Buffalo Journal of International Law

Volume 2 | Number 1 Article 4

4-1-1995

Chemical Prospecting, Biodiversity Conservation, and the Importance of International Protection of Intellectual Property Rights in Biological Materials

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CHEMICAL PROSPECTING, BIODIVERSITY CONSERVATION, AND THE IMPORTANCE OF INTERNATIONAL PROTECTION OF INTELLECTUAL PROPERTY RIGHTS IN BIOLOGICAL MATERIALS

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CHEMICAL PROSPECTING, BIODIVERSITY CONSERVATION, AND THE IMPORTANCE OF INTERNATIONAL PROTECTION OF INTELLECTUAL PROPERTY RIGHTS IN BIOLOGICAL MATERIALS

I. INTRODUCTION

A. *The Demand for Chemical Prospecting*

We are entering an era that has been termed as a "green revolution" in which novel chemical compounds extracted from natural sources will dramatically improve our quality of life by revolutionizing health and agriculture.[2] This era will also be marked by what some feel is the greatest loss in human history — the extinction of many of the species that could fuel this green revolution.[3]

Scientists estimate that there are between 5 and 30 million species of living organisms on Earth.[4] About half of these species are located in tropical rain forests, which collectively constitute a mere 7% of the Earth's land surface.[5] These forests are quickly being converted to other land uses, and as

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[2] John Vidal, *The Gene Rush*, TORONTO STAR, July 10, 1993, at D6.

[3] Harvard biologist and conservationist Edward O. Wilson said in 1980 that "the worst thing that can happen . . . is not energy depletion, economic collapse, limited nuclear war, or conquest by a totalitarian government. As terrible as these catastrophes would be for us, they can be repaired within a few generations. The one process ongoing in the 1980s that will take millions of years to correct is the loss of genetic and species diversity by the destruction of natural habitats. This is the folly our descendents are least likely to forgive us." *quoted in* PAUL and ANNE EHRLICH, EXTINCTION: THE CAUSES AND CONSEQUENCES OF THE DISAPPEARANCE OF SPECIES 3 (1981).

[4] *See* Edward O. Wilson, *The Current State of Biological Diversity*, *in* BIODIVERSITY, 5 (E.O. Wilson ed., 1988). Of these, only about 1.4 million species have actually been described. *Id.*

[5] *Id.* at 8.

they disappear, so does the biological diversity (biodiversity) that they contain.[6]

Biodiversity is usually defined as "the total of genes, species and ecosystems on Earth" or some more elaborate version of this definition.[7] Non–biological definitions of biodiversity are rare, however; possibly reflecting the public's perception of biodiversity as something which exists apart from man's use. Rather than a scientific unit, biodiversity can alternatively be seen as an exploitable resource; just as gold, for example, can be seen as both a chemical element and as a valuable metal which has many aesthetic and productive uses.[8] Speaking of biodiversity as "living, exploitable, renewable resources" helps to highlight the ample economic value

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[6] One estimate figures that roughly 1% of the biome, all living organisms on the Earth, is being destroyed each year, with an additional 1% being severly degraded, leading to the extinction of as many as 10,000 species each year. *See* Norman Myers, *Tropical forests and their species: Going, Going . . . ?, in* BIODIVERSITY, 29, 30 (E.O. Wilson ed., 1988). Another source estimates that about 25% of all species could be lost in the next several decades. This source also notes that extinction is a natural process, but that the current anthropogenic extinction rate is 1,000 times the natural rate of extinction. *See* Peter H. Raven, *Our Diminishing Tropical Forests, in* BIODIVERSITY, 121 (E.O. Wilson ed., 1988).

[7] *See* JEFFREY A. MCNEELY ET AL., CONSERVING THE WORLD'S BIOLOGICAL DIVERSITY, International Union for Conservation of Nature and Natural Resources, World Resources Institute, Conservation International, World Wild life Fund–US and the World Bank 11 (1990). The UNCED Convention on Biological Diversity defines biological di versity as "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems." art. 2, 31 I. L. M 818 (1992).

[8] The International Union for Conservation of Nature and Natural Resources (IUCN) has defined biodiversity as simply "living resources" in IUCN, *World Conservation Strategy: Living Resource Conservation for Sustainable Development*, Gland, Switzerland: IUCN (1980). The UNCED Convention on Biological Diversity distinguishes "bio logical diversity" from "biological resources," *see* art. 2, 31 I.L.M. 818 (1992).

of biodiversity and its potential consumptive and transformative uses.[9]

Biodiversity has received a great deal of attention in recent years as a vast resource in the search for new and useful pharmaceutical products.[10] Plants and plant extracts have been used throughout history for their medicinal applications. Today, developing countries rely on plant– derived medicines for 85% of their health care needs.[11] In the U.S., it is estimated that 25% of all prescription drugs dispensed from community pharmacies contain chemicals

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[9] There is abundant literature on the economic value and uses of biodiversity, including pharmaceutical use: *see* Norman R. Farnsworth, *Screening Plants for New Medicines,in* BIODIVERSITY, 83 (E.O. Wilson ed., 1988); *see also* Marjory L. Oldfield, *The Value of Conserving Genetic Resoures*, Washington: U.S. Department of Interior, Na tional Park Service (1984); agriculture: Hugh H. Iltis, *Serendipity in the Exploration of Biodiversity: What Good Are Weedy Tomatoes?, in* BIODIVERSITY, 98 (E.O. Wilson ed., 1988); Mark J. Plotkin, *The Outlook for New Agricultural and Industrial Products from the Tropics, in* BIODIVERSITY, Chap. 11 (E.O. Wilson ed., 1988); and other utilitarian benefits; NORMAN MYERS, THE SINKING ARK: A NEW LOOK AT THE PROBLEM OF DISAPPEARING SPECIES, (1979). For a discussion of the non–utilitarian, aesthetic, ethical and philosophical value of biodiversity, *see* THE PRESERVATION OF SPECIES: THE VALUE OF BIOLOGICAL DIVERSITY, (Bryan G. Norton, ed., 1986) and BRYAN G. NORTON, WHY PRESERVE NATURAL VARIETY? (1987).

[10] Probably the most widely publicized pharmaceutical discovery from a natural source is the alkaloids *vincris tine* and *vinblastine* which were extracted from the Madigascar rosy periwinkle and have provided an effective cure for Hodgkin's disease and acute lymphocytic leukemia. The value of this discovery is estimated at $200 million a year. An other remarkable discovery is *cyclosporine* which was extracted from a Norwegian fungus and is used as the principal immunosupressent in organ transplant operations. Edward Wilson states that "millions of years of testing by natural se lection have made organisms chemists of superhuman skill, champions at defeating most of the kinds of biological prob lems that undermine human health." *See* EDWARD O. WILSON, THE DIVERSITY OF LIFE, at 320 (1992).

[11] This figure is for medicinal products directly extracted from plants. N.L. Farnsworth , et al., *Medicinal Plants in Therapy*, 63 BULL. WORLD HEALTH ORGANIZATION 695 (1985).

directly extracted from plants.[12] All of these chemicals are derived from a mere 90 species of plants; the rest of the 250,000+ species of higher plants on Earth are untapped for their potential medicinal value.[13]

In agriculture, genetic discoveries have dramatically improved many crop varieties. The production of corn has been revolutionized by the discovery of a species of perennial maize that is immune to two serious viral diseases affecting its cultivated relative.[14] The benefits of a perennial corn crop would dramatically increase the productivity of corn growers and help to feed more people less expensively throughout the world. The potential applications of chemical prospecting and biotechnology to agriculture, as well as to industry, are almost limitless, making biodiversity our greatest natural resource.

The vast resource of biodiversity is generally perceived as a public good. As such, it is seen as indivisible, with a constant amount of public benefit available to all, independent of any single person's consumption. As a public good, biodiversity is also seen as nonexcludable, with no one individual being able to prevent others from consuming this resource. Because one can consume as much biodiversity as one wishes without being excluded by others, there is little incentive to contribute to the conservation of biodiversity. When contributions are made to the conservation of biodiversity by one person, another can merely take a "free ride" on this contribution without having to contribute themselves. The incentive is to wait around for others to pay for what you consume and the result is that the conservation of biodiversity is underprovided and inefficient. This phenomenon is commonly referred to as "market failure."

A market for biodiversity can and does exist. The effectiveness of this

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[12] Farnsworth, *supra* note 8, at 83. Farnsworth presents a chart listing all 119 pure chemical substances ex tracted from higher plants that he has identified as in common use throughout the world. Forty six of these have never been used in the U.S. *See id.* at 84.

[13] *Id.* at 92. Estimates place the number of species of higher plants between 250,000 and 750,000. Probably the most extensive search for medicinal chemicals was conducted by the National Cancer Institute in the U.S. which has screened 35,000 of these species for potential anti–cancer properties. *Id.*

[14] *See* Oldfield, *supra* note 8.

market depends on the degree of protection afforded to property rights in biodiversity. One of the most effective ways of establishing property rights in biodiversity is the protection of intellectual property rights (IPRs) in the genetic, chemical and biological materials that constitute biodiversity. "[I]f those who control a habitat hold proprietary rights to develop its biological resources, then they have a means for obtaining economic benefits from those resources, and, consequently, an incentive to conserve rather than destroy them."[15]

Chemical prospecting has emerged as a means of capturing the value of biodiversity. Dr. Thomas Eisner of Cornell University coined the term "chemical prospecting" and defined it as "the search for new medicinals, agrochemicals, and other substances of use from animal, plant, and microbial sources."[16] In order to capitalize on the fruits of chemical prospecting, large investments in research and development must be made to produce marketable products. Such investments will not be made, however, unless they can be protected and the company sowing the seeds can also reap the harvest.

Thus, pharmaceutical and biotechnology companies will be unable and unwilling to establish contracts for chemical prospecting without adequate protection of their IPRs in any products that result from that process.[17] When IPRs are inadequately protected, grave financial consequences are suffered by

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[15] Michael A. Gollin, *An Intellectual Property Rights Framework for Biodiversity Prospecting*, *in* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT, 130 (Walter V. Reid et al. eds., 1993).

[16] Thomas Eisner, *Chemical Prospecting*, Abstract of a talk given at the U.S. Economic Opportunities in Global Environmental Agreements Conference, Smithsonian Institution, Washington, D.C., March 6–7, 1992. The term "chemical prospecting" probably first appeared in Thomas Eisner, *Prospecting for Nature's Chemical Riches*, 6(2) IS SUES IN SCI. & TECH. 31 (1989).

[17] Elissa Blum in her article states that R. Wilder, in a personal communication on Oct. 30, 1992, told the au thor of an article in Environment magazine that ". . . [the biotech industry] depends upon having strong intellectual prop erty protection to develop new technologies . . . and, once it's developed, to transfer it or to otherwise make use of it." Elissa Blum, *Conservation Profitable: A Case Study of the Merck/INBio Agreement*, 35(4) ENV'T 17, 44.

the owner of the IPRs. Besides losing much of the value of the initial investment made to produce a marketable product, companies lose royalties and sales of the product abroad or for export abroad. Profits are also lost to piracy when foreign corporations sell counterfeit products abroad or import the illicit products into the U.S.[18] Thus, the international protection of IPRs is a matter of critical importance to U.S. corporations, whether seeking chemical prospecting opportunities or any other market. This became evident when the protection of biotechnology patent rights was a major barrier to U.S. ratification of the Convention on Biological Diversity.[19]

Where international and domestic protection of IPRs is inadequate, there is an alternative. Pseudo–IPRs can be established by creating a contract that internalizes the external effects of a lack of IPR protection.[20] Such a contract was concluded in 1991 by Costa Rica's National Biodiversity Institute

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[18] Some sources estimate this loss at $25 billion annually, or more. Solomon F. Balraj, Note, *General Agree ment on Tariffs and Trade: The Effect of the Uruguay Round Multilateral Trade Negotiations on U.S. Intellectual Property Rights*, 24 CASE W. RES. J. INT'L L. 63, 66 (1992).

