imported Native American-style jewelry to prevent confusion of imitations with the genuine article.[218] However, tribes still lose profits to the sales of cheap imitations.[219] These imitations do not have a trademark and certification mark and should be clearly marked with the country of origin. But the Native Americans lose potential sales to consumers who perhaps are not aware of these marks or who do not care whether they purchase authentic articles or imitations.

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[212] House Rep. No. 1476, 94th Cong., 2d Sess. 124-5 (1976).

[213] Telephone interview with Geoffrey Stamm, *supra* note 202.

[214] *Id.* and 25 U.S.C.A. § 305a (1983 & Supp. 1992); 25 C.F.R. parts 301, 304, 307, 308, and 310 (4-1-92 edition).

[215] 25 U.S.C.A. § 305e (Supp. 1992).

[216] 18 U.S.C.A. § 1159 (Supp. 1992).

[217] 18 U.S.C.A. § 1158 (Supp. 1992).

[218] 19 C.F.R. § 134.43(c-d) (4-1-92 edition).

[219] Telephone interview with Geoffrey Stamm, *supra* note 202.

b. Traditional Scientific Knowledge

(1) Copyrights.

Indigenous people could record their traditional knowledge about the medicinal uses of plants and animals in some tangible medium[220] and they could have a copyright under American law[221] in that expression, that documentation of their knowledge. Ethnobotanists who published articles or books on traditional knowledge could have copyrights in their works, and they could share the copyright with the indigenous people. However, the copyright would only protect the specific expression, not the knowledge being expressed. Anyone could still use the knowledge they gleaned from reading the book, or viewing the film, or listening to the recording of the expression of knowledge.

(2) Trademarks.

If indigenous peoples were able to overcome all other legal obstacles and market a medicinal product based on their traditional knowledge, they could obtain a trademark under American law[222] and protect that product from infringement. But trademarks would seem of limited usefulness also. Just as people still purchase artistic works and craft items that are imitations of indigenous articles, persons could still purchase traditional medicines, traditional crop breeding germplasm, or other products of indigenous knowledge regardless of whether they were actually produced and marketed by indigenous peoples. More importantly, perhaps, the greatest economic benefits are gained from the biotechnological products derived from traditional knowledge, not the traditional product itself.

(3) Patents.

Section 101 of Title 35 of the United States Code states that "[w]hoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Under Sections 101-103 any patentable invention must meet the criteria of novelty, utility and non-obviousness.[223] Upon the granting of a patent, the patentee receives the right to exclude others from making, using, or selling the invention throughout the U.S. and, if the invention is a process, the right to exclude others from using or selling in the U.S. or importing into the U.S.

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[220] 17 U.S.C.A. § 102(a) (Supp. 1992).

[221] Title 17 of the United States Code.

[222] Title 15 of the United States Code.

[223] 35 U.S.C.A. §§ 101, 102, 103 (1984 & Supp. 1992).

products made by the patented process.[224] The patent term is seventeen years, subject to the payment of fees.[225]

(a) Product of nature doctrine

The first issue in determining whether traditional knowledge about the medicinal uses of plants and animals is patentable is whether it is the type of subject matter described by section 101. Certain subject matter, including laws of nature, products of nature, printed matter, mathematical formulae or algorithms, and business methods, is not patentable.[226] Basically, ideas themselves are not patentable, although applications of ideas may be.[227] The central issue here is whether the traditional knowledge is merely the discovery of a product of nature. A patent applicant cannot obtain a patent for discovering a product of nature but may get patent protection for a process using the newly discovered product of nature. Unless a product which is the subject of a patent application is substantially different from the product as found in nature, that is, unless it is in a form not found in nature and thus the product of human invention, the product is unpatentable.

The decisions regarding whether an article is merely a product of nature and not a manufacture, composition of matter, or a machine, are very fact-specific, and as a consequence general guidelines have proven difficult to delineate. In one of the basic cases, *American Fruit Growers, Inc. v. Brogdex*,[228] a patent was sought for an orange whose rind was infused with a fungicide which then rendered the orange mold-resistant. The United States Supreme Court ruled that "a modified natural product does not become statutory subject matter until its essential nature has been substantially altered." The mere coating of an orange with a fungicide, it held, had not altered the essential nature of the orange. In *Ex parte Latimer*,[229] the applicant sought a patent for "the cellular tissues of the *Pinus australis* eliminated in full lengths from the silicious, resinous, and pulpy parts of the pine needles and subdivided into long, pliant filaments adapted to be spun and woven." The Commissioner of Patents ruled that the fibers were not patentable because they were products of nature, although he noted that a patentable invention could comprise the process by which the fiber could be removed from the natural leaf.

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[224] 35 U.S.C.A. § 154 (Supp. 1992).

[225] 35 U.S.C.A. § 154 (Supp. 1992).

[226] D. Chisum, 1 Patents: A Treatise on the Law of Patentability, Validity and Infringement §§ 1.02 and 1.03 (1991).

[227] *Id.*, at §§ 1.03[2][d] and 1.03[6][c], [e], [g].

[228] 283 U.S. 1 (1931).

[229] 1889 Comm'n Dec. 13 (1889).

In *Dennis v. Pitner*,[230] a patent infringement suit, the patentee claimed "an insecticide and vermifuge comprising ground cube root with the fibrous element removed...." The insecticide was produced by grinding the root, dissolving the resultant powder in a suitable solvent, and filtering the solvent so that the fibrous parts of the root were removed from the solution. When the solvent evaporated, a concentrated powdered extract remained. The plaintiff alleged that the defendant produced the insecticide from the ground root and that it was not patentable because it was merely a product of nature in modified form. But the Court of Appeals for the Seventh Circuit rejected the argument, finding that "(a) discovery in the field of science of a new quality or phenomenon of an old product may be ... the proper subject of a patent."[231] The court found that the insecticidal properties of the powdered root were such a phenomenon (although it ultimately invalidated the patent on the grounds the insecticide lacked novelty because the ground root had long been so used by indigenous peoples[232]).

In *In re Mancy*[233] the applicants isolated a new strain of microorganism from soil samples and sought a patent for the process of producing a known antibiotic from the microorganism by a known cultivation technique. The product and the technique were known, but the particular technique had not previously been used with that microorganism to produce the particular antibiotic. The Court of Customs and Patent Appeals upheld the process patent claim but noted in dictum that the applicants probably would not have been able to get a patent on the novel microorganism itself because it was a product of nature. However, in *In re Bergy*,[234] the same court called this dictum "ill-considered" and stated that it had been thinking of something "merely plucked from the earth and claimed as such." The applicant in *Bergy* was seeking a patent for a biologically pure strain of a microorganism, *Streptomyces vellosus*, which produced the antibiotic lincomyzcin. It had been denied a patent on the grounds that patentable subject matter did not include living organisms.[235] The Court of Customs and Patent Appeals reversed this ruling, however, holding that a biologically pure strain of this microorganism was not a product of nature because it did not occur in nature in that form and could be cultured only under controlled circumstances. Ultimately, the Supreme Court, in the companion case

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[230] 106 F.2d 142 (7th Cir. 1939).

