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Community Control and Compensation: An Analysis for Successful Intellectual Property Right Legislation for Access and Benefit Sharing in Latin American Nations

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***Abstract**: Indigenous communities have worked for centuries to develop systems of knowledge pertaining to their local environments. Much of the knowledge that has been directly acquired or passed down over generations is of marketable use to corporations, especially in the pharmaceutical industry. Upon gaining the necessary information to convert traditional knowledge into a marketable entity, the corporation will place a patent on the product of their research and development and reap the monetary benefits under the protection of intellectual property legislation. Without appropriate benefit sharing, indigenous communities are robbed of their cumulative innovation and development and denied access to the very medicines that they assisted in development. This study will examine the efforts made by indigenous communities to develop benefit-sharing agreements under national 'sui generis' legislation and the international legislation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD).*

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List of Acronyms

ABS	**Access and benefit sharing**
CBD	**The Convention on Biological Diversity**
CHM	**Clearing House Mechanism**
CIEL	**Center for Environmental Law**
COICA	**Coordinator of Indigenous Organizations of the Amazon Basin**
GATT	**General Agreement on Tariffs and Trade**
GDP	**Gross domestic product**
IPC	**Intellectual Property Committee**
IPR	**Intellectual property rights**
LMO	**Living modified organism**
MAT	**Mutually agreed terms**
NAFTA	**North American Free Trade Agreement**
NGO	**Non-governmental organization**
PIC	**Prior informed consent**
R&D	**Research and development**
TRIPS	**Agreement on Trade-Related Aspects of Intellectual Property Rights**
WIPO	**World Intellectual Property Organization**
WTO	**World Trade Organization**

Introduction

The legality of intellectual property rights – the ownership of one's unique ideas – is difficult to manage on an international scale, given the complexity of global society. Patent laws have been designed to establish the propriety of innovations, but the process of extending national patent legislation to an international scale has received criticism for disregarding smaller actors' rights to their own intellectual property.

Indigenous communities have worked for centuries to develop systems of knowledge pertaining to their local environments. They understand the applicable uses of natural products derived from their resources. Much of this traditional knowledge is of marketable use to corporations. Elisabetsky, Costa-Campos (1996) and Narby (1998) state that 74% of modern medicine's plant-based remedies were first discovered by indigenous groups. Upon learning of traditional knowledge and converting it into a marketable entity, such as a pharmaceutical drug, a corporation will place a patent on the product of their research and development, often without citing the origin of their research.

Patent protection incentivizes the research and development (R&D) process. Because R&D in the pharmaceutical industry is generally between 10 and 15 years in duration and $231 to $500 million dollars in cost (Kate and Laird 2000), pharmaceutical companies are looking to privatize their products, disallowing the creation of generic forms of their drugs. Generic drugs could be sold at a lesser cost, could create competition in the market, and would eliminate the patent holding firm's monopoly of the good. Advocates of strict IPR legislation claim without the protection of patents, pharmaceutical R&D would slow. Companies wouldn't want to invest heavily in a product that would be available to their competitors upon its completion.

This paper will give an overview of the issues surrounding intellectual property conflicts over the traditional medicinal knowledge of indigenous peoples and local communities in Latin America, a region of the globe containing a wealth of natural resources and biodiversity. First, this paper will describe the historic and economic roots of IPR and traditional knowledge. Second, the legal standing of IPR and its relation to traditional knowledge will be examined on an international and national scale. Third, this paper will examine access and benefit sharing agreements between source nations that contain traditional knowledge and diverse resources and the pharmaceutical companies that wish to use such goods. Lastly, implications of such agreements and solutions to problems arising in current IPR legislation and use of traditional knowledge will be discussed. Pharmaceutical development is necessary to develop technologies capable of protecting human lives and the biodiversity of the globe may provide the key ingredients for progress. Collaboration between modern scientists and traditional societies will expedite technological process so it is important to ensure worthwhile partnerships that will lead to increased innovations and developments.

History of Intellectual Property Rights

John Locke introduced the idea of 'enclosure of the commons' during the Enlightenment of the eighteenth century. Under the enclosure of the commons model, natural resources are converted into private commodities. Resources are enclosed, removed from the public sphere, and only available for use by their newly assigned owners. This same enclosure occurs with intellectual property when a commonly shared idea is patented and becomes the private property of a specific party.

There exists a knowledge commons, but it is quickly closing with the advent of stricter patent law. When Einstein developed his theory of relativity it was not patented and stored away. Instead the knowledge was shared with the scientific world and today's physicists are still striving to prove its implications for our universe. Both public and private universities make free information available online. Privatized processes for developing life saving pharmaceuticals have the potential to save thousands of lives. However, these processes and their resulting patents are in the control of private pharmaceutical firms and not available for common use. The idea to protect one's intellectual property arose from philosophers, but soon was awarded legal standing by those wishing to protect what they believed was rightfully their own.