[19] Timothy Wirth, the State Department's counselor for global affairs was quoted as saying that "the Clinton administration will have to convince the Senate that biotechnology patent rights will be protected before the Senate con sents to ratification of the biodiversity treaty." *Wirth Says Test for IPR Protections Will be Ratification of Biodiversity Pact*, 10 Int'l Trade Rep. (BNA) 1530 (Sept. 15, 1993). *See also*, PTO, *Biotech Group Explain Objections to Earth Summit's Biodiversity Treaty*, 44 Pat. Trademark & Copyright J. (BNA) 120 which argues that the U.S.'s refusal to sign the biodiversity treaty was influenced by the opposition of the Patent and Trademark Office which saw the treaty as po tentially undermining the U.S. efforts in the Uruguay round of the GATT negotiations to secure greater international pro tection of intellectual property. When the U.S. signed the treaty in May, 1992, it noted that it finds the provisions for protection of intellectual property rights to be "unsatisfactory." United States: Declaration Made at the United Nations Environment Programme Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, 31 I.L.M. 848 (1992).

[20] Ronald Coase suggested that negotiation among affected parties can internalize the costs of externalities if the transaction costs are low enough. Ronald H. Coase, *The Problem of Social Cost*, 4 J. L. & ECON. 1 (1960).

(*Instituto Nacional de Biodiversidad* (INBio)) and Merck & Co., Ltd., the world's largest pharmaceutical firm, achieving what neither international nor domestic law had been able to do— protect property rights, development concerns and biodiversity, all at the same time.[21]

B. *The Merck/INBio Agreement*

This contract — the most widely publicized and successful chemical prospecting agreement concluded to date — provided Merck with access to chemical extracts and other biological materials collected by INBio for drug screening and other research, in exchange for over $1 million paid in advance to INBio as well as an agreement to pay royalties on all commercial drugs and products developed by Merck from research facilitated by INBio.[22] In addition, INBio agreed to dedicate 50% of all royalties received from Merck, and 10% of its budget, to conservation of the wildlands that are used for its chemical prospecting, and Merck agreed to train INBio scientists and parataxonomists.

The Merck/INBio agreement was finalized at a strategic time — during the final rounds of negotiations at the "Earth Summit" and the Convention on Biological Diversity. At the time, there were no real precedents to the agreement that paralleled its scope, purpose, formality and commitment to conservation. Yet, at the same time, over 150 nations were agreeing to develop national legislation and policy to encourage just such agreements. A model would be highly useful and was desperately needed and the Merck/INBio agreement played just this role, with the world-wide media bringing this timely and groundbreaking partnership to people's attention. Several other nations were, at the same time, working on similar agreements, and the Merck/INBio agreement influenced them, as it will continue to

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[21] *See* Thomas Eisner and Elizabeth A. Beiring, *Biotic Exploration Fund— Protecting Biodiversity Through Chemical Prospecting*, 44(2) BIOSCI. 95, 97 (1994).

[22] For a brief discussion of the Merck/INBio Agreement, *see* Blum, *supra* note 16.

influence future biodiversity prospecting agreements that will inevitably follow.[23]

It is no coincidence that INBio developed in Costa Rica and that Merck chose INBio for its collaborative research. Costa Rica has a unique political, social and economic environment that provides the stability, resources and security necessary to make such an investment worth pursuing. Costa Rica is also biologically rich, harboring more species per hectare than any other nation on Earth. More than 10% of Costa Rica's land is protected in one of the world's most successful national park systems.

II. OVERVIEW OF THE CHEMICAL PROSPECTING PROCESS AND FRAMEWORK

There are two basic legal frameworks for establishing a chemical prospecting arrangement. The first of these is an international contract which specifically delineates the rights and obligations of each party, protecting all parties to the contract with some legal remedy in the event the contract is breached. The second is a collection and research permit which can provide benefits to both the stewards and users of wildlands, ensuring fair and sustainable use, without the complexity, formality and obligations of a contract.

Chemical prospecting contracts have two primary parties— the collector and the prospector. The prospector is most often a pharmaceutical or biotechnology company that is interested in screening biological samples for potentially useful chemicals. The collector supplies these biological samples, often first performing basic taxonomic and preparatory work before shipping

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[23] Japan has worked out a biodiversity research program with Micronesia, and Indonesia and Kenya are both developing biodiversity research facilities similar to INBio. *See* WALTER V. REID ET AL., *A New Lease on Life*, *in* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT, 2 (Walter V. Reid et al. eds., 1993). Many developing countries such as China, Chile, Mexico, India, Indonesia, Nepal and Nicaragua have been studying the INBio model with hopes of establishing similar operations in their respective countries. *See also* Blum, *supra* note 16, at 42.

the samples to the prospector. Other interested parties who may benefit from inclusion in chemical prospecting contracts, or the formation of separate contracts, are the national government of the prospecting site, local communities, and auxiliary collectors assisting the larger collecting institution. The role of each of these parties is critical to the chemical prospecting process.

The collection process begins in the field with the identification and harvesting of biological materials, including plants, bark, roots, insects, microörganisms and other materials.[24] The collection process is not random, as scientists and researchers know that certain phylogenetic groups are richer in certain types of chemicals, thus prioritizing them in the collection process.[25] Extracts are usually prepared in the laboratory from the original biological materials. The extracts are solutions containing all the chemicals found in the natural product without the bulk of fiber and water.

The most important part of the chemical prospecting process takes place in the laboratory. Here, extracts are screened for biologically active and pharmacologically useful compounds. The screening process has been revolutionized by the development of automated receptor– based screening techniques that increase the screening process by hundreds of times.[26] This

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[24] While the source of new chemicals in the chemical prospecting process is normally a plant or in sect, every phylogenetic group has emerged as demonstrating promise as a rich genetic resource — even many familiar and well–known groups such as birds. The October 30, 1992 issue of SCIENCE described the discovery of the first known poisonous bird, the Pitohui of New Guinea, which contains the toxin homobatrachotoxin in its flesh and on its feathers. This is the same toxin produced by poison–dart frogs and is similar to known de fenses of many insects, reptiles, amphibians and fish. It is a neurotoxin hundreds of times more toxic than strychnine and has numerous potential applications. Natalie Angier, *Rare Bird Indeed Carries Poison in Bright Feathers*, N.Y. TIMES, Oct. 30, 1992, at A1.

[25] *See* Andrew Beattie, *Discovering New Biological Resources – Chance or Reason?* 42 BIOSCI. 290 (1992) (describing the process of "biorational deduction.").

[26] One source describes the receptor–based screening process: "Common targets for drug developers are re ceptors, molecules on the exterior of or inside cells to which other molecules attach, triggering specific changes. Once a gene for a receptor is located, the receptor can be cloned and mass–produced. These receptors become targets that are exposed to new compounds in the screening process. If a compound,

increases the feasibility and profitability in the search of thousands of chemicals that must be screened before finding the few useful chemicals needed.

Parataxonomists and indigenous collectors play a significant role in the chemical prospecting process. With limited funds and time, efficient collecting draws upon the resource of local and rural populaces to assist in the field and laboratory. These individuals living near the prospecting site are hired and trained to collect specimens for screening with minimal supervision, supplies and training. Basic natural science courses are taught to parataxonomists, such as entomology, botany, herpetology, etc., as are basic applied courses in collection and preparation techniques, taxonomy and relevant chemistry. Practical skills are also taught as necessary, such as operation of basic machinery, maps, computers and field guides. The objective of the parataxonomists is to inventory the biota of an entire area surrounding a prospecting site. A beneficial side effect of parataxonomy is to increase local awareness of biodiversity, and its study and conservation.

Collection and research permits allow basically the same process as chemical prospecting contracts. They differ, however, in their specificity and function. Rather than privately negotiated contracts, governments can issues collection permits to specific prospectors for a specified amount of time for the extraction of specified types of information. Research permits also determine exactly how the information is to be used and controlled.[27]

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be it synthesized or extracted from a plant, insect, or microorganism, binds to the target, it could be pharmacologically valuable. So it is selected for further testing. Other biochemical targets are enzymes, which catalyze reactions and can be inhibited by alkaloids and other plant com pounds." Christopher Joyce, *Western Medicine Men Return to the Field,* 42 BIOSCI. 399 (1992).

[27] *See* Daniel H. Janzen et al., *Research Management Policies: Permits for Collecting and Research in the Tropics, in* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT, 131 (Walter V. Reid et al. eds., 1993).

III. THE ROLE OF IPRs IN CHEMICAL PROSPECTING

A. *Incentives for Invention and Innovation*

The United States Constitution grants Congress the power to create IPRs to "promote the Progress of Science and useful Arts."[28] The intent is to offer a reward and economic incentive for the creation of useful innovation that furthers the "prior art" and that may inspire further innovation.[29] The incentive offered is "the right to exclude others from making, using, or selling the invention throughout the United States."[30] This exclusive right is granted for a period of twenty years to the patentee and his heirs or assigns.[31]

Chemical prospecting is an investment–intensive enterprise. The facilities required to study potential discoveries include laboratories, advanced equipment and highly trained personnel usually found only in developed nations. Without adequate IPR protection, investment necesssary to support chemical prospecting may never take place, and the inventive process would not get off the ground.

The chemical prospecting process only begins with discovery and invention. It is a much more intensive process to produce and prepare the invention for practical commercial use. An incentive is necessary, after the

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[28] U.S. CONST. art. I,§ 8, cl. 8. *See also,* Grant v. Raymond, 31 U.S. (6 Pet.) 218 (1832) (Chief Justice Mar shall arguing that the purpose of the patent statute is to foster invention.).

[29] *See* Mazer v. Stein, 347 U.S. 201, 219 (1954) ("The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in 'Science and useful Arts.' Sacrificial days devoted to such creative activities deserve rewards commensurate with the services rendered."), *reh'g denied,* 347 U.S. 949 (1954).

[30] United States Patent Act, 35 U.S.C. §154 (1988).

[31] The patent term under the orginal patent act was seventeen years. *Id.* The World Trade Organization Agree ment (resulting from the Uruguay Round of the GATT Talks) caused the patent term to be extended to "20 years from the date on which the application for the patent was filed in the United States," as of June 8, 1995. Dec. 8, 1994, Pub.L. 103–465, Title V,§ 532(a)(1), 108 Stat. 4983 (1994).

issuance of the patent, to promote the development and application of new technologies during the patent term.[32] The monopoly conditions created by the patent can be the best means of achieving this.[33]

Competition can suppress innovation by creating a number of uncertainties and unfavorable conditions. Competition can place prohibitive constraints on the time, resources and financial commitments necessary to successfully invest in innovative and developmental research.[34] The stability and inflated rent[35] resulting from the grant of a period of exclusive rights can finance and stimulate the significant investment involved in developing and marketing biodiversity.

One theory of post–invention innovation notes that, "while information may be used without exhausting it, resources available to use information are scarce, and property rights in inventions can improve the efficiency with which these resources are managed."[36] The transfer of technology, for instance, is facilitated with greater IPR protection, reducing the amount of duplicative research. There is little cost or risk involved in sharing information with potential competitors, as their use of the information is limited to purely

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[32] *See* Rebecca S. Eisenberg, Article, *Patents and the Progress of Science: Exclusive Rights and Experimen tal Use*, 56 U. CHI. L. REV. 1017, 1037 (1989).

