

ECOLOGICAL IMPLICATIONS OF INTERNATIONAL PATENT REGIMES: A
COMPARATIVE ANALYSIS OF LAWS AND CASES FROM THE UNITED
STATES, INDIA, AND BRAZIL

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Ecological Implications of International Patent Regimes

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Patents spur technological innovation; often, patented technologies have helped diminish the impact of some of the world's most pressing concerns: from population growth, to world hunger, to global warming. A more contentious side of patents has emerged within the last several decades as more information is gathered on the sources and origins of biotechnological patents, evidencing misappropriation of traditional knowledge and resources, biopiracy. Biopiracy has been studied in detail for the social justice implications of wrongfully acquiring property of indigenous and traditional groups, but the literature is nearly void of the ecological implications of different patent regimes. International treaties and discussions have addressed the need to combat biopiracy and enable appropriate mechanisms of benefit sharing, but the implementation and success of laws and regulations guided by the treaties on a national level have been varied and inadequately quantified. This comment explores the international agreements governing intellectual property and access to natural resources, and examines how such agreements have been enacted in three countries: the United States, India, and Brazil. This comment then draws connections between the laws and policies of each country and their ecological environment. The goal of this comment is to draw attention to the direct ecological impact of patent laws in each country and the different national approaches to combat biopiracy. This comment will highlight the strengths and weaknesses of the variety of approaches and suggest ways to move forward with patent law and alternative mechanisms that are more conducive to balancing private property rights and technological innovation with biodiversity conservation and social justice.

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INTRODUCTION

The landmark 1980 case, *Diamond v. Chakrabarty*, laid the foundation for patentable subject matter in the United States, determining that while laws of nature and physical phenomena are not patentable (such as a new mineral discovered in the earth or a new plant found in the wild), genetically engineered organisms are.¹ The dispute arose when a microbiologist filed a patent application on a genetically engineered bacterium that was capable of breaking down crude oil, and thus highly promising for the treatment of oil spills.² The patent examiner rejected the application for two reasons: 1) because living things are not patentable, and 2) neither are products of nature.³ The applicant appealed, and the case was eventually brought before Supreme Court of the United States.⁴ The Supreme Court granted the patent, but not before Chief Justice Burger acknowledged the slippery slope that biological patents presented:

The briefs present a gruesome parade of horrible. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that with Hamlet, it is sometimes better “to bear those ills we have than fly to others that we know not of.”⁵

¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

² *Id.* at 305.

³ *Id.*

⁴ *Id.*

⁵ *Id.* at 316.

But, the Court reasoned that these concerns were policy considerations outside the scope of authority for the judiciary.⁶

More than thirty years later, the uncertainty associated with the potential consequences of biological patents and genetic engineering is still great, and the line between laws of nature/physical phenomena and the product of human ingenuity is still controversial. International agreements governing intellectual property rights have excluded the biotechnology sector due to a lack of consensus regarding appropriate patentable subject matter.⁷ This lack of consensus presents an untenable situation regarding the limits of biological patents and enforcement of patent laws creating consequences beyond the currently quantified economic and social sphere.

By examining the laws of the United States, India, and Brazil, this paper argues that a largely overlooked concern associated with patents is the impact on the ecological environment. This paper argues that many current patent laws not only enable, but also encourage isolation and extraction of organisms integral to precarious and vital ecosystems. The direct ecological impacts associated with bioprospecting and patenting coupled with the social ramifications that indirectly influence the natural environment is a serious threat to natural resource conservation.

The countries selected for comparative analysis in this comment were selected for several key reasons. The first is that each can be placed in a different category of development, usually typifying very different trade practices, policies, and priorities.⁸ Furthermore, Brazil and India

⁶ *Id.* at 317.

⁷ Marcelo Dias Vaerlla & Maria Edelvacy Pinto Marinho, *Contesting Monsanto's Patents on Life: Transnational Juridical Dialogue and the Influence of the European Court of Justice on Soybean-Exporting Countries*, 16 TUL. J. TECH. & INTELL. PROP. 79, 83 (2013).

⁸ *Human Development Report Summary 2013*, UNITED NATIONS DEVELOPMENT PROGRAM, 1, 16-19 (Mar. 2013) <http://www.undp.org/content/dam/undp/library/corporate/HDR/2013GlobalHDR/English/HDR2013%20Summary%20English.pdf>. The United States is ranked number three on the Human Development Indices which is classified as

are two of the three leading economies in the developing world whose share of economic output is projected to increase exponentially in the next forty years.⁹ The second reason that these three countries make good comparisons is their shared colonial history with very different trajectories post-colonialism. The third reason is because of the way both Brazil and India are viewed by the United States – as countries that undermine international intellectual property goals.¹⁰ Finally, much of the world’s biodiversity is concentrated in Brazil and India, therefore, the impact of their laws and policies weigh heavily on conservation efforts worldwide.¹¹

This paper will proceed in three parts. Part I is a background section that will describe the major international patent laws, standards, and enforcement mechanisms. It will then describe how these patent laws can theoretically and practically impact the natural environment (in both positive and negative ways). Part II is divided into three different sections: the United States, Brazil, and India. Each section will describe the evolution of the countries’ patent laws to orient the reader and, using case studies, illustrate the implications of each unique patent regime on the environment. Part III will conclude by synthesizing the strengths and weaknesses of each national approach, and ultimately arguing that the ecological effect of patent laws and

very high human development; Brazil is ranked at number eighty-five on the indices which is classified as high human development; and India has a medium level of human development sitting at number 136 on the indices. *Id.* The Human Development Index considers life expectancy, educational attainment, and income. *Id.*

⁹ *Human Development Report 2013*, UNITED NATIONS DEVELOPMENT PROGRAM, 1, 13 (Mar. 2013) <http://www.undp.org/content/dam/undp/library/corporate/HDR/2013GlobalHDR/English/HDR2013%20Report%20English.pdf>. In fact, combined with China, Brazil and India are expected to contribute to 40% of the global output by 2050, a percentage that rivals the long-standing industrial powers of the North- Canada, France, Germany, Italy, the United Kingdom, and the United States. *Id.*

¹⁰ U.S. Trade Representative, 2013 Special 301 Report (May 2013), 1, 38, *available at*: <http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf> [hereinafter 2013 Special 301 Report].

¹¹ Laura Hood, *Biodiversity: Facts and Figures*, SCIENCE AND DEVELOPMENT NETWORK (Aug. 10, 2010), <http://www.scidev.net/global/biodiversity/feature/biodiversity-facts-and-figures-1.html>. It is estimated that seventy percent of the world’s species are found in just twelve countries, including Brazil and India. *Id.* Brazil has the more vascular plant species (56,215 species estimated) than any other country on the planet, and India ranks fifth for number of vascular plant species by country (18,664 species estimated). *Id.*

technological development have not been effectively quantified; while international policy and jurisprudence have been moving towards a more socially and environmentally balanced intellectual property regime, true improvements in the system will not be realized until more scholarship is generated in this field.

I. BACKGROUND

A. International Framework Governing Biotechnology

Patent law is a matter of national law; it does not protect a patent holder outside of the country in which the patent was granted.¹² In order to harmonize national patent laws and provide for reciprocal enforcement of national laws, international agreements were implemented. These agreements set minimum standards for legal protection and enforcement for intellectual property rights internationally.¹³ The United States and the European Union were instrumental in initiating negotiations on international treaties because of their interests as substantial producers and exporters of patented goods.¹⁴

Within the international framework governing patent law are several agreements aimed at promoting sustainable development and biodiversity protection. This section will detail the major agreements that impact the development and trade of biotechnology patents (and patents generally) and the biodiversity agreements that impact patent law as well. It will then briefly describe the enforcement mechanisms that are in place to affect these regulations.

¹² See, *Patent Laws Around the World*, PATENT LENS, <http://www.patentlens.net/daisy/patentlens/ip/around-the-world.html> (last visited Apr. 1, 2014). There is no such thing as an “international patent.” *Id.*

¹³ See, Graham Dutfield, *The US and Europe are ‘Intellectual Property Fundamentalists,’* SCIENCE AND DEVELOPMENT NETWORK, <http://www.scidev.net/global/health/opinion/the-us-and-europe-are-intellectual-property-funda.html> (last visited Mar. 25, 2014).

¹⁴ See, e.g., *Fact Sheets on the European Union- 2014*, EUROPEAN PARLIAMENT, 3, http://www.europarl.europa.eu/ftu/pdf/en/FTU_6.2.2.pdf (last visited Apr. 14, 2014). (“Together with the US, the EU has played a central role in developing the international trading system since World War II”).

1. Governing Agreements

Paris Convention

The 1883 Paris Convention for the Protection of Industrial Property was the first diplomatic conference concerned only with international property rights.¹⁵ The Convention established an international bureau for administrative duties which eventually gave rise to the World Intellectual Property Organization (WIPO).¹⁶ The Convention is administered by WIPO and the agreement reached at the Paris Convention is still in effect for WIPO parties today.¹⁷ As of April 1, 2014, the Convention has 175 members and contains provisions related to inventions, trade names, trademarks, industrial designs, utility models, indications of source, origin, and unfair competition.¹⁸ The most important feature is the requirement that no country may, under its patent laws, provide preferential treatment to its citizens over non-nationals.¹⁹ The Convention also sets the right of priority for members.²⁰ Individuals who want international recognition of their patents can file with a contracting state, and are given twelve months to file with any other contracting state.²¹ The patent applications filed within those twelve months will be given the same priority date as the first application filed, and is not affected by any publications or sales of

¹⁵ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention]; see also, *WIPO Seminar on Intellectual Property for Faculty Members and Students of Ajman University*, WIPO, 1, 5 (Apr. 2004), available at:

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=6&ved=0CFoQFjAF&url=http%3A%2F%2Fwww.wipo.int%2Fedocs%2Fmdocs%2Farab%2Fen%2Fwipo_ip_uni_dub_04%2Fwipo_ip_uni_dub_04_1.doc&ei=2_UxU6fAFIzLsQT3t4HYAw&usq=AFQjCNFYGcZfP0ThaZfExSmneZbB1qkkSQ&sig2=u1HiDb1n3MVOjHRc2_g8Dw&bvm=bv.63587204,d.cWc&cad=rja.

¹⁶ Paris Convention, *supra* note 15, at art. 15.

¹⁷ The Convention was revised six times and amended on Sept. 28, 1979. See, *Summary of the Paris Convention for the Protection of Industrial Property (1883)*, WIPO, http://www.wipo.int/treaties/en/ip/paris/summary_paris.html (last visited Apr. 1, 2014).

¹⁸ Monique L. Cordray, *GATT v. WIPO*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 121, 122 (1994).

¹⁹ *Id.* at 123, citing to Paris Convention, *supra* note 15, at art. 2.

²⁰ Paris Convention, *supra* note 15, at art. 4.

²¹ *Id.*

similar articles in the interim.²² However, the Paris Convention does not require countries to recognize intellectual property protection at all, and thus, cannot compel international cooperation with individual intellectual property rights.²³

WIPO Convention

The World Intellectual Property Organization was officially established by the Convention Establishing the World Intellectual Property Organization (WIPO Convention) on July 14, 1967.²⁴ WIPO replaced the international bureau required by Article 15 of the Paris Convention.²⁵ It is a specialized agency of the United Nations. The objectives of the WIPO Convention are twofold: 1) to promote the protection of intellectual property throughout the world through cooperation among states, and, where appropriate, in collaboration with any other international organization; and 2) to ensure administrative cooperation among the unions.²⁶ Essentially, WIPO administers various multilateral treaties and provides a forum for dispute resolution (discussed in the enforcement section, *infra*). As of April 1, 2014 there are 187 contracting parties to the WIPO Convention.²⁷

Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) is an agreement administered by WIPO that enables individuals to file international patents.²⁸ As of April 1, 2014, 148 countries are parties.²⁹ The

²² *Id.*

²³ Cordray, *supra* note 18, at 127.

²⁴ Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3 [hereinafter WIPO Convention].

²⁵ *Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967)*, WIPO, http://www.wipo.int/treaties/en/convention/summary_wipo_convention.html (last visited Apr. 1, 2014).

²⁶ *Id.* at art. 3.

²⁷ *Contracting Parties: WIPO Convention*, WIPO, http://www.wipo.int/treaties/en/ShowResults.jsp?treaty_id=1 (last visited Apr. 1, 2014).

²⁸ Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645.

CBD is touted as the most important single convention for protecting the variety and variability of organisms and ecosystems.³⁵ The objectives of the CBD are:

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.³⁶

There are two main ways that the CBD attempts to facilitate conservation: through emphasizing *in situ* collection, which implies a need for protected areas, and *ex situ* banks so as to not unnecessarily threaten precarious ecosystems.³⁷ The Convention's ambitious goal of abating biodiversity loss comes attached to many limitations. Some argue that CBD has prioritized either access and benefit sharing, or protection of intellectual property rights over biodiversity conservation, while stakeholder debates fail to consider them as dependent objectives, and mutually exclusive if one takes priority over the other.³⁸ Without the requisite balance between the two objectives, the ultimate objective of slowing biodiversity loss is far from being achieved.³⁹ Furthermore, the CBD is only a commitment from parties; the *goals* are (1) to pursue mechanisms for obtaining prior informed consent, mutually agreed terms in bioprospecting agreements, disclosure of traditional knowledge holders; (2) establish a certification system for trade in genetic resources; and (3) halt biodiversity loss.⁴⁰ In recognizing

³⁵ See, Stas Burgiel, *Convention on Biological Diversity: a Progress Report*, SCIENCE AND DEVELOPMENT NETWORK (Feb. 1, 2004), <http://www.scidev.net/en/agriculture-and-environment/policy-briefs/convention-on-biological-diversity-a-progress-repo-1.html>.

³⁶ Convention on Biological Diversity, *supra* note 33, art. 1.

³⁷ Phillip Cullet, *The Convention on Biological Diversity*, INTERNATIONAL ENVIRONMENTAL LAW RESEARCH CENTRE (2003), <http://www.ielrc.org/content/f0301.htm>.

³⁸ Kristin G. Rosendal, *Balancing Access and Benefit Sharing and Legal Protection of Innovation From Bioprospecting: Impacts on Conservation of Biodiversity*, 15 J. ENV'T DEV. 428, 429 (2006).

³⁹ *Id.*

⁴⁰ Cullet, *supra* note 37. The text of the CBD makes it clear that countries cannot be compelled to act, for example, the CBD requires that "[e]ach Contracting Party, shall, *as far as possible and as appropriate* establish a system of

that intellectual property rights may impact the goals of the CBD, the convention states that international and national laws should be supportive of the objectives.⁴¹ In effect, the CBD is only a set of guidelines; there is no dispute settlement process to the CBD and there is no enforcement mechanism.⁴² Therefore, there is no obligation to perform under the treaty and no recourse for those attempting to enforce the treaty.⁴³

A conference of the parties under the CBD recently implemented a strategic plan with biodiversity targets for 2020 in an effort to actualize the original goals of the Convention, particularly in the area of the access and benefit sharing provisions of the CBD.⁴⁴ The goals include addressing the underlying causes of biodiversity loss and enhancing the benefits to all from biodiversity and ecosystem services.⁴⁵ The strategic plan includes the supplemental Nagoya Protocol and specific Aichi Biodiversity targets.⁴⁶ The Aichi biodiversity targets set specific goals for reducing direct pressures on biodiversity,⁴⁷ safeguarding ecosystems,⁴⁸ and enhancing benefits to all from biodiversity and ecosystem services,⁴⁹ among others. The Nagoya Protocol

protected areas or areas where special measures need to be taken to conserve biological diversity...” (emphasis added). Convention on Biological Diversity, *supra* note 33, art. 8.

⁴¹ *Study on the Inter-Relations Between Intellectual Property Rights Regimes and the Conservation of Genetic Resources*, *supra*, note 32, at 9, citing to Convention on Biological Diversity, *supra* note 33, art. 15.

⁴² Burgiel, *supra* note 35.

⁴³ See Laura Grebe, *Requiring Genetic Source Disclosure in the United States*, 44 CREIGHTON L. REV. 367, 384-85 (2011).

⁴⁴ *Strategic Plan for Biodiversity 2011-2020*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://www.cbd.int/sp/> (last visited Mar. 25, 2014).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ One specific goal (Target 5) for reducing direct pressures on biodiversity is to halve the rate of all natural habitat loss by 2020, and “where feasible,” bring the rate close to zero. *Aichi Biodiversity Targets*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://www.cbd.int/sp/targets/> (last visited Apr. 1, 2014).