[231] *Id.*, at 146.

[232] *See infra* note 261 and accompanying text for further discussion of this point.

[233] 499 F.2d 1289 (1974).

[234] 563 F.2d 1031, 1036 (C.C.P.A. 1977), *remanded sub. nom. Parker v. Bergy*, 438 U.S. 902 (1978), *on remand* 596 F.2d 952 (C.C.P.A. (1979), *aff'd sub. nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[235] *Ex parte Bergy*, 197 U.S.P.Q. 78 (Pat. & Trademark Office Bd. App. 1976).

of *Diamond v. Chakrabarty*,[236] held that a human-made strain of microorganism, genetically engineered to improve its ability to degrade crude oil, was not an unpatentable product of nature, because the genetically engineered strain was not a naturally occurring manufacture or composition of matter.[237] Consequently, apparently any substantial alteration from a natural state makes a product into a manufacture or a composition of matter and not a product of nature. The issue is what constitutes such an alteration. As the cases described above illustrate, this is not always clear.

Even if a product is determined not to be a product of nature, it must still satisfy the nonobviousness and novelty standards of the patent law. But some judges and commentators consider the "product of nature" doctrine actually to be a method of evaluating the nonobviousness or novelty of a product, rather than a definition of eligible subject matter *per se*. The applicant must have discovered previously unknown, nonobvious qualities and uses of the product. In *In re Kratz*[238] the patent applicant claimed a process and a product adding a strawberry flavor through a certain synthetically produced and substantially pure acid. The court ruled that although the acid in question is a naturally occurring component of strawberries, the patent claim should not have been rejected as a product of nature. The court observed that previous cases indicated a two-part test for rejecting claims based on a product of nature: first, the natural composition must inherently contain the naturally occurring compound and, second, the claim must cover both the known natural composition and the naturally occurring compound. The court held that the patent claim should have been upheld under the second half of the test, because the claims were for the "substantially pure" acid, not for the acid as it occurred in nature and not for a composition encompassing strawberries. The "substantially pure" form of the acid apparently does not occur in nature. It held that although the techniques used by the applicants to analyze the components of strawberries were common, nothing in the prior art indicated the selection and use of the claimed acid as the key component in the claimed flavoring compositions. So the court found that the "substantially pure" form of the acid was *not* an *obvious* component of the flavoring composition and was not a product of nature.

In *Funk Bros. Seed Co. v. Kalo Innoculant Co.*[239] the United States Supreme Court found that the product and process claims for a mixture of several strains of *Rhizobia* bacteria were invalid because they were for works of nature. Various strains of *Rhizobia* effectively inoculated various species of legumes, infecting their roots and forming nodules on them, thereby enabling

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[236] 447 U.S. 303 (1980).

[237] In *In re C.H. Boehringer Sohn*, German Federal Patent Court (1977), noted in Chisum, *supra* note, at § 1.02[7], n. 8, and 10 Int'l Rev. Indus. Prop. & Cr. L. 494 (1979), under German law, an applicant may claim a synthetically produced substance that also occurs in nature.

[238] 592 F.2d 1169 (C.C.P.A. 1979).

[239] 333 U.S. 127 (1948).

them to fix nitrogen from the air. Each strain was specifically effective for certain plant species. However, each strain could only be sold packaged separately from the others because certain strains mutually inhibited the inoculant effect of each other. The patentee had discovered that certain strains were mutually non-inhibitive and thus could be mixed together and sold as inoculants for more species of plants. The Supreme Court disallowed a patent on the mixture and the method for making it, because "patents cannot issue for the discovery of the phenomena of nature. . . . The qualities of these bacteria . . . are part of the storehouse of knowledge of all men."[240] The Court did note that "the application of the law of nature to a new and useful end" could be patented[241] but ruled that the "aggregation of species fell short of invention within the meaning of the patent statutes" since the mixture had no new use beyond the prior art other than providing more convenient packaging. The discovery that certain species of bacteria could be mixed together because they were not mutually inhibitive was *not* considered a *non-obvious*, inventive step in light of the existing knowledge and use of the bacteria.

In *Merck v. Olin Mathiesen Chemical*[242] the Court of Appeals for the Fourth Circuit interpreted the "product of nature" doctrine as a way of determining novelty and nonobviousness. It noted that unpatentable products "had frequently been characterized as 'products of nature.' . . . But where the requirements of [the Patent] Act are met, patents upon products of nature are granted and their validity sustained."[243] The court suggested that the "product of nature" doctrine did not have validity so much as a classification of subject matter but as a type of argument regarding novelty and non-obviousness. As mentioned above, these arguments seemed to fall into two categories: "[one,] that a patent may not be granted for an old product although it may be derived from a new source by a new and patentable process, and [two,] that every step in the purification of a product is not a patentable advance, except, perhaps as to the process, if the new product differs from the old 'merely in degree, and not in kind.'"[244] This case involved a patent for a vitamin B-12 active composition, which had effectiveness in the treatment of pernicious anemia. Scientists had known for some time that the liver of cattle benefitted patients suffering from pernicious anemia, but they had been unsuccessful in isolating and identifying the active component of the liver. After twenty years the patentees had finally managed to produce, isolate and identify the active compound which they named vitamin B-12. However, they had done so through experimentation with the fermentation products of bacterial cultures rather than with liver extracts. Upon finding a promising substance in the fermentates of one culture, they fractionated, purified and tested the components of the fermentate until they

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[240] 333 U.S. at 130.

[241] This is similar to the dictum of the court in *Dennis v. Pitner*, 102 F. 2d at 146.

[242] 253 F.2d 156 (4th Cir. 1958).

[243] 253 F.2d at 162.

[244] *Id.*

arrived at a crystalline form of vitamin B-12. The court found that this purified form was patentable, saying that the B-12 in the purified form was so much more effective than either the liver extracts or the initial products of the fermentation that it did not differ from them merely in degree of purity, but differed from them in kind. The court also noted that the patent claims were not for the pure vitamin B-12, but for a purified form just short of being pure vitamin B-12. The claims also only covered the B-12 composition produced by the fermentates of the bacterial cultures, not B-12 derived from liver extracts. In other words, the patentees did not make claims that would be non-obvious because others had performed similar experiments, nor did they attempt to claim the pure B-12 itself, arguably a mere "product of nature," but the particular composition containing B-12 which they had isolated and found effective against pernicious anemia. In addition to the careful drafting of their claims to satisfy the non-obviousness standard, the deciding factors apparently were that the purified vitamin B-12 differed substantially from the naturally occurring form, particularly with regard to commercial usefulness and applications, and had not been previously identified as the source of a useful property.