[33] The work of Joseph Schumpeter elucidated the advantages of monopoly conditions, created by a patent, over competition in promoting technological innovation. *See id.* at 1039.

[34] *Id.*

[35] In a competitive market, prices are set at the point at which marginal cost equals marginal benefit (the point at which the supply curve and demand curve intersect). When one supplier is able to monopolize or dominate the market, however, the single supplier supplies the good at the point at which marginal cost equals marginal revenue (as opposed to demand or marginal benefit). The monopolist is able to restrict supply and inflate prices over the efficient, competi tive allocation, capturing greater rent and maximizing his surplus at the expense of social benefit.

[36] Eisenberg, *supra* note 31, at 1040, (discussing the "Prospect Theory" as presented by Edmund Kitch.) *See also* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 265 (1977). The Prospect Theory analogizes the function of patent monopolies to exclusive mineral claim awards granted by the U.S. government.

experimental use.[37] Any other uses of the patented information require the payment of royalties to the inventor, who is usually more than happy to capture this value.

B. *Incentives for Conservation*

The justification for chemical prospecting is based on its utility as a device for preserving the biodiversity that fuels it.[38] The discovery of a valuable biological resource, however, can potentially lead to disaster. Like gold prospectors rushing to tear down a mountain at the first yell of "Gold!," chemical prospectors will surely rush to capture the value of rare chemical discoveries. Without adequate protection of IPRs in a genetic discovery, there is little incentive to conserve the wild stock of a species. The natural result is an open-access resource and the only issue is how to collect, extract and sell the valuable natural product before others do the same. This can lead to destructive extractive practices, sometimes even causing the eradication of the source of the natural product.[39]

IPRs can provide some protection from such destruction. If the fruits of extensive research, development, improvement and study can be enjoyed, then these activities will take place. There are several benefits of this technological development. First, synthetic versions of the natural product can be developed in the laboratory, reducing the need for direct extraction of the natural product

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[37] While there is no specific provision for experimental use in the United States Patent Act, 35 U.S.C. §§ 1–376 (1988), the courts have consistently recognized the legitimacy of strictly experimental use of a patented invention. *See* Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F2d 858 (1984); Eisenberg, *supra* note 31.

[38] *See* Thomas Eisner, *Prospecting for Nature's Chemical Riches*, 6(3) ISSUES IN SCI. & TECH. 30 (1990).

[39] A mission sponsored by the U.S. National Cancer Institute to Kenya collected 27,215kg of Maytenus buchananni for extraction of the anti-cancer compound maytansine, eliminating the entire adult population of Maytenus buchananni. *See* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT, 3 (Walter V. Reid et al. eds., 1993).

and collection of its source.[40] Second, biotechnology development is a dynamic process, and even the best studied and most highly refined biological resources, such as crop plants, are perpetually being genetically altered and improved by hybridization with wild stock or relatives.

A major benefit of chemical prospecting is the cataloging and description of species that it will promote. Many scientists feel that the starting point of biodiversity conservation is knowing what is out there to conserve.[41] Unfortunately, we know very little about the total number of species in nature, and even for those species which we've discovered, little more is known about them than superficial anatomical description and the scientific name assigned to them.[42] In the search for the few jewels among species, hundreds of thousands of species will be described, catalogued and possibly even studied along the way. Such a biological inventory of the world's biodiversity will aid in developing the theoretical and factual background for biodiversity conservation strategies.

Chemical prospectors are attracted to locations where biodiversity is in its greatest concentration and where there are high degrees of endemism.[43] This involves chemical prospectors in the efforts to identify and conserve such areas, particularly those areas threatened by development or destruction, commonly referred to as "hotspots."[44] The work of chemical prospectors will

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[40] The Pacific Yew, for example, was being collected in great volumes for extraction of the anti-cancer drug camptothecin, and there were worries about the survival of the species in the wild, until the U.S. National Cancer Insti tute developed a synthetic version of camptothecin in the laboratory, reducing the need to collect Yew bark in the wild. *Rain Forests Can Supply Many Important Drugs,* 55(6) BETTER NUTRITION FOR TODAY'S LIVING 28 (1993).

[41] *See* Martha Rohas, *The Species Problem and Conservation: What are We Protecting?*, 6 CONSERVATION BIOLOGY 170 (1992).

[42] *See* Wilson, *supra* note 9, at 132. Wilson states that this is the case for 99% of known species.

[43] Endemism is often presented as the percentage of species in a defined area, local, regional or national, that occur only in that location.

[44] This term was initiated by Dr. Norman Myers, international consultant on environment and development, and was intended to prioritize sites in greatest need of protection based on both the amount of biodiversity and the severety of the threat to

often take place at these hotspots of diversity, adding recognition and political significance to the sites. Additionally, under an ideal chemical prospecting contract, royalties will be paid from the profits made from biological samples obtained at a particular site to governments or organizations in a position to protect those sites but which lack adequate funding.[45] Thus chemical prospecting proceeds along a highly rational and scientifically prudent system.

C. *Incentives for Public Disclosure*

Many of the arguments in favor of biotechnology research are motivated by a concern for human welfare. The Human Genome Project, for instance, will involve fifteen years of intensive genetic research and over three billion dollars.[46] The justification for this massive project is based primarily on its value in identifiying and eradicating human disease. Most of the research necessary to accomplish this goal must take place *after* the genetic code is revealed by the Human Genome Project research. This necessitates making the data acquired by the project available to the international scientific community.[47] To do otherwise would undermine efforts to attain the very

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its preservation at that location. Norman Myers, *Threatened Biotas: "Hotspots" in Tropical Forests*, 8 ENVIRONMENTALIST 1 (1988).

[45] Sarah A. Laird, *Contracts for Biodiversity Prospecting*, *in* BIODIVERSITY PROSPECTING: USING GENETIC RE SOURCES FOR SUSTAINABLE DEVELOPMENT, 108 (Walter V. Reid et al. eds., 1993). Laird states that "A royalty reflects the value of the biological and intellectual informatoin provided by a collector, balanced by the relative amount of intel lectual and financial investment a company must make to develop a useful product," *Id.* at 112.

[46] The Human Genome Project is a massive project of the U.S. government to map the location and actual nucle otide sequence (genetic code) of each gene in human somatic cells. Each human somatic cell contains twenty–three pairs of chromosomes and some 100,000 genes, composed of some three billion nucleotide pairs. Leslie Roberts, *Report Card on the Genome Project*, 253 SCI. 376 (1991).

[47] The data acquired by the Human Genome Project are placed in three public databases and are available to the international scientific community. *See* Catherine M. Valerio Barrad, *Genetic Information and Property Theory*, 87 NW. U. L. REV.

results the project was established to achieve.

Public disclosure of new information is a fundamental justification for the U.S. patent system.[48] Under this system, an inventor is granted a monopoly of limited duration on the production, use and sale of the invention.[49] As a quid pro quo for this reward, an inventor is required to disclose a specification of the invention, including information which fully describes the invention, the "manner and process of making and using it," and the "best mode contemplated by the inventor of carrying out his invention."[50] The information disclosed can then be made available to other inventors to improve the invention, create new inventions and advance technology further.

In satisfying the disclosure requirements of 35 U.S.C. § 112, it is often necessary to deposit biological materials with the regional facility designated by the Budapest Treaty.[51] This is highly significant in regard to biodiversity research which typically deals with species that are previously unknown and undescribed. The written description is not enough for taxonomic purposes which generally require type specimens to be deposited before the classification will be recognized by the international scientific community. Even more significant is the availability of living samples of the species to researchers who wish to "carry out the best mode" of creating the invention, which may be impossible if the species is obtained from nature.[52]

1037, 1043 (1992).

[48] Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989).

[49] *See supra* note 29.

[50] United States Patent Act, 35 U.S.C. § 112 (1988). The written description must be "in such full, clear, con cise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly con nected, to make and use the same." *Id.*

[51] *See* Sheryl Rubinstein Silverstein, Note, *Biotechnology Patents And The Deposit Requirement: Removing Uncertainty After Agmen v. Chugai Pharmaceutical.* 66 S. CAL. L. REV. 937 (1993).

[52] The Federal Circuit upheld a decision of the Patent Office in Agmen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1210, *cert. denied*, 502 U.S. 856 (1991) (reaffirming the necessity of depositing biological materials ob tained from nature, but deciding that when "the organism is created by insertion of genetic material into a cell

D. *Rewarding the Creation of Commercial and Social Value*

In *Mazer v. Stein*, the Supreme Court indicated that the creation of social value resulting from the investment of labor and creativity is deserving of a reward in the form of property rights.[53] Chemical prospecting is a highly technical, complex, time consuming, labor–intensive and expensive process, but the products of this process save lives, make lives more enjoyable, and generally increase human welfare. Thus, the investment of these efforts is highly justified by the potential value that can be created, and sufficient IPR protection rewards those who create this value by giving them a stake in it.

It is estimated that the value of prescription drugs with active ingredients derived from plants exceeds $15 billion in the United States alone.[54] The value of all prescription and over–the– counter drugs derived from plant sources in the developed world is probably more than $50 billion annually.[55] Farm–level sales of agricultural biotechnology have been projected to be as high as $100 billion annually by the year 2000.[56]

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obtained from generally available sources, then all that is required is a description of the best mode and an adequate description of the means of carrying out the invention, not deposit of the cells.") *Id.* at 1211. The relaxed standard for genetic engi neering of organisms means that a great deal of effort will need to be expended by researchers merely to reproduce the existing patent, having to "reinvent the wheel" as some critics argue. *See* Silverstein, *supra* note 50, at 950.

[53] *See supra* note 28, at 218.

[54] *See* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT, 7 (Walter V. Reid et al. eds., 1993).

[55] In 1985, one source estimated this figure to be $43 billion. Inflation and incresed sales makes $50 billion a likely underestimate of this statistic. Peter Principe, *The Economic Significance of Plants and Their Constituents as Drugs*, 3 ECON. AND MEDICINAL PLANT RES. 1, 1–17 (H. Wagner et al. eds., 1989). Developed countries, for the pur poses of this statistic are: all European nations, Japan, Australia, Canada and the United States. *Id.*

[56] *See World Bank, Agricultural Biotechnology: The Next Green Revolution?*, World Bank Technical Paper No. 133 (1991).

Many other uses for chemical and genetic discoveries in nature, besides pharmaceuticals and agricultural biotechnology products, have been patented. This includes numerous industrial uses, such as textile production, oils, dyes, lubricants, waxes, glues and other industrial substances. [57] Another interesting use of the "fruits" of chemical prospecting includes environmental applications, as organisms, genes and chemicals are discovered that remove environmental pollutants or heavy metals from the atmosphere and water, act as bioindicators of environmental health, or allow more efficient treatments of wastes.[58] Chemical and genetic resources are still largely unexplored, and we should not underestimate the potential of the world's forests and oceans, or the soil beneath our feet; nor should we allow the efforts of those who bring these technologies to us to go unrewarded.

IV. THE APPLICATION OF IPRs TO BIOLOGICAL MATERIALS IN UNITED STATES LAW

Patents are the most useful intellectual property device to the chemical prospector.[59] A period of exclusive rights can permit a prospector to capture a great deal of economic rent from a patented natural product or a derivative

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[57] According to Norman Myers, international consultant on the environment and development, lubri cants are exceptionally significant industrial products derived from biological sources. He states that the U.S. Department of Agriculture has recently screened 6,400 plants for lubricating oils and waxes and found promis ing leads in 460. Some of these products can not be synthesized in the laboratory, and require extraction from natural sources. NORMAN MYERS, *The Sinking Ark: A New Look at the Problem of Disappearing Species*, 73 (1979).