⁴⁸ A goal for safeguarding ecosystems is Target 12, to prevent the extinction of known threatened species and improve their conservation status by 2020. *Id.*

⁴⁹ Target 14 aims to restore and safeguard ecosystems that provide essential services while taking into account the needs of women, indigenous and local communities, and the poor and vulnerable. *Id.*

was adopted on October 29, 2010 to address the issues of enforcement and set rules on access and benefit sharing, but its success has been questioned.⁵⁰

Despite being considered a clear advance towards implementing the foundational objectives of the CBD, there are several criticisms of the protocol.⁵¹ One concern of the Nagoya Protocol is that implementation depends entirely on national legislation and implementation at the national level which impacts both the conservation goal and the benefit sharing goal.⁵² The amount of protected areas has increased worldwide since the CBD, but the protected areas are generally in less biologically-diverse countries or in already degraded areas and thus, fail to offset the increase in destruction.⁵³ Many protected areas, particularly in the tropics, are faced with widespread threats enabled by vague and ambiguous definitions of protected area.⁵⁴ Other concerns are that the Nagoya Protocol did not address the lack of forums for indigenous people to adjudicate biopiracy claims and weak penalties for violating the rules.⁵⁵ Furthermore, access and benefit sharing schemes have been implemented in a limited number of countries but their success is tightly correlated to other multilateral agreements and suffers from the same

⁵⁰ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Oct. 29, 2010, UNEP/CBD/COP/DEC/X/1 of 29.

⁵¹ Gurdial Singh Nijar, *Traditional Knowledge Systems, International Law and National Challenges: Marginalization or Emancipation*, 24 EUR. J. INT'L L. 1205, 1218 (2013).

⁵² See, *Nagoya Protocol on Access and Benefit Sharing*, UNION FOR ETHICAL BIOTRADE (2010), available at: <http://ethicalbiotrade.org/dl/benefit-sharing/UEBT-ABS-Nagoya-Protocol.pdf>; see also, ELISA MOREGERA, MATTHIAS BUCK, & ELSA TSIUMANI, *THE 2010 NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING IN PERSPECTIVE* (2013).

⁵³ See, S. Chape et al., *Measuring the Extent and Effectiveness of Protected Areas as an Indicator for Meeting Global Biodiversity Targets*, 360 PHILOSOPHICAL TRANSACTIONS ROYAL SOC'Y BIOLOGY 443, 450 (2005) (indicating that the number and extent of protected areas are only a superficial indication of the "political commitment" to conserve biodiversity). Frequently, protected areas do not correlated to areas to high conservation priorities. *Id.* at 451.

⁵⁴ *Id.* at 445, 451-52. There are over 1,000 known ways of defining the term "protected area" around the world. *Id.* at 445.

⁵⁵ Tim K. Mackey & Bryan K. Liang, *Integrating Biodiversity Management and Indigenous Biopiracy Protection to Promote Environmental Justice and Global Health*, 102 AM. J. PUB. HEALTH 1091, 1091 (2012). Biopiracy is discussed in section I.B.2, *infra*.

weaknesses.⁵⁶ The Protocol also contains qualifiers weakening obligations that are similar to the CBD.⁵⁷ Of the 193 parties to the CBD, only 92 have signed the Nagoya Protocol.⁵⁸ India has ratified the Protocol as of October 2009, while Brazil has only signed and the United States has neither signed nor ratified the Protocol.⁵⁹ The United States' lack of support for the protocol and the CBD generally is attributed to concerns regarding the requirement of technology transfer to developing countries (believing it would undermine U.S. intellectual property interests).⁶⁰

Trade-Related Aspects of Intellectual Property

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established internationally-agreed trade rules for intellectual property rights in order to introduce more predictability to the system, and to provide a framework for systematic dispute resolution.⁶¹ The agreement was pursued by the United States and other developed countries through the General Agreement on Tariffs and Trade after becoming dissatisfied with WIPO's inability to

⁵⁶ See the following sections on Trade Related Aspects of Intellectual Property and Enforcement, for example.

⁵⁷ For example, Nagoya Protocol at Art. 5 states: "Each Party shall take... measures, *as appropriate*, with the aim of ensuring that benefits... are shared in a fair and equitable way with the communities concerned..." (emphasis added).

⁵⁸ *List of Parties*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://www.cbd.int/convention/parties/list/default.shtml#tab=2> (last visited Mar. 25, 2014).

⁵⁹ *Id.* The legal implication of signing versus ratifying is the formal consent to be bound; however, signatories still have an obligation to refrain from acts which would defeat the object and purpose of a treaty. Vienna Convention on the Law of Treaties, Jan. 27, 1980, 1155 U.N.T.S. 331, 336-7. *See also*, *Treaty Description* CONVENTION ON BIOLOGICAL DIVERSITY, <http://www.cbd.int/world/ratification.shtml> (last visited Mar. 25, 2014).

⁶⁰ Cyril Kormos, *When it Comes to the Convention on Biological Diversity, the U.S. Stands with... Somalia and Andorra? Maybe It's Time We Join the 192 Other Countries*, WILD FOUNDATION (Aug. 27, 2009), <http://www.wild.org/blog/when-it-comes-to-the-convention-on-biological-diversity-the-us-stands-with%E2%80%A6somalia-and-andorra-maybe-it%E2%80%99s-time-we-join-the-192-other-countries/>. The technology transfer requirement requires parties provide or facilitate access to and transfer technologies that are relevant to conservation and sustainable use of biological diversity or make use of genetic resources. Convention on Biological Diversity, *supra* note 33, at art. 16.

⁶¹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]; *see also*, *Understanding the WTO: The Agreements*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Mar. 25, 2014). As of Mar. 2, 2013, there are 159 members of the WTO. *Id.*

enforce intellectual property rights.⁶² The agreement was negotiated at the 1986-94 Uruguay Round and obligates members of the World Trade Organization to adopt minimum standards of intellectual property protection.⁶³ Although the treaty retained the standards of the Paris Convention, it strengthened them enormously. The relevant patent provisions are: compulsory terms that require adequate remuneration for the use and efforts to obtain authorization prior to using the patent, *inter alia*;⁶⁴ a minimum patent term of twenty years;⁶⁵ disclosure virtually equivalent to the U.S. enablement requirements (discussed in the benefits section and U.S. law, *infra*);⁶⁶ and exclusion of patentable inventions that may prejudice the environment, harm animal, human, or plant life or health, or be immoral.⁶⁷ TRIPS also obligates Members to provide either patent and/or a unique system of protection to plant varieties.⁶⁸ Contrary to the Paris Convention, TRIPS also expressly grants a patentee the right to exclude others from “making, selling, offering for sale, or importing infringing products or processes.”⁶⁹

TRIPS does not create new patent law; rather, it set standards for national laws to create “equal trading partners” in the global marketplace.⁷⁰ The discussion at the Uruguay Round was criticized heavily for its lack of developing country representation.⁷¹ Some argue that the

⁶² Cordray, *supra* note 18, at 121.

⁶³ *Id.* at 126.

⁶⁴ TRIPS Agreement, *supra* note 61, at art. 31. Compulsory licensing is defined as use of a patent without authorization, the justifications for which are not specifically defined by TRIPS. *Id.*

⁶⁵ *Id.* at art. 33.

⁶⁶ *Id.* at art. 29.1.

⁶⁷ *Id.* at art. 27.2. See Cordray, *supra* note 18, at 126-27, for a discussion of the most relevant provisions of TRIPS.

⁶⁸ TRIPS Agreement, *supra* note 61, at art. 27.3(b). See also, DANIEL F. ROBINSON, CONFRONTING BIOPIRACY: CHALLENGES, CASES, AND INTERNATIONAL DEBATES, 29 (2010).

⁶⁹ TRIPS Agreement, *supra* note 61, at art. 28.

⁷⁰ Jeffrey Colin, *Coming Into Compliance with TRIPS: A Discussion of India's New Patent Laws*, 25 CARDOZO ARTS & ENT. L.J. 877, 877-78 (2007).

⁷¹ See, e.g., Jean M. Dettmann, *GATT: An Opportunity for an Intellectual Property Rights Solution*, 4 TRANSNAT'L LAW. 347, 371 (1991) (developing countries assert that they lack the bargaining power to negotiate and that consequently their interests are not adequately reflected in the results”)

agreement narrowed developing countries access to technology, and discouraged diffusion of new technologies needed for competitive economic growth.⁷² This result was anticipated by developing countries who strongly opposed the United States' efforts to obtain higher standards through WIPO, forcing the United States to take their ideas to GATT where they had more influence.⁷³ India, Brazil, and the United States are all parties to TRIPS.

International Convention for the Protection of New Varieties of Plants

The International Convention for the Protection of New Varieties of Plants (UPOV) was adopted in 1961.⁷⁴ The purpose of UPOV is to acknowledge breeders of new varieties of plants by granting them intellectual property rights.⁷⁵ The adoption represents the first point at which there was recognition of the rights of plant breeders on an international basis.⁷⁶ Although not technically a patent, the breeders term must be at least twenty years⁷⁷ and the scope of the breeders rights with respect to the propagated material of the protected variety includes: production or reproduction condition for the purpose of propagation, offering for sale, selling or marketing, exporting, importing, or stocking.⁷⁸ Plant varieties that are eligible for protection must be new, distinct, uniform, and stable.⁷⁹ This Treaty is not self-executing; it requires states to adopt their own laws to mirror these policies.⁸⁰

⁷² Evelyn Su, *The Winners and the Losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries*, 23 HOUS. J. INT'L L. 169, 172 (2000).

⁷³ Cordray, *supra* note 18, at 124.

⁷⁴ International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89 [hereinafter UPOV].

⁷⁵ *Id.*

⁷⁶ *About UPOV: Overview*, UPOV, <http://www.upov.int/about/en/overview.html> (last visited Apr. 1, 2014).

⁷⁷ UPOV, *supra* note 71, at art. 19.

⁷⁸ *Id.* at art. 14.

⁷⁹ *Id.* at arts. 6-9.

⁸⁰ *UPOV Lex*, UPOV, http://www.upov.int/upovlex/en/upov_convention.html (last visited Apr. 4, 2014).

There are strong criticisms of UPOV. Chief among the concerns is that this new protection encourages the development of genetically uniform seeds (because UPOV requires uniform seeds) which limits who can operate on the seed market and what kinds of seeds will be marketed; the marketed seeds will produce monocultures with their own plethora of ecological and economic consequences.⁸¹ Farmers are also virtually excluded from the process because most farmers do not have the means or formal “innovation” to submit applications for protection.⁸² Additionally, many farmers rely on seeds for exchange with other farmers, but this activity is precluded under UPOV.⁸³ As of December 5, 2012, there are seventy-one members of UPOV, including both the United States and Brazil; India is not a member.⁸⁴

International Treaty for Plant Genetic Resources for Food and Agriculture

The International Treaty for Plant and Genetic Resources for Food and Agriculture (ITPGRFA) was adopted in 2004 under the United Nations Food and Agriculture Organization.⁸⁵ It has since been ratified by 131 nations and recognizes the inherent tension between plant patents and world hunger; the main goal of ITPGRFA is to recognize and protect farmer’s rights and traditional knowledge while promoting food security through conservation.⁸⁶ The Treaty has three main aims:

⁸¹ *Top Ten Reasons Not to Join UPOV*, GRAIN (May 1998), <http://www.grain.org/article/entries/1-ten-reasons-not-to-join-upov>.

⁸² *Id.*

⁸³ Robinson, *supra* note 68, at 35.

⁸⁴ *Members of the International Union for the Protection of New Varieties of Plants*, UPOV (Dec. 5, 2012), <http://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf>.

⁸⁵ International Treaty on Plant Genetic Resources for Food and Agriculture Annex I, Nov. 3, 2001, S. Treaty Doc. No. 110-19 [hereinafter ITPGRFA].

⁸⁶ *International Treaty on Plant Genetic Resources for Food and Agriculture: Farmer’s Rights*, FAO, <http://www.planttreaty.org/content/farmers-rights> (last visited Mar. 25, 2014). See also, *Future Revisions of International IPR Agreements Affecting the Protection of Plant Varieties: the WTO Doha Round and the ITPGR*, FAO (2004), available at: <ftp://ftp.fao.org/docrep/fao/007/y5714e/y5714e00.pdf> (“[D]eveloping nations saw the

- 1) recognizing the enormous contribution of farmers to the diversity of crops that feed the world;
- 2) establishing a global system to provide farmers, plant breeders, and scientists with access to genetic material; and
- 3) ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated.⁸⁷

The most innovative feature of the Treaty is that Members are obligated to share access to what have been identified as the world's most important crops for food security through public gene banks.⁸⁸ The Treaty is also associated with a fund to invest in "high impact" projects for farmers in developing countries to develop and conserve crop diversity.⁸⁹ The effectiveness of the Treaty has not been quantified and there is no clear textual guidance; issues range from how to identify the strains specific technologies evolved from, to who deserves what amount of compensation for the innovation (simply defining the mechanisms for benefit sharing), and how to develop national capacity to implement the Treaty.⁹⁰ Furthermore, Brazil and India both parties to ITPGRFA, but the United States is not a party.⁹¹

review process as a means to harmonize TRIPs with the CBD and the undertaking in order to promote biodiversity, recognize farmers' rights and protect traditional knowledge and the rights of indigenous communities").

⁸⁷ *The International Treaty on Plant Genetic Resources for Food and Agriculture: Overview*, FAO, <http://www.planttreaty.org/content/overview> (last visited Mar. 25, 2014).

⁸⁸ *The International Treaty on Plant Genetic Resources for Food and Agriculture: What is the Multilateral System*, FAO, <http://www.planttreaty.org/content/what-multilateral-system> (last visited May 25, 2014). The gene banks comprise a pool of genetic resources containing 64 crops that in total, account for 80% of all human consumption. *Id.*

⁸⁹ *The International Treaty on Plant Genetic Resources for Food and Agriculture: What is the Multilateral System*, FAO, <http://www.planttreaty.org/node/3072> (last visited May 25, 2014).

⁹⁰ Emily Marden & R. Nelson Godfrey, *Intellectual Property and Sharing Regimes in Agricultural Genomics: Finding the Right Balance for Innovation*, 17 *DRAKE J. AGRIC. L.* 369, 383-84 (2012).

⁹¹ *Status of the International Treaty on Plant Genetic Resources for Food and Agriculture*, FAO, http://www.fao.org/fileadmin/user_upload/legal/docs/4_033s-e.pdf (last visited Apr. 9, 2014). *See also*, Robinson, *supra* note 68, at 37.

2. Enforcement

Intellectual property rights are enforced internationally when nations bring proceedings against other nations for treaty violations of treaty obligations.⁹² Enforcement mechanisms for TRIPS parties must ensure that procedures available under national law encourage “effective action against any act of infringement of intellectual property rights covered by [TRIPS], including expeditious remedies to prevent infringements and remedies which constitute deterrent to further infringements.”⁹³ When Member nations may not be in compliance with certain aspects of TRIPS, they can file complaints with the WTO.⁹⁴ Both WIPO and the WTO provide alternative dispute resolution that allow settlements to be made outside of court, but only the WTO has binding adjudicatory processes.⁹⁵ Individuals are not able to bring proceedings against nations for violations of treaty obligations, but may enforce intellectual property rights in national courts. Depending on the national law, there may be both criminal penalties and civil remedies for violations of national intellectual property law.

WIPO

The World Intellectual Property Organization (WIPO) is the body governing international intellectual property.⁹⁶ It is an agency of the United Nations that enforces intellectual property rights. WIPO maintains an arbitration and mediation center that enables private parties to settle technological disputes outside of court.⁹⁷ WIPO’s physical ability to enforce rights is very weak;

⁹² See, *Patent Laws Around the World*, *supra* note 12.

⁹³ Naomi A. Bass, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT’L L. REV. 191, 201 (2002), citing to TRIPS Agreement, *supra* note 58, at art. 41.

⁹⁴ Bass, *supra* note 93, at 201-02.

⁹⁵ See, Stuart. S. Malawer, *U.S.-China Litigation in the World Trade Organization*, 250 N.Y. L.J. 5, 5 (2013).

⁹⁶ Cordray, *supra* note 18, at 121.

⁹⁷ *Alternative Dispute Resolution*, WIPO, <http://www.wipo.int/amc/en/> (last visited Mar. 28, 2014).

their dispute settlement mechanisms have been considered by some to be worthless.⁹⁸ Referral of disputes to the International Court of Justice is permitted under certain WIPO conventions, but no referrals have been made.⁹⁹ Other impediments to enforcement are varied; many members of the Paris Convention do not recognize the jurisdiction of WIPO's court, the process is long and complex, and countries are reluctant to initiate enforcement actions because it is perceived as an "unfriendly" action.¹⁰⁰ Recent discussions by WIPO members have sought to "gain respect for intellectual property," but as of March 6th, 2014, no resolution on the future of enforcement has been reached.¹⁰¹

WTO

Under the WTO, when one country adopts a trade policy measure or takes action that may be in violation of WTO agreements (or fails to take action in violation of agreements), countries can use the WTO dispute settlement mechanism.¹⁰² With the TRIPS agreement came a stronger enforcement mechanism, although its true effectiveness is also questioned.¹⁰³ The dispute settlement mechanism is compulsory; all Members consent to the jurisdiction of the WTO and no other fora may be used for a WTO-related dispute.¹⁰⁴ Within the WTO dispute settlement

⁹⁸ Cordray, *supra* note 18, at 131.