In *In re Bergy*, mentioned above, the U.S. Supreme Court initially remanded the case to the Court of Customs and Patent Appeals for reconsideration. That court, nonetheless, reaffirmed its earlier decision. Judge Baldwin in a concurring opinion found "a common thread" among the major Supreme Court cases interpreting the "law of nature" doctrine, closely related to the "product of nature" doctrine. He observed that:

> claims which directly or indirectly preempt natural laws or phenomena are proscribed, whereas claims which merely utilize natural phenomena via explicitly recited manufactures, compositions of matter or processes to accomplish new and useful results define statutory inventions.... In each of ... the cases, the Supreme Court centered its analysis on the phenomenon which made the invention valuable to the inventor and then proceeded to determine whether or not the inventor attempted to preclude others from using those bare phenomena.[245]

This common thread is observable in *Dennis v. Pitner* and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, both discussed above. In the former case, the insecticidal properties of the ground cube root were not considered an unpatentable law of nature; the insecticidal composition of matter merely took advantage of the insecticidal phenomenon of the cube root. On the other hand, in the latter case, the mixture of mutually non-inhibitive inoculants apparently was considered an attempt to patent a phenomenon of nature. However, as discussed above, the court may simply have felt that the mixture was obvious and thus did not justify the grant of a patent; arguably, the mixture was an invention which merely utilized the laws of nature to achieve the convenience of a single package of inoculant rather than several.

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[245] 596 F.2d at 988, 996 (concurring opinion).

One commentator, Karl Bozicevic, has described seven guideposts on how the Patent and Trademark Office and the courts distinguish "products of nature" from products derived from nature.[246] First, one should recognize and appreciate the influence of public opinion on the development of law interpreting section 101, defining patentable subject matter. Bozicevic believes that the Supreme Court ruled that microorganisms may be patentable because the microorganism in *Chakrabarty* was designed to clean up oil spills by degrading the oil. Environmentalists constituted the major opposition to the patenting of life forms, even microorganisms, because of concern about the impact of genetic engineering on the environment. But because the *Chakrabarty* organism was designed to clean the environment, the major opposition and public opinion were not so strongly against patenting it. Second, one should consider claiming chemical compounds known to exist in nature by claiming them apart from their natural surroundings. The *Merck* and *Kratz* cases are examples of this strategy--respectively, they claimed the vitamin B-12 and the acid responsible for strawberry flavor in the synthetic form created in the lab, not as extracted from natural surroundings. Third, the discovery of a product in nature, although not an invention, may well lead to an invention that can be claimed through careful drafting. Again, the *Merck* case is an example: although vitamin B-12 does occur in nature, the patentee only claimed the vitamin as it was created in the lab, a form with far greater medicinal effectiveness and synthesized from bacterial fermentates rather than from cattle livers. Fourth, the patentability of a compound derived from nature can in part be judged by determining the "novelty of that compound as compared with the "product of nature" (or "prior art") from which the compound was derived. Fifth, one should compare the claimed invention with the product as it exists in nature and determine non-obviousness by applying the criteria in *Graham v. John Deere Co.*, described below. (This guidepost resembles the reasoning of other commentators, noted above, that the "product of nature" doctrine actually is a form of novelty or non-obviousness analysis.) Sixth, the first to induce a "product of nature" to possess a new characteristic, regardless of the manner of inducement, is likely to have produced a patentable invention. In *Ex parte Hibberd*[247] scientists obtained a patent for corn which had the new characteristic of having more tryptophan, and in *Chakrabarty* the inventor obtained a patent on a microorganism with the new characteristic of degrading oil. The former invention resulted from conventional breeding techniques, the latter from genetic engineering. Seventh, the means of modifying a "product of nature" has little if any effect on the patentability of the modified product of nature, although it may affect the patentability of the process for producing the product of nature. That is, the fact that the scientists in *Hibberd* knew about tryptophan and used known breeding techniques to create a new species of corn with higher levels of tryptophan made no difference in the patentability of the corn itself.

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[246] Bozicevic, *Distinguishing "Products of Nature" from Products Derived from Nature*, 69 J. Pat. & Trademark Off. Soc'y 415 (1987).

[247] 227 U.S.P.Q. 443 (P.T.O. Bd. Pat. App. & Int'f 1985).

The product of nature doctrine and the law of nature doctrine are important to any potential patent protection for the traditional scientific knowledge of indigenous people. Like the patentees in *Dennis v. Pitner* and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, patent validity and eligibility would depend on whether or not the traditional knowledge is deemed to be a mere discovery of a law of nature or use of a product of nature. If an indigenous people use a plant in its natural state because they discover that it has certain valuable properties, it may not be patentable. If they alter it substantially by, for instance, brewing a tea from it or processing it in some manner to produce a medicinal substance, then the resultant product may be patentable subject matter. The difference would be that they have produced a non-obvious composition of matter derived from a product of nature by using their knowledge of the laws of nature. (Any such claim, of course, would still have to meet the patent law's requirements of novelty, utility, and nonobviousness.)

One example of the product of nature issue as it applies to traditional knowledge is the seed of the neem tree, including the species *Azadirachta indica* and *Melia azadirachta*. Neem seeds have been used as a pesticide in India for hundreds of years. The neem seed itself is not patentable because it is a product of nature. Similarly, the mere knowledge that neem seeds are effective pesticides is not patentable by anyone. Also, the method of scattering ground neem seeds as a pesticide would not be a patentable process, because this process has been known and practiced for centuries and likely would be deemed obvious. However, patents have been granted for (1) extracts from pre-treated neem bark shown to be effective against certain cancers,[248] (2) neem-seed extracted azadirachtin in a stable storage form,[249] and (3) azadiractin-derivative insecticides which have greater stability than the naturally occurring form of azadirachtin.[250] Azadirachtin itself is a natural product found in the seeds of the neem tree and it is the significant active component. There is no patent on it, perhaps because everyone recognizes it as a product of nature. But as mentioned above, a synthetic form of a naturally occurring compound may be patentable, because the synthetic form is not technically a product of nature, and the process by which the compound is synthesized may be patentable. Thus, the laboratory-synthesized derivative of azadirachtin, which was more stable and easier to store and therefore more useful than the naturally occurring azadiractin, was considered patentable by the Patent and Trademark Office. Likewise, the stable storage formula or medium for neem-seed extract was patentable, and the pretreated, neem-bark extracts shown to be active against tumors apparently were considered novel and therefore patentable. Although traditional knowledge inspired the research and development that led to these patented compositions and processes, they were considered sufficiently novel and

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[248] U.S. Pat. No. 4, 537, 774. These extracts are distinguished from the prior art because the process involves the pretreatment of the bark rather than a direct extraction method. The pretreatment results in extracts with a higher degree of purity.

[249] U.S. Pat. No. 4, 556, 562.

[250] U.S. Pat. No. 5, 047, 242.

different from the original product of nature and the traditional method of use to be patentable.