[58] *See id.* at 78.

[59] The World Intellectual Property Organization defines a patent as, "A legally enforceable right granted by vir tue of a law to a person to exclude, for a limited time, others from certain acts in relation to a described new invention; the privilege is granted by a government authority as a matter of right to the person who is entitled to apply for it and who fulfils the prescribed conditions." This is the role of the patent system in the transfer of technology to developing countries, UNCTAD, U.N. Doc. TD/B/398 (1975).

of it.[60] There are vast applications and uses for nature's storehouse of genetic information, once its biological materials are developed into marketable commodities or services. Patent protection, where applicable, can change what might be used as a cattle pasture into a biotechnology factory.

The first step toward patent protection is determining whether an invention is patentable subject matter. The Patent Act defines the scope of patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[61] There are, however, a number of exceptions to this generous rule. The Supreme Court has refused to allow patents for laws of nature, mere principles and abstract ideas.[62] Also disallowed by the courts are naturally occuring substances, including biological organisms.[63] This seems to create a major complication for chemical prospecting, which has as its objective the discovery of products of nature.

Not all products of nature are unpatentable, however. In fact, the U.S. Patent and Trademark Office (PTO) granted a patent to Louis Pasteur in 1873

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[60] *See supra* notes 8 and 9.

[61] 35 U.S.C. § 101 (1988).

[62] *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 116 (1853) (declaring that "the discovery of a principle in natu ral philosophy or physical science, is not patentable."); Parker v. Flook, 437 U.S. 584, (1978) and Gottschalk v. Benson, 409 U.S. 63, (1972).

[63] *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) in which the Supreme Court ruled that bacteria are excluded from patentability, even when applied to novel applications. In that case, the patentee had discov ered that two species of root–nodule bacteria were not mutually inhibitive, thus permitting "innoculation" of legumes by mixing cultures of the two bacteria. Holding their combination unpatentable, the Court ruled that, "Their use in combi nation does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort by the patentee." *Id.* at 131. The Supreme Court later held in Diamond v. Chakrabarty, 447 U.S. 303 (1980), that when bacteria are altered significantly from their natural state, producing new characteristics, that it is patentable subject matter.

for a microorganism.[64] A case can be made that all inventions are really the products of nature, having their source in a naturally occuring organic or inorganic resource. It is inaccurate to assume that courts are concerned with the source of an invention, however. The real concern is that the invention is the product of human ingenuity and transformation.[65] The reason for this concern is that the Patent Act also requires a patentable invention to be novel[66] and non-obvious.[67] An invention that merely occurs naturally but has not yet been discovered or described is neither new nor non-obvious, but is merely hidden from public consciousness. Courts have decided that it is not enough to bring the product of nature to the attention of the public; it is necessary to produce a new and useful invention through the application of the creative process. Only then is the reward of patent protection justified. With biological materials, the creative process is typically the isolation, purification or genetic engineering of a microörganisms or plant.

Enforcement of patents is achieved by infringement suits[68] which, if successful, can result in treble damages[69] and an award of attorney's fees.[70] Infringement suits may be brought against a domestic or foreign infringer for violations of any U.S. patent, without regard to the location the of manufacture or business, as long as the infringing product is in the U.S.[71] Products produced by means of processes patented in the U.S. are also subject to

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[64] *See* Diamond v. Chakrabarty, *supra* note 62, at n.9. Also mentioned in that case were two patents for microörganisms from 1967 and 1968, prior to the passage of the Plant Variety Protection Act. *Id.*

[65] One interesting aspect is the difference in the decisions in the Funk Bros. and Chakrabarty cases, *supra* note 62.

[66] 35 U.S.C. § 102 (1988).

[67] 35 U.S.C. § 103 (1988).

[68] 35 U.S.C. § 281 (1988).

[69] 35 U.S.C. § 284. Treble damages are rarely awarded, however. Telephone Interview with SUNY at Buffalo, School of Law , Adjunct Professor Edwin T. Bean, Jr., (various discussions throughout Feb. 1995).

[70] 35 U.S.C. § 285 (1988).

[71] 35 U.S.C. § 271 (1988).

infringement suits.[72] An alternative to infringement suits is available under the Tariff Act of 1930 which permits the International Trade Commission to issue exclusionary orders preventing infringing products from entering the U.S.[73]

While patents are not generally allowed for products of nature, some exceptions are made, particularly for plants. The first intellectual property rights available for plants were created by the Plant Patent Act (PPA) of 1930.[74] This law gave plant breeders who develop new cultivars the exclusive right to propagate the patented plant by asexual reproduction for 17 years. Since the passage of the Plant Patent Act in 1930, over 6,000 plant patents have been issued, encouraging the development of new geneotypes of cultivated plants by private industry.[75]

The Plant Variety Protection Act of 1970[76] (PVPA) expanded protection to new, sexually reproduced cultivars. Patent–like protection is granted by the Department of Agriculture which was authorized by Congress to issue Plant Variety Protection (PVP) Certificates, which protect specific genotypes for 18 years. The PVPA contains a "farmer's exemption" which permits farmers to save seeds for replanting in subsequent years or to sell to other farmers from the reserve that they had saved for their own use. The PVPA also contains a

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[72] These actions can be brought under 35 U.S.C. § 271(g), but note that this section may not protect against the use of patented intermediate products used in the manufacturing process. *See* Ann Sturtz Viksnins, Comment, *Amgen, Inc. v. United States International Trade Commission: Designer Genes Don't Fit*, 76 MINN L. REV. 161 (1991).

[73] 19 U.S.C. § 1337(e) (1988). The Tariff Act of 1930 was amended significantly in favor of greater protection of U.S. IPRs against unfair competition by foreign infringers by the Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100–418, 102 Stat. 1107 (1988).

[74] The Townsend–Parnell Plant Patent Act of May 23, 1930, Pub. L. No. 245, (to be codified at 35 U.S.C. 161 et seq.).

[75] *See* Robert J. Jondle, *Overview and Status of Plant Proprietary Rights, in* INTELLECTUAL PROPERTY RIGHTS ASSOCIATED WITH PLANTS, American Society of Agronomy, special publication, no. 52, at Chap. 1. (comprised in part of papers presented at a workshop held Jan. 31–Feb. 3, 1989, in Anaheim, Calif. (1989) at 5.).

[76] Plant Variety Protection Act of Dec. 24, 1970, Pub. L. No. 91–577, 84 Stat. 1542 (codified in 7 U.S.C. 2321 et seq.).

research exemption which permits protected cultivars to be used for research and development of new lines in laboratories and development programs. Over 2100 PVP certificates have been issued since 1970.[77]

Biotechnology processes, genes, seeds, plant parts, and hybrids, not protectable under the PPA or PVPA, may be eligible for protection by utility patents, which are issued by the Patent and Trademark Office, and are valid for a period of 17 years.[78] Unlike the PVPA, utility patents contain no farmer's exemption or research exemption. Unlike PVPA protection, however, a utility patent (as well as a plant patent) requires a sufficient showing of novelty and utility that often prevents protection for close look–alike hybrids and cultivars, reflecting only minor variation in color, taste, yield, etc. Also, utility patents can be obtained not only for plants and hybrids, but also for microbes and animals.

The expansion of IPRs in plants in the U.S. may have been a reaction to a preceeding trend in Europe. In the 1940's many European nations established Plant Breeders Rights (PBR) which extended protection to all sexually reproducing plants. Breeders in the U.S. have their choice among the three statutory schemes described above, all of which have helped the U.S. remain a world leader in agricultural and biotechnological development, which is growing rapidly worldwide. More than 600 field tests of genetically engineered crops are being conducted at present in over 20 nations. [79]

Trade secret law proves a level of protection which is inferior to that conferred by a patent, but which requires a lesser degree of inventiveness and is less expensive and complicated to achieve. A trade secret is defined by the Restatement of Torts as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a

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[77] *See supra* note 74, at 7.

[78] *Id.* at 8. The PTO began issuing utility patents for plants in 1985.

[79] Vidal, *supra* note 1.

list of customers."[80]

To have a valid trade secret, one must show that a substantial element of secrecy exists, but the secrecy need not be absolute.[81] Limited disclosure of trade secrets is expected, and is, in fact, a primary justification for the creation of trade secret law. The information can be presented to employees, corporations, potential purchasers of the secret and others, but the disclosure should be made with an understanding of confidentiality and the information disclosed must be obtained properly and used fairly.[82] Trade secret law may be most useful in protecting the knowledge of indigenous peoples. It is also important when the prospector is not the same individual or entity as the inventor, in order to protect the information until it is transferedto the inventor.

V. THE PRESENT STATUS OF IPR PROTECTION IN INTERNATIONAL LAW

A. *From Paris to Uruguay*

The Patent Cooperation Treaty (PCT) was ratified by the United States on November 26, 1975, and came into force in 1978. The PCT provides for a standardized and centralized process for review of patent applications including international searches. The PCT enables the applicant to file one application (an international application) and have that application

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[80] RESTATEMENT OF TORTS, § 757, cmt. b (1939).

[81] RESTATEMENT OF TORTS, § 757, cmt. b (1939) states, "[One] may, without losing his protection, communicate [the secret] to employees involved in its use. He may likewise communicate it to others pledged to secrecy . . . . Neverthe less, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information." For an overview of trade secret law *see* Metallurgical Indus., Inc. v. Fourtek, Inc., 790 F.2d 1195 (1986).

[82] RESTATEMENT OF TORTS, § 757 (1939) provides that, "One who discloses or uses another's trade secret, with out a privilege to do so, is liable to the other if (a) he discovered the secret by improper means, or (b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him."

acknowledged as a regular national filing in those member countries which the applicant "designates" or "elects." Filing in the desired countries (known as "entering the the national phase") must still be made within specified time periods. Thus, a patent grant must still be obtained in each desired country in order to have patent rights therein, but the PCT application allows the applicant to defer filings in individual countries.

Under Chapter I of the PCT, the applicant must enter the national stage within 20 months from the priority date of the application. Chapter II of the PCT states, the applicant may optionally file within 19 months of the priority date a demand for international preliminary examination in which event the applicant has until 30 months (31 months for an EPO application) from the priority sdate to enter the national phase. An international preliminary examination report is issued which comments on the novelty, inventiveness, and utility of the invention. The member countries are not bound by this report.

The U.S., until 1987, refused to be bound by Chapter II of the PCT, offficialy filing a reservation when the treaty was ratified. This objection was based on there being different standards of examinations by the U.S. and foreign patent officers.

The PCT has been used extensively by many nations, but the U.S. has accounted for about one–third of all applications filed under this treaty. The PCT contains eight chapters.

The Paris Convention for the Protection of Industrial Property[83] was completed in 1883 and has since been revised six times.[84] It extended protection to patents and other IPRs in products of "agricultural and extractive industries."[85] The Paris Convention has remained the primary international instrument for the protection of patents, and has only recently been

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[83] The Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, T.I.A.S. No. 6923, 828 U.N.T.S. 305 (entered into force April 26, 1970) [hereinafter Paris Covention].

[84] The revisions were made at Brussels in 1900, Washington in 1911, The Hague in 1925, London in 1934, Lisbon in 1958, and Stockholm in 1967.