Patent law was first drafted in Europe as a protection of an author's right over his written work. This 'right of copy', known today as copyright, rewarded inventiveness and intellectual labor during a time when increased literacy and the advent of the printing press threatened the author's privilege to his own words and ideas (Brown 2003). Additionally, monarchs used the tool of patents to establish import monopolies in newly discovered lands, such as Latin America, and grant privilege, rights, ranks, and titles to individuals under their rule (Shiva 2001). In 14th century England, foreign inventors and craftsmen were brought to work in Europe where their products and techniques were domestically patented to encourage the transfer of these new technologies, despite their existence in other parts of the globe (Shiva 2001). The tradition and legality of patents were established during this time and persisted as the primary way to protect an inventor's work.

Private property, the basis of patent legislation, is a concept formally introduced to Latin America by the Spanish conquistadors settling the lands in the sixteenth century. They confiscated communal indigenous lands, converted them to indigo and banana plantations, and

used the indigenous as unpaid workers. Mineral resources such as mercury, gold, and silver were extracted in the name of the Spanish king. Agricultural products such as corn, potatoes, and cocoa were shipped to Europe. Rubber trees were taken from Brazil and planted in Malaysia. The Europeans enslaved the indigenous; everything they had ever known was suddenly the private property of these invaders. The draw of Latin America's natural resources encouraged exploitation of the land and enclosure of the indigenous commons at the hands of the Spanish conquistadors.

At the time of the Spanish conquest, large native groups formed empires of high civilization such as the Inca, Maya, and Aztecs. They domesticated plants, developed agricultural technologies, practiced science, and believed in the cyclical nature of the environment. Just as Europeans revere the Greek empire as the basis of classical knowledge, many indigenous Latin Americans look to the developments of these societies as the basis of their innovation and scientific accomplishments.

Colonialism continues today, but in a different form. There still exists control over Latin American biological resources, but now by patent law instead of monarchist rulers. Intellectual property rights heavily favor scientifically categorized libraries of knowledge rather than communally held innovative techniques of a traditional nature, such as those originating in the times of the Inca, Maya, and Aztecs. Collective, community rights to knowledge are not protected by IPR. The system in place is one to privatize knowledge, not share it.

Ethnobotanical Knowledge

The process of research and development (R&D) in the pharmaceutical sector is an extremely costly and time-consuming process, which encourages scientists to look for more streamlined methods of development. Imagine, as a pharmaceutical researcher, the hope of bypassing the process of R&D simply by watching a shaman at work. As the shaman applies medicinal plants to a patient who complains of a headache, a pharmaceutical researcher simply needs to record the ingredients and export samples to their labs. Using traditional knowledge to screen plants for medicinally useful chemicals has increased the success rate of finding marketable naturally based pharmaceuticals fourfold (Sampath 2003).

When applying for patent protection, the 'first-to-file' system comes into effect, which allows an inventor to patent his or her product regardless of whether someone else had achieved the same success first (Downes 2000). Generally, these patents filed with the knowledge of traditional consultants in the R&D process do not give due credit to the true innovators (Brown 2003). This ignores cumulative innovations of indigenous societies and the knowledge acquired from trial and error processes repeated over thousands of years.

Ethnobotany, the study of how people utilize plants, provides many examples of the medicinal properties indigenous communities have discovered. These medicinal uses are one of the primary arguments for biodiversity conservation (Elisabetsky and Costa-Campos 1996, Brown 2003). Although there is a common sentiment among first world nations that developing countries cannot possibly care about an obscure plant when they are struggling to feed their own citizens, this simply isn't true (Steinberg 2001). Many of the plants scientists consider to be

'obscure' are actually utilized by communities and ultimately included in patents when modernized scientists discover their marketable uses.

Take the substance curare as an example. This paralytic was first discovered by indigenous in the Amazon who used it as poison on the tips of their weapons. The indigenous Tukano of the Colombian Amazon claim the recipe was invented by the creator of the universe and given to their people as a gift (Narby 1998). Varieties of the brewed curare substance have been developed across the Amazonian region and forty types of it are known today (Narby 1998). The substance is a persuasive indicator of the level of knowledge the indigenous hold due to the scientific process in which it is brewed. Ingredients come from several types of plants and are brewed for seventy-two hours, while producing lethally toxic fumes (Narby 1998). The resulting paste is the curare paralytic, which is applied to the tips of blow darts for injection, as the paste is not functional if applied directly to the skin or ingested (Narby 1998). The indigenous developed the complex ingredients, brewing process, and use. Curare was seen as useful for surgeries due to its muscle relaxing and nerve interrupting processes so starting the 1940s, it was produced for modern pharmaceutical uses (Narby 1998, Kate and Laird 1999). With that advent of biotechnology, pharmaceutical companies were able substitute for the naturally based product with the synthetically created substances known as vencuronium and atracurium, which have completely replaced the natural product in clinical use (Kate and Laird 1999). Developments in the field of biotechnology have facilitated the production of a synthetic form of this pharmaceutical, but the origin of the new medicine lies in the ethnobotanical knowledge of the indigenous.

The medicines used by shamans are part of a broad base of ecological knowledge of indigenous peoples. Their knowledge has practical application in conservation, land

management, agricultural research, music and arts. In an economic sense, these applications already contain inherent value, making them attractive to developers. In particular, biodiversity conservation is a valued use of indigenous ecological knowledge. Increasingly, areas are being nominated as protective zones for biodiversity and indigenous peoples inhabit as many as 85% of these protected areas (Colchester 2000). Many indigenous groups have close ties to their ancestral lands and maintain these lands for future generations. Common property management schemes have given traditional societies a tool to protect their lands over generations (Colchester 2000).