A process is not a tangible article, "a structural entity," like the other classes of patentable subject matter (machine, manufacture, and composition of matter), but a "series of steps leading to a useful result."[251] It is "a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery."[252] A process producing a compound that is found in a product of nature could be patented if the process itself satisfied the requirements of U.S. law of being inventive, novel and useful, even though the product may not be patentable itself. A unique combination of known techniques may also constitute a patentable process. Even if there is a known process and a known product, if the process or technique has never before been used as a method of making the product, and so the use of the known process to produce the known product actually yields a non-obvious result, the new use of the process is patentable. Originally, medical processes and methods of treatment were not favored for patent protection,[253] but with the medical/technological developments of recent decades, treatment methods have been patented and such patents have been upheld by the courts[254]--*e.g.*, the use of vinblastine in the treatment of arthritis.[255] This category of patents would not seem of great potential benefit to indigenous peoples, however.

(b) The utility requirement

Under Section 101 of Title 35 of the United States Code a patentable invention must have specific utility. The National Institutes of Health (NIH) have had problems with the patenting of genes because as yet some of this knowledge has no proven application regarding medical treatments, such as gene therapy. They are not even certain yet of the exact function of some genes or gene fragments, although the gene sequence or partial has been isolated and identified. Recently, the NIH failed to receive a patent for gene fragments that are used as markers to aid in the mapping of genes. The Patent and Trademark Office rejected, *inter alia*, the claim of NIH that the gene fragments satisfied the

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[251] Chisum, *supra* note 226, at § 1.03.

[252] *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877).

[253] Chisum, *supra* note 226, at § 1.03[3]. *See Morton v. NewYork Eye Infirmary*, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862); *Ex parte Brinkerhoff*, 24 Comm'n MS Decision 349 (1883).

[254] Chisum, *supra* note 226, at § 1.03[3]; *see Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628 (S.D.N.Y. 1930); *Ex parte Scherer*, 103 U.S.P.Q. 107 (Pat. & Trademark Off. Bd. App. 1954).

[255] U.S. Pat. No. 4, 208, 414, Vinblastine in rheumatoid arthritis, Jun. 17, 1980. "This invention provides a method of treating rheumatoid arthritis which comprises administering to a mammal suffering from rheumatoid arthritis and in need of treatment, an amount of a vinca-derived oncolytic agent, specifically vinblastine, effective to arrest the progress of the disease."

utility requirement by their use as markers in the mapping of genes.[256] Obviously, traditional knowledge which has led to the development of products and processes patented under developed countries' laws has a proven utility. However, one cannot show that everything has usefulness; not all traditional knowledge has a utility which is claimable under U.S. standards. For instance, indigenous peoples might believe that certain rituals and potions have utility even if we do not. The point is that knowledge itself is not patentable, but useful products and processes are.

(c) The novelty requirement

An invention must also be novel to be patentable. Section 102 of Title 35 of the United States Code establishes the standards for novelty and related requirements. Novelty focuses on events that occurred prior to the invention by the patent applicant. To qualify, an invention must not have been known, used, patented, or described in a printed publication by others in the U.S., and it must not have been made in the U.S. by another who had not abandoned, suppressed, or concealed it. It also must not have been described in a patent that was filed in the U.S. by another before the invention by the patent applicant.[257] It must not have been described in an international application that was filed by another in the U.S., with an oath that he believes himself to be the first inventor, before the invention by the patent applicant.

Events in foreign countries also affect novelty. The invention must not have been patented nor described in a printed publication by others abroad, before the claimed invention by the patent applicant. An inventor must also diligently pursue the successful development of his invention or his patent application may lose to an inventor who conceived an invention later but reduced it to practice first. In other words, merely having a concept first is not enough; the patentee must make the dream a reality and do so before anyone else or do so through continuous effort. An inventor who conceives first and reduces to practice last can only get a patent if he exercised reasonable diligence from a point in time before the second inventor conceived the invention. This rule, established in subsection 102(g), can lead to confusion where more than two inventors are involved, because it is possible for each inventor to be prior to another but for no one to be prior to everyone else.

The remaining provisions of section 102 are not novelty provisions in the strict sense, because they mostly focus on events that occur more than twelve months before the filing of the U.S. patent application rather than on events occurring before the claimed invention. The purpose of these provisions is to encourage inventors to pursue their patent rights promptly and diligently, in

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[256] *Ethics, Legality Of Gene Patenting Are Weighed In Senate Subcommittee Hearing, supra* note 80, at 535.

[257] Since the patent laws aim to encourage disclosure and dissemination of knowledge, this rule tends to cause inventors to choose to patent an invention rather than treat it as a trade secret.

part so that the information published in the patent will be available as soon as possible, and partly to make inventors choose between patent and trade secret protection. These statutory bars provide that the invention cannot have been patented, described in a printed publication, publicly used or sold in the U.S. by anyone, including the inventor himself, more than one year before the date of the U.S. patent application.[258] The invention cannot have been patented or described in a printed publication in a foreign country by the inventor or anyone else more than one year prior to the U.S. application. The patent applicant must not have received a patent in a foreign country, prior to the date of the U.S. application, for an application filed more than twelve months before the U.S. application. The applicant must not have abandoned the invention, and he himself must have invented the subject matter of the patent application. The purpose of these provisions is to encourage inventors to pursue their patent rights promptly and diligently, in part so that the information published in the patent will be available to the public as soon as possible.

Section 104 of Title 35, United States Code, provides that a patent applicant or patentee cannot establish the date of invention by referring to knowledge, use, or other activity that occurred in a foreign country. There are two exceptions. If the inventor, civil or military, was serving the United States in a foreign country, that person's rights of priority are the same as if the invention were made in the U.S. Secondly, if a patent applicant has previously filed an application in a foreign country, the date of filing for the U.S. application will relate back to the date of filing for a foreign application made within twelve months of the U.S. filing date, if that foreign country offers the same privilege to applicants who have previously filed in the U.S. or who are U.S. citizens.[259] A foreign filing does not toll the running of the one-year grace period for filing in the U.S. after publication, public use or sale. It also does not have the same effect as a U.S. filing in the determination of prior art and the patentability of inventions by others.[260] Aside from filing in a foreign country and then filing in the U.S. within the twelve-month grace period, a foreign inventor may introduce his invention into the U.S. in an appropriate manner, *e.g.*, by disclosure to a patent attorney, and then use that date of introduction as the date of invention for establishing priority and patentability in the U.S.

The novelty requirements and related statutory bars alone would seem to bar patent protection for traditional knowledge. No individual applicant from the indigenous group could claim to have invented the subject matter himself, nor could he claim to be the first to invent, because the nature of traditional knowledge is that it has been passed on from generation to generation and it may be known to more than one member of the group. So the knowledge that

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[258] 35 U.S.C.A. § 102(b) (1984).

[259] 35 U.S.C.A. § 119 and 365 (1984 & Supp. 1992); Chisum, *supra* note 226, at vol. 3, § 10.03[3] and vol. 4, § 14.01.