[85] Paris Convention, *supra* note 82, art. 1 § 3.

overshadowed by the patent protection provisions of the Uruguay Round of the General Agreement on Trade and Tariffs (GATT). The World Intellectual Property Organization (WIPO) has assumed administrative responsibilities for the Paris Convention since 1967.[86]

The Paris Convention establishes equality of treatment in patents, or the requirement of member states to deal with domestic and foreign patent applicants in the same manner and with the conferral of the same rights.[87] The Convention does not, however, set any specific standards or mandate any specific rights, exclusions or other provisions, but rather leaves these decisions to the individual member states.[88] Member states are not permitted, however, to grant compulsory licenses for a period of four years from the date of filing or three years from the date of the grant of a patent, nor institute proceedings to revoke a patent for a period of two years from the grant of the first compulsory license.[89]

When an individual files for a patent in any member state, the Paris Convention grants a priority right of twelve months from the date of the filing during which applications can be made in all other member states. [90] Member states may not prevent the importation of patented articles, and may not forfeit a patent as a result of importation.[91] International disputes regarding patent protection are subject to negotiation, and if this proves insufficient, the dispute can be referred to the International Court of Justice in The Hague.[92]

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[86] WIPO is a specialized agency of the United Nations based in Geneva, Switzerland that handles all issues dealing with Intellectual Property.

[87] Paris Convention, *supra* note 82, art. 2(1) states "[n]ationals of any country of the Union shall, as regards the pro tection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention."

[88] *Id.* at art. $4^{bis}(1)$.

[89] *Id.* at arts. 5(A)(4) and 5(A)(3), respectively.

[90] *Id.* at art. 4(A)(1). The term of the period of the priority right is set in art. 4(C)(1).

[91] *Id.* at art. 5(A)(1).

[92] *Id.* at art. 28(1).

The Patent Cooperation Treaty (PCT)[93] was ratified by the United States on November 26, 1975, and came into force in 1978. Chapter I of the PCT provides for a standardized and centralized process for review of patent applications, including international searches to determine the state of the prior art in all member states. Chapter I also permits applications for international patents that grant international recognition to patents that are also recognized by the U.S. Patent and Trademark Office, or equivalent offices in foreign nations. The applicant must begin this process at any patent application office, within 20 months of the earliest filing date of the patent application.

Chapter II provides an additional, optional procedure for preliminary examination of patents by an International Preliminary Examining Authority which comments on the novelty, inventiveness and utility of patent applications. The U.S., until 1984, refused to be bound by Chapter II of the PCT, officially filing a reservation which the treaty has ratified.[94] This objection was based on the fact that the standards of foreign patent offices were often used in place of the standards of the PTO, and they differed significantly, until about ten years later when large scale harmonization of patent office standards took place internationally. The PCT has been used extensively by many nations, but the U.S. has accounted for about one-third of all applications filed under this treaty.[95] The PCT contains eight chapters, but only the first two are substantive.

International protection of IPRs featured prominently in the recent Urguay Round talks of the General Agreement on Trade and Tarrifs (GATT).[96] The

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[93] It was opened for signature on June 19, 1970, 28 U.S.T. 7645, T.I.A.S. No. 8733 (entered into force Jan. 24, 1978).

[94] *See* Marian Nash Leich, *Contemporary Practice of the United States Relating to International Law,* 78 AM. J. INT'L L. 884, 889 (1984) (letter to President Reagan, dated June 28, 1984, from Secretary of State George P. Shultz).

[95] This was the approximate proportion of applications filed by U.S. applicants during the mid-1980's. *See* Marian Nash Leich, *Contemporary Practice of the United States Relating to International Law,* 78 AM. J. INT'L L. 884, 889 (1984).

[96] *See* Draft Agreement on Trade-Related Intellectual Property Rights, Dec. 20, 1991, GATT Document MTN.TNC/W/35/Rev.1 [hereinafter TRIPS Draft Agreement].

stated objective of the GATT IPR provisions is to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[97]

Article 3 of the TRIPS Draft Agreement preserves the national treatment provisions of Art. 2(1) of the Paris Convention, providing that all member nations must accord equal rights and protections to nationals of all other member states that are provided to the nationals of their own nation.[98] Article 4 adds most-favored-nation treatment, requiring that "any advantage, favour, privilege or immunity granted by a [Member] to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other [Members]."[99]

It has been suggested that the efforts of the U.S. to use the GATT as a forum for promoting international IPR protection is a conscious effort to shift control away from WIPO, an organization that the U.S. has little leverage in, and in favor of GATT, "an organization in which the U.S. remain[s] the dominant player."[100] This shift also links the IPR issue to international trade, forcing those nations who wish to retain good trade status with the U.S. to also swallow numerous U.S. demands for international IPR protection. The U.S. opposes WIPO's approach to IPR protection which includes compulsory licensing provisions and weak enforcement mechanisms.[101]

The International Convention for the Protection of New Varieties of Plants (UPOV) was established in 1961 and has filled part of the gap in international patent protection left by the Paris Convention. UPOV provides patent protection to plant breeders who develop distinctive, uniform and stable

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[97] *Id.* at art. 7.

[98] *Id.* at art. 3.

[99] *Id.* at art. 4.

[100] Graham Flack, Note, *The Development of an International Patent Regime: Sound Legal Theory or Misguided Leap of Faith*, 2 DALHOUSIE J. OF LEGAL STUDIES 1, 54 (1992).

[101] Balraj, *supra* note 17, at 87.

varieties of plants. Participation in UPOV has been limited, with only 19 developed nations as members, and deals exclusively with plant germplasm. UPOV does represent, however, a significant model for further international recognition of IPRs specifically in biological materials.

An obstacle to the international protection of IPRs in plant germplasm is the long-standing treatment of plant germplasm as part of the "common heritage of mankind" which is freely accessable to all bona fide users.[102] The principal organization responsible for the conservation of plant genetic resources is the International Board for Plant Genetic Resources (IBPGR), a constituent of the United Nations Food and Agriculture Organization created in 1974. IBPGR maintains gene banks[103] from over 100 nations and is responsible for the collection, characterization and documentation of the genetic resources of cultivated (crop and forage) plants.[104] IBPGR freely provides biological samples and information to all interested and legitimate users.

The same ethic pervades other major gene banks such as that of the International Rice Research Institute and the many botanical gardens of the world.[105] Extensive and comprehensive records are often kept of species in gene banks and botanical gardens, with computerized access available to researchers throughout the world. The international scientific community has a universal concensus that scientific information, including genetic and biological information, belongs properly to the entire scientific community which is engaged in a collective effort to empirically discover as much about the real world as possible, and the information that individual researchers discover is instrumental in the research community's struggle toward this end,

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[102] *See* J. Trevor Williams, *Identifying and Protecting the Origins of Our Food Plants, in* BIODIVERSITY, 241 (E.O. Wilson ed., 1988).

[103] Gene banks are repositories of seeds, tubers and other plant materials which attempt to store and preserve as many representative samples of plant genetic diversity as possible for future use in the breeding, improvement and prop agation of cultivated plants.

[104] *See supra* note 101.

[105] *See* Peter S. Ashton, *Conservation of Biological Diversity in Botanical Gardens, in* BIODIVERSITY, 276 (E.O. Wilson ed., 1988).

and therefore must be relinquished.[106]

A number of regional agreements and treaties are also affecting and harmonizing IPR protection in many nations. The North American Free Trade Agreement (NAFTA) contains provisions for patents, trademarks, copyrights, trade secrets and plant breeders rights that bind the United States, Canada and Mexico. NAFTA requires member states to adhere to the provisions of most of the other international agreements discussed above, and as many of these agreements, mandates national treatment, or protection offered to foreigners, at least equal to that offered to domestic entitites.[107]

NAFTA permits member states to exclude from patentability plants and animals, other than microörganisms, and "essentially biological processes for the production of plants or animals, other than non–biological and microbiological processes for such production." [108] NAFTA does mandate, however, that parties provide for plant variety protection or a system of *sui generis* protection.[109] One of the most significant effects of NAFTA's IPR provisions is that it will bring Mexico's patent protection up to par with that of the U.S. and Canada, as Mexico has lagged significantly behind. Canada, however, would be required under NAFTA to repeal a law limiting the duration of pharmaceutical patents and providing for compulsory licensing of pharmaceuticals.[110]

The European Economic Community (EEC), now known as the European Union (EU), began to address IPR concerns well before NAFTA was even conceived. Article 36 of the EEC Treaty provides an exception for industrial and commercial property to the elimination of quantitative restrictions between member states contained in articles 30–34 of that treaty. The principal concern of the EU is that import restrictions grounded on industrial and

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[106] *See* Eisenberg, *supra* note 31.

[107] Intellectual Property Provisions of North American Free Trade Agreement, 1994, [hereinafter NAFTA] Canada–Mexico–United States, arts. 1701 and 1703, 6 *World Intellectual Property Rept.* 284, 284–295 (1992). NAFTA's member state treaty obligations are listed in Art. 1701 and national treatment is established by Art. 1703.

[108] *Id.* at art. 1709 § 3(b)–(c).

[109] *Id.* at art. 1709 § 3.

[110] *See* 6 *World Intellectual Property Report*, 208, 208–209 (1992).

commercial property concerns do not constitute "a means of arbitrary discrimination or a disguised restriction on trade between Member States."[111] Importation of products into an EU nation can be prevented under Article 36 if a valid patent is held in that nation, even if the infringing product is produced legally elsewhere.[112]

Legal patents are one of the few conditions within the scope of IPR protection under Article 36, however, as differing national standards are not generally a sufficient basis for restricting the free movement of goods.[113] Additionally, the exhaustion of rights doctrine applies to patents, copyrights and trademarks in the EU and imposes a narrow construction on Article 36 ensuring that the benefits of the economic monopoly created by IPR protection are proportionate to the ends they serve, and are terminated once the right is exploited and economic rewards are received.[114]

One positive and simplifying factor in the IPR regimes of European nations is the process of harmonization of national laws, which is exemplified

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[111] Treaty Establishing the European Economic Community [hereinafter EEC Treaty] art. 36. *See* Case 144/81, Keurkoop B.V. v. Nancy Kean Gifts B.V., E.C.R. 2853 (1982).

[112] *See* Case 24/67, Parke Davis v. Probel, E.C.R. 55 (1968) (holding that a major U.S. pharmaceutical company which held a valid patent in the Netherlands could prevent the importation into that country of the same pharmaceutical produced in Italy where drug patents are disallowed under national law.)

[113] *See* Case 16/83, Criminal Proceedings Against Karl Prantl, E.C.R. 1299 (1984) (the European Court of Justice ruled that an exclusive right to use a certain type of bottle granted by national legislation in a Member State may not be used as a bar to imports of wines originating in another Member State put up in bottles of the same or similar shape in accordance with a fair and traditional practice observed in that Member State.)

[114] *See* Case 16/74, *Centrafarm B.V. v. Winthrop B.V.*, E.C.R. 1183 (1974) and its parallel decision Case 15/74, Centrafarm B.V. v. Sterling Drug Inc., E.C.R. 1147 (1974). *See also* Case 3/78, Centrafarm B.V. v. American Home Products Corp., E.C.R. 1823 (1978).

in Article 100 of the EEC Treaty.[115] Apart from such general convergence of the domestic legal systems of Europe, which has been particularly accellerated with regard to environmental regulation,[116] several agreements have promoted the harmonization of European patent law.[117]

B. *The UNCED Convention on Biological Diversity*

The United Nations Conference on Environment and Development (UNCED) met in June of 1992 in Rio de Janeiro and produced a Convention on Biological Diversity (Biodiversity Treaty) that was signed by 150 nations.[118] The Biodiversity Treaty was seen at first as a threat to the international protection of intellectual property rights. Some saw the treaty as potentially threatening to interfere with the United States' efforts to advance

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[115] *See* EEC Treaty, *supra* note 112, at art. 100. ("The Council shall, acting unanimously on a proposal from the Commission, issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the common market.")