The value of biodiversity lacks a working market and is extremely hard to measure, making its protection a difficult political battle in the face of development. Based on previous studies and his own calculations, Soejarto (1996) estimates there to be 40,000 plants used for modern medicinal purposes. However, less than 2% of all plant species have been fully tested in labs for biotechnical uses (Narby 1998), leaving a huge wealth of resources available to developers if biodiversity is maintained. Encouraging traditional ownership over lands and giving communities the tools to protect their knowledge may be essential to the maintenance of biodiversity and future discoveries for pharmaceutical research.

A problem arises when those who do share their practices feel uncompensated for their work and those who do not actively share their innovations feel as though they have been robbed (Shiva 2001). Many communities that shared their medicinal practices have been given no credit in reports brought back to corporate development offices (Brown 2003). This type of theft of indigenous knowledge of biological resources is called 'biopiracy'. Developments made from the medicinal practices of indigenous healers are approved for patents worldwide, ignoring the cumulative innovation from centuries of practice (Shiva 2001).

Pharmaceutical companies generally take four approaches when searching for medically viable compounds in genetic resources: random, taxonomic, ecological, and ethnobotanical. Random or 'blind' sampling screens local biological resources from a given geographical region so as to obtain a representative, but random, sample of local genetic materials. Taxonomic screening examines samples of biological resources with close genetic relation to other valuable chemical sources. Ecological sampling observes interactions between species of a given ecosystem that may produce secondary compounds. Ethnobotanical screening samples collections based on the knowledge of indigenous groups. Because ethnobotanical research has increased the probability of locating a marketable drug fourfold, it is increasingly used by pharmaceutical companies (Sampath 2003).

Ethnobotanical knowledge has been passed down by elders and experienced through a tacit understanding of ecology (Narby 1998). Many of the practices are acquired experimentally and transferred using demonstration instead of codified writings or discussion (Sampath 2003). This can make it difficult to actually obtain useful information from indigenous communities. Gaining marketable extractions from genetic resources based on traditional knowledge involves extensive relationship building within the community before any knowledge is passed along. As this can take years, some companies look to bypass relationship building by simply referring to the works of published ethnobotanists, anthropological specialists in the field (Sillietoe 1998). These are blatant cases of biopiracy, but are not investigated before patent approval by the US Patent Office (Shiva 2001).

Researchers who communicate directly with an indigenous group to obtain ethnobotanical knowledge generally take five steps from gathering the knowledge to producing a pharmaceutical product. Cox (1995) (as referenced by Sampath 2003) described these steps as:

1. Recording indigenous healing knowledge from interviews
2. Collection and identification of useful plants
3. Screening of plants
4. Isolation of molecular entities involved in the pharmacological activities
5. Determination of the structure of the purified materials.

Although ethnobotanical knowledge often leads researchers to plants containing useful chemical compounds, it is sometimes the case that the plant itself is of marketable use. Remedies for common ailments like colds, headaches, and fatigue can be derived simply from the methods used by indigenous shamans to prepare a given mixture of plants (Sampath 2003). Regardless of whether a pharmaceutical is developed based on chemical extracts from local plants or the direct application of the ethnobotanical knowledge itself, modern scientists will codify their research after extensive testing and earn the credit for the 'discovery'.

Additional Genetic Resources

Plants aren't the only sources of genetic resources that provide a basis for modern day pharmaceutical research. Various chemicals produced by animals and microbes, even DNA, are also valuable sources of viable compounds. Traditional communities have extracted secretions from the skin of a tropical frog in the Amazon to create paralyzing blow darts for centuries and now Abbott Laboratories is using the same active chemical from the frog secretion, known as epibatidine, to develop a side-effect-free version of morphine (Pollack 1999, Kate and Laird 1999). Inspired by snake venom of a Brazilian viper, Bristol-Myers Squib pharmaceutical company produces synthetic Capoten, a cardiovascular medicine, which generated $1.27 billion dollars in sales in 1993 (Rohter 2007, Kate and Laird 1999). Kate and Laird (1999) cite a study

in which, "Grifo et al. (1997) found that 23% of all compounds contained in prescription drugs dispensed in the USA are derived from animals."

Human cell lines may hold the cures to genetically transmitted diseases like Huntington's, Alzheimer's, or cystic fibrosis. Pharmaceutical researchers seek out indigenous communities throughout the world out for their DNA. This type of research is not included in any international legislation regarding IPR or biodiversity due to its controversial nature and moral grey area. Therefore, this type of pharmaceutical prospecting remains a largely unregulated area (Kate and Laird 1999).

Diversa, a biotechnology firm located in San Diego, California, has examined microbes for their use in antibiotics, antitumor agents, immosuppressive agents, hypocholesterolemic agents, and enzyme inhibitors, among other uses (Kate and Laird 1999). The firm's CEO in 1998, Terrance J. Brugg stated "Less than 1 percent of all the microorganisms in our world have been identified. Yet from that small percentage, scientists have developed a large number of important drugs and industrial products that have changed the world we live in" (Kate and Laird 1999). A large number of microbes can be extracted from a very small soil sample, making it very difficult to monitor the extraction of such samples. A tourist simply walking through a Costa Rican forest might leave with more soil on their boots than a researcher would need to find a sufficient number of microbes for lab screening.