[260] Chisum, *supra* note 226, at vol. 4, § 14.01.

a plant has a particular property would not be novel in the usual sense. Many persons would have prior possession of that knowledge and it would have been "published" and "publicly used" within the indigenous group for generations. Novelty and the requirement that the applicant be the actual inventor might be more easily satisfied if collective rights in traditional knowledge were recognized for indigenous people, because then that knowledge could be regarded as novel to the outside world (although within the group it may be common knowledge) and the indigenous people could be considered the inventors collectively. Although the original individuals who discovered and used the knowledge lived long ago, the indigenous group which has maintained the knowledge discovered in its midst could be deemed inventors for the purpose of U.S. laws.

Even if collective rights were recognized, however, the knowledge would not be patentable under U.S. law if the traditional knowledge had been published and documented by ethnobotanists and other scholars more than a year before the U.S. patent application. Also, the fact that traditional knowledge by definition has been handed down for generations means that such knowledge would likely be statutorily barred because of use by the inventor himself more than twelve months prior to filing the U.S. patent application. Finally, where more than one distinct indigenous group has possessed the same traditional knowledge, as in the example of the use by the Kiowa and other tribes of the same plants for the same purpose, it may be difficult to determine which group discovered the knowledge and made use of it first. Assuming collective rights could be recognized, the requirement of novelty would appear to dictate that only the group who invented first could receive protection.

Although indigenous people may be barred by novelty and other statutory requirements from obtaining patent protection, the indigenous knowledge/inventions may sometimes bar others from obtaining patents on grounds of novelty. In *Dennis v. Pitner*,[261] a patent infringement suit, the court found that the use of the powdered root as an insecticide was not novel because other scientists has previously investigated the insecticidal and fish-poisoning properties of the roots of the cube, derris, and tephrosia plants, which belong to the *Leguminosae* genus of plants, and because Chinese gardeners had long used the derris root as an insecticide and inhabitants of Peru used the derris and cube roots for fishing. Thus, the patentee was not the first to have discovered and used the poisonous qualities of the roots of plants in the *Leguminosae* genus. Although an insecticide made from the powdered root extract of the cube root was *not* considered a product of nature by the court, it was, nonetheless, unpatentable for lack of novelty due to traditional knowledge and use.

(d) Non-obviousness or inventiveness

The third major requirement for patentability is non-obviousness or inventiveness. Section 103 of Title 35, United States Code, provides that even if an invention is novel, it may not be patentable "if the differences between the

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[261] 106 F.2d 142 (7th Cir. 1939).

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." In *Graham v. John Deere Co.*[262] the Supreme Court of the United States described the analysis required by section 103:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others [to make the invention], etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.[263]

Traditional knowledge presents unique problems in determining non-obviousness because it would be difficult to determine what the prior art might have been. Presumably the prior art would be knowledge that the indigenous people had prior to the invention, but since both prior art and claimed invention would be generations old, it would be difficult to determine at what point in time an indigenous group had acquired or developed a particular segment of knowledge. This is similar to problems with ascertaining novelty.

Also, there is the issue of whether prior art for purposes of non-obviousness should include knowledge possessed by indigenous groups other than the potential patent applicant, when these other groups are neighbors of, or are known to have had contact with, the applicant group. Comparisons between a shared knowledge base and knowledge unique to one group may be relevant to the non-obviousness of an invention claimed by one group. The fact that other indigenous peoples do not use a plant in a particular way known to one group, although the others also have access to the same plant and use it in other ways common to many groups, might be evidence of the inventiveness of one group's particular, unique use. For example, the fact that the Kiowa and other tribes sometimes had different uses for the same plant or that the Kiowa had the same uses for a particular plant as other tribes plus additional uses that other tribes did not seem to know about could be evidence of the inventiveness of the knowledge of the Kiowa. Knowledge that is common to several groups, on the other hand, may be a simplistic or obvious product or process. The fact that persons outside the indigenous group(s), such as scientists from industrialized countries, do not have particular traditional knowledge may be evidence of non-obviousness. However, if everyone is going through a trial-and-error screening process based on access to a plant or animal, and the indigenous

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[262] 383 U.S. 1 (1966).

[263] *Id.* at 17-18.

groups have simply gone through the trial-and-error screening process generations before, the traditional knowledge derived from the screening process may be deemed an obvious invention.

Even if an indigenous product is patentable, a pharmaceutical company may also have a patentable product if it develops a non-obvious derivative and/or develops a more sophisticated process for extracting, isolating, or synthesizing the active chemical in the plant or animal extracts or compositions used by the indigenous people. For example, the use of the ground neem seed as a pesticide and the common methods of extraction and purification would constitute prior art for the scientist extracting and isolating the active component, azadirachtin, and developing a pesticide from neem seed. Any product-of-nature and novelty argument aside, that scientist would be barred by non-obviousness from patenting ground neem seed or azadirachtin, because the former is identical to the prior art and the latter is obvious to one familiar with the art, the indigenous knowledge, and common methods of extraction, identification, isolation, and purification of the active components in plants. As noted above, however, there is a patent on azadirachtin derivatives. These derivatives are synthesized in the laboratory, not merely extracted from nature, and are more stable than the azadiractin found in nature in the neem seed. Therefore, the derivatives have been deemed not obvious.

Another example is the rosy periwinkle and its derivative alkaloids. As discussed above, traditional use of a tea brewed from the rosy periwinkle as a treatment for diabetes originally inspired scientists to investigate the plant.[264] Indigenous peoples possibly could have received patents for the tea, if the tea really was effective as a treatment for diabetes. The tea might not have been non-obvious, but it probably would not be deemed a product of nature itself. Scientists from developed countries isolated and received patents for vincristine and vinblastine, alkaloids found in the rosy periwinkle.[265] Although these products are derived from nature, they were isolated, purified, and identified as being effective against malignancies, particularly leukemia, for the first time by the scientists. Scientists have subsequently received patents for various methods of preparing vincristine, normally isolable from the rosy periwinkle in much smaller quantities than vinblastine, by converting vinblastine to vincristine.[266] They have also received patents for compounds made by converting alkaloids of the rosy periwinkle that are relatively inactive against malignancies into active ones effective against malignancies,[267] and for a method using vinblastine in the treatment of rheumatoid arthritis.[268]

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[264] *See supra* note 158 and accompanying text.

[265] U.S. Pat. No. 3, 205, 220 (vincristine) and U.S. Pat. No. 3, 097, 137 (vinblastine).

[266] Gorman--U.S. Pat. No. 3, 354, 163; Derwent Abstract 33812Y/19--based on Soviet Union Pat. No. 521, 845; U.S. Pat. No. 3, 899, 943; and U.S. Pat. No. 4, 303, 584.

[267] U.S. Pat. No. 4, 143, 041.

[268] U.S. Pat. No. 4, 208, 414.

Although the traditional medicine inspired the initial investigation, these patents represented developments that were non-obvious (and novel) with respect to the traditional knowledge and with respect to the prior patented inventions based on the rosy periwinkle research.