[116] Article 235 of the EEC Treaty, *supra* note 112, specifically addresses harmonization of EU environmental law, and many directives have been aimed at species preservation. *See also* EEC Habitats Directive, Council Directive 92/43/EEC (May 21, 1992).

[117] The primary agreement harmonizing European patent law is the Convention on the Grant of European Patents, Convention, Oct. 5, 1973, TS No. 20 (1978), 13 I. L. M. 270, which was later supplemented by the Community Patent Convention, Dec. 15, 1975, O. J. L 17/1 (Jan. 26, 1976), as modified, O. J. L 401/10 (Dec. 30, 1989). Both these agreements fail to recognize the patentability of biotechnological innovations, but such an agreement has been intro duced into the European Parliament in recent years, and is likely to be incorporated into European IPR law.

[118] UNCED Convention on Biological Diversity, June 5, 1992 – September 30, 1993, 31 I. L. M. 818 (1992), UNEP/Bio.Div./N7–INC.5/4 [hereinafter Biodiversity Treaty].

intellectual property rights protection in the GATT talks.[119] The treaty was later seen as a potentially beneficial instrument for encouraging both biodiversity conservation and IPR protection.

Chemical prospecting arrangements will occur in the absence of any international agreements as matters of private international law.[120] Many feel, however, that international cooperation in the formation of chemical prospecting contracts is facilitated by the adherence of contracting parties to internationally agreed upon provisions for goodwill, commitment and fairness in the protection of biodiversity in each respective nation and internationally.[121]

Agreements such as the Merck/INBio Contract are explicitly encouraged by article 18 of the Biodiversity Treaty, which requires parties to promote technical and scientific cooperation through the establishment of appropriate institutions,[122] training,[123] clearinghouses [124] and joint ventures.[125] The private contract established benefited from clear intellectual property provisions and governments that were willing, interested and trustworthy to enforce those contractual provisions. Encouraging other governments to do the same will permit chemical prospecting agreements to become important international mechanisms for the conservation of biodiversity and will fuel biotechnical and chemical innovation.

Article 1 identifies the objectives of the Biodiversity Treaty as "the

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[119] *Patent and Trademark Office and Biotech Group Explain Objections to Earth Summit's Biodiversity Treaty,* 44 Pat. Trademark & Copyright J. 120 (June 11, 1992).

[120] Thomas Eisner *quoted in* Blum, *supra* note 16, at 41.

[121] *See* Blum, *supra* note 16, at 41. The author suggests that the U.S. refusal to sign the Biodiversity Treaty may be seen by some nations as the refusal to agree to preserve its own biodiversity while insisting on the same obligations for other nations, or as an admission of the likelihood of the U.S. getting the better end of the bargain in any arrrangements that may be worked out.

[122] *See supra* note 117, at art. 18(1).

[123] *Id.* at art. 18(2).

[124] *Id.* at art. 18(3).

[125] *Id.* at art. 18(5).

conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."[126] This statement seeks to establish a system of reciprocity in which both access to genetic resources and appropriate transfer of technology is protected, while also working toward the conservation of the genetic resources. Article 1 assumes that these objectives are complimentary, or at least that it is possible to pursue one or more of them at the same time.

Article 3 imposes upon states "the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction."[127] This may involve measures to evaluate patents for their potential environmental impact and possibly the denial of patents for technologies that are harmful to the environment of other nations. As with other areas of law involving a showing of causation, it will be necessary to define the degree of proximity and forseeability required as evidence that a technology has a negative environmental impact. Refusing to grant a patent on a chemical that is extracted from its natural source by destructive means is the kind of intellectual property rights restriction that the Biodiversity Treaty may require.[128]

Article 4 deals with the jurisdictional scope of the Biodiversity Treaty. For "components of biological diversity," Article 4 limits the jurisdictional scope to "areas within the limits of its national jurisdiction."[129] "Processes and activities," however, fall within the jurisdictional scope of the Biodiversity Treaty "regardless of where their effects occur."[130] This provision mandates the extraterritorial applicability and enforcement of the Biodiversity Treaty

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[126] *Id.* at art. 1.
[127] *Id.* at art. 3.
[128] *See supra* note 39.
[129] *See supra* note 117, at art. 4(a).
[130] *Id.* at art. 4(b).

and will require domestic legislation to expand jurisdiction accordingly.[131]

Article 7 requires all parties to the Biodiversity Treaty to identify and monitor components of biological diversity within their territory. Special consideration is to be given to categories of biological diversity identified in Annex I to the Biodiversity Treaty.[132] Article 7(d) requires parties to maintain and organize data collected from their identification and monitoring activities.[133] This will encourage the creation or expansion of databases and publication of information related to biodiversity. The copyright and trade secret protection of this information will inevitably have to be weighed against the benefits of public disclosure of the information. A system should emerge to adequately compensate private acquisition of data in return for public disclosure and use.

Article 8(j) of the Covention on Biological Diversity requires each contracting party to "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."[134] This subsection also requires parties to "encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." The Biodiversity Treaty, thus, appears to

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[131] Other U.S. conservation laws have extraterritorial applicability. *See* D.C. Brennan, *Extraterritorial Application of Federal Wildlife Statutes: A New Rule of Statutory Interpretation*, 12 CORNELL INTL. L. J. 143 (1979),; J.C. Beiers, *The International Applicability of Section 7 of the Endangered Species Act of 1973*, 29 SANTA CLARA L. REV. 171 (1989).

[132] Annex I of the Biodiversity Treaty delineates three categories of biological diversity: 1) ecosystems and habitats, 2) species and communities, and 3) described genomes and genes of social, scientific or economic importance. A strong utilitarian emphasis is demonstrated by the prioritization scheme described in Annex I. This is conducive to the estab lishment of IPRs in components of biological diversity, as it is this consumptive value that provides the incentives for acquisition of patents. Wise biological diversity prospectors will also naturally prioritize the most threatened and unique species and those that are most useful in the conservation and monitoring of biological diversity.

[133] *See supra* note 117, at art. 7(d).

[134] *Id.* at art. 8(j).

presuppose the provision of patents or trade secrets for indigenous information. Domestic intellectual property law may, therefore, need to be reformed to prevent the exclusion of indigenous information, unless there is no such discrimination.[135] Article 10(c), additionally, requires nations to "protect and encourage customary use of biological resources in accordance with traditional cultural practices." Protecting intellectual property rights in such customary uses will permit licensing of the uses, generating revenue for indigenous peoples, providing an incentive that will encourage such uses.[136]

Article 9 deals with *ex situ* conservation, requiring the establishment of a variety of facilities such as gene banks, plantations and zoos that are equipped to both conserve and conduct research on the biological materials they store. This encouragement of research should certainly include chemical prospecting as well as more basic research. The research is preferably to be conducted in the country of origin of the genetic resources, thus favoring a Merck/INBio–style agreement to research conducted in a foreign gene bank from exported biological materials.[137]

Article 15(1) reaffirms "the sovereign rights of States over their natural resources [and that their] authority to determine access to genetic resources rests with the national governments and is subject to national legislation." At the same time, Article 15(2) requires parties to "create conditions to facilitate access to genetic resources for environmentally sound uses by other

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[135] It seems to be the case in the United States that that the legal system does not treat indigenous peoples any differ ently with regard to the protection of intellectual property rights. *See* Michael A. Gollin, *The Convention on Biological Diversity and Intellectual Property Rights*, *in* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAIN ABLE DEVELOPMENT, Annex 3, 289 (Walter V. Reid et al. eds., 1993).

[136] *See supra* note 117, at art. 11. Article 11 specifically encourages the establishment of incentives, stating: "Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity."

[137] *Id.* at arts. 9(a) and 9(b). Articles 9(a) and 9(b) both note that it is preferable to locate *ex situ* conservation facili ties in the country of origin of the genetic materials.

Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention." The two standards that the Biodiversity Treaty sets for access to genetic resources are that it is based on mutually agreed terms[138] and that there is prior informed consent[139] by the source nation. Article 15(6) stresses that agreements should include provisions to ensure that nations accessing foreign genetic resources actually participate in scientific research which utilizes the resources. Any proceeds from the commercial exploitation of the genetic resources must be shared equitably and fairly with the country of origin.[140] Finally, article 15(7) requires nations to adopt the appropriate legislative, administrative or policy measures necessary to make certain that the sharing of the proceeds from the exploitation of the resources is in fact fair and equitable.

Many critics of the Biodiversity Treaty have found article 16 ambiguous and consisting of convoluted language. [141] This uncertainty of obligation with regard to the transfer of technology is often cited as the motivation behind the U.S.'s refusal to sign the Biodiversity Treaty.[142] Indeed, article 16(2) can be seen as contrary to free trade principles, by requiring the transfer of technology to developing countries to be "provided and/or facilitated under fair and most favorable terms." This does not obligate developed nations to give developing nations the better end of the deal, however, as this section also provides that the transfer must be as "mutually agreed." Similarly, articles 16(3) and 16(4)

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[138] *Id.* at art. 15(4).

[139] *Id.* at art. 15(5).

[140] Merck, for instance, agreed to pay royalties of 1–3% of its profits to INBio, and also committed significant funds to assist the Costa Rican government in conservation programs.

[141] Gollin, *supra* note 134, at 295.

[142] The U.S. in a resolution adopted on May 22, 1992 invited the Governing Council of the United Nations Environ ment Programme to consider requesting the Executive Director of the Programme to convene meetings of an Intergov ernmental Committee on the Convention on Biological Diversity starting in 1993 which would consider, among other issues, "modalities for the transfer of technologies, in particular to developing countries, relevant to the conservation of biological diversity and the sustainable use of its components, as well as technical cooperation in support of national capacity–building in those areas." art. 2(d), 31 I. L. M. 842, (1992).

require parties to the Biodiversity Treaty to adopt any legislative, administrative or policy measures to ensure adequate transfer of technology to developing nations when access to genetic resources is given, again subject to mutually agreed terms. The effect of article 16 seems to send a message that parties should favor developing nations in the transfer of technology, but that they are not obligated in any way to do so.

Article 16(5) sends an equally ambiguous and ineffectual message regarding the international protection of intellectual property rights. This section states: "the Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives." This eliminates only the possible extreme views of intellectual property rights as either essential or entirely unrelated to the equitable sharing of technology.[143] Any indication of the practical import of this provision with regard to the limitations to be imposed on intellectual property rights remains a mystery.

Articles 15 and 16 establish a balance between two competing interests in chemical prospecting— access to genetic and chemical resources on the one hand and the transfer of technology on the other. The term "reciprocity" is used to describe the equitable flow of genetic resources from biologically rich developing nations to technologically rich developed nations in exchange for the transfer of technology. For developing nations, the tradeoff is between protecting sovereignty over all resources or allowing foreign nations at least limited access to those resources, treating the resources as the common property of the international community. For developed nations, the tradeoff is between refusing to compromise their intellectual property rights and technological superiority or sharing useful technologies and assisting in the economic development of developing nations. Neither article 15 nor article 16 requires the establishment of international agreements for the exchange of genetic resources for technology, but both of these articles, and the Biodiversity Treaty as a whole, do require nations to encourage such

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[143] *See* Gollin, *supra* note 134, at 297.

agreements. In addition, article 22 explains that this Biodiversity Treaty does not affect any of the rights or obligations of parties under existing international agreements addressing intellectual property rights, "except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."[144] Most of these existing international agreements are discussed in ¤5(A) above.