Because the annual market of pharmaceuticals derived from genetic resources generates enormous profits, the ability to speed along the R&D process using traditional knowledge screening is a huge asset to pharmaceutical developers. However, the idea of increased R&D due to patent protection, as previously mentioned, has not been effective. It has been shown that research in the biotechnology industry has slowed following the implementation of strict patent

law because companies look not to what is widely needed, but to what areas of research are free of patents (Brown 2003).

Intellectual Property Legislation

The United States Supreme Court decision in *Diamond vs. Chakrabarty* in 1980 was the first to grant patent rights on genetic materials, specifically a genetically engineered bacteria strain. Following this trendsetting case, the DuPont corporation was granted a patent on it's genetically engineered 'onco mouse' in 1988 and the United States government granted a patent to itself on a cell line from New Guinea in 1995 (Shiva 2001). The French company, Genset, has patents on DNA from various tribes in remote regions (Shiva 2001) and it remains to be seen what the US-based Genographic Project will do with the 100,000 samples of indigenous DNA they are currently collecting around the world.

Article I, Section 8 of the United States Constitution says the US government has the right to, "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." As the United States begins to lag behind Japan in the development of new technology, they began to promote patent legislation as a manner of maintaining economic growth (Shiva 2001). In 1947, 10% of US exports were intellectual property related (Shiva 2001). As patent legislation progressed, this number increased to 37% in 1986 and then 75% in 1994 (Shiva 2001). Currently in the US, patents for non-obvious, useful, and unique plant materials as well as patents for plant variety protection are protected under patent law (Larson 2007).

The United States government has a huge monetary incentive to protect intellectual property law on patents as worldwide industry profits generate between $75 billion and $150 billion dollars each year (Downie 2008, Kate and Laird 1999). Corporate interests with influential lobbyist groups, specifically the pharmaceutical, chemical, and entertainment industries, have motivated the US to pursue patent protection of intellectual property rights on an international scale (Downes 2000). Twelve corporate executives formed the Intellectual Property Committee (IPC) just six months before the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiations (Sell 2003). Along with Europe and Japan, the IPC drafted a trade agreement based on their existing patent laws and presented it to the GATT Secretariat (Shiva 2001, Sell 2003).

The product of the Uruguay Round of GATT negotiations was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It was enacted in 1995 by the World Trade Organization (WTO) whose member countries had either one, five, or eleven years to implement the changes into their current national patent legislation or face international trade sanctions as punishment. Least-developed countries were given eleven years to implement changes, but implementation deadlines have now been extended until 2013 to ensure their laws and practices conform with the TRIPS regulations and until 2016 to comply with TRIPS legislation for pharmaceutical patents and undisclosed information.

The TRIPS agreement is broken up into seven sections and covers eight different types of intellectual property disputes. The second section of the international agreement describes the various types of intellectual property, one of which being patents, the focus of this paper. Noteworthy sections include Article 27.1, which permits the patent of products or processes given that they are new, involve an inventive step, and are capable of industrial application.

Many indigenous products and processes have evolved over centuries and involve innovative steps. However, if they do not involve industrial application, patent law cannot protect them. This creates a system that rewards solely monetary benefits with no regard to social benefits derived from an innovation. Additionally, many indigenous recognize the contributions of their ancestors, so they do not feel as though they would be entitled to patent their work as new and inventive (Burri-Nenova 2008).

Many have criticized patent legislation because it interferes with access to medicine, a right included in the United Nation's Universal Declaration of Human Rights. Patents can create unjustifiably high prices in all sectors, especially medicines (Bhat 1996), but are defended on the basis that pharmaceutical research and development is a costly and time consuming process that wouldn't be undertaken without patent protection on the finished product and therefore wouldn't provide any medicinal benefits at all.

Article 27.2 of the TRIPS agreement addresses this criticism and describes the excludability of patents based on morality - that they may interfere with human, animal or plant health or environmental degradation. This allows nations to grant compulsory licenses, which allow other firms to produce generic versions of patented drugs if they pay a royalty to the patent-holding firm, creating a loophole to the patent system based upon the human right of access to medicine. The Andean Community of Nations utilized the provisions of this article to pass a subregional law that protects their native plants from patent protection (Vieira 2004, Landon 2007).

Article 29 of the TRIPS agreement discusses the requirements for patent application. It includes a thorough description of the product or process for the patent, but neglects to include avenues of research used in development. Thus, if traditional knowledge was the basis of the

discovery or production method, the patent application officer will never be informed. This eliminates the requirement of *prior art* to the patent process. The opportunity for patent repeal is possible under Article 32 of TRIPS. However, a repeal process is extremely costly, eliminating this possibility for many indigenous and local communities in Latin America.