Finally, even if all problems with the requirements for patentability of the products and processes of traditional knowledge were removed by making statutory exceptions for indigenous peoples, the patent protection for traditional knowledge might not result in any financial benefit for an indigenous patentee. The traditional knowledge by itself may have limited use or no use for the public in developed countries, who may instead utilize and buy new inventions resulting from the research and development inspired by traditional knowledge. Furthermore, a new invention reaching commercial use ultimately may be a non-obvious derivative of the original indigenous knowledge. When new research and development results in patentable inventions, the inventors likely would not owe any compensation to the indigenous group, because the inventions would go beyond what might be obviously derived from the traditional knowledge by a person skilled in the art. The novelty and non-obviousness of the invention, when compared to traditional knowledge, would indicate that the inventors merit protection of their own and would not owe an obvious debt to traditional knowledge. Thus, the indigenous people may not be able to realize a profit from any patent on traditional knowledge, even if it were statutorily possible, nor would they necessarily share in the rewards of a more sophisticated invention based on their knowledge.

(4) Trade secrets.

Trade secrets derive from state statutes and from the case law of state and federal courts.[269] An invention may not qualify for a patent because it does not satisfy the requirements for patentability. Yet the invention may still have great utility and commercial value. In that situation an inventor can seek protection in trade secrets law.[270] Even if an invention is patentable, the inventor may choose to treat the invention as a trade secret in order to prevent disclosure to others and to retain control over his invention for as long as he can keep it a secret, rather than for just the patent period. Trade secrets may be protected under tort law, contract law, and criminal law. The misappropriation of trade secrets or the breach of a confidential relationship without a contract is a matter of tort law; an action may be brought for breach of a contract providing for the confidentiality of trade secrets disclosed by one party to another; and there are criminal sanctions for misappropriation of trade

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[269] For a summary of trade secrets law, *see* Office of Technology Assessment (OTA), New Developments in Biotechnology: Patenting Life 46 (1990).

[270] In *Kewanee Oil v. Bicron Corp.*, 416 U.S. 470 (1974), the Supreme Court upheld a state trade secret law against a claim of preemption by federal patent law, finding that the two were compatible since they both served to promote invention.

secrets.[271] Although there is a model statute, the Uniform Trade Secrets Act,[272] not all states have enacted it, and the states that have enacted it have not adopted all of its features. Thus, the laws regarding trade secrets vary from state to state. Even so, the main features of trade secrets laws in general are the maintenance of confidentiality and the encouragement of invention and competition through the prevention of unfair trade practices and unfair competition.[273]

Confidentiality is the key to trade secrets; obviously, once the secret is revealed, there is no trade secret and the value of the intellectual property has been nullified. The trade secret must be information, including a formula, pattern, compilation, program, device, method, technique, or process, that derives independent economic value, actual or potential, from not being generally known to and not readily ascertainable through proper means by other persons.[274] The owner of the trade secret must make reasonable efforts to preserve secrecy by restricting access to the information only to others with a reasonable need to know, such as employees engaged in making a product, and/or by contracting for the confidentiality of any information shared with these others.[275]

In many cases indigenous knowledge is already not a secret, because scholars have interviewed the indigenous shamans and other members of the indigenous group and may have published that knowledge in print media. Thus, it may be difficult for indigenous peoples to maintain traditional knowledge as a trade secret. The model letter of intent of the National Cancer Institute has a provision for confidentiality, in which knowledge will not be published without the permission of the indigenous individuals who provided the information and acknowledgement of their contribution to the NCI effort.[276] If a particular piece of traditional knowledge was not generally revealed to outsiders, the indigenous people might be able to maintain it as a trade secret *vis à vis* the rest of the world and take reasonable steps to disclose it only to a specific outside organization in return for compensation and/or confidentiality. However, knowledge generally known to all members of a tribe may not qualify as a trade

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[271] Lydon, *The Deterrent Effect of the Uniform Trade Secrets Act*, 69 J. Pat. & Trademark Off. Soc'y 427 (1987) (note 12); *e.g.*, 18 U.S.C.A. § 1905 (1984 & Supp. 1992).

[272] 14 U.L.A. 541 (1980).

[273] OTA, supra note 269, at 46.

[274] Uniform Trade Secrets Act § 1(4), 14 U.L.A. 542 (1980). *See also* M. Jager, Trade Secrets Law, ch. 3 (1992) (the modern definition of trade secrets); the overview of trade secrets law in Note, *The "Genetic Message" from the Cornfields of Iowa: Expanding the Law of Trade Secrets*, 38 Drake L. Rev. 631, 633 (1988-89); and the analysis of the Uniform Trade Secrets Act in Lydon, *supra* note 270.

[275] OTA, *supra* note 269, at 46 and Note, *supra* note 274, at 636.

[276] Letter of Intent, *supra* note 72, at ¶ 2 under the definition of the role of the "country organization."

secret. If a shaman or other individual has exclusive access to information because of his status in the group, that individual or the indigenous group together probably has a trade secret, if, for example, it is knowledge which is also valuable to others and could give one business/organization an edge over another in developing a pharmaceutical product.

The law of trade secrets tries to prevent unfair practices and unfair competition by offering civil remedies, including punitive damages, and/or criminal sanctions against the misappropriation of trade secrets notwithstanding the reasonable efforts of the owner to maintain secrecy.[277] Some persons intentionally misappropriate trade secrets through improper means, such as industrial espionage, theft, breach of a duty of confidentiality, bribery, fraud, etc. Fiduciaries such as employees can misappropriate information by revealing information belonging to a former employer to a new employer who is a competitor. Third parties who acquire and/or disclose information with notice that it is a trade secret and with reason to know it was acquired through improper means are misappropriators. Finally, if a party acquires information that he has reason to know is a trade secret and was acquired by accident, that party becomes a misappropriator upon disclosing or using the information. Unless an indigenous group designates information as a trade secret and takes steps to protect it, any acquisition by outsiders would not be misappropriation. From a policy standpoint, encouraging indigenous peoples to start treating traditional knowledge as trade secrets may not be as desirable as offering them some other form of protection, because if only the organization with whom the indigenous peoples choose to deal directly could acquire the knowledge, then the dissemination of traditional knowledge to other researchers might be stifled.

CONCLUSION

Human activities are seriously eroding global biological diversity. The current extinction rate greatly exceeds the natural "background" loss of species. In the words of wildlife biologist Aldo Leopold: "If the biota, in the course of aeons, has built something we like but do not understand, then who but a fool would discard seemingly useless parts? To keep every cog and wheel is the first precaution of intelligent tinkering."[278] As biodiversity is lost, the world loses novel chemical compounds which might have had value in industry, agriculture or medicine.

Although plant-based treatments have always been important in the medical arena, technological advances in the early 1970s appeared likely to sharply reduce modern society's future reliance on biodiversity to meet health needs. However, since approximately 1980 there has been renewed interest in eco-derived products, in part due to the active participation of NCI and some

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[277] *See* Note, *supra* note 274, and Lydon, *supra* note 271.