The United States government has expressed a concern that the technology sharing provisions of the Biodiversity Treaty may require compulsory licensing, a practice opposed by the U.S.[145] Compulsory licensing "enables the government granting the patent to force the patentee to license the invention if the government does not approve of the patent's use. Consequently, another individual or company is allowed to make and sell the invention."[146] Compulsory licensing is an accepted practice in most of the world's patent systems, but is entirely rejected only by the U.S. The U.S. has been successful in incorporating restrictions on compulsory licensing in the recent GATT negotiations. The Biodiversity Treaty is seen as a potential threat to these concessions at GATT and as a "slipperly slope" could lead to near extortion of U.S. companies that do not satisfy the expectations of foreign nations.[147]

For the most part, the biological Treaty promotes free trade in genetic resources, incentives for the transfer of biotechnology, and the protection of intellectual property rights which are seen as important in the conservation and sustainable use of genetic resources. There are many uncertainties and ambiguities in the text of the Biodiversity Treaty, and it must be viewed as a starting point for intellectual property rights protection in chemical prospecting. The Biodiversity Treaty must find its place among other international agreements addressing intellectual property, many of which are themselves still in formative stages.

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[144] *See supra* note 117, art. 22(1).

[145] *See* Catherine J. Tinker, *Introduction to Biological Diversity: Law, Institutions, and Science*, 1 BUFF. J. INT'L L. 1, 19 (1994).

[146] Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 J. INT'L L. BUS. 666 (1988).

[147] *See* Richard Stone, *The Biodiversity Treaty: Pandora's Box or Fair Deal? Convention on Biological Diversity*, 256(5064) SCI. 1624 (June 19, 1992).

The world's biodiversity is concentrated in a very small number of countries, primarily within the tropics. These dozen or so countries contain 60–70% of the world's terrestrial, freshwater and marine species[148] and have been referred to as "megadiversity countries" to reflect their high degrees of endemism, diversity and biological importance.[149] The efficacy of chemical prospecting as a conservation tool in these countries is heavily dependent upon the state of protection of IPRs in megadiversity nations, and it is here that the Biodiversity Treaty is playing an important role.

VI. CHALLENGES IN THE PROTECTION OF IPRs FOR BIODIVERSITY CONSERVATION

A. *Property Rights and Land Tenure Conditions*

Because biodiversity is inextricably tied to the land, IPRs in biological materials are subject to the property rights and tenure conditions of that land. The scope of property rights in any nation, and the system by which they are allocated, affect land use in many ways. Systems in which property rights are not adequately protected or in which property rights are acquired only through use often encourage deforestation of the land and the resultant destruction of biodiversity.[150]

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[148] These countries certainly include, but may not be limited to, Brazil, Colombia, Ecuador, Peru, Mexico, Zaire, Madagascar, Australia, China, India, Indonesia and Malaysia. *See* MCNEELY ET AL., *supra note* 6, at 88.

[149] *See* R.A. Mittermeier and T.B. Werner, *Wealth of Plants and Animals Unites "Megadiversity" Countries,* 4(1) TROPICUS 1 (1990).

[150] In many nations, such as Brazil, exclusivity over land can only be gained through logging, ranching or farming the land, all of which involve removal of the natural biota. Much of this deforestation is done by squaters who are able to gain rights to up to 100 hectares per person by "using" the land for over one year, gaining title to the land after five years of continous use and occupancy. Hans P. Binswanger, *Brazilian Policies that Encourage Deforestation in the Amazon*, Environment Department Working Paper no. 16, World Bank 1989. This policy is little more than a specific application of traditional adverse posession law which has a solid foundation in

Open-access resources[151] are subject to short term competitive exploitation in which all resource rent value is dissipated without consideration of long-term value or sustainable use. This form of extraction leads to the "tragedy of the commons" that Garrett Hardin described as the result of average value exceeding marginal costs in an open-access resource.[152] There are a number of reasons for the dissipation of resource value in open-access resources. First, in the absence of formal property rights, claims to the resource are limited to claims of use, creating a system which encourages maximum present utilization of the resource and the dissipation of rental value. This is the pattern of use that has characterized over-fishing in systems that fail to protect private property rights in fisheries. The fisheries are overexploited, often to the point of extreme scarcity, and at the same time incomes drop as prices drop due to the artificially high supply brought about by the perverse incentives created by the open-access or common property conditions.[153]

Destructive squatters' laws and land tenure conditions in many third world nations could potentially benefit from and even encourage chemical prospecting. If chemical prospecting were to be recognized as a valid and profitable use of land, then it is likely that, in many places, more destructive resource uses would be abandoned in favor of chemical prospecting as a means of acquiring title to lands in their natural state. As one source points out, education and moral suasion have their limited role, but "the economic

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American law.

[151] Resources lacking any form of exclusive rights, as distinguished from common property resources in which there are multiple owners where the exclusivity is shared among the members of a group.

[152] Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243 (1968).

[153] Several studies have examined the effects of property rights on fisheries. Richard J. Agnello and Lawrence P. Donnelley, *Prices and Property Rights in the Fisheries*, 42 S. ECON. J. 253 (1979); G. R. Monroe, *Fisheries, Extended Jurisdiction, and the Economics of Common Property Resources*, 15 CAN. J. ECON. 405 (1982). The problem of overfishing is of increasing concern, with the last decade bringing the near exhaustion of many of the world's fisheries, wasting $15 billion-30 billion a year. *See The Catch About Fish*, The ECONOMIST, Mar. 19, 1994, at 13 (citing figures from the U.N. Food and Agriculture Organization.)

approach seeks ways to internalize external diseconomies by compensation, creating incentives for alternative behavior."[154]

It is advantageous for property rights to extend over as large an area as possible. The costs of securing and protecting small land claims is high due to poor enforcement, lack of political concern, competing claims and inefficient private policing.[155] Large areas of land could be acquired and managed by a land trust or similar organization that would then lease portions of the land out to interested prospectors. Such organizations could also help facilitate *in situ* research and conservation activities by permitting the sharing of costs by multiple prospectors.

B. *Patent Scope*

Most chemical products are not discovered in the same form as they are marketed. They are derived from other products, through a process of modification that ranges from moderate alteration to radical transformation. Somewhere along this continuum lies the point at which an initial chemical A is altered enough to be considered practically and legally a new, distinct product— chemical B. This is also the ideal point at which the IPRs held in chemical A should end and IPRs to chemical B begin.[156]

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[154] Martin T. Katzman and William G. Cale, Jr., *Tropical Forest Preservation Using Economic Incentives*, 40 BIOSCI. 827 (1990).

[155] In Brazil, the size of land holdings has been highly linked to the security of property rights in that land, primarily due to economies of scale in the provision of private policing and the lobbying of local officials. Gary D. Libecap, *Property Rights, Rent Dissipation, and Environmental Degradation in the Brazilian Amazon*, at 14, Address at Politi cal Economy Research Center Seminar for Congressional Staff Members (1991), Lone Mountain Ranch, Big Sky, Mon tana.

[156] *See Paying for Nature's Riches*, 2(4) FOREST PERSPECTIVES 23 (Winter 1993). For example, SmithKline Beecham recently derived the semi–synthetic drug topotecan from camptothecin, a naturally occuring drug found in the plant *Camptotheca acuminata*, (Pacific Yew) discovered and developed by the National Cancer Institute (NCI). It is unclear whether any royalty must be paid to NCI even though significant additional research and development were required to produce topotecan, and this

Merely creating chemical B from chemical A does not necessarily mean that chemical B is not within the umbrella of IPR protection established for chemical A. At one extreme is mere repackaging. Taking a medicinal agent, giving it a new name and selling it in new packaging under that brand name is not the development of a new pharmaceutical. It requires the payment of royalties to the holder of IPRs in that pharmaceutical, or it is an infringement on the existing IPRs. It would be unfair to allow such parasitism of another's efforts and rights without compensation. Even if the pharmaceutical were chemically altered, but remained functionally and biochemically similar, it would be unfair to reward the party making the smaller investment and less significant contribution.

On the other hand, it is essential that the incentives for innovation provided by IPRs not undermine incentives for further innovation. New discoveries have a tendency to blossom— multiplying and inspiring further discoveries, as the full potential and utility of the initial discovery is better understood and developed. It is important that many parties have the opportunity to contribute their unique expertise and perspective to the effort to fully utilize discoveries in biotechnology. A greater number of minds and dollars means more progress more quickly, and more benefits to society. Like many other areas of our legal system, patent scope should be determined by what is in the interest of public health, safety and welfare.

C. *Unfair Competition and Process Patents*

The recent case *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 13 U.S.P.Q.2d (BNA) 1737, 1738 (D. Mass. 1989), aff'd in part and rev'd in part, 927 F.2d 1200 (Fed. Cir. 1991) has brought a great deal of attention to the

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work was done exclusively by SmithKline, which took advantage of NCI's discov ery. The argument in favor of limiting NCI's patent to cover only camptothecin is that compainies like SmithKline would otherwise have no incentive to further the technology and progress made possible by the initial discovery, and that those who would suffer are the customers and patients who ultimately benefit from drugs such as topotecin which has already helped many people abroad.

issue of unfair trade in products produced or developed using patented biotechnology processes. Amgen, an American biotech company located in California, developed a cell which produces high levels of a hormone called erythropoietin ("EPO").[157] Chugai Pharmaceutical Co. used Amgen's genetically–altered, EPO–producing cells to develop a process for producing recombinant erythropoietin ("rEPO"). Amgen filed a cliam with the United States International Trade Commission (ITC) for the alleged infringement on its patent by Chugai, in violation of art. 337 of the Tariff Act,[158] for producing rEPO by using Amgen's patented cells. The court interpreted the Tariff Act narrowly, permitting the import of rEPO, to which Amgen had no claim, despite the fact that Chugai used Amgen's genetically altered cells to produce the rEPO.

Amgen clarified the scope of patent protection in biotechnology. The biological material that one starts with is generally the product of nature, and thus not patentable, and the end product is usually also found in nature, and subject to the same restriction. Even the procedures and processes used in most biotechnology projects are widely known and used and will not meet a challenge on the grounds of obviousness or novelty. It is only the intermediary products along the way that are patentable, such as the genetically altered cells developed by Amgen. Despite this protection, products developed using these patented intermediaries will be allowed into the U.S. for import, as was the case in *Amgen*. The problem for domestic enterprises is apparent— the competitive advantage of foreign enterprises that piggyback on U.S. innovations takes money out of the pockets of the American biotech industry. Critics argue that the court has misread the legislative intent of the Tariff Act of 1930, and that the same standards should be applied to imported products as is currently applied to domestic products.[159]

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[157] U.S. Patent No. 4,703,008. Amgen's patent claims include purified and isolated DNA sequences encoding eryth ropoietin as well as host cells transformed or transfected with a DNA sequence.

[158] 19 U.S.C. § 1337 (1988).

[159] *See* Viksnins, *supra* note 71.

The Process Patent Act[160] attempts to correct this problem, in part. This law gives the holder of a process patent (to be distinguished from a product patent in that it protects the means by which a product is produced) to "exclude others from using or selling throughout the United States, or importing into the United States, products made by that process.[161] The Process Patent Act contains specific remedies for violations involving products produced abroad using a patented process when those products are intended for import into the U.S., particularly in personam jurisdiction, as compared to the in rem exclusion orders previously available from the ITC under the Tariff Act of 1930.[162] Thus, in addition to the intermediary biological or chemical products produced in the development of biodiversity, the processes used to create the end product may receive effective international protection, reducing the number of derivative products or other products produced using the patented process. This is important because many processes used in drug development and chemical prospecting will have wide application and utility in other contexts, and it is important to encourage development and disclosure of such processes.