Although TRIPS allows for flexibilities to weaken or override some of the regulations under Articles 27 of the agreement, developed nations with strong IPR protection are using individualized agreements with developing nations to continue to force strict patent legislation across the globe (Mercurio 2006). In addition to the provisions by TRIPS, many developing nations are under pressure to adopt even more restrictive conditions for their patent laws. These provisions, known as TRIPS-Plus, can include

1. "Evergreening" or the extension of a patent longer than the twenty-year minimum
2. Limits to the use of compulsory licensing
3. "Second indications of a known product" provides that off-patent uses of a product are considered under patent protection due to their secondary functions
4. Data exclusivity protects the confidential status of patent applications during medical phase testing of a product
5. Recognition of all product and process patents including those not currently protected due to the delayed implementation of the regulations of TRIPS in least developed nations
6. Constraints to the review process of a granted patent, a mechanism provided under TRIPS for developing countries to have the ability to challenge patents
7. Restriction of parallel imports

TRIPS-Plus provisions are accepted by developing nations entering into bilateral agreements with developed nations like the US in exchange for trade concessions like free access to agricultural goods (Smith *et al.* 2009). Additionally, a developing nation might enact some TRIPS-Plus provisions in order to attract foreign investment or political support from developed

nations (Smith *et al.* 2009). Although the implementation of these additional measures is optional, the economic influence of the United States can sway developing nations to comply with their wishes regarding IPR legislation. Implementation of these TRIPS-Plus provisions has been a requirement of free trade agreements of the United States and will continue to be a policy pursued by the US in future endeavors.

Creating additional standards for IPR protection under TRIPS-Plus have clear negative effects on developing nations. Allowing restrictions for the creation of generic medicines and their trade through parallel imports severely restricts medicine access in developing nations. By restricting access to phase testing results through data exclusivity, pharmaceuticals can be sold without any knowledge concerning the negative results produced during the testing procedures made available to the public. Although this measure denies access to pharmaceutical competitors who may be interested in marketing a similar drug, the measure also denies access to medical patients who may be considering using the pharmaceutical without complete information as to the true side effects of the medicine.

Most relevant to the protection of indigenous knowledge is the TRIPS-Plus provision to constrain the patent revision process. Requesting the revision of a granted patent is a tedious and expensive legal process that many indigenous communities do not have the resources to pursue as presently stated under patent law. When patents are reviewed it is because the community, often with the aid of non-governmental organizations (NGOs), has decided to pursue the grievance despite their limited resources. Denying the due process for a community to dispute the claim over their biological resources and knowledge is in direct violation of Article 27(b) of the United Nation's Declaration of Human Rights which states, "Everyone has the right to the protection of the moral and material interest resulting from scientific, literary, or artistic

production of which he is the author." Although one could claim the violation occurred in the implementation of TRIPS legislature, the claim cannot be justified while a patent repeal process exists, allowing piracy to be corrected. The appeal process exists to correct mistakes so without it errors of the US Patent Office and other national patent offices would go unchanged, even in the case of violations to the freedoms of an indigenous group. This would be the case, if the indigenous communities of the Amazon did not have the option to appeal the patent for *ayahuasca* based on its violation of religious freedoms.

The Story of Ayahuasca

Ayahuasca is a hallucinogenic brew made from combining two native Amazonian plants – a root and a vine - and has been used for centuries by thousands of indigenous groups as an integral part of their religions. It is also known as yagé in Colombia and caapi in Brazil. The scope of ayahuasca use is tremendous. To many indigenous groups of the Amazon, the brew, consisting of the root and vine, is an embodiment of their beliefs, much as the Eucharist would be for a Christian.

An American collector by the name of Loren Miller claimed he was given the ayahuasca vine by a tribe in Ecuador in 1974. In return he built a school for the community (Pollack 1999). Although Mr. Miller believed he had participated in proper benefit sharing, he did not understand the full magnitude of his actions. He would never be able to provide proper compensation for the communities that use ayahuasca in religion. After cultivating the plant in Hawaii, Loren Miller had planned to explore its uses in psychotherapy and cancer treatment. The intended uses

of the plant by Mr. Miller were not disclosed to the indigenous communities that use the plant and therefore consent was never received.

Mr. Miller sent an application to the US Patent Office for the ayahuasca vine, *Banisteriopsis caapi*, on the basis of the novelty of his 'discovery' (Brown 2003, Downes 2000). The patent was granted. The ignorance of granting this patent based on novelty demonstrates the US Patent Office's lack of knowledge and lack of research into the origins of patent pending inventions. Additionally, the patent had almost no economic value, as the intended uses of the plant as a cancer treatment or psychotherapy aid had never been researched (Brown 2003).

CIEL (the Center for Environmental Law), COICA (the Coordinator of Indigenous Organizations of the Amazon Basin), the Coalition for Amazonian Peoples and their Environment, and several US-based organizations challenged Miller's patent through lawsuit (Brown 20003, Downes 2000). It was rescinded not on the lack of novelty, but on the basis of ayahuasca's religious value (Downes 2000). The fact that a patent was ever initially granted over the plant shows the failure of the US Patent Office to investigate the claims made on the patent application. There has been extremely wide use of the ayahuasca vine for centuries among Latin American native populations – demonstrating lack of novelty. Under the current definition for the patent protection of plants they must be non-obvious, useful, and unique or of a unique variety (Larson 2007). Ayahuasca fits neither description.