[278] Leopold, Aldo (1966). A Sand County Almanac, With Essays From Round River. Sierra Club/Ballantine Books, New York.

prominent success stories (*e.g.*, the rosy periwinkle and serpent-wood). In addition, the pharmaceutical industry has again become interested in "chemical prospecting," *i.e.*, gathering samples of plants and animals and testing them for certain activities using rapid screening procedures. Chemical prospecting combines the use of natural genetic diversity and refined screening technology.

As a way to pinpoint promising plants, a small number of organizations have begun to use the knowledge of indigenous peoples who are very familiar with the properties of local flora. Proponents of this concept believe that (1) traditional knowledge can reduce the time and money involved with drug discovery, and (2) indigenous people should be adequately compensated for their knowledge. To provide a framework for remuneration, NCI has produced a Letter of Intent (*see* Appendix) which outlines guiding principles for the compensation of indigenous peoples and their countries and the conservation of biological diversity. The Merck-INBio agreement followed the NCI principles and has stimulated interest in similar contracts between industrialized countries and species-rich countries. In addition, at least one pharmaceutical company, Shaman Pharmaceuticals, is relying exclusively on the knowledge of indigenous peoples in its chemical prospecting and has dedicated some of its profits to helping indigenous peoples survive and to preserving biodiversity. Finally, extractive reserves have been posited as a potentially viable means of interrelating biodiversity screening and harvesting with the preservation of indigenous peoples and biodiversity.

The question of whether the traditional knowledge of indigenous peoples about the medicinal uses of plants might be entitled to protection as a form of intellectual property has only recently arisen in discussions about the rights of indigenous peoples, and for that reason the issue remains both complex and uncertain. But it appears doubtful that much protection exists under the existing national and international system of laws relating to intellectual property. The developing countries that are host to many indigenous peoples generally have subordinated protection for intellectual property to their interest in rapid economic development. The human rights of indigenous peoples have not yet been fully defined, and discussions of their rights to date have generally not addressed the issue of intellectual property rights. The Paris Convention and the Patent Cooperation Treaty are largely procedural in nature and do little to address or harmonize substantive intellectual property law. Proposed and/or pending agreements such as the WIPO draft patent harmonization treaty, the GATT TRIPS, and the Biodiversity Convention would provide indigenous peoples no intellectual property rights in their traditional knowledge. And such knowledge would not appear to be able to meet the requirements of U.S. patent law that inventions be novel, useful, non-obvious, and not be a product of nature. Some protection might be afforded by U.S. copyright law and state trade secrets law, but it seems doubtful that those protections would be of much economic benefit.

Several proposals for extending intellectual property protection to the traditional knowledge of indigenous peoples have been made. One possibility that has been suggested is a convention or other agreement between the host

country and their indigenous peoples. Generally, indigenous peoples such as Indian tribes cannot make treaties or international agreements with countries. But they can make contractual agreements with the governments of the countries which they inhabit. As is true with contracts between indigenous peoples and private concerns such as pharmaceutical companies, these agreements could provide recognition for the indigenous peoples' traditional knowledge and make use of that knowledge by outsiders compensable.[279]

A special international convention focusing on property rights in traditional knowledge might also be negotiated, under the auspices of WIPO, the United Nations Environmental Program, or the UN Working Group on Indigenous Peoples. The convention could create a uniform standard for property rights in traditional knowledge (if such a standard can be defined). Alternatively, the convention could create standard procedures for negotiating with indigenous peoples for the right to use their knowledge and create procedures for reimbursing them.

A third possibility is that a subsidiary agreement to the Biodiversity Convention could be negotiated requiring that the government of a country that has genetic resources and receives benefits, technology, or royalties from a developed country for access to its genetic resources must pass on some of the benefits to the relevant indigenous peoples. The Biodiversity Convention briefly mentions the rights of indigenous peoples but does not address the specific issue of requiring reimbursement for their traditional knowledge or otherwise requiring protection of their knowledge. The Convention requires only that the country itself be compensated.

There are other possibilities for compensating indigenous peoples for traditional knowledge. A central authority could be created to collect royalties from the profits of biotechnology derived from traditional knowledge and to disburse them equitably among all indigenous peoples.[280] A central

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[279] The status of treaties with indigenous peoples under international law is ambiguous because of issues concerning whether indigenous peoples are groups with international legal personality capable of concluding a treaty and whether the treaties are enforceable as a practical matter. Nations generally regard treaties between a government and its indigenous peoples as a domestic matter. For example, apparently the Canadian government has never considered its treaties with Indian tribes to be true international agreements, although there is case law suggesting that to the extent that such agreements were misrepresented to the Indian tribes as international agreements or treaties, the Canadian government may have a moral, if not legal, obligation to honor simple contractual obligations as if they were treaty obligations. Case law in the United States indicates that treaties could be concluded with Indian tribes who were recognized as sovereign nations, such as the Cherokees, until 1871. In that year Congress passed a statute which prohibited the conclusion of any more treaties with Indian tribes, or the recognition of any future agreement as having the status of a treaty rather than a contract. *See* Lawrey, *supra* note 97, at 726-733; Moss, *Aboriginal Rights*, Current Issue Review from the Research Branch, Library of Parliament, Canada 5-6 (1991).

[280] Some of the lawyers in the Working Group on the Intellectual Property Aspects of Folklore Protection and a report by the Group of Experts on the International Protection of Expressions of Folklore by Intellectual Property mention the concept of "domaine public payant" under which,

negotiating authority for indigenous people could be created that would deal with developed countries, their agencies, and the private sector to obtain fair deals for indigenous peoples and to educate them about their potential rights and bargaining power.[281] A code of ethics could be created and informally agreed to by all private and public organizations dealing with indigenous peoples.[282] Developed countries could condition foreign assistance to developing countries on the creation of a mechanism to disperse royalties received from biotechnology agreements, such as the Merck-INBio agreement, to indigenous peoples. Finally, foreign assistance could be used to promote such agreements.

For the immediate future, however, the most likely avenues for providing compensation to indigenous peoples for the use of their traditional knowledge while promoting the preservation of biodiversity appear to be contracts between such peoples and pharmaceutical companies and other research organizations and, perhaps, the development of extractive reserves.

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if there is no identifiable individual author, copyright royalties are paid to the state. The experts involved preferred a method of compensating the source-groups of the folklore. With regard to indigenous rights in scientific folklore, perhaps the concept of domaine public payant and the goal of directly compensating the source-group can be combined. Where more than one indigenous group has contributed knowledge to the screening and investigation of a plant, a central authority could collect and disseminate any royalties equitably. *See* Jabbour, *supra* note 154, at 14 and Group of Experts, *supra* note 206, at part II, ¶¶ 29-32.