⁹⁹ Frederick M. Abbot, *The Future of Multilateral Trading System in the Context of TRIPS*, 20 HASTINGS INT'L & COMP. L. REV. 661, 664 (1997). Only states have standing to appear before the International Court of Justice; the Court has no jurisdiction over individuals, non-governmental organizations, corporations, or other private parties. *Practical Information*, THE INTERNATIONAL COURT OF JUSTICE, <http://www.icj-cij.org/information/index.php?p1=7&p2=2#2> (last visited May 7, 2014).

¹⁰⁰ Abbot, *supra* note 99, at 664.

¹⁰¹ Catherine Saez, *WIPO Enforcement Committee: Positive Sharing of Experiences but Future Work Elusive*, INTELLECTUAL PROPERTY WATCH (Mar. 6, 2014 9:17 AM), <http://www.ip-watch.org/2014/03/06/wipo-enforcement-committee-positive-sharing-of-experiences-but-future-work-elusive/>.

¹⁰² *Understanding the WTO: Settling Disputes*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (last visited Mar. 28, 2014).

¹⁰³ See, Peter K. Yu, *The TRIPS Enforcement Dispute*, 89 Neb. L. Rev. 1046, 1047 (2011)

¹⁰⁴ *Introduction to the WTO Dispute Settlement System*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c1s3p3_e.htm (last visited Apr. 6, 2014).

process is a sixty-day period of mandatory mediation, followed by a hearing in front of a panel appointed by the director of the WTO or selected by the parties that is comprised of experts in the field, and a final report to the parties and WTO members.¹⁰⁵ If a case runs through the entire process, the WTO estimates resolution will take less than one year or fifteen months if appealed.¹⁰⁶ Final decisions are binding and cooperation with the decision is mandatory.¹⁰⁷ Failure to abide by a ruling enables the enforcing party to retaliate through suspension of certain obligations or trade sanctions (with permission from the dispute settlement body).¹⁰⁸

While this is certainly more detailed than WIPO provisions, the process still faces heavy criticism. Challenges faced in actually implementing the enforcement provisions stem from a lack of historical development, resource and capacity constraints, and non-intellectual property/trade related issues that attach to these disputes.¹⁰⁹ Commentators believe that all the enforcement provisions really dictate are minimum standards of due process that member states must provide parties to a dispute and is a foundation on which to build *future* legislation.¹¹⁰

WIPO-WTO COOPERATION TREATY

On Jan. 1, 1996, WIPO and the WTO signed a cooperation treaty.¹¹¹ The organizations have a “mutually supportive relationship” where all countries that are parties to WIPO but not the WTO (and vice versa) will make available the same legal-technical assistance in resolving

¹⁰⁵ *Understanding the WTO: Settling Disputes*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (last visited Mar. 28, 2014).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ Peter K. Yu, *TRIPS and Its Achilles' Heel*, 18 J. INTELL. PROP. L., 479, 483-504 (2011).

¹¹⁰ *Id.* at 499, citing to J.H. Reichman & David Lange, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMP. & INT'L L. 11, 34 (1998).

¹¹¹ World Intellectual Property Organization-World Trade Organization: Agreement Between WIPO and WTO, Dec. 22, 1996, 35 I.L.M. 754 [hereinafter WIPO-WTO Cooperation Agreement].

disputes.¹¹² The Agreement provides cooperation in three main areas: notification of, access to, and translation of national laws and regulations; implementation of procedures for the protection of national emblems; and technical cooperation.¹¹³

B. Patents and Ecology

The agreements discussed the previous section clearly show a strong correlation between international intellectual property rights and the environment. This section will specifically describe how patent law theoretically and practically can benefit biodiversity conservation and conclude with a description of the three factors associated with patent law that are driving ecological degradation.

1. Benefits

Patent law is considered by a variety of scholars to be a panacea to many of the world's most pressing ailments: food scarcity, pollution, population growth, etc.¹¹⁴ In their most basic sense, patents are used to incentivize and reward innovation.¹¹⁵ Patents allow developers exclusive market control of their invention for a period of time, preventing other developers from utilizing that specific technology.¹¹⁶ Biotechnology, an industry fueled by patent incentives,¹¹⁷ is considered “essential” to developing a “sustainable global environment.”¹¹⁸ When applied to the

¹¹² *Id.*

¹¹³ *Trade Topics: TRIPS Cooperation*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/intel3_e.htm (last visited Apr. 5, 2014).

¹¹⁴ See, Andrew W. Torrance, *Patent Law, HIPPO, and the Biodiversity Crisis*, 9 J. MARSHALL REV. INTELL. PROP. L. 624 (2010).

¹¹⁵ See generally, Michael Kremer & Heidi Williams, *Incentivizing Innovation: Adding to the Tool Kit*, 10 INNOVATION POLICY AND THE ECONOMY 1, 2 (2010).

¹¹⁶ *Id.*

¹¹⁷ Joseph Damond, *Biotechnology Industry Organization: 2014 Special 301 Submission to the Office of the U.S. Trade Representative*, BIOTECHNOLOGY INDUS. ORG. 1, 3, (2014), <http://www.bio.org/sites/default/files/2014%20BIO%20Submission.pdf>.

¹¹⁸ Thomas P. Redick, *Biotechnology, Biosafety and Sustainable Development*, 12 NAT. RESOURCES & ENV'T 114, 114 (1997).

biophysical world, the theoretical incentives for patenting technology should be able to solve any problem inventors set their mind to, the possibilities are limitless.

There are two categories of the ecological benefits of patents. Arguably one of the strongest correlations between patent law and conservation is the incentive to preserve the wealth of currently untapped resources.¹¹⁹ The other benefit that patent law provides conservation initiatives with is through promoting “green” technological innovation.¹²⁰ Within these two categories are several theories of how ecologically sustainable development is enhanced through strong intellectual property regimes.

The first category discussed is the monetary value that preserved swaths of natural ecosystems retain. In the most basic sense, the benefits that can be reaped from the world’s medicine cabinet “creates financial incentives for the protection and sustainable use of biological resources.”¹²¹ Not only does the sheer prospect at locating microorganisms with the potential to be engineered into a patentable product incentivize preservation,¹²² but many patent laws (including those of the United States), deny any patent applications when source taxon cannot be

¹¹⁹ D. May, *Intellectual Property and Environmental Law*, 15 NAT. RESOURCES & ENV’T 214,

¹²⁰ Michael A. Gollin, *Using Intellectual Property to Improve Environmental Protection*, HARV. J.K. & TECH. 193, 193 (2001).

¹²¹ Holly Doremus, *Nature, Knowledge and Profit: The Yellowstone Bioprospecting Controversy and the Core Purposes of America’s National Parks*, 26 ECOLOGY L.Q. 401, 486 (1999).

¹²¹ *Edmonds Inst. v. Babbitt*, 42 F.Supp.2d 1, 5 (D.C. Cir. 1999).

¹²² For a philosophical discussion on the inherent value of untapped resources, see ALDO LEOPOLD, *ROUND RIVER: FROM THE JOURNALS OF ALDO LEOPOLD*, 146 (1993):

The last word in ignorance is the man who says of an animal or plant, ‘What good is it?’ If the land mechanism as a whole is good, then every part is good, whether we understand it or not. If the biota, in the course of aeons, has built something we like but do not understand, then who but a fool would discard seemingly useless parts? To keep every cog and wheel is the first precaution of intelligent tinkering.

located for reasons of rareness or extinction.¹²³ The enablement requirement the United States (and included in the TRIPS agreement) states that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.¹²⁴

U.S. courts have interpreted this section of the statute as requiring some type of depository to exist for the organism that is the subject of the patent be publicly accessible.¹²⁵ For microorganisms *ex situ* deposits are common, but having access to large multi-cellular organisms like plants and animals may require access to *in situ* deposits where the organisms have not been removed from their natural location.¹²⁶ When relying on organisms being available *in situ*, the inventor runs the risk of an “extinction bar” to patentability; if an organism is no longer accessible due to rareness or extinction, the enablement requirements are not satisfied.¹²⁷ One author goes as far to suggest that the incentive behind *in situ* resources could “spur” the creation of privately funded “patent parks.”¹²⁸

The second category of patents benefiting the environment is through the technology developed through the incentivized process. Some scholars believe that the best mechanism for protecting the environment is incentivizing beneficial technology and restricting harmful

¹²³ See Torrance, *supra* note 114, at 643-35.

¹²⁴ 35 U.S.C. § 112 (2014).

¹²⁵ See, e.g., *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342m 1359 n.25 (Fed. Cir. 1998) (“Both of these cell lines... are readily available to the public, and the... patent discloses the locations at which both of these starting materials may be procured. Such public deposits of living materials may enable a claimed invention whose manufacture or use depends thereupon.”).

¹²⁶ See Torrance, *supra* note 114, at 635, citing to *Ex parte Rinehart*, No. 564-47, 1989 WL 281892 (B.P.A.I. Jan. 10, 1985).

¹²⁷ *Id.* at 637.

¹²⁸ *Id.* at 639.

technology.¹²⁹ Patents can be used to further environmental goals by protecting specific environmental technologies including: “(1) industrial processes which minimize resource consumption and waste production, (2) consumer products which are environmentally benign throughout their life cycles, (3) recycling equipment and processes, (4) waste management technologies for solid and hazardous waste, (5) pollution control devices, and (6) products and methods for cleaning up pollution.”¹³⁰ For example, in terms of combating invasive and exotic species, there are numerous patented inventions currently in use. These inventions range from nondestructive methods for detecting wood boring insects to noxious weed control through attracting livestock to target areas by food type.¹³¹ Patented pollution control technologies have also been highly successful.¹³² Genetically engineered *Pseudomonas* bacterium has been used to clean large scale oil spills and decontamination of heavy metals, carcinogenic pesticides, and hydrocarbons in soil and water.¹³³ Other technologies have helped alleviate unintended overexploitation through by-catch in the fishing industry.¹³⁴ Finally, while many patents will not directly decrease the rate of human population growth, some researchers go as far to say that the technological innovation that patents inspire can offset the negative impact that affluence and wealth have on biodiversity.¹³⁵

¹²⁹ Gollin, *supra* note 120, at 193-94.

¹³⁰ *Id.* at 196.

¹³¹ Torrance, *supra* note 114, at 639-45.

¹³² *Id.* at 646-651.

¹³³ Oregon State University, *New Strain of Bacteria Could Aid in Oil Spill, Other Environmental Cleanup*, News and Res. Comm. (2010), available at: <<http://oregonstate.edu/ua/ncs/archives/2010/jun/new-strain-bacteria-discovered-could-aid-oil-spill-other-environmental-cleanup>>.

¹³⁴ Torrance, *supra* note 114, at 653.

¹³⁵ *Id.* at 651-653 (“technological innovation can also act as an essential counterweight to the negative effects P [population] and A [affluence] have on biodiversity”).

2. Pitfalls of Patents

The market exclusivity that makes patents so appealing to many technology developers also makes technology arguably less accessible and more expensive, the root of many of the issues associated with patent development.¹³⁶ The benefits previously mentioned can be negated through similar pitfalls associated with patents. The beneficial technologies created through patent incentives are subject to a “tragedy of the anticommons” theory and are entirely dependent on the market for green technology; the inherent value in the preserved wilderness is subject to an explosion of the bioprospecting industry; and the bioprospecting industry has spawned a generation of bio-pirates, those who convert traditional knowledge into patented technologies without sharing benefits. The world has acknowledged the problems through the previously discussed treaties and agreements, but the physical impacts have not been quantified which could be one reason the treaties have been ineffective.

Tragedy of the Anticommons Theory

Biologist Garrett Hardin coined the phrase “tragedy of the commons” in the 1968 as a response to an article regarding the future of nuclear war.¹³⁷ Hardin was not responding to the authors’ theories on national security in a nuclear world, but responding to authors’ conclusion that there was no technical solution to a problem.¹³⁸ He was not criticizing the conclusion but actually contributing to dialogue of problems with no solution, namely, population growth. Hardin concluded that individual humans acting rationally with access to a common pool of resources will ultimately use those resources to the detriment of society as a whole.¹³⁹ An

¹³⁶ Gollin, *supra* note 120, at 196.

¹³⁷ Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243, 1243 (1968), citing to Jerome B. Wiesner & Herbert F. York, *National Security and the Nuclear-Test Ban*, 211 SCI. AM. 27 (1964).

¹³⁸ Hardin, *supra* note 137, at 1243.

¹³⁹ *Id.* at 1244.

example Hardin gives is pollution: the rational man will find that the cost of waste discharged into a common pool is less than the cost of purifying his waste before release them.¹⁴⁰ Compounded by every rational man believing the costs outweigh the benefits, the commons becomes a cesspool.¹⁴¹ Hardin ultimately argues that freedom to breed (a commons in reproduction) will bring ruin to all.¹⁴²

A corollary to Hardin's theory is the "tragedy of the anticommons." This theory postulates that too many property owners of scarce resources leads to underuse and inhibits socially desirable outcomes.¹⁴³ This theory was specifically developed in relation to the biotechnology industry. When too many inventors own exclusive rights to upstream technologies, too many downstream innovators are excluded.¹⁴⁴ Each patent granted in the field acts like a "tollbooth," increasing the cost and slowing down the pace of technological innovation.¹⁴⁵ This anticommons is often called a "patent thicket" and is an issue for research and development all over the world.¹⁴⁶ Factors contributing to this patent thicket include strengthened patent rights and broadening of patentable subject matter and the growth of trade in high technology products (which increases demand and patenting trends).¹⁴⁷ There is little empirical evidence on the effect of thickets on innovative activity, but there are quantified barriers to entry into a particular technology sectors (primarily semiconductors and telecommunications, but also

¹⁴⁰ *Id.* at 1245.

¹⁴¹ *Id.*

¹⁴² *Id.* at 1248.

¹⁴³ Michael A. Heller & Rebecca S. Eisenberg, *Can Patent's Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998).

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* at 699.

¹⁴⁶ See, e.g., Bronwyn Hall, et al., *A Study of Patent Thickets*, NAT'L INST. OF ECON. AND SOC. RESEARCH 1, 1 (Oct. 29, 2012), available at: http://elsa.berkeley.edu/~bhall/papers/HHvGR_Patent_Thickets_FIN_29Oct12.pdf (discussing patent thickets and their economic impact in the United States and Europe).

¹⁴⁷ *Id.*

biotechnology).¹⁴⁸ What is clear is that highly protected technologies run the risk of slowing the transfer technological capabilities to developing nations.¹⁴⁹

Further, with regard to genetically modified organisms, the patent thicket has become readily apparent. In the 2004 case, *Monsanto Canada, Inc. v. Schmeiser*, the Supreme Court of Canada held that farmers whose crops were contaminated by protected seeds could not continue to propagate or use the progeny resulting from their own seed in any way:

[A] farmer whose field contains seed or plants originating from seed spilled into them, or blown as seed, in swaths from a neighbour's land or even growing from germination by pollen carried into his field from elsewhere by insects, birds, or by the wind, may own the seed or plants on his land even if he did not set about to plant them. He does not, however, own the right to the use of the patented gene, or of the seed or plant containing the patented gene or cell.¹⁵⁰

When applied to environmental technological innovation there is a potential for these strict property rights to undermine the benefits associated with patents and exacerbate ecological degradation. Many countries, like the United States, have a compulsory licensing or eminent domain-type law that allows government to appropriate any technology that may have a societal benefit for reasonable compensation that alleviate this fear.¹⁵¹ However, compulsory licensing may also seriously undercut the incentive to develop environmentally useful technologies.¹⁵²

Bioprospecting Explosion

Physical diminution in biodiversity on the planet is clearly a result of many factors. One that is rarely considered is the race to invent. Patents have led to the bioprospecting explosion where

¹⁴⁸ *Id.* at 27-29.

¹⁴⁹ Shawn Kolitch, *The Environmental and Public Health Impacts of U.S. Patent Law: Making the Case for Incorporating a Precautionary Principle*, 36 ENVTL. L. 221, 234 (2006), citing to the English Statute of Monopolies of 1623, 21 Jac. 1, c. 3, reprinted in DONALD S. CHISUM, CHISUM ON PATENTS app. 8-3 (perm. ed., 2005).