The patent of ayahuasca was overturned with the collaborative effort of more than four unique organizations. This clearly demonstrates the inability for small indigenous groups to overturn patents on their resources singlehandedly. They do not understand the legal systems of foreign nations and even if they did, small communities do not hold the necessary funds to pursue a legal case against a large-scale pharmaceutical corporation. If patent applications are

approved with little background research, they will most likely remain, as the affected communities will be hard pressed to file any sort of formal allegation. Additionally, if the nation of origin has agreed to TRIPS-Plus provisions, a patent of this sort, even one that violates religious freedoms, may never been rescinded. Because IPR legislation is organized around financial incentives, it may be necessary to propose economic solutions to change regulations instated by the adoption of TRIPS. This requires a basic understanding of the economic incentives provided in IPR protection.

Economics of Intellectual Property Rights

Knowledge itself is a public good. Once it is produced, it is impossible to exclude its consumption and therefore there exists no market incentive to generate more of it. Patent law provides guidelines of knowledge protection that generate market incentives. Patents encourage companies to spend time and money on research and development. If they invest in their work, they will be the sole owners of their product. This has led to marvelous developments in the sciences, but it has also turned the focus away from science to achieve a greater good in medicine to science that will be the most profitable. There are clear benefits for corporations to have sole rights over their product. The profits are tremendous and the monopolies created by patents allow firms to set the prices wherever they see fit.

Social benefits produced from the development of a new product are now converted into private profits as patent holding corporations control the distribution. These patent monopolies can lead to an increase in price, making the products inaccessible to the poor and decreasing the potential social benefits. There is no restriction as to how high the prices can rise, leading to

injustice across the world, unless nations allocate compulsory licenses, allowing competition in the market to drive the price down.

Trade liberalization opens markets and makes them more accessible, while patent law reverses this process (Downes 2000). Strong patent laws cannot be both strong in protection of corporations and in protection of individuals. Corporations have lobbying resources to change laws and because of this, patent legislation generally works in their interests. Their incentives include competitive edge and market control over prices, resource use, and distribution.

There may be some short-term economic loss with implementation of strict IPR legislation due to job loss from decreased production of patented products (Bhat 1996). However, in the long run, nations rich in biodiversity are predicted to see increased research activities and technological advancement contributing to the growth of gross domestic product (GDP) (Bhat 1996). By successfully negotiating terms of bioprospecting agreements – agreements concerning the commercialization of traditional knowledge and biodiversity – developing nations can ensure international investments and create a market for both the protection of and the access to biodiversity.

Foreign interest in the resources of developing nations could provide a long-term revenue stream. The financial, organizational, and technological capabilities of the pharmaceutical industry can be extended to developing nations in the search of useful biological compounds. This can create quick, positive impacts on GDP (Silva 1997). By promoting private property rights over community-based ventures, developing nations can attract international bioprospecting researchers, who will pay large sums for access to tropical biodiversity.

Eduardo Silva (1997) explains there are three main building blocks to sustainable development: a healthy economy, attention to social equity, and environmental quality.

Intellectual property legislation may provide opportunities for the economic advancement of developing nations. In an effort to commit to sustainable development, nations must incorporate measures to ensure social equity and environmental quality into access and benefit sharing negotiations.

Benefit Sharing and the Convention on Biological Diversity

"We're not against science, but we also don't want to just be suppliers of data. We want to be a part of the whole process, from research to the economic results."

– Marcos Terena of Brazil's Terena Tribe (Rohter 2001)

There is a romanticized vision of indigenous people throughout the world living in remote villages, using primitive technology, and speaking unknown languages. Although some tribes still encompass this vision, many indigenous groups have been a part of the modernization and globalization of the 21st century. Some read the newspaper daily, while others have legal teams. Bioprospecting does not simply involve a modernized research team exploiting a primitive tribe, but instead can consist of a collaborative effort between researchers and locals in the scientific process. As Marcos Terena states, indigenous communities want to be incorporated into ethnobotanic R&D and reap the benefits like education and revenue generation from the collaborative discoveries.

Indigenous hold a wealth of assets among their communities, though these resources may often be the intangible assets of their knowledge. Expensive and complicated procedures of patent applications, reaching costs of hundreds or thousands of dollars depending on certain conditions (United States Patent and Trademark Office 2011), are unreasonable means for

indigenous communities to protect their assets. The burdens of deferring to intellectual property law as a means of protecting tacit understandings far exceed any benefits that an indigenous society would produce from the protection of their knowledge. Instead, by collaborating with researchers and developers, indigenous communities can transform their intangible assets into tools for economic growth through revenue generation and infrastructure building, among other benefits.

The international community recognized this possibility for progress and worked to create a treaty for its promotion. Three years before TRIPS went into effect, the Convention on Biological Diversity (CBD) was signed in an effort not only to conserve biodiversity, but to "respect, preserve, and maintain knowledge, innovations, and practices of indigenous and local communities" (Article 8(j) of CBD). 158 parties have ratified the CBD of the 1992 Earth Summit in Rio de Janeiro, but the United States never has. The US asserted that CBD would conflict with patent legislation because the convention states members should "encourage the equitable sharing of the benefits arising from the utilization of [traditional] knowledge, innovation, and practices" (Article 8(j) of CBD). The Convention on Biological Diversity does discuss equitable benefit sharing in Article 8(j), but it doesn't discuss any concrete mechanism to guarantee the compensation of traditional knowledge. It has received criticism by the indigenous for this reason (Narby 1998).