[281] Some indigenous peoples have already acquired sufficient sophistication to realize that they may have greater access to modern goods and services, if they wish, and that the "sale" or "licensing" of their unique knowledge, as well as whatever lands and tangible resources they possess, are effective bargaining chips in their access to such goods and services and in ensuring their physical and cultural survival. *See* Chapin, *How the Kuna Keep Scientists in Line*, 15 Cultural Survival Quarterly 17 (Summer 1991). This article describes how the Kuna Indians of Panama manage the conduct of scientists who are granted permission to do research in Kuna territory. The Kuna established the Project for the Study of Wildlife Areas of Kuna Yala (PEMASKY) in 1983 to establish and manage a forest preserve. The project includes research conducted by non-Kuna scientists from Panama and abroad. The Smithsonian Tropical Research Institute (STRI) in Panama tried to ensure that the scientists they sponsored did not enter local communities without permission and that they understood their responsibility to keep the Kuna informed about their activities, through reports and animal and plant specimens. In 1988 the Kuna produced a manual of information for researchers, "Research Program: Scientific Monitoring and Cooperation." It establishes guides for conduct, how to obtain permission to enter an area, and encourages the scientists to utilize local Kuna assistants with a view toward transfer of knowledge and technology. Researchers are asked to provide copies of publications about research conducted on the Kuna territory.

[282] *See* Recommendation, *supra* note 208, at subsection E(g).

APPENDIX

Revised 9/3/91

DEVELOPMENTAL THERAPEUTICS PROGRAM
DIVISION OF CANCER TREATMENT
NATIONAL CANCER INSTITUTE

Letter of Intent

The Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI) is currently investigating plants, marine macro-organisms and microbes as potential sources of novel anticancer and AIDS-antiviral drugs. The DTP is the drug discovery program of NCI which is an institute of the National Institutes of Health supported by the United States Government. While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation of biological diversity, and recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders.

As part of the drug discovery program, DTP has contracts with various organizations for the collection of plants and marine macro-organisms worldwide. DTP has an interest in investigating "name of organisms" from "name of country", and wishes to collaborate with "country organization" in this investigation. Such a collaboration will be within the framework of the collection contract between NCI and "collection contractor".

The role of DTP, DCT, NCI in the collaboration will include the following:

1) DTP will screen the extracts of all "name of organisms" provided from "country" for anticancer and AIDS-antiviral activity, and will provide the test results to "country organization" as soon as they are available. Such results will be channelled via "collection contractor".

2) The test results will be kept confidential by all parties, with any publication delayed until DTP has an opportunity to file a patent application in the United States of America on any active agents isolated.

3) Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compound(s) responsible for the observed activity. Since the relevant bioassays are only available at DTP/NCI, such fractionation will be carried out in DTP/NCI laboratories.

4) Subject to the provision that suitable laboratory space and other necessary resources are available, DTP/NCI agrees to invite a senior technician or scientist designated by "country organization" to work in the laboratories of DTP/NCI or, if the parties agree, in laboratories using technology which would be useful in further work under this agreement. The duration of such a visit would not exceed one year except by prior agreement between "country organization" and DTP/NCI. The designated Guest Researcher will be subject to provisions usually governing Guest Researchers at NIH. Salary and other conditions of exchange will be negotiated in good faith.

5) In the event of the isolation of a promising agent from a "name of organism" collected in "country", further development of the agent will be undertaken by DTP/NCI.

6) DTP/NCI will, as appropriate, seek patent protection on all inventions developed under this agreement by NCI employees alone or by NCI and "country organization" employees jointly, and will seek appropriate protection abroad.

7) All licenses granted on any patents arising from this collaboration shall contain a clause referring to this agreement and shall indicate that the licensee has been apprised of this agreement.

8) Should the agent eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI, in consultation with "country organization", will make its best effort to negotiate with the company for inclusion of terms in the licensing agreement requiring payment of a percentage of royalties accruing from sales of the drug, to "country organization" and/or groups and individuals of the country who have provided material and information.

9) Such terms shall apply equally to instances where the invention is the actual isolated natural product, or where the invention is a product structurally based on the isolated natural product (ie. where the natural product provides the lead for development of the invention), though the percentage of royalties negotiated as payment might vary depending on the nature of the drug being licensed.

10) In obtaining licensees, the DTP/NCI will require the applicant for license to seek as its first source of supply the natural products available from "country". If no appropriate licensee is found who will use natural products available from "country", or if "country organization" or its suppliers cannot provide adequate amounts of raw materials, the licensee will be required to pay to "country organization" an amount of money (to be negotiated) to be used

for expenses associated with cultivation of medicinal plant species that are endangered by deforestation, or for other appropriate conservation measures.

11) Sections 7-10 shall not apply to organisms which are freely available from different countries (e.g., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g. medicinal, pesticidal) was provided by local residents to guide the collection of such an organism from their country, or unless other justification acceptable to both the "country organization" and DTP/NCI is provided. In the case where an organism is freely available from different countries, but a genotype producing an active agent is found only in "name of country," sections 7-10 shall apply.

12) DTP/NCI will test any pure compounds submitted by "country organization" scientists for antitumor and AIDS-antiviral activity, provided such compounds have not been tested previously in the NCI screens. If significant antitumor or AIDS-antiviral activity is detected, further development of the compound and investigation of patent rights will, as appropriate, be undertaken by DTP/NCI in consultation with "country organization".

Should the agent eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI, in consultation with "country organization", will make its best effort to negotiate with the company for inclusion of terms in the licensing agreement requiring payment of a percentage of royalties accruing from sales of the drug to "country organization".

13) DTP/NCI may send selected samples to other organizations for investigation of their anticancer, anti-HIV or other therapeutic potential. Such samples will be restricted to those collected by NCI contractors unless specifically authorized by the country organization. Any organization receiving samples must agree to compensate the source country organization and individuals, as appropriate, in the same fashion as is described in sections 8-10 above, notwithstanding anything to the contrary in section 11.

The role of "country organization" in the collaboration will include the following:

1) "Country organization" will collaborate with "collection contractor: in the collection of "name of organisms", and will work with "collection contractor" to arrange the necessary permits to ensure the timely collection and export of materials to DTP/NCI.

2) Should "country organization" have any knowledge of the medicinal use of any "name of organisms" by the local population

or traditional healers, this information will be used to guide the collection of such organisms on a priority basis where possible. Details of the methods of administration (e.g. hot infusion, etc.) used by the traditional healers will be provided where applicable to enable suitable extracts to be made. All such information will be kept confidential by DTP until both parties agree to publication. The permission of the traditional healer or community will be sought before publication of their information, and proper acknowledgment will be made of their contribution.

3) "Country organization" and "collection contractor" will collaborate in the provision of further quantities of active raw material if required for development studies.

4) In the event of large amounts of raw material being required for production, "country organization" and "collection contractor" will investigate the mass propagation of the material in "country". Consideration should also be given to sustainable harvest of the material while conserving the biological diversity of the region, and involvement of the local population in the planning and implementation stages.

5) "Country organization" scientists and their collaborators may screen additional samples of the same raw materials for other biological activities and develop them for such purposes independently of this agreement.

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Name (Signature)

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Name (Print or type)

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Title

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Institution or Agency

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Director, National Cancer Institute

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