¹⁵⁰ *Monsanto Canada, Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, ¶92 (Can.).

¹⁵¹ See Gollin, *supra* note 120, at 221, citing to 28 U.S.C. § 1498 (2014). Some environmental laws also have mandatory licensing provisions when no other alternative methods to solving an environmental problem are available. *Id.* at 222-226 (citing to the Clean Air Act 42 U.S.C. §§ 7401-7671 (2014)).

¹⁵² *Id.*

people have spent millions of dollars extracting and analyzing species for their potential commercial and social value.¹⁵³

The term “bioprospecting” refers to a relatively new method of natural resource exploitation. Natural resource use on federal lands historically has consisted largely of traditional consumptive uses such as timber harvesting, mining, hunting, and grazing. Bioprospecting presents a totally new, related (whether the fundamental nature is different than traditional consumptive or indistinguishable is a matter of much debate) use that targets microscopic resources—the genetic and biochemical information found in wild plants, animals, and microorganisms.¹⁵⁴

Although many organisms can be extracted and developed in laboratories, some are often too complex to be synthesized in laboratories immediately after discovery.¹⁵⁵ As a result, many pharmaceuticals have been developed at the expense of entire plant species. For example, the alkaloids vinblastine and vincristine are derived from the Madagascar periwinkle, *Catharanthus roseus*, which has been successful at treating cancers, Hodgkin’s disease, and diabetes.¹⁵⁶ One ounce of vincristine required extraction of fifteen tons of the periwinkle.¹⁵⁷ While the degradation of Madagascar’s natural resources cannot be strictly attributed to bioprospecting, there is a strong correlation between the “discovery” of useful properties of the periwinkle and their precipitous population decline.¹⁵⁸ The species is easily cultivated so there is no risk permanently losing the species altogether (and thus, it was never truly endangered), but it provides a powerful example of the potential for over-extraction associated with bioprospecting

¹⁵³ See, e.g., IKECHI MGBEOJI, GLOBAL BIOPIRACY, 70-72 (2006) (calling this phenomena the “gene-rush”).

¹⁵⁴ *Edmonds Institute v. Babbitt*, 42 F.Supp.2d 1, 5-6 (D.C. Cir. 2000).

¹⁵⁵ Mgbеoji, *supra* note 153, at 70-72.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

pressure.¹⁵⁹ This case is also considered to be a paradigmatic of biopiracy, discussed in the following section.

Biopiracy

Tightly tied to bioprospecting is the act of biopiracy. In a broad sense, biopiracy is simply the wrongful acquisition of another's intellectual property.¹⁶⁰ However, biopiracy can also be defined as appropriation of knowledge and/or genetic resources of farming and indigenous communities by individuals or institutions who seek exclusive monopoly over them.¹⁶¹ The social and ecological consequences associated with biopiracy have been documented, but detailed empirical analyses regarding the impacts are sparse.¹⁶² Not only do victims of biopiracy not gain any reward for their contribution to a lucrative technology, but they are then restricted from using that technology.¹⁶³ The biggest critique of biopiracy is the lack of benefit sharing and access to the technologies derived from traditional knowledge. While 97% of patents worldwide are held by industrialized countries, the technologies of many came from developing countries.¹⁶⁴ Further, the biotechnology industry is controlled by what some have termed the tech cartel; the “big six” (Dow Agrosciences, DuPont, Monsanto, BASF, Bayer, and Syngenta) account for 40%

¹⁵⁹ S. ROBERT LICHTER & STANLEY ROTHMAN, ENVIRONMENTAL CANCER-- A POLITICAL DISEASE?, 42 (1999).

¹⁶⁰ See Urrutia-Vélez, *supra* note 34, at 327

¹⁶¹ Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 450 (2005), citing to Keyword Definitions, ETC GROUP, http://www.etcgroup.org/key_defs.asp.

¹⁶² See, e.g., D.K.N.G. Pushpakumara, et al., *Prospects of Pharmaceutical Prospecting to Finance Biodiversity Conservation in Sri Lanka*, 4 SRI LANKAN J. AGRIC. ECON. 39, 44 (2002) (discussing a lack of empirical information on the potential to improve willingness to pay for pharmaceutical prospective in light of the complimentary link between biodiversity and traditional knowledge).

¹⁶³ Urrutia-Vélez, *supra* note 34, at 327.

¹⁶⁴ SARA E. DAVIS, GLOBAL POLITICS OF HEALTH, 164 (2010). More than 80% of patents granted in developing countries belong to residents of industrialized countries. *Executive Summary: genetics, Genomics and the Patenting of DNA*, GENOMICS RESEARCH CENTER OF THE WHO, www.who.int/genomics/publications/background/en/ (last visited Apr. 8, 2014).

of all agricultural biotechnology patents and have an agenda that promotes chemical dependence and monopolizes patents preventing any alternative innovation in the public and private sector.¹⁶⁵ This demonstrates how “poor but gene-rich states are coerced into paying rent on their own biocultural knowledge and products whenever these form the subject of patents.”¹⁶⁶ Simply showing that developed countries are inventing technologies in less developed countries and getting exclusive rights to those inventions does not in-and-of-itself demonstrate biopiracy is occurring, but studies such as Farnsworth (1988) do: Professor Farnsworth found that in a survey of 119 plant-based medicinal compounds, 74% had the same or related uses as the medicinal plants from which they were derived.¹⁶⁷ This indicates a strong correlation between traditional medicine and commercial pharmaceuticals that was not previously documented, and hints at the misappropriation of such knowledge.¹⁶⁸

Many bioprospecting agreements have turned in to claims of biopiracy. In 1998, inspired by the Convention on Biological Diversity, researchers from the University of Georgia embarked on a five year project entitled “Drug Discovery and Biodiversity Among the Maya of Mexico.”¹⁶⁹ The goal of the project was to examine the pharmacological value of plants located in Mayan regions of Chiapas, Mexico, while simultaneously sharing any profits with the Maya people.¹⁷⁰ The project was seen as a chance for Maya healers and communities to be compensated for their

¹⁶⁵ Hope Shand, *The Big Six: A Profile of Corporate Power in Seeds, Agrochemicals & Biotech*, THE HERITAGE FARM COMPANION (2012), available at: http://www.seedsavers.org/site/pdf/HeritageFarmCompanion_BigSix.pdf; John L. King & David Schimmelpfennig, *Mergers, Acquisitions, and Stocks of Agricultural Biotechnology Intellectual Property*, 8 AGBIOFORUM 83, 84 (2005).

¹⁶⁶ Mgbeoji, *supra* note 153, at 33.

¹⁶⁷ N.R. Farnsworth, *Screening Plants for New Medicines*, in BIODIVERSITY 83, 95 (E.O. Wilson, ed., 1988).

¹⁶⁸ *Id.* at 93.

¹⁶⁹ *Research Grant Killed in Face of ‘Biopiracy’ Clash at University of Georgia*, SAVANNAH MORNING NEWS, Nov. 20, 2001, <http://savannahnow.com/stories/112001/LOCbiopirates.shtml>.

¹⁷⁰ *Id.*

traditional knowledge and bring economic development to an extremely poor nation.¹⁷¹ Researchers claimed it was a way to preemptively protect the people from biopiracy.¹⁷² However, many indigenous communities immediately opposed the project; a primary consideration was that they opposed commercial exploitation of life and life processes.¹⁷³ The project founders stated that the project's eventual closure was primarily due to unresolved issues in defining what constitutes prior informed consent, who decides if it has been obtained, and what constitutes consensus.¹⁷⁴

The social justice implications for pirating traditional knowledge are staggering and are strongly tied to ecological destruction. In particular, the same implications for neocolonialism on traditional people exist with biopiracy; there is an associated dependence of less developed nations on the research and development of more advanced economies, and the ecological and economic costs and benefits are disproportionately distributed.¹⁷⁵ One result is the drastic increase in pressure on the environment including incentivizing less “sustainable” behavior and displacing ecological pressures to other critical or sensitive areas. Oftentimes, as has been documented with many community based conservation efforts,¹⁷⁶ indigenous groups of people

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ Brent Berlin & Elois Ann Berlin, *NGOs and the Process of Prior Informed Consent in Bioprospecting Research: the Maya ICBG Project in Chiapas Mexico*, 55 *INTL. SOCIAL SCIENCE J.* 629, 633 (2004). Authors state that these issues only came to light after NGOs campaigned against the project, and deliberately sabotaged the project with publication of false claims and misinformation, branding the project as the “worst kind of biopiracy”. *Id.* at 634.

¹⁷⁵ John Merson, *Bio-Prospecting or Bio-Piracy: Intellectual Property Rights and Biodiversity in a Postcolonial Context*, 15 *OSIRIS* 282, 294-296 (2000).

¹⁷⁶ See, e.g., Jill Belsky, *Community-Based Ecotourism in Belize*, 64 *RURAL SOC.* 641, 656 (1999) (discussing the unintended consequences of a community ecotourism endeavor in Gales Point, Belize; the subsequent development of the community caused a shift in commercial fishing to bush/sea extraction where there were no restrictions or management practices leading to an effort to provide opportunities for more sustainable income, ecotourism. The results of the endeavor were highly exacerbated tensions within the community and revived political rivalries, and the physical income generated was captured by the elite members of the community, inter alia).

that are forced to conform to more “westernized” notions of survival/integrate into the national economies there is a backlash socially, culturally, and even environmentally.¹⁷⁷ There is an increase cost associated with assimilation that incentivizes more lucrative and less sustainable ways of living, or eliminates the choice of livelihood strategies altogether (i.e. a transition from subsistence farming to large scale agriculture and ranching).¹⁷⁸ This cost is seen in the price of food and seeds,¹⁷⁹ the costs of medicines, and the cost of adapting infrastructure, all which impair traditional ways of living.¹⁸⁰ This type of poverty-driven deforestation acts synergistically with other drivers of tropical forest decline.¹⁸¹

Further, the benefit of incentivizing preservation is completely undermined by an increase in biopiracy-related practices; this is because the resource holders are not the eventual patent holders. Discussed in the benefits sections *supra*, an author suggested a strong incentive to create patent parks suggested that countries may even decide on their own that the opportunity cost of liquidating natural resources is too high.¹⁸² What this idea fails to recognize is that most biodiverse countries are not obtaining biotech patents and will ultimately receive very little

¹⁷⁷ See, Dani Rodrik, *Has Globalization Gone Too Far?*, 39 CAL. MGMT. R. 29, 30 (1997).

¹⁷⁸ See, e.g., Mgbeoji, *supra* note 153, at 68. See also, Kenny Matampash, *The Maasai of Kenya*, in INDIGENOUS VIEWS OF LAND AND THE ENVIRONMENT 31, 38-39 (Shelton Davis, ed., 1993).

¹⁷⁹ Cost of cotton seeds shot up by 8,000% after Monsanto patented a genetically modified seed; 95% of all cotton seed sold commercially in India is owned by Monsanto. Some have called this a monopolistic debt trap that is linked to over 250,000 farmer suicides over fifteen years. Vandana Shiva, *Preventing Biopiracy: Defending Traditional Knowledge and People's Rights to Food and Medicine*, Navdanya (Apr. 4-5, 2012), <http://www.navdanya.org/news/234-preventing-biopiracy-defending-traditional-knowledge-and-peoples-rights-to-food-and-medicine->.

¹⁸⁰ See, e.g., Matampash, *supra* note 178, at 33-39 (discussing how a traditional population in Kenya developed a strong sense of apathy to cope with environmental degradation associated with new, inappropriate farming technology brought in by outsiders; many in the population sold their land after being unable to transition from a nomadic pastoral system to a farming lifestyle due to high cost of infrastructure, inter alia.).

¹⁸¹ Helmut J. Geist and Eric F. Lambin, *Proximate Causes and Underlying Driving Forces of Tropical Deforestation*, 52 BIOSCIENCE 143, 146 (2002).

¹⁸² Torrance, *supra* note 114, at 639.

compensation for the technologies derived from their country.¹⁸³ Just as any other type of park formation has historically demonstrated, ecological pressures will build up on park boundaries, people would likely be displaced from traditional livelihood strategies, and the more lucrative methods of survival will replace these traditional strategies.¹⁸⁴ There is a major disconnect between the sociological and the environmental policies.¹⁸⁵

Biopiracy is clearly a problem, but the current patent system is not equipped to protect traditional knowledge (even if traditional people chose to embrace the system).¹⁸⁶ Patent protection applies only to actions involving a single act of discovery, the patent application must be written and in technical language, the process of applying for patents and enforcing patent protection expensive, and traditional knowledge is developed over hundreds (or thousands of years) and is generally held to be a collective achievement, not belonging to a single individual.¹⁸⁷ One aspect of the U.S. patent law in particular makes pirating traditional knowledge particularly easy and that is the standard of novelty required for patented

¹⁸³ Mgbeoji, *supra* note 153, at 33.

¹⁸⁴ Marcus Colchester, *Conservation Policy and Indigenous People*, 28 CULTURAL SURVIVAL Q. (2004), available at: <http://www.culturalsurvival.org/publications/cultural-survival-quarterly/none/conservation-policy-and-indigenous-peoples>. See also, Kevin J. Gaston, et al., *The Ecological Performance of Protected Areas*, 39 ANN. R. ECOLOGY, EVOLUTION, AND SYSTEMATICS 93, 192 (2008). See also, Crystal L. Fortwangler, *The Winding Road: Incorporating Social Justice and Human Rights into Protected Area Policies*, in CONTESTED NATURE: PROMOTING INTERNATIONAL BIODIVERSITY WITH SOCIAL JUSTICE IN THE TWENTY-FIRST CENTURY, 25, 32 (Steven R. Brechin, et al. eds., 2003).

¹⁸⁵ This disconnect between the study of people and the study of ecology is a common issue. See, e.g., Till M. Meyer, *The Shack Revisited: Aldo Leopold's Perceptions of Wilderness From a Historic, Legal, and International Perspective*, USDA FOREST SERVICE PROCEEDINGS, 238, 240 (2003), http://fs.fed.us/rm/pubmrs_p027/rmrs_p027_238_246.pdf

One of the anomalies of modern ecology is the creation of two groups, each of which seems barely aware of the existence of the other. The one studies the human community, almost as if it were a separate entity, and calls its findings sociology, economics and history. The other studies the plant and animal community and comfortably relegates the hodge-podge of politics to the liberal arts. The inevitable fusion of these two lines of thought will, perhaps, constitute the outstanding advance of this century.

¹⁸⁶ Graham Dutfield, *TRIPS-related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 247 (2001).

¹⁸⁷ *Id.* at 254-58.

technology.¹⁸⁸ Under U.S. law, only documented prior uses are considered to counter a claim of novelty.¹⁸⁹ Traditional knowledge that is documented orally is automatically excluded from consideration of novelty.¹⁹⁰

II. CASE STUDIES: ECOLOGICAL IMPACTS OF VARIOUS PATENT REGIMES

A. The United States

1. History and Current Status of U.S. Patent Laws

The British patent system was carried over to the American colonies which granted a period of exclusive use to inventors that sought protection of their inventions.¹⁹¹ The British statute granted patents to “the first true inventor” for a new manufacture.¹⁹² The framers of the Constitution included a provision granting the authority to implement a patent system, and shortly thereafter, Congress passed the first patent statute in 1790.¹⁹³ Not unlike the modern approach to patent law, the Patent Act of 1790 granted a person who invented or discovered any useful art, manufacture, engine, machine, or device, or improvement of, a patent for fourteen years, after fully describing the act in a petition for the patent and passing an examination proving the utility of the article.¹⁹⁴ After several revisions and amendments, this original version requiring an examination of the utility of the invention and the required components is still intact.¹⁹⁵ The common law evolution of patentable subject matter has progressed significantly and is highly controversial.

¹⁸⁸ Ho, *supra* note 161, at 449.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 450.

¹⁹¹ LEE, ENTERTAINMENT AND INTELLECTUAL PROPERTY LAW § 4:5 (2013).

¹⁹² Kolitch, *supra* note 149, at 234.

¹⁹³ *Id.*, citing to U.S. Const. art. I, § 1, cl. 8.

¹⁹⁴ Kolitch, *supra* note 149, at 234.