Equitable benefit sharing can include both monetary and non-monetary packages. In 2002, the Secretariat of the Convention of Biological Diversity provided a concrete mechanism to guarantee compensation for access to biological materials and traditional knowledge. The Secretariat published the Bonn Guidelines on Access to Genetic Resources and Fair Equitable Sharing of the Benefits Arising out of their Utilization. This document specified not only the

monetary and non-monetary benefits that can be shared through mutually agreed upon compensatory packages, but also the specific guidelines to receiving prior informed consent and negotiations using mutually agreed terms.

In accordance with the CBD, some pharmaceutical companies have engaged in benefit-sharing activities. A key aspect of benefit sharing between pharmaceutical researchers and indigenous lies in the prior informed consent (PIC) of communities sharing their knowledge with the scientific community. Under PIC, sovereign nations, or communities with tenure over their local resources, must be informed using accurate information as a third parties use of their biological resources and the implications that will arise from such use. After receiving such information, nations and communities can consent to allow a third party access to their resources. The Bonn Guidelines specify that PIC must be legally transparent, facilitated at minimum cost, and include all stakeholders defined by domestic law. Elements of PIC defined uses, timelines, and specifications for access. Enforcing PIC, confirms that local communities understand the risks they are taking by conceding their rights over their intellectual property and entering into a bioprospecting agreement.

Mutually agreed terms (MAT) facilitate a clear set of guidelines as to what terms should be met within the agreement. Typical terms include legal acquisition, consent to use genetic resources, restrictions on samples acquired, transfer agreements, treatment of confidential information including indigenous knowledge, and benefit sharing agreements. The requirement to obtain PIC and MAT before accessing a sovereign nation's genetic materials is required under Article 15 of CBD and the Bonn Guidelines. To ensure compliance, national governments can implement their own *sui generis* legislation into national laws, allowing for the prosecution of those in violation of the terms of PIC and MAT.

The Bonn Guidelines also define mechanisms for benefit sharing. Traditionally, fees per sample extracted, milestone payments, profit sharing, and royalties (Kate and Laird 2000) have been included as monetary benefits, but with these compensations come complications. Opportunity costs not only for the pharmaceutical research group, but also for the local community need to be taken into account. Opportunity costs for indigenous are often non-monetary including the social, cultural, and spiritual costs, all three of which can be extremely difficult to measure.

Fees for sample extraction may be viewed as substantial compensation while drafting an agreement, but in actuality only small sample amounts are needed to extract chemical information so substantial fees are never accrued. Incorrect estimations of profits, inflated valuation of market value, or simply not finding a profitable compound can leave communities involved in bioprospecting agreements feeling as though they never received proper monetary compensation.

Incorrect estimations do not leave the pharmaceutical company at fault if the analysis was done properly at the time, as future markets can be highly uncertain. Additionally, if up-front payments like fees per sample extracted are used and then the compounds cannot be developed into a useful product, this simply adds to research and development costs of the corporation. As R&D costs increase, pharmaceutical companies are less likely to enter in benefit-sharing agreements in the future, eliminating a possible revenue stream for local communities.

Magnitudes of royalties are generally determined from a data set including current market prices, likely market share, contribution of partners to product development, proportion of final product based in the genetic resource, and provision of ethnobotanical knowledge (Kate and Laird 2000). It is worth noting that of these criteria, only one is based on empirical data, while

the others are predictions of future outcomes subject to large uncertainties.

Some non-monetary benefits can be shared between researchers and communities. Sharing of research results, participation in research, medical assistance, local infrastructure development, transfer of technologies, training, and capacity building are all examples of non-monetary benefits (Kate and Laird 2000). Brazil constructed the Amazon Biotechnology Center, complete with 22 laboratories (Rohter 2001), to foster foreign research, which would result in benefits for the nation, not only monetarily, but in education as well. As fiscal responsibilities to local communities create conflict, research organizations are gradually tending to favor a mixture of monetary and non-monetary benefits in bioprospecting agreements (Kate and Laird 2000).

Even if a pharmaceutical company has a community's best intentions in mind, the creation of a benefit-sharing agreement might still go astray. For example, many traditional methods of a given indigenous community will also be shared by other indigenous groups located nearby who share access to the same set of biological resources. For example, in the indigenous community of the Kraho Indians in Brazil, the Federal University of Sao Paulo sought a mutual benefit sharing agreement, but only informed 250 of the ethnic group's 2,000 people who reside in 17 different villages. Failing to receive prior informed consent from the community as a whole resulted in an $8 million dollar lawsuit for the biopiracy of medicinal plants and collection of knowledge on the plants' uses from Kraho shamans and elders by the university (Jones 2002). Ela Wiecko, the Brazilian prosecutor of the case, stated it was the government's role to "make sure that if any of the collected material [400 samples] is patented, that all of the Indians are going to profit from it" (Jones 2002).