D. *Proper Timing of IPR Establishment*

Chemical prospecting has been compared with the purchase of lottery tickets, all of which have different potential payoffs, but few of which pay off at all.[163] The problem is that one can not know whether one has a winning ticket for quite some time, and possibly may never find out. The timing of the establishment of IPRs, therefore, becomes an important issue. Losing tickets should not be subjected to the expensive and burdensome process of obtaining

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[160] Process Patent Amendments Act of 1988, 102 Stat. 1107, 1563-67; (codified by 35 U.S.C. §§ 154, 271, 287, 295).

[161] *Id.* at 1563.

[162] *See* Mark E. Wojcik, The Perilous Process of Protecting Process Patents from Infringing Importations, 14 LOY. L.A. INT'L. & COMP. L.J. 207 (1992).

[163] Roger A. Sedjo, *Property Rights, Genetic Resources, and Biotechnological Change*, 35 J. LAW ECON. 199, 204 (1992).

IPRs; winning tickets need to be protected as quickly and effectively as possible. Even uncertain prospects need to be protected adequately to capture possible future payoffs.

Ideally, the timing of IPR establishment should be the time of discovery of a useful application of the biological discovery. The mere discovery of the chemical or gene is often quite easy when compared to the investment necessary to find a useful application for the discovery. Changing the timing in this way would encourage the development of useful applications by providing the incentive of IPR protection at that point. It is also conceivable that several levels or classes of IPR protection could be developed to provide increasing incentives for application. The patent term of 20 years in many nations may also be an inadequate measure of IPR timing if the clock begins to run at the time of discovery of the chemical rather than the application, which may not come along for several years.

The payoffs of chemical prospecting are big. Merck discovered Mevacor, a cholesterol– lowering agent, in a fungus and sold $735 million of the chemical in 1990 alone.[164] The sale of the anti–cancer drugs Vincristine and Vinblastine, discovered in the *Madagascar Periwinkle*, is estimated at $200 million annually.[165] Such enormous payoffs can easily cover the costs of investment in research, development and conservation incurred in the chemical prospecting process.

E. *Conservation Concerns*

Many chemicals are harvested in the wild not in small amounts for study, but for sale as useful extracts of biological materials. The concept of extractive reserves has gained increasing popularity in recent years as a sustainable means of producing such products. Even the chemical prospecting process itself can require large amounts of raw biological materials, or their extracts.

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[164] *See* Wilson, *supra* note 9, at 321.

[165] *Id.*

Methods of collection of biological materials also have a significant effect on the sustainability of the extractive process. Many methods of collection employed today are destructive and result in severe damage or destruction of the species involved.[166] Methods such as stripping too much bark off trees or removing the roots of plants may be unnecessary or excessive, and are certainly destructive. Nondestructive methods such as removing a small portion of the bark of a tree or harvesting leaves are preferable, but are unfortunately not the common practice, even among local healers.[167]

Proper rotations of harvests, maximizing the time between harvests of any individual plot, can dramatically increase the productivity and long-term sustainability of the chemical extractive process. [168] It will also assist in the conservation of biological resources if they are harvested from multiple locations, possibly involving several nations and if cultivation programs are established wherever possible to produce the biological materials more efficiently and intensively. Proper field etiquette and collection techniques should also be observed, and can be easily learned from materials available from all major professional scientific organizations.

F. *Protecting the Interests of Indigenous Peoples*

The rights and protection of indigenous peoples was a major concern at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro in June 1992. There were two dominant perspectives on indigenous peoples present at the conference, both of which supported efforts to protect them.[169] One of these perspectives was an environmental

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[166] *See* Michael J. Balick and Robert Mendelsohn, *Assessing the Economic Value of Traditional Medicines From Tropical Ranforsests*, 6 CONSERVATION BIOLOGY 128 (1992).

[167] *Id.*

[168] *Id.*

[169] Lee P. Breckenridge, *Symposium: Environmental Rights and International Peace: Protection of Biological and Cultural Diversity: Emerging Recogntion of Local Community Rights in Ecosystems under International Environmental Law*, 59

focus and was premised on the utility of indigenous peoples in the protection of biodiversity. The other perspective was cultural and saw the protection of idigenous peoples as an issue of human rights and cultural diversity. The former perspective tends to perceive biodiversity as a valuable resource of the international community held "in trust" by the nation in which it is found, while the latter views biodiversity as an essential resource of local peoples who directly utilize biodiversity for their sustenance.[170]

The Working Group on Indigenous Populations, an organ of the United Nations Sub– Commission on Prevention of Discrimination and Protection of Minorities, has produced a Draft Universal Declaration on the Rights of Indigenous Peoples which grants indigenous peoples "the right to special measures for protection, as intellectual property, of their traditional cultural manifestations, such as . . . seeds, genetic resources, medicine and knowledge of the useful properties of fauna and flora.".[171] Article 8(j) of the Biodiversity Convention, as discussed previously, also requires parties to adhere to such protections of indigenous knowledge. It is likely that indigenous peoples will have such rights widely recognized, both as a matter of principle and pragmatics, as indigenous knowledge has been used in the development of nearly three–quarters of all plant–derived pharmaceutical compounds.[172]

The argument against incorporating indigenous peoples into the chemical

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TENN. L. REV. 735 (1992).

[170] *Id.*

[171] *Report of the Working Group on Indigenous Populations on Its Tenth Session*, U.N. Subcommission on Prevention of Discrimination and Protection of Minorities, 10th Sess., Preambular and Operative Paragraph No. 19 of the Draft Declaration as agreed upon by the Members of the Working Group at First Reading, Annex I to Discrimination Against Indigenous Peoples: U.N.Doc. E/CN.4/Sub.2/1992/33 (1992).

[172] *See* Kirsten Peterson, *Recent Intellectual Property Trends in Developing Countries*, 33 HARV. INT'L L. J. 277, 285 (1992) (The author refers to a number of recent examples of plant-derived pharmaceutical compounds developed using traditional knowledge. For example, the skeletal muscle relaxant d-tubocuraine was used by Amazonian Indians as an arrow poison before its present use in anesthesiology.)

prospecting process is that their role is both limited and less effective than alternative techniques. Much ethnobotanical knowledge has already been tapped, and while there is certainly more to be found, it becomes more scarce all the time. Indigenous peoples also have limited knowledge of biodiversity, great though it may seem in relation to our own. We would be overlooking many uses of many species if we relied to too great an extent on leads from indigenous peoples. Scientists from developed countries can simply find more useful chemicals by utilizing modern chemical screening techniques than they can by spending their time searching for and following up on ethnobotanical leads.[173] In a free market, it is the efficacy of each technique that will ultimately determine the extent to which indiginous peoples are brough into the chemical prospecting process, and at present it seems that companies are not willing to invest large sums of money in ethnobotanical programs.

G. *In situ versus Ex situ Conservation*

There are two fundamental approaches to conservation of genetic resources. The first of these, *in situ* conservation, operates by preserving species in their natural habitat by protection the ecosystems in which they are found. Chemical prospecting is suited to *in situ* conservation, provided that an adequate legal environment and technical support structure are present. When either of these are inadeqate, however, *ex situ* conservation can be a valuable alternative.

Ex situ conservation is accomplished through the application of biotechnological procedures in the laboratory, usually far away from the place in which the species occur naturally. *Ex situ* conservation is quite limited in its applicability, permitting the long term conservation or storage of species that are either already known or at least discovered. Those species that have not yet been discovered, along with the numerous species that are dependent

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[173] *See*, statement of Dr. Thomas Eisner in Peter Aldhous, *'Hunting License' for Drugs*, 353 NATURE 290, Sept. 26, 1991. Eisner points to receptor-molecule-based screening techniques as the most effective means of biodiversity prospecting, although he certainly doesn't deny the advantages to be gained from ethnobotany as well.

on natural ecosystems, can only be protected by conserving entire ecosystems. Furthermore, *ex situ* conservation is probably ineffective in preserving the adaptive and neutral evolutionary potential of wild plant populations.[174] *Ex situ* conservation, therefore, is best used as a last resort or necessary substitute for *in situ* conservation.

A major problem with *ex situ* conservation is the North–South conflict it creates. The technologically and financially rich nations of the North must import genetic resources from the gene rich, but technologically and financially poor, nations of the South. An efficient exchange would be technology and finances from the North in return for genetic resources from the South. Unfortunately, the South's end of the bargain is rarely as generous as the North's, making many nations of the South reluctant to engage in *ex situ* conservation.

VII. CONCLUSION

Private agreements which create their own version of intellectual property rights, such as the Merck/INBio agreement, will prosper in coming years.[175] Their effect will parallel in many ways what the Convention on Biological Diversity has hoped to accomplish. Hopefully, the Convention will work to encourage chemical prospecting as well as motivate member–states to the Convention to adopt appropriate national legislation and policy to support such agreements. What is certain is that incentives matter in the development of biotechnology and in conservation, and chemical prospecting coupled with a strong intellectual property framework create a powerful incentive that accomplishes both these objectives.

The Merck/INBio agreement has shown that chemical prospecting can be

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[174] *See* Matthew B. Hamilton, *Ex Situ Conservation of Wild Plant Species: Time to Reassess the Genetic Assumptions and Implications of Seed Banks*, 8 CONSERVATION BIOLOGY 39 (1994).

[175] *See* Thomas Eisner and Elizabeth A. Beiring, *Biotic Exploration Fund--Protecting Biodiversity Through Chemical Prospecting*, 44(2) BIOSCI. 95, 97 (1994).

profitable both to the developed countries who often initiate such activity, and to biodiversity–rich developing countries that control the resources to make it possible. While it's true that by providing heightened IPR protection, developing countries permit technology and capital–rich developed nations to protect the vast majority of discoveries that end up in their hands, developed nations can share in much of the value created by these IPRs. The benefits in both the short and long term of this economic activity can outweigh even the limited but substantial opportunities for piracy existing without adequate IPR enforcement. Those nations that are able to recognize these benefits are certain to attract the interest and investment of corporations that will not only share their prosperity, but will even seek solutions to problems specific to those nations.

A number of conditions must exist to support chemical prospecting in any location. The most important of these is a clearly–defined and well–enforced property rights structure. Better– defined intellectual property rights need to be developed, preferably with specific reference to the type of biotechnological research coupled with the chemical prospecing process. Such issues as patent scope, proper timing of IPR establishment, and protection of the processes used in conducting biotechnology research and development must be dealt with. It must be determined to what extent indigenous peoples will be incorporated into the prospecting process, and what portion of the process, and also conservation, will be conducted *in situ.*

IPRs can be both an incentive and a potential problem for the conservation of biodiversity. On the one hand, IPRs make the discovery of new chemicals and genes more valuable because of the potential benefits that can be realized by exclusive rights to the profit from such discoveries. On the other hand, the process by which one obtains a patent for a useful natural product may cause excessive harvesting and destruction of the species for research and development purposes. Additionally, IPRs may not be enough for conservation; a greater, general property interest in the source of the natural product may be necessary to realize any of the value of the IPRs. Such questions, as IPRs in products of nature, will force us to consider this and many other issues such as sustainable development, international law, and the role of international private agreements in achieving multinational objectives.