¹⁹⁵ *Id.*

The language of the statute is vague, broadly defining patentable subject matter as: “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”¹⁹⁶ Under this language, plant varieties were excluded from patentable subject matter until the Plant Protection Act was enacted in 1930.¹⁹⁷ The Plant Protection Act created a method for patenting new, distinguishable plants that were generated by asexual reproduction.¹⁹⁸ The same language authorizing the patenting of any “new and useful” product was incorporated into the Patent Act of 1952, one year before the revolutionary discovery of DNA and the science of genetic engineering.¹⁹⁹ Because genetic engineering was not considered in the Patent Act, courts were reluctant to extend protection to genetically modified organisms.²⁰⁰ In 1970 the Plant Variety Protection Act was enacted expanding plant protection to sexually reproduced plants.²⁰¹ The ability to patent living organisms was cemented in 1980. The case, *Diamond v. Chakrabarty*, transformed the scope of patentable subject matter and explicitly authorized patent protection for biotechnological innovations.²⁰² Justice Burger stated that “[t]he relevant distinction [i]s not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions... [that are] the result of human ingenuity and research.”²⁰³

¹⁹⁶ 35 U.S.C. § 101 (2014).

¹⁹⁷ Pub. L. No. 88-525, 46 Stat. 703.

¹⁹⁸ Lester Ross & Libin Zhang, *Agricultural Development and Intellectual Property Protection for Plant Varieties: China Joins the UPOV*, 17 UCLA PAC. BASIN L.J. 226, 229 (2000).

¹⁹⁹ 88 Am. Jur. 3d *Proof of Facts* § 75 (2006), citing to Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792.

²⁰⁰ *Id.*

²⁰¹ 7 U.S.C. §§ 2321-2583 (2014). This act did not provide patent protection for plants, but rather gave the applicant a certificate of protection giving the owner exclusive marketing rights; the certificate did not prevent seed saving by farmers or independent research on the protected variety. See, Janice M. Strachan, *Plant Variety Protection: An Alternative to Patents*, USDA, <http://www.nal.usda.gov/pgdic/Probe/v2n2/plant.html> (last visited May 7, 2014).

²⁰² *Id.*, citing to 447 U.S. 303, 313 (1980). See also, Introduction, *supra*.

²⁰³ *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

Following the decision *Chakrabarty*, recent case law has cemented the patentability of organisms- including plants and seeds.²⁰⁴ The only major restriction on patents with regard to biological material is that genetic material must have “markedly different characteristics” from any found in nature.²⁰⁵ With such limitless potential for patentable subject matter, some fear the direction that biologic patents could take. “The [U.S. Patent and Trademark Office] routinely grants patents for inventions that have unforeseen (and in many instances, suspected or even known) harmful impacts on public health and the environment, and in fact is required by law to do so.”²⁰⁶ There are no exclusions for public health and safety. Furthermore, despite being a party to the TRIPS agreement, the United States has not ratified the ITPGRFA or the Convention on Biological Diversity.²⁰⁷ In terms of domestic treatment of foreign patents, there is an unpredictable pattern regarding the willingness of U.S. courts to assert jurisdiction in cases involving patent infringement on foreign patents in the United States.²⁰⁸

2. Application: U.S. Patent Law and Ecological Degradation

The United States does a proportionately small amount of bioprospecting within their own borders; the majority of the ecological implications for the U.S. patent system are abroad. However, there are two highly controversial, distinct cases of patent laws impacting local ecology: pharmacological development of Taxol and bioprospecting concessions in Yellowstone National Park.

²⁰⁴ *Pioneer Hi-Bred Int'l., Inc. v. J.E.M. Ag Supply, Inc.*, 200 F.3d 1374, 1377 (Fed. Cir. 2000), *aff'd*, 534 U.S. 124 (2001), citing to *Chakrabarty*, 447 U.S. at 313. The Supreme Court in *Pioneer* held that sexually reproducing plants that were eligible for protection under the Plant Variety Protection Act could also be protected under the Patent Act with a utility patent. *Id.*

²⁰⁵ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116-17 (2013), quoting *Chakrabarty*, 447 U.S. at 310 (denying patents on isolated DNA fragments).

²⁰⁶ Kolitch, *supra* note 149, at 238.

²⁰⁷ See Part I, *supra*.

²⁰⁸ Kendra Robins, *Extraterritorial Patent Enforcement and Multinational Patent Litigation*, 93 VA. L. REV. 1259, 1278-79 (2007).

The Pacific Yew Tree

The Pacific yew (*Taxus brevifolia*) is a valuable hardwood that is native to the Pacific Northwest and northern Rocky Mountains ranging from southeastern Alaska through eastern Oregon.²⁰⁹ The tree is an important food source for many species, and is considered critical moose winter habitat.²¹⁰ The development of Taxol is seen by the National Cancer Institute as a true “success story;” it is “the most well-known natural-source cancer drug in the United States.”²¹¹ Indigenous groups of North America had used the bark, foliage, and fruits of the tree for many ailments ranging from stomach ache, lung issues, and treating wounds.²¹² In 1962 researchers from the U.S. Department of Agriculture began collecting bark from the Pacific yew tree in an effort to find natural products that may cure cancer.²¹³ Researchers found that the inner bark is concentrated with paclitaxel, an anti-cancer compound.²¹⁴ In 1991, after confirming the miraculous anti-cancer properties, the U.S. Department of Agriculture announced that they would allow drug manufacturer Bristol-Myers Squibb to harvest 750,000 pounds of bark- the equivalent of 38,000 trees.²¹⁵

²⁰⁹ *Index of Species Information: Taxus brevifolia*, U.S. FOREST SERVICE, www.fs.fed.us/database/feis/plants/trees/taxbre/all.html (last visited Mar. 22, 2014).

²¹⁰ *Id.*

²¹¹ *Success Story: Taxol (NSC 125973)*, NATIONAL CANCER INSTITUTE, http://dtp.nci.nih.gov/timeline/flash/success_stories/S2_taxol.htm (last visited Mar. 22, 2014).

²¹² *Taxus brevifolia Nutt. (Pacific Yew)*, AGRIC. AND AGRI-FOOD CANADA, <http://www.agr.gc.ca/eng/science-and-innovation/science-publications-and-resources/resources/canadian-medicinal-crops/medicinal-crops/taxus-brevifolia-nutt-pacific-yew/?id=1301435640373> (last visited Mar. 22, 2014).

²¹³ *Success Story: Taxol (NSC 125973)*, NATIONAL CANCER INSTITUTE, http://dtp.nci.nih.gov/timeline/flash/success_stories/S2_taxol.htm (last visited Mar. 22, 2014).

²¹⁴ *Taxus brevifolia Nutt. (Pacific Yew)*, AGRIC. AND AGRI-FOOD CANADA, <http://www.agr.gc.ca/eng/science-and-innovation/science-publications-and-resources/resources/canadian-medicinal-crops/medicinal-crops/taxus-brevifolia-nutt-pacific-yew/?id=1301435640373> (last visited Mar. 22, 2014).

²¹⁵ Marlene Cemons, *Firm to Harvest Yew Bark to Get Scarce Cancer Drug: Medicine: The U.S. will let Bristol-Myers Squibb Have Bark to Speed Output of Taxol. Concerns are Raised About Whether the Species Can Survive*. L.A. TIMES (June 20, 1991), http://articles.latimes.com/1991-06-20/news/mn-1463_1_pacific-yew-bark.

Just two months after Bristol-Myers Squibb was given access to Pacific yew bark, the U.S. Fish and Wildlife Service addressed a petition to list the Pacific yew as threatened.²¹⁶ The agency concluded that regulatory protection was not justified because there was “insufficient scientific information,” despite the potential for a “severe” underestimation of the species’ distribution.²¹⁷ By 2011, this severe decline was recognized when the International Union for the Conservation of Nature listed the species as endangered.²¹⁸

No product patent was ever granted on Taxol because the generic, Paclitaxel, was developed in the public domain by the National Cancer institute.²¹⁹ However, Bristol-Myers Squibb commercialized Taxol, registered it as a trademark, and in 1992 the drug was approved for marketing by the Food and Drug Administration.²²⁰ Bristol was also granted a use patent²²¹ on Taxol which extended their exclusive rights to use the drug and spawned years of controversy, litigation, and federal investigations.²²²

The interesting twist with the development of Taxol is that despite the potential correlation between harvesting the plant and its population decline, the value of the plant as an anti-cancer

²¹⁶ Endangered and Threatened Wildlife and Plants; Notice of 90-day Finding on Petition to List *Taxus Brevifolia* as Threatened, 56 Fed. Reg. 40654 (Aug. 16, 1991).

²¹⁷ *Id.* at 40875.

²¹⁸ Hanna Gersmann & Jessica Aldred, *Medicinal Tree Used in Chemotherapy Drug Faces Extinction*, THE GUARDIAN, Nov. 9, 2011, <http://www.theguardian.com/environment/2011/nov/10/iucn-red-list-tree-chemotherapy>.

²¹⁹ Ken Garber, *Battle Over Generic Taxol Concludes, but Controversy Continues*, 94 J. NAT’L CANCER INST. 324 (2002), available at: <http://jnci.oxfordjournals.org/content/94/5/324.full>.

²²⁰ *Id.*

²²¹ A use patent does not prevent manufacturers from marketing a generic form of the patented drug so long as the use is different from that claimed in the original use patent. See Courtenay C. Brinckerhoff, *U.S. Courts Look at Method of Use Patents in Generic Drug/ANDA Litigation*, KLUWER PATENT BLOG (May 21, 2012), <http://kluwerpatentblog.com/2012/05/21/u-s-courts-look-at-method-of-use-patents-in-generic-druganda-litigation/>.

²²² *Id.* Bristol was using a strategy known as “evergreening,” a loophole used to extend use-exclusivity which prevents the Food and Drug Administration from approving generic drug applications for thirty months when a use patent holder sues the applicant for infringement. *Id.* Bristol used this strategy multiple times, thus, launching the investigations and further lawsuits. *Id.*

drug was used as leverage by environmentalists in their petition to list the tree as threatened.²²³ If the tree had declined to such a level to warrant an Endangered Species listing, then any collection of the species would have been heavily restricted, even for critical research endeavors.²²⁴ So while a faction of environmentalists and ecologists saw the discovery of Taxol as just another pressure on the Pacific Northwest's old growth forests, others capitalized on the value to push for more stringent logging protections.²²⁵

Yellowstone National Park

Another example of bioprospecting's ecological impacts is seen through the 'commodification' of Yellowstone National Park. Yellowstone is an iconic symbol known throughout the world for providing "unparalleled opportunities for conservation, study, and enjoyment of large-scale wildland ecosystem processes."²²⁶ On the heels of Yellowstone's 125th anniversary, the Park, the National Park Service, and Diversa Corporation reached a bioprospecting agreement granting Diversa access to the park's unique microbial habitats.²²⁷ This agreement was the first time an American national park would be compensated for scientific discoveries within the park borders.²²⁸ Diversa paid a hefty price for the agreement and although the information was never publicly disclosed, the price tag included research support to park staff, \$20,000 annual payments, access to libraries of genetic data for Park scientists' own

²²³ Endangered and Threatened Wildlife and Plants; Notice of 90-day Finding on Petition to List *Taxus brevifolia* as Threatened, 56 Fed. Reg. 40654, 40855 (Aug. 16, 1991).

²²⁴ *Id.*

²²⁵ See the discussion on the benefits of patent laws in Part I(b), *supra*.

²²⁶ *Yellowstone National Park*, UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION WORLD HERITAGE CONVENTION, <http://whc.unesco.org/en/list/28> (last visited March 22, 2014). For a discussion of how Yellowstone may be seen in a much more controversial light, see KARL JACOBY, *CRIMES AGAINST NATURE: SQUATTERS, POACHERS, THIEVES, AND THE HIDDEN HISTORY OF AMERICAN CONSERVATION* (2001).

²²⁷ Doremus, *supra* note 121, at 407.

²²⁸ *Edmonds Inst. v. Babbitt*, 42 F.Supp.2d 1, 5 (D.C. Cir. 1999).

research, and most importantly, royalties on any product derived in the park.²²⁹ While the agreement came along with a plethora of environmental protections, the specific measures to limit any significant impacts on the environment and other park uses were never specified or publically disclosed.²³⁰

The National Park Service's decision to explicitly authorize and encourage bioprospecting in America's sweetheart of national parks was met with heated resistance.²³¹ Environmental plaintiffs filed an action to enjoin activities under the research agreement alleging that the agreement required an administrative rule-making procedure due to a change in policy under the Administrative Procedure Act and required an environmental impact assessment under the National Environmental Policy Act, *inter alia*.²³² Plaintiffs succeeded on their NEPA claims; the District Court for the District of Columbia eventually required the National Park Service to conduct an environmental assessment under the National Environmental Policy Act.²³³ However, after the Park Service provided a reasonable basis for how the agreement was consistent with the National Park Organic Act and their own park regulations, they were allowed to go forward with the agreement.²³⁴ The court reasoned that because patents cannot be granted on any substance occurring in nature under *Diamond v. Chakrabarty*, Diversa was not patenting or making "commercial use" of Park resources (something expressly prohibited under park regulations); the commercial use was on later developed products.²³⁵ The burden on the plaintiffs in this case was

²²⁹ *Id.*

²³⁰ Doremus, *supra* note 121, at 408.

²³¹ *Id.* at 411.

²³² *Edmonds Inst.* at 9-10.

²³³ *Edmonds Inst. v. Babbitt*, 93 F.Supp.2d 63, 69 (D.C. Cir. 2000), citing to National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4347 (2014).

²³⁴ *Edmonds Inst.*, 93 F.Supp2d at 69.

²³⁵ *Id.* at 72, citing to 447 U.S. 303, 313 (1980).

extremely high because the park’s interpretation of their own regulation will always prevail unless it is plainly erroneous.²³⁶

Riding on their successful execution of the first bioprospecting agreement in American national parks, the Park Service officially released a formal plan to allow commercial bioprospecting in 2006.²³⁷ Not until December of 2013 (more than fifteen years after the decision to incorporate bioprospecting into park activities) did the Park Service finally release a document to actually define the policies and procedures of this “benefit sharing plan.”²³⁸ The benefits sharing plan confers the status of “laboratory” to national parks as defined by the Federal Technology Transfer Act of 1986 (FTTA).²³⁹ Critics of the plan argued that commodifying national park assets undermined the purpose of parks and would open the door to more invasive commercial endeavors.²⁴⁰ Commenters believed that this terminology was inconsistent with the purpose of national parks: “to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.”²⁴¹ Opening up parks to exploitation, even if sustainable, sullies the symbol of the nation’s “sincere intention to seek a dignified accommodation with nature.”²⁴²

²³⁶ *Edmonds Inst.*, 93 F.Supp2d. at 71.

²³⁷ See NATIONAL PARK SERVICE, Director’s Order #77-10: National Park Service Benefits Sharing (Dec. 12, 2013), available at:

<http://parkplanning.nps.gov/showFile.cfm?projectID=41624&MIMEType=application%252Fpdf&filename=DO%5F77%2D10%2Epdf&sfid=0>.

²³⁸ *Id.*

²³⁹ *Id.*, citing to the Federal Technology Transfer Act of 1986, Pub. L. 99-502, 100 Stat. 1785.

²⁴⁰ National Park Service Benefits Sharing: Public Comments 1-4 with NPS Response, National Park Service, <http://parkplanning.nps.gov/showFile.cfm?projectID=41624&MIMEType=application%252Fmsword&filename=Public%5Fcomments%5F1%2D4%5Fwith%5FNPS%5FResponse%2Edoc&sfid=0> (last visited Mar. 22, 2014).

²⁴¹ National Park Service Benefits Sharing: Public Comments 1-4 with NPS Response, National Park Service, <http://parkplanning.nps.gov/showFile.cfm?projectID=41624&MIMEType=application%252Fmsword&filename=Pu>

Others that commented remain optimistic about the benefits sharing plan. Montana State University stated in their comment that the proposed guidelines were “fair, understandable, and appropriate.”²⁴³ Their comment on the project went even further to propose that developing countries could use just such a benefits sharing system to capitalize on scientific interest in their natural resources, a potential benefit of patents discussed in Section I(b), *supra*.²⁴⁴

Ultimately, granting of patents has had very little impact on the ecology of the United States when compared to other countries abroad, and this is likely a result the nature of bioprospecting; the United States acquired resource colonies to exploit their natural resources.²⁴⁵ The wealth of the United States has also made the biotechnology sector powerful. For example, Monsanto, a U.S. corporation, has 27% of the world’s market share in seeds, agrochemicals and biotechnology; in 2009 Monsanto was generating revenue of US\$7,297,000,000.²⁴⁶ The combined total of the world’s top ten seed companies originating in the United States accounts for 50% of the world’s market share and almost US\$9,032,000,000 per annum in sales.²⁴⁷ The impact of this “chokehold” on the global agricultural research agenda is discussed in the following section, but expands far beyond the ecological lens this paper takes.²⁴⁸

blic%5Fcomments%5F1%2D4%5Fwith%5FNPS%5FResponse%2Edoc&sfid=0 (last visited Mar. 22, 2014), citing to 16 U.S.C. § 1 (2014).