If independent groups each claim ownership over the traditional medicinal techniques, then a conflict is created as to how much researchers need to compensate each group. This same

situation can also create an economic disadvantage for the region as a whole as the individual groups may each attempt to negotiate the most attractive deal for the bioprospectors. This will drive the amount of compensation down for each community as they each vie for the best price of R&D for the pharmaceutical company. Market failures at the local level due to the uncertainties of geographic origin can theoretically be solved by a national government.

In addition to direct benefits received through bioprospecting negotiations, indirect benefits will also be shared not only in the community, but also throughout the nation and world wide. These benefits are received on a national scale through the building of infrastructure supported by the pharmaceutical discovery programs such as technology transfer, shared research opportunities, and training (Miller 2007). Additionally, on a global scale, as benefit-sharing agreements place a value on the biodiversity of the planet, the resources will be conserved – leading to future benefits.

Access Rights to Biological Resources

In addition to benefit-sharing practices, the Convention on Biological Diversity also defines ownership of genetic resources. Article 3 of the Convention explicitly states a nation's sovereign right to the biological resources contained within its boundaries. As owners to the resources, nations have the right to restrict access to parties wishing to exploit the biodiversity contained within their jurisdictions. This defined autonomy provides legal justification for actions to be taken against those involved in biopiracy activities. Dr. Callejas of the University of Antioquia in Colombia asserts that fears of biopiracy are particularly intense in South

America. For scientific researchers it is "much, much easier to get permits for collecting in the Philippines or Vietnam" (Revkin 2002). This quote demonstrates that access laws exist not only in theory, but have been implemented into national legislation of Latin American countries.

National movements to restrict access and prevent biopiracy have been politically popular, uniting conservative nationalists, indigenous organizations, and antiglobalization groups (Revkin 2002). The political support encourages developing nations to enact restricted access measures into national law. The CBD provides an inexact mechanism in Article 15 through which nations can provide or restrict access. In practice, because uncertainties exist in international and national access laws, conflicts have developed between source nations and scientists. In Latin America, Brazil has set some of the most restrictive access laws that have slowed scientific progress and even imprisoned lead researchers.

To be granted access to biological resources under national legislation, research proposals must be extremely detailed. "You have to provide coordinates for all sites to be visited and have to have the approval from all the communities that live in those areas. I am still waiting after 14 months for a permit for collecting in Chocó," Dr. Callejas states in an interview with Andrew C. Revkin (2002) of the New York Times. Authorization from as many as five different government agencies may be necessary to obtain a research permit in Brazil (Rohter 2007). Andes Pharmaceuticals, a US based pharmaceutical company, faced frustration when they failed to specify which species they hoped to sample and what monetary benefits would be shared. This failure resulted in the denial of access to Colombia's rainforests (Pollack 1999).

Restricted access leading to difficulties in attaining patents, more than most other aspects of the IPR conflict over pharmaceuticals, has made headlines in the US media due to the controversial nature of many of the biopiracy claims. Newspapers and magazine articles from

the US tend to favor the idea that patent legislature is a necessary means to furthering medical research. Any national legislation to combat biopiracy is standing in the way of further development (Rohter 2007, Margolis 2005, Jones 2002, Revkin 2002, Rohter 2001, Pollack 1999). This perspective is not surprising because restricted access interrupts the R&D process and therefore disrupts the future revenue generation of pharmaceutical firms, creating resentment among those who would benefit from the profits in the US.

Efforts to restrict access may be hindered by those nations already involved in free trade agreements such as the North American Free Trade Agreement (NAFTA), which removes trade barriers, reduces or eliminates tariffs, and sets guidelines as to what quantities of goods can be taken from each nation. Under NAFTA, an agreement between Mexico, the United States, and Canada, raw materials to be used in the production of pharmaceuticals are not subject to protectionist tariffs that Mexico could use to restrict access of bioprospectors (Landon 2007). Although Mexico enacted the General Law of Ecological Equilibrium and Environmental Protection, requiring the authorization of national and local governance before pursuing bioprospecting activities (Global Exchange 2001), the US often ignores this national legislation based on the higher claimed authority of the international free trade agreement NAFTA. It is through such agreements that nations favoring strict IPR legislation are able to enact the restrictive provisions of TRIPS-Plus.

Access and Benefit Sharing Legislation: Protocols to CBD

The Convention on Biological Diversity encouraged the implementation of access and benefit sharing agreements. Observation shows that in response to the Convention there has been an increase in scientific cooperation and capacity building in nations with a wealth of biological resources (Miller 2007). However, because it provides no specific guidelines for access and benefit sharing (ABS) agreements or any mechanisms to enforce PIC or MAT there existed no firm legal ground developing nations could use to protect themselves from biopiracy.

Some Latin American nations responded to this inconsistency by creating national, *sui generis*, access laws. Costa Rica included indigenous knowledge within the breadth of its national legislature regarding its biodiversity (Larson 2007). Brazil enacted Provisional Measures No. 2.186-16, which restricted access to genetic materials and associated traditional knowledge (Kariyawasam and Guy 2007). The Andean Community of Nations, consisting of Bolivia, Colombia, Peru, Ecuador, and Venezuela, created the first sub-regional ABS measure under the protection of Article 15 of CBD. It's Decision 391 of 1996 established regional access legislation, removing the