²⁴² Doremus, *supra* note 119, at 487.

²⁴³ National Park Service Benefits Sharing: Public Comments 1-4 with NPS Response, National Park Service, <http://parkplanning.nps.gov/showFile.cfm?projectID=41624&MIMEType=application%252Fmsword&filename=Public%5Fcomments%5F1%2D4%5Fwith%5FNPS%5FResponse%2Edoc>

²⁴⁴ *Id.*

²⁴⁵ See, e.g., *America Acquires an Empire: Factors Prompting American Internationalism During the 1890s and Beyond*, AUSTIN CMTY. COLL., <http://www2.austincc.edu/lpatrick/his1302/acquire.html> (last visited Apr. 14, 2014).

²⁴⁶ Hope Shand, *The Big Six: A Profile of Corporate Power in Seeds, Agrochemicals & Biotch*, THE HERITAGE FARM COMPANION (2012), available at: http://www.seedsavers.org/site/pdf/HeritageFarmCompanion_BigSix.pdf.

²⁴⁷ *Id.*

²⁴⁸ *Id.*

B. India

1. History and Current Status of Indian Patent Laws

The evolution of India's patent laws has come from what authors consider a "mosaic" of pressures; the confluence of post-colonialism backlash to foreign influences, a fully developed pharmaceutical industry, and widespread poverty and disease among a huge population has taken India on a very circuitous route to developing the patent standards that exist today.²⁴⁹

The roots of India's patent system are intertwined with the United States' as they both stem from British law.²⁵⁰ The British Empire first set foot on Indian soil in 1608, and immediately took full control of exploiting the country's resources through the East India Company.²⁵¹ While technically only a [monopolistic] trading body, the East India Company (the Company) was considered an agent of British Imperialism.²⁵² The Company had the power to sue, levy and collect taxes, purchase land, and was comprised primarily of soldiers.²⁵³ In 1784, the British Government assumed complete control of the Company, and with that, control of India.²⁵⁴ The relevance of this section of Indian history is the policies imposed by the Company were entirely concerned with advancing British interests while the welfare of the Indian population was neglected.²⁵⁵

²⁴⁹ Janice A. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovations*, 68 U. PITT. L. REV. 491, 491-92 (2007).

²⁵⁰ *Id.* at 505.

²⁵¹ *Id.* at 506.

²⁵² Danny Abir, *Foreign Sovereign Immunities Act: The Right to a Jury Trial in Suits Against Foreign Government-Owned Corporations*, 32 STAN. J. INT'L L. 159, 174 (1996).

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ Mueller, *supra* note 249, at 506.

The Company first introduced patent laws to India in 1856.²⁵⁶ The purpose of the laws was simply to “provide exclusive privileges to inventors”.²⁵⁷ By 1888, after numerous revisions, the Patents and Design Act of 1911 was implemented which stood as law through Indian independence in 1947.²⁵⁸ Between 1900 and 1947 India suffered from social unrest; intensified by hostility between the Hindu and Muslim religious groups and Britain’s decline as a world power during the World Wars, several protests were enough to convince Britain to relinquish control over the region.²⁵⁹ In 1947, India and Pakistan became two independent democratic nations, followed by an overhaul of Indian laws and policies.²⁶⁰

The British legacy in India is controversial when quantified financially: on one hand the British invested large amounts of money into public infrastructure, industry and the education system which enabled India to integrate into the world economy; however, the returns from capital investment in India were never reinvested to develop the Indian economy and the agricultural practices left India prone to famine (among other things) and extremely poor.²⁶¹ Patent law in particular heavily favored foreign investors and technology.²⁶² As such, India began crafting new laws that were more favorable to domestic interests immediately after gaining independence.²⁶³ The goal of the first post-independence patent laws were considered

²⁵⁶ Colin, *supra* note 70, at 879.

²⁵⁷ Mueller, *supra* note 249, at 506.

²⁵⁸ Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT’L L. 507, 509 (1996), citing to Patents and Designs Act, No. 2 of 1911.

²⁵⁹ See, Chandrika Kaul, *From Empire to Independence: The British Raj in India 1858-1947*, *BBC History* (Mar. 3, 2011), http://www.bbc.co.uk/history/british/modern/independence1947_01.shtml. See also, PAUL JOHNSON, *MODERN TIMES: THE WORLD FROM THE TWENTIES TO THE EIGHTIES* 470 (1983).

²⁶⁰ See Kaul, *supra* note 259.

²⁶¹ *Id.*

²⁶² Mueller, *supra* note 249, at 509.

²⁶³ *Id.* at 510-11.

radical and emphasized increasing access to technical education and creating more Indian research institutions.²⁶⁴

Despite the immediate acknowledgment of the deficiencies in the pre-independence patent laws, new laws were not passed until 1970.²⁶⁵ The Patents Act of 1970 officially repealed the British Patents and Design Act in favor of laws that better aligned with Indian interests.²⁶⁶ The Patents Act of 1970 explicitly excluded from patentable subject matter “substances intended for use, or capable of being used as food or medicine or drug, or... relating to substances prepared or produced by chemical processes.”²⁶⁷ This specific amendment propelled generic drug manufacturing in India, which in turn enabled access to low-cost drugs throughout the country.²⁶⁸

India’s success in achieving national priorities through restructuring patent laws did not last. India became a member of the World Trade Organization in 1995.²⁶⁹ After joining the World Trade Organization, India was given ten years to amend their laws in a manner consistent with TRIPS regulations; most notably India was required to lift the restriction on pharmaceutical patents. The patent laws in India (just as other areas of law in India) mirror the phases created by British occupation- evolving from strictly extraction oriented, to oppressive, and then, reflecting independence, becoming nationalistic and protectionist, and then compromising to better integrate into the global marketplace.

²⁶⁴ *Id.* at 511-12.

²⁶⁵ *Id.* at 512.

²⁶⁶ *Id.*

²⁶⁷ The Patents Act, No. 39 of 1970, § 5(a)-(b), INDIA CODE (2000) vol. 20 [hereinafter “The Patents Act”].

²⁶⁸ Mueller, *supra* note 249, at 515.

²⁶⁹ *Member Information: India and the WTO*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tjewto_e/countries_e/india_e.htm (last visited March 21, 2014).

The effects of TRIPS on Indian patent law are enormous and the subject of many journal articles, primarily for the impacts on the burgeoning pharmaceutical industry in India and the subsequent impacts on national public health.²⁷⁰ Because of TRIPS, India's current patent system is very similar to all other World Trade Organization Members. For example, WTO members must provide patent protection for any invention, and the patent must last *at least* twenty years for the date the application was filed.²⁷¹ India is slightly distinguishable from other countries like the United States in that their patent system's novelty requirement is much more stringent, allowing patents on known substances in forms that do not result in enhanced efficacy to be denied, *inter alia*²⁷²

Despite the assimilation with global patent standards, India is still able to promote other national goals despite the restrictions required by TRIPS. India implemented the National Biodiversity Act in 2002.²⁷³ The act has one highly protective provision in it: the first prohibits non-resident Indians, foreign nationals and companies from obtaining "any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio survey or bio utilization" without the permission of the National Authority.²⁷⁴ The National Biodiversity Act also involves provisions designed to conserve important, biologically diverse areas, and "secure sharing of benefits with local people as conservers of biological resources and holders of knowledge and information relating to the use of biological

²⁷⁰ See, e.g., Adelman & Baldia, *supra* note 258 (analyzing the impact of TRIPS specifically on the pharmaceutical industry in India and calling for subsidized drug costs for poor consumers); Colin, *supra* note 70, at 894 (discussing how TRIPS compliance may create issues with multi-national corporations outcompeting national firms under new laws significantly disrupting the Indian economy in addition to the problem associated with decreased public access to medicines).

²⁷¹ TRIPS Agreement, *supra* note 58, at art. 33.

²⁷² The Patents Act § 3(d).

²⁷³ National Biodiversity Act, 2002, No. 18 of 2003, INDIA CODE (2000) vol. 20 [hereinafter NBA].

²⁷⁴ *Id.* at § 3(1)

resources.”²⁷⁵ More specifically, benefit sharing requires mutually agreeable terms and may include: monetary payment, technology transfer, or joint ownership of the intellectual property rights.²⁷⁶ State biodiversity authorities consult a local management committee on proper procedure.²⁷⁷ The issues of what type of knowledge is protected, what level of benefit sharing satisfies the National Biodiversity Act, and who receives the benefits is still not entirely clear, but is decided by State Biodiversity Boards on a case-by-case basis.²⁷⁸ State biodiversity boards also advise state governments on matters relating to conservation and benefit sharing that result from utilization of biological resources and consist of appointed experts, appointed members representing concerned government departments, and a government appointed chairperson.²⁷⁹

India has also developed a Traditional Knowledge Digital Library (TKDL) to document traditional knowledge based on the Indian Systems of medicine: Yoga, Ayurveda, Unani, and Siddha.²⁸⁰ As of 2006, India entered into an access agreement with the European Patent Office to provide access to their documented prior art.²⁸¹ Two patents have since been cancelled, many applications amended or withdrawn based on TKDL evidence, and over 231 instances of patent examiners referring to the Traditional Knowledge Digital Library in their reports.²⁸²

²⁷⁵ K. Venkataraman & S. Swarna Latha, *Intellectual Property Rights, Traditional Knowledge and Biodiversity of India*, 13 J. INTELL. PROP. L. 326, 332 (2008), citing to NBA, *supra* note 273, at art. 21.

²⁷⁶ Venkataraman & Latha, *supra* note 275, at 333.

²⁷⁷ NBA *supra* note 273, at art. 41.

²⁷⁸ *Id.*

²⁷⁹ NBA *supra* note 273, at art. 22.

²⁸⁰ V. K. Gupta, *Traditional Knowledge Digital Library*, CSIR, http://www.csir.res.in/External/Utilities/Frames/career/main_page1.asp?a=tkdl_topframe.htm&b=tkdl_left.htm&c=../..../Heads/tkdl/main.htm (last visited May 9, 2014).

²⁸¹ *Id.*

²⁸² *Id.*

India is currently on the U.S. Trade Representative Priority Watch List for their weak intellectual property right legal framework and enforcement system.²⁸³ The Special 301 Report is an annual report that reviews protection, enforcement, and market access associated with global intellectual property rights, and ultimately identifies the priority countries that are deemed to have inadequate intellectual property laws.²⁸⁴ Many of the United States' concerns appear to stem from India's additional attempts to further national priorities under the constricted system required by the TRIPS framework. India's attempts to foster their domestic pharmaceutical industry has made it difficult for innovators to secure and enforce patents in India; pharmaceuticals in India require "enhanced efficacy" to be considered novel, which the United States believe precludes too many reasonable patents.²⁸⁵ India has also recently set precedent restricting patent rights of inventors based on whether or not they will be manufactured in India.²⁸⁶ The report suggests that India is deliberately undermining the innovation climate to foster domestic policy objectives through their unpredictable and unstable patent system.²⁸⁷ A similar ranking system, the Global Intellectual Property Center of the U.S. Chamber of Commerce mapped the IP environment for twenty-five countries and found India to have the weakest IP environment due to "use of compulsory license, patent revocations, and weak

²⁸³ 2013 Special 301 Report, *supra* note 10.

²⁸⁴ Press Release, Office of the United States Trade Representative, USTR Releases Annual Special 301 Report on Intellectual Property Rights (May 1, 2013), <http://www.ustr.gov/about-us/press-office/press-releases/2013/may/ustr-releases-annual-special-301-report>.

²⁸⁵ Special 301 Report, *supra* note 10, at 38.

²⁸⁶ *Id.*

²⁸⁷ *Id.*

legislative and enforcement mechanisms.”²⁸⁸ The report claimed Indian policy “continued to breach international standards of the protection of innovation and patent rights.”²⁸⁹

2. Application: Indian Patent Law and Ecological Degradation

Knowledge of biopiracy and the impact of unequal benefit sharing garnered substantial attention in India after ratified the Convention on Biological Diversity. Several early attempts to share benefits with traditional groups were studied to determine a potential appropriate framework for benefit sharing.²⁹⁰ The Kani tribe of Kerala, India was one such group. This is a unique case study involving a local research institute and a local pharmaceutical manufacturer, Arya Vaidya Pharmacy, Ltd., that made a sincere attempt at distributing benefits to the traditional community.

The Kani tribal people live in the forests of Thiruvananthapuram district of Kerala, India.²⁹¹ Livelihood of the tribe is dependent on gathering forest products and subsistence is maintained through individual gardens.²⁹² The community is extremely impoverished and the social structure is highly stratified.²⁹³ The drug that was subject to this case study is known as Jeevani.²⁹⁴ It is derived from *Arogyapaacha trichopus zeylanicus* and had been used by the Kani tribe for

²⁸⁸ *India Ranked at the Bottom of Intellectual Property Index*, ZEE NEWS (Jan. 29, 2014 17:19), http://zeenews.india.com/business/news/technology/india-ranked-at-the-bottom-of-intellectual-property-index_93478.html.

²⁸⁹ *Id.*

²⁹⁰ Sachin Charturvedi, *The Role of Scientists and the State in Benefit Sharing: Comparing Institutional Support for the San and Kani*, in *Indigenous Peoples, Consent, and Benefit Sharing, Lessons from the San-Hoodia Case*, 261, 262 (R. Wynberg, et al. eds., 2009).

²⁹¹ *Id.* at 10.

²⁹² *Id.*

²⁹³ *Id.* at 11-12.

²⁹⁴ Anil K. Gupta, *Value Addition to Local Kani Tribal Knowledge: Patenting, Licensing and Benefit Sharing*, INDIAN INST. OF MANAGEMENT AHMEDABAD, 7 (Aug. 2, 2002), <http://www.iimahd.ernet.in/publications/data/2002-08-02AnilKGupta.pdf>.

numerous ailments, including its immune boosting, anti-peptic ulcer, and anti-fatigue effects.²⁹⁵ The plant was first noted by researchers in 1987 after Kani guides offered berries of the plant to fatigued researchers.²⁹⁶ Although reluctant to disclose the identity of the plant, Kani eventually led the research team to the source of the berries.²⁹⁷ After twelve years of clinical trials the researchers filed a process patent application in India for the manufacture of an herbal sports medicine containing *arogyapaacha*.²⁹⁸

In an attempt to remain faithful to the CBD, a trust was established in November 1997 for the Kerala Kani people.²⁹⁹ The president and vice president of the Trust were the original Kani guides who initially disclosed the plant to researchers.³⁰⁰ Goals of the trust were to improve the welfare and development of this tribe, prepare a biodiversity register to document the knowledge base of the Kanis, and promote sustainable use and conservation of biological resources.³⁰¹

While this sounds like a progressive move towards protecting traditional knowledge and increase benefit sharing, the attempt failed. The Kanis had no presence in the negotiation process either in terms of who the drug was sold to or how their benefits were to be realized.³⁰² The terms of their trust authorized spending for the entire Kani community, but also allowed spending for individual benefit.³⁰³ There was also an initial concern of exacerbating internal social problems such as alcohol abuse within the community.³⁰⁴ There is little information

²⁹⁵ *Id.*

²⁹⁶ *Id.* at 13.

²⁹⁷ *Id.*

²⁹⁸ *Id.* at 17.

²⁹⁹ *Id.* at 23.

³⁰⁰ *Id.*

³⁰¹ *Id.*

³⁰² Charturvedi, *supra* note 290, at 267. The Kanis were invited to the discussion during second phase of development in 2006. *Id.* at 263.

³⁰³ *Id.* at 267.

³⁰⁴ *Id.* at 268.

concerning how the spending program has actually worked in practice. Given the propensity for communities with an influx of income to fall under elite capture of income and other social problems that may follow and the already stratified structure of the community, this mechanism was inappropriate for the Kani.³⁰⁵ Some authors argue that the most depressing aspect of this case were a result of the “horrors” of no coordination.³⁰⁶ There was “bitter feuding” between different agencies of the state and national government that divided tribe members between factions supporting commercialization of the drug and those that did not.³⁰⁷ Many social institutions within the community collapsed because the role of traditional healers (Plathis) was compromised; Plathis previously played a key role in rights to use and transfer of traditional medicines and the traditional system of social security.³⁰⁸ Finally, the natural resources in the area were severely depleted after the raw materials for manufacturing were collected illegally in huge quantities.³⁰⁹ Today, “all that remains of the attempt to share the benefits... are a defunct Trust... and the ruins of an unfinished computer training centre.”³¹⁰

Basmati Rice, Turmeric, and the Neem Tree

There are many other instances of biotechnology patents that evolved from traditional Indian knowledge. In 1997 the United States granted a patent for Ricetec of Texas, becoming a

³⁰⁵ See, e.g., Anil K. Gupta, *supra* note 294, at 26 (“[through the Trust], an avoidable impression was created among the Kani tribals that the trust was supposed to benefit only a few community members”).

³⁰⁶ Meetal Jain, *Global Trade and the New Millennium: Defining the Scope of Intellectual Property Protection of Plant Genetic Resources and Traditional Knowledge in India*, 22 HASTINGS INT’L & COMP. L. REV. 771, 810-12 (1999).

³⁰⁷ *Id.*

³⁰⁸ Charturverdi, *supra* note 290, at 264.

³⁰⁹ *A Benefit-Sharing Model That Did Not Yield Desirable Results*, THE HINDU (Oct. 18, 2012 01:58 IST), <http://www.thehindu.com/news/national/a-benefits-sharing-model-that-did-not-yield-desired-results/article4006840.ece>.

³¹⁰ *Id.*

“touchstone for anti-globalization protest in the 1990’s.”³¹¹ The patent claimed that their rice line had “characteristics similar or superior to those of good quality basmati rice.”³¹² Both India and the Pakistani government challenged the claims, arguing that their own documented varieties already had many of the same characteristics claimed by Ricetec.³¹³ Ricetec subsequently narrowed the patent which satisfied the Indian government.³¹⁴ This did not, however, satisfy the traditional farmers in India. The remaining patents covered strains bred from traditional Indian varieties and as such, the remaining patents satisfied the government’s interest in maintaining the quantity of rice exported from India but did not help farmers protect certain traditional type.³¹⁵

Similar stories exist from the 1990’s where critics say India was becoming complacent with their weak intellectual property laws. India was able to successfully challenge a 1995 Turmeric³¹⁶ patent granted to the University of Mississippi Medical Center after proving the medicinal use of turmeric for thousands of years.³¹⁷ The case of turmeric was the first time a U.S. patent was revoked after it was challenge by developing country based on documented traditional knowledge.³¹⁸ Then in 2000, European patents on a neem-based anti-fungal granted to the U.S. Department of Agriculture were revoked after evidence of farmer use proved a lack of

³¹¹ Saritha Rai, *India-U.S. Fight on Basmati Rice is Mostly Settled*, N.Y. TIMES (Aug. 25, 2001), <http://www.nytimes.com/2001/08/25/business/india-us-fight-on-basmati-rice-is-mostly-settled.html>.

³¹² Michael Woods, *Food For Thought: The Biopiracy of Jasmine and Basmati Rice*, 13 ALB. L.J. SCI. & TECH. 123, 138 (2002), citing to U.S. Patent No. 5,663,484 (issued Sept. 2, 1997).

³¹³ Rai, *supra* note 311.

³¹⁴ *Id.*

³¹⁵ *Id.*

³¹⁶ U.S. Patent No. 5,401,504 (filed Dec. 28, 1993).

³¹⁷ Annie Baxter, *Mpls. Law Firm Blocked Turmeric Patent, Curried Favor in India*, MPR NEWS (Oct. 25, 2007), http://www.mprnews.org/story/2007/10/12/turmeric_patent.

³¹⁸ SHAHID ALIKHAN & R. A. MASHELKAR, *INTELLECTUAL PROPERTY AND COMPETITIVE STRATEGIES IN THE 21ST CENTURY*, 77 (2004).

novelty.³¹⁹ In fact, the use of the neem tree has been used in India and throughout the world for over 2,000 years.³²⁰ Despite revoking European patents on the anti-fungal, the U.S. patents on neem tree products have remained valid.³²¹ Although these cases represent success in rectifying some consequences of biopiracy, they also represent only a small sample of the plethora of patents that rely on traditional knowledge and are criticized as examples of India's complacency in protecting knowledge before they have to challenge issued patents.³²²

The Eggplant

The National Biodiversity Authority of India has only initiated legal proceedings once- the investigation of biotech giant Monsanto.³²³ The eggplant has been dubbed the unlikely protagonist in a raging debate over genetically modified foods in India.³²⁴ India considered introducing the genetically modified eggplant after acknowledging the impacts climate change could have on agriculture.³²⁵ The idea came after genetically modified cotton crops were introduced in October 2009, pushing India into a new level of production ranking only second after China in the world.³²⁶ The cotton plant was modified to produce a bacterium that is toxic to insects.³²⁷ Despite such success with genetically modified cotton, the backlash was enough for

³¹⁹ *India Wins Neem Patent Case*, THE HINDU (Mar. 9, 2005), <http://www.hindu.com/2005/03/09/stories/2005030902381300.htm>.

³²⁰ Robinson, *supra* note 68, at 71.

³²¹ *Id.*

³²² Rai, *supra* note 311.

³²³ William Pentland, *India Sues Monsanto Over Genetically-Modified Eggplant*, FORBES (Aug. 12, 2011 7:09 PM), <http://www.forbes.com/sites/williampentland/2011/08/12/india-sues-monsanto-over-genetically-modified-eggplant/>.

³²⁴ Rina Chandran, *Debate Over GM Eggplant Consumes India*, REUTERS (Feb. 16, 2010 1:28 AM), <http://www.reuters.com/article/2010/02/16/us-india-food-idUSTRE61F0RS20100216>.

³²⁵ *Id.* See also, B. Venkateswarlu, *Agriculture and Climate Change in India*, CLIMATE & DEV. NETWORK, <http://cdkn.org/2012/01/agriculture-and-climate-change-in-india/> (last visited Mar. 29, 2014).

³²⁶ Rina Chandran, *Debate Over GM Eggplant Consumes India*, REUTERS (Feb. 16, 2010 1:28 AM), <http://www.reuters.com/article/2010/02/16/us-india-food-idUSTRE61F0RS20100216>.

³²⁷ Richard Van Noorden, *India Academies' GM Crop Report Slammed*, Nature News Blog (Sept. 28, 2010 10:18 GMT), http://blogs.nature.com/news/2010/09/post_64.html.

former minister of the environment to impose an indefinite moratorium on the cultivation of the eggplant.³²⁸ The largest opposition to cultivating the genetically modified eggplant came from a lack of public trust regarding the biosafety- interest groups commented that the biosafety testing done was inadequate and scientifically unsound.³²⁹ Many feared that the cultivation would cause extinction of native crops and that the physical yields of the new crop were hypothetical and tentative.³³⁰ Public sentiment towards the technology is more than skeptical: “Monsanto’s seed monopolies, the destruction of alternatives, the collection of super profits in the form of royalties, and the increasing vulnerability of monocultures has created a context for debt... and agrarian distress which is driving the farmers’ suicide epidemic in India.”³³¹

While the lack of scientific information regarding the health and safety of the new eggplant variety was enough to delay the commercial introduction of the species in India, environmental groups brought suit against Monsanto for biopiracy in India. The complaint was filed by environmental group ESG on November 24th, 2012.³³² The complaint alleges that Monsanto criminally accessed at least ten varieties of eggplant without any prior informed consent from the National Biodiversity Authority and applicable state and local biodiversity boards and

³²⁸ *Id.*

³²⁹ *Id.* The report featured no citations or references, and copied lines directly from a Monsanto-funded prior publication. *Id.*

³³⁰ Sreeja VN, *Indian High Court Reinstates Criminal Proceedings Against Monsanto and its Partners in India’s First Case of Biopiracy*, INT’L BUS. TIMES (Oct. 18, 2013 8:18 AM), <http://www.ibtimes.com/indian-high-court-reinstates-criminal-proceedings-against-monsanto-its-partners-indias-first-case>.

³³¹ Vandana Shiva, *Monsanto and the Seeds of Suicide*, Asian Age (Mar. 27, 2013), <http://www.commondreams.org/view/2013/03/27-4>.

³³² Press Release, Environmental Support Group-Trust, National Biodiversity Authority to Prosecute Mahyco/Monsanto and Collaborators Promoting Bt Brinjal in Violation of Biodiversity Protection Law (Aug. 11, 2011), <http://www.esgindia.org/campaigns/brinjal/press/national-biodiversity-authority-prosecut.html#sdfootnote1sym>.

committees.³³³ The decision was stayed on January 3rd, 2013 but officially reinstated in October 11, 2013.³³⁴

ESG also filed a public interest suit against the National Biodiversity Board, among others, for failures resulting in an irreversible contamination of native varieties and a loss of native species and “lacksidaisical” responses to citizen initiatives to protect biodiversity or no action altogether.³³⁵ In their complaint, ESG alleges that respondents “abysmally” failed in their duties with regard to biodiversity protection and have blindly ignored egregious biopiracy of the eggplant by international corporations and public institutions.³³⁶ The outcome of these cases will determine the future of genetically modified organisms and biopiracy prosecution in India, but until cases under the Act are decided, the success of the National Biodiversity Act and India’s initiatives to protect traditional knowledge are difficult to evaluate.

Overall, India has several key issues associated with their current patent regime that must be overcome in order to better promote biodiversity through innovation and social justice. India has an innovative legal framework to protect traditional knowledge and important biological resources in their National Biodiversity Act. However, only one case has been brought under the Act which is an indication that the law is ineffective at changing biopiracy practices that concerned the country when the law was initially put in place or the law is not capturing the bad actors. This is likely the result of confusion on a local level of who owns resources and knowledge, who can contract under the Act, and where the patent applicants actually obtained

³³³ *Id.* citing to Criminal Complaint No. 579/2012. The next hearing scheduled for this case is June 7th, 2014.

³³⁴ Press Release, Environmental Support Group-Trust, Criminal Proceedings against Monsanto/Mahyco and others, back on Track (Oct. 12, 2013), <http://www.esgindia.org/campaigns/press/criminal-proceedings-against-monsantomah.html>.

³³⁵ Press Release, Karnatake High Court Issues Notice in PIL Highlighting Egregious Biopiracy and Governmental Apathy (Nov. 21, 2012), <http://www.esgindia.org/campaigns/press/karnataka-high-court-issues-notice-pil-h.html>, citing to Writ Petition No. 41532/2012, 6.

³³⁶ *Id.* at 17.

their resources and knowledge from at the application stage. Additionally, India's patent laws are considered by influential countries to be incompatible with global standards. The most appropriate mechanism to protect or prevent biopiracy in India implemented thus far appears to be the TKDL. It is a preemptive, protective mechanism that does not require amending or creating law. However, it requires disclosure of traditional knowledge, but will not impact unauthorized research or extraction like the National Biodiversity Act seeks to curtail.

C. Brazil

1. History and Current Status of Brazilian Patent Laws

Brazil joined the international intellectual property system early on through their Portuguese colonizers.³³⁷ Like the United States and India, the system closely mirrored the British Statute of Monopolies.³³⁸ In 1809, Brazil became the fourth country in the world to grant exclusive rights to inventors for their work.³³⁹ After gaining independence, Brazil continued to pursue intellectual property rights and became one of the founding members of the Paris Convention in 1883.³⁴⁰ All laws passed in Brazil regarding intellectual property were aimed at developing Brazil, a legacy of the Portuguese priorities in resource extraction and development.³⁴¹ In the 1900's Brazil banned most manufactured imports.³⁴² In 1978 Brazil joined the Patent Cooperation Treaty.³⁴³ Eventually, the ban on manufactured imports and the nationalist priorities curbed the

³³⁷ Intellectual Property in Brazil: Owing Ideas, *ECONOMIST* (Nov. 3, 2012), *available at*: <http://www.economist.com/news/americas/21565606-getting-serious-about-patents-owning-ideas>.

³³⁸ *Id.*

³³⁹ *Id.*

³⁴⁰ *International Patent History and Laws: Brazil*, ARTICLE ONE (Mar. 31, 2011), <http://info.articleonepartners.com/international-patent-history-and-laws-brazil/>.

³⁴¹ Intellectual Property in Brazil: Owing Ideas, *ECONOMIST* (Nov. 3, 2012), *available at*: <http://www.economist.com/news/americas/21565606-getting-serious-about-patents-owning-ideas>.

³⁴² *Id.*

³⁴³ Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645. *See* Part I(A), *supra* for a discussion on the Patent Cooperation Treaty.

development of Brazil's technology sector, and Brazil eventually joined the WTO and the associated international intellectual property standards.³⁴⁴

Like the United States, the Constitution provides a basis for enacting patent law in Brazil.³⁴⁵ However, Brazil's Constitution makes it clear that patents are not "rights" but "privileges" and must not interfere with the country's economic development or social interest.³⁴⁶ So, while Brazil is a member of the WTO and their patent laws closely mirror other member countries,³⁴⁷ they have a much more flexible compulsory licensing scheme and set strict limits on patenting living organisms.³⁴⁷ There is currently an inherent conflict in Brazilian patent law as written, creating some ambiguity regarding the patenting of life.³⁴⁸ Living things are technically not considered patentable, but chemical products that fulfill other patent criteria are patentable, suggesting that genes may be entitled to chemical product patents.³⁴⁹ Another unique aspect of Brazilian patent law is the Brazil "local working" component that requires all goods receiving patent protection to be manufactured in some part within Brazil.³⁵⁰ Regardless of Brazil's goals

³⁴⁴ *Id.*

³⁴⁵ John Giust, *Comparative Analysis of the United States Patent Law and the New Industrial Property Code of Brazil*, 21 HASTINGS INT'L & COMP. L. REV. 597, 600 (1998).

³⁴⁶ *Id.* at 601, citing to C.F. art. 5 § XXIX (Braz.). The text specifically states: "The law will ensure to authors of industrial inventions of a temporary privilege for their use... with due regard for social interests and for the technological and economic development of Brazil." *Id.*

³⁴⁷ Giust, *supra* note 345, at 637, citing to Decreto No. 9.729, de 14 de Maio de 1996 Diario Oficial Da Uniao [D.O.U] de 15.5.2007 [Indus. Prop. Code]. The Industrial Property Code prohibits inventions which are contrary to morals, good customs and public security, order and public health and the whole or part of living beings except transgenic microorganisms which are not mere discoveries. *Id.* at art. 18.

³⁴⁸ Executive Summary: Genetics, Genomics and the Patenting of DNA, WHO, <http://www.who.int/genomics/publications/background/en/> (last visited May 9, 2014), citing to Lei de Propriedade Industrial No. 9.279, de 14 de Maio de 1996 Diario Oficial Da Uniao [D.O.U] de 15.5.1996.

³⁴⁹ Executive Summary: Genetics, Genomics and the Patenting of DNA, WHO, <http://www.who.int/genomics/publications/background/en/> (last visited May 9, 2014).

³⁵⁰ Bass, *supra* note 93, at 207. The local working component was challenge by the United States, but the United States withdrew the complaint leaving the validity of the provision undecided; there is no express provision in the TRIPS agreement preventing local working requirements. G.B. Reddy & Harunrashid A. Kadri, *Local Working of Patents- Law and Implementation in India*, 18 J. INTELL. PROP. RIGHTS 15, 17 (2012).

to further social and economic interests, current approach to patents under the Industrial Property Law has left them ranking 54th in the world for resident patent applications, significantly below the “economic relevance” of the country.³⁵¹ In other words, the patents being granted in Brazil are going to other countries (50.6% going jointly to the United States, Japan, and Germany).³⁵²

Brazil is currently working on passing a bill that would better align Brazilian laws with the country’s social interests in domestic technological and economic development.³⁵³ Among these provisions, representatives of the lower House of Congress seek to reduce the scope of patentable subject matter and expand the availability of compulsory licensing.³⁵⁴ Brazil has also implemented an open research model in an effort to keep the benefits of their rich biodiversity within their own country.³⁵⁵ The model coordinates the efforts of many small laboratories into a data repository on the internet.³⁵⁶ The research is funded publicly and is focused on forming collaborative partnerships between indigenous groups and other representatives of civil society, researchers, and government officials, aiming not only to develop technologies but human capital as well.³⁵⁷ All products publicly funded are immediately returned to the public which counters the anticommons issue discussed in Part I, *supra*.³⁵⁸

Brazil is also on the Special 301 Watch List.³⁵⁹ The primary reason for including Brazil on the Watch List is their weak enforcement mechanisms.³⁶⁰ Although copyright issues seem to be

³⁵¹ *Committee on Development and Intellectual Property*, WIPO, 1, 16 (Mar. 8, 2013) http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_11/cdip_11_inf_3.pdf.

³⁵² *Id.*

³⁵³ Damond, *supra* note 117, at 18.

³⁵⁴ *Id.*

³⁵⁵ *Id.*

³⁵⁶ Alessandro Octavani, *Biotechnology in Brazil: Promoting Open Innovation*, in *ACCESS TO KNOWLEDGE IN BRAZIL*, 79, 83 (Lee Shaver, ed. 2010).

³⁵⁷ *Id.* at 84.

³⁵⁸ *Id.* at 88.

³⁵⁹ 2013 Special 301 Report, *supra* note 10, at 45.

the primary concern, unfair commercial use for pharmaceuticals and an unpredictable and opaque patent examination process is also a big concern.³⁶¹ The Special 301 committee from the Biotechnology Industry Organization (the Organization) recently wrote an opinion to the Office of the U.S. Trade Representative recommending that Brazil be upgraded to the Priority Watch List for 2014.³⁶² Reasons for the Organization's concern about Brazilian patent laws are numerous. The Organization is concerned about the Brazilian Patent Office's (INPI) ability to process the number of pharmaceutical applications and cites a backlog of over 20,000 applications.³⁶³ Other administrative issues (like prohibition on amending patent claims) lead the Organization to suggest the Brazil harmonize their laws with the U.S. or other countries.³⁶⁴

In response to the CBD and issues of biopiracy, Brazil established a Genetic Heritage Management council.³⁶⁵ Because of the difficulties associated with protecting traditional knowledge, Brazil has made traditional knowledge a part of Brazilian cultural heritage and it is held by the whole community.³⁶⁶ The community has a right to be acknowledged for their contribution to further development of the technology, prevent non-authorized use of the technology, and receive benefits from the economic use by third parties of traditional

³⁶⁰ *Id.*

³⁶¹ *Id.*

³⁶² Damond, *supra* note 117, at 22.

³⁶³ *Id.* at 17.

³⁶⁴ *Id.* at 18.

³⁶⁵ Lei Provisional No. 2.186-16, de 23 de Agosto de 2001 Diario Oficial Da Uniao [D.O.U] de 24.8.2001 [Hereinafter No. 2.186-16].

³⁶⁶ Eduardo Vélez, *Brazil's Practical Experience with Access and Benefit Sharing and the Protection of Traditional Knowledge*, International Centre for Trade and Sustainable Development, 2, (June 2010), <http://ictsd.org/downloads/2011/12/brazils-practical-experience-with-access-and-benefit-sharing-and-the-protection-of-traditional-knowledge.pdf>. Defining who "owns" the genetic resources and traditional knowledge (and who should be signing contracts for use) is difficult and could include public or private landowners, representatives of indigenous communities, representatives of a local community, or Brazilian governmental indigenous agencies. *Id.*

knowledge.³⁶⁷ Under the benefit sharing regime, access to natural resources for bioprospecting on federal land requires a permit established by a “Contract for Use” between users, and the landowner or community representative.³⁶⁸ Patent applicants must also disclose the origin and associated knowledge “as appropriate.”³⁶⁹ Benefits can include sharing profits or payment of royalties, technology transfer, and training of people from the region from where the resources have been taken.³⁷⁰ The council has the authority to cancel patents, seize products derived from wrongfully acquired samples, prohibition on future government contracts, and/or partial or total closure of a business, activity, or undertaking, inter alia.³⁷¹ However, biopiracy is not a crime in Brazil and any fines from evading benefit-sharing can be written off after companies agree to better regulate their benefit sharing policies.³⁷²

2. Implications

The number of natural products extracted from the Amazon and the Brazilian Amazon in general are endless, and there are likely many cases of biopiracy that go undocumented.³⁷³ One of the most notorious cases was a suit brought by the Coordinating Body of Indigenous Organizations of the Amazon Basin and the Coalition for Amazonia Peoples and Their Environment for a 1986 patent issued by the U.S. Patent and Trademark Office on a variety of

³⁶⁷ *Id.*

³⁶⁸ No. 2.186-16, *supra* note 365, at art.7.

³⁶⁹ *Id.* at art. 31.

³⁷⁰ *Brazil Fines 35 Firms US\$44 Million for Biopiracy*, SCIENCE AND DEVELOPMENT NETWORK (July 20, 2012), <http://www.scidev.net/global/biodiversity/news/brazil-fines-35-firms-us-44-million-for-biopiracy.html>.

³⁷¹ Decreto No. 5.459, de 7 de Junho de 2005 Diario Oficial Da Uniao [D.O.U] de 8.6.2005 (regulates No. 2.186-16 regarding penalties for conduct and activities injurious to genetic heritage and traditional knowledge).

³⁷² *Brazil Fines 35 Firms US\$44 Million for Biopiracy*, SCIENCE AND DEVELOPMENT NETWORK (July 20, 2012), <http://www.scidev.net/global/biodiversity/news/brazil-fines-35-firms-us-44-million-for-biopiracy.html>.

³⁷³ Cf. Vanessa Danley, *Biopiracy in the Brazillian Amazon: Learning from International and Comparative Law Successes and Shortcomings to Help Promote Biodiversity and Conservation in Brazil*, 7 FLA. A & M U. L. REV. 291, 295-96 (2012) (stating that the Brazilian Institute of the Environment and Natural Resources estimates that thousands of medicinal plants and wood are illegally exported each year).

Ayahuasca found in an undisclosed location in the Amazon basin.³⁷⁴ In their request for reexamination, challengers claimed several reasons the patent should be invalidated: the plant's medicinal properties were not novel because indigenous people had used them for medicinal and psychotherapeutic uses for many generations; the species' "distinctive" physical features were already identified in prior art records of the species; and the plant is found in an uncultivated state in the Amazon basin, which, makes them unpatentable.³⁷⁵ The patent was rejected in 1999 after opponents appealed to the U.S. Patent and Trademark Office, but the decision was reversed in 2001, restoring the patent after reexamination by the U.S. Patent and Trademark Office.³⁷⁶ The patent expired in 2003.³⁷⁷ The legacy of this case is that it can be interpreted as the United States physically condoning biopiracy; the plant met the criteria for patentable subject matter in the United States despite full disclosure that the plant had been domesticated and found growing in a garden a foreign country.³⁷⁸ Ultimately, scholars believe the use of the plant was premised both on spiritual and cultural connection to the environment *and* a conservation ethic, so appropriation of the plant simultaneously threatens cultural and biological diversity in the Basin.³⁷⁹

Another example includes indiscriminate harvesting of the Brazilian *Pilocarpus jaborandi* (literally "slobber-mouth plant") that pushed the plant to the brink of extinction in the 1980's.³⁸⁰

³⁷⁴ Legal Elements of the Ayahuasca Patent Case, *GRAIN* (Mar. 30, 1999), <http://www.grain.org/article/entries/1979-legal-elements-of-the-ayahuasca-patent-case>, citing to U.S. Plant Patent No. P.P. 5,751 (Issued June 17, 1986). *See also*, Michael K. Dorsey, *The Political Ecology of Bioprospecting in Amazonian Ecuador*, in *CONTESTED NATURE: PROMOTING INTERNATIONAL BIODIVERSITY WITH SOCIAL JUSTICE IN THE TWENTY-FIRST CENTURY*, 137, 138 (Steven R. Brechin, et al. eds., 2003).

³⁷⁵ Legal Elements of the Ayahuasca Patent Case, *GRAIN* (Mar. 30, 1999), <http://www.grain.org/article/entries/1979-legal-elements-of-the-ayahuasca-patent-case>, citing to U.S. Plant Patent No. P.P. 5,751 (Issued June 17, 1986).

³⁷⁶ Dorsey, *supra* note 374, at 145.

³⁷⁷ *Id.*

³⁷⁸ Robinson, *supra* note 68, at 69.

³⁷⁹ Dorsey, *supra* note 374, at 145.

³⁸⁰ KERRY TEN KATE & SARAH A. LAIRD, *THE COMMERCIAL USE OF BIODIVERSITY: ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING*, 73 (2000).

The plant's commercially exploitable properties were first realized through the Tupi community who had traditionally been using the plant for a variety of ailments due its ability to induce salivation and perspiration.³⁸¹ Like the Pacific Yew discussed in Part A, *infra*, the manufacturing of the commercially valuable compound was more easily accomplished through plant harvest rather than synthesize it in a lab.³⁸² The collection was done primarily by indigenous communities and became a major source of income.³⁸³ This resulted in a dependency on labor that depleted local, culturally significant natural resources, and was a “detriment [to] other aspects of their local economy and the general welfare and psychological well-being of their community.”³⁸⁴

July 20, 2012 Brazil fined thirty-five companies for not sharing benefits associated with the country's biodiversity after the Genetic Heritage Department filed a formal complaint.³⁸⁵ The effort was the first time since the Genetic Heritage Department was formed that Brazil has fined companies for evading benefit-sharing on such a large scale.³⁸⁶ There is no current information on how the actual fine played out. The companies have a right to appeal and spokespeople from corporations have been quoted saying the complaints are unfounded, and have submitted their own evidence of compliance with Brazilian law.³⁸⁷

It is clear that success of efforts under the Genetic Heritage Management Council is yet to be seen, or like India's National Biodiversity Act, there is a strong potential that the laws are

³⁸¹ *Id.*

³⁸² *Id.*

³⁸³ *Id.* At one point, up to 25,000 people engaged in Jaborandi harvesting in the 1990's. *Id.*

³⁸⁴ *Id.*, citing to Theodore Macdonald, Jr., Dominique Irvine, and L. Esther Aranda, *The Quichua of Eastern Ecuador*, in *INDIGENOUS VIEWS OF LAND AND THE ENVIRONMENT* 11, 11-31 (Shelton Davis, ed., 1993).

³⁸⁵ *Brazil Fines 35 Firms US\$44 Million for Biopiracy*, SCIENCE AND DEVELOPMENT NETWORK (July 20, 2012), <http://www.scidev.net/global/biodiversity/news/brazil-fines-35-firms-us-44-million-for-biopiracy.html>.

³⁸⁶ *Id.*

³⁸⁷ *Id.*

simply not capturing the bad actors and/or undesirable behavior. There is a general failure of the legislation to: clarify who beneficiaries should be, address the capacity of stakeholders to negotiate appropriate contracts, and acknowledge issues of confidentiality in addition to a lack of national and international law enforcement have undermined these regulations.³⁸⁸ Also like India, the weak patent system in Brazil is seen as a threat to global standards; any laws that appear to be too nationalistic or protective will be challenged by countries like the United States at the WTO, so combating biopiracy will not be achieved through amending or creating patent laws or laws that impact the patent system.

III. CONCLUSIONS/RECOMMENDATIONS

In the introduction, I identified two broad categories of environmental benefits associated with patent laws: green technological innovation and the inherent monetary value of sustaining the “world’s vanishing medicine” cabinet. The ecological benefits are strongly undermined, if not entirely negated, by the intense levels of extraction and cascading impacts of patenting traditional ecological knowledge. There is a growing recognition of the connections between intellectual property rights, biodiversity conservation, and basic human rights as seen through international agreements and discussions, but intellectual property rights are ultimately governed at the national level and strongly reflect international trade pressures influenced by powerful nations and their goals.

The United States has little incentive to acknowledge the ecological impacts of their patent system because the United States is not losing their natural resources from biopiracy at the rate of other nations; the United States has made it painfully obvious that there is little incentive to

³⁸⁸ *Brazil’s Practical Experience with Access and Benefit Sharing and the Protection of Traditional Knowledge*, INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT, 6 (June 2010), <http://ictsd.org/downloads/2011/12/brazils-practical-experience-with-access-and-benefit-sharing-and-the-protection-of-traditional-knowledge.pdf>; Eduardo Vélez, *supra* note 366, at 1.

constrain biopiracy by failing to sign on to the Convention on Biological Diversity. India, on the other hand, has recently joined the global market, sacrificing their dominant generic drug manufacturing industry but building up their indigenous agriculture industry and enacting laws to protect it. The efficacy of the National Biodiversity Act is yet to be seen; with only one case still pending in the High Court it has either deterred ‘pirates’ from wrongfully acquiring traditional knowledge or lack adequate policing and enforcement mechanisms to be effective. Brazil, like India, has implemented a system to protect traditional knowledge, but detecting violations of the system is very difficult and rare.

Current debates for reform focus on several main areas: banning patents on life, amending the international systems governing intellectual property and biodiversity, or strengthening/supporting the national systems that have evolved to accommodate the growing concern of biopiracy. There are several arguments that are advanced in favor of banning patents on life. Because biological processes are not under the direct control of scientists and require spontaneous reactions, they should not be regarded as inventions.³⁸⁹ Genes and genomes are more akin to “discoveries” which are prohibited under patent law.³⁹⁰ Many countries have banned GMO’s, patents on seeds, or attempted to ban life patents altogether, but patents are crucial incentive for research and development companies to be able to recoup their investments and profit.³⁹¹

The international framework to protect biodiversity and traditional knowledge appears to be in place; most of the world adheres to the Nagoya Protocol and has committed to equitable

³⁸⁹ Mae-Wan Ho & Terje Traavik, *Why We Should Reject Biotech Patents From TRIPS*, INST. SCI. SOC’Y <http://www.i-sis.org.uk/trips99.php> (last visited May 9, 2014).

³⁹⁰ *Id.*

³⁹¹ *See, e.g.*, Fergus Walsh, *Stem Cell Patent Ban*, BBC News, (Oct. 18, 2011 3:50 PM) <http://www.bbc.co.uk/news/health-15355991>.

benefit sharing and access to natural resources. Furthermore, there is a growing interest by pharmaceutical actors to link their bioprospecting profits to conservation.³⁹² However, the approach taken by individual countries is highly varied; this is exemplified by Brazil's approach of requiring disclosure and consent from all prior users, and India's approach of requiring consent from biodiversity authorities who theoretically have local interests in mind. And although enforcement of international agreements has been criticized, the cases of India and Brazil show that even if enforcement was stronger internationally, the confusion with physical implementation at the national level makes international enforcement of patent laws and the biodiversity agreements irrelevant (even if every country fully complied with their TRIPS and CBD requirements, here is little evidence that traditional knowledge and biodiversity would be protected, that indigenous communities would be appropriately compensated for acquired knowledge, or, that cultural heritage would be preserved through a national patent systems).

Clearly a balance must be struck in order to accommodate the rapid technological advancements that benefit mankind and acknowledge the disparate impact of world property laws on lesser developed countries; clearly conservation implications of such property laws are of little importance when the social consequences are disastrous (i.e. farmer suicides in India and cultural homogenization of entire groups of ethnically diverse people). Furthermore, any national laws that appear to be too nationalistic or protectionist are challenged by powerful WTO countries for violations of international agreements like TRIPS.³⁹³ Therefore, the solution may be

³⁹² Dorsey, *supra* note 374, at 137.

³⁹³ Most recently, the US is threatening to move trade disputes to the WTO:

India's been pursuing trade policies that undermine US intellectual property to promote its own domestic industries. What they are doing seems to me to be a clear violation of their WTO obligations...enforcement action at the WTO may be the most effective tool that we have to get India to change its behaviour,' said Orrin G Hatch, a Republican from Utah. Similarly, Democrat Robert Menendez pointed to specific concerns over "India's pharmaceutical patent violations.

outside the legal forum and in mechanisms like TKDL. Efforts to document traditional knowledge and share with patent examiners may be a significant part of the solution, as seen in India. But physically recording information has barriers: cultural, physical, and social, that may be inappropriate for a vast majority of communities.³⁹⁴ Furthermore, communities that publish their knowledge in a library will lose the ability to profit from such knowledge. While TKDL-type protection would limit biopiracy, that is only one aspect of the ecological destruction associated with patent law, albeit the most significant.

One area of potential reform that may curtail some aspects of biopiracy without taking away the ability for traditional communities to benefit from their own knowledge would be to consider a wider variety of prior art during patent examination processes. TRIPS could require all WTO parties to consider oral traditional knowledge (and other forms) as opposed to technical, written, and publicly documented evidence of previously known inventions. However, publication of some sort would likely still be required for practical purposes, and therefore the same concerns associated with the TKDL would still be applicable. Ultimately, the potential for reform in order to acknowledge traditional knowledge and benefit sharing is highly unlikely. The U.S. model of patent law is ingrained in most developed countries, and there is no catalyst to change these laws. More research demonstrating the connection between biodiversity and intellectual property could help illustrate the imperative to adapt laws, and enable lawmakers to find a creative solution to the biodiversity crisis through the intellectual property system.

What this paper illustrates is that the concerns of property rights, social justice, and conservation of biodiversity are interrelated. This idea is not new, but the research discerning

Sidhartha, *US Faces Pressure to Take India to the WTO on Patent Rules*, THE ECONOMIC TIMES (May 6, 2014 12:41 PM) <http://economictimes.indiatimes.com/news/economy/foreign-trade/us-faces-pressure-to-take-india-to-wto-on-patent-rules/articleshow/34726025.cms>.

³⁹⁴ See Dutfield, *supra* note 186, at 347-358.

ecological impacts of international intellectual property law is scarce despite international agreements calling for national laws to protect biodiversity through intellectual property laws. National laws and policy cannot successfully accommodate these agreements until there is more evidence of what mechanisms work, and what mechanisms do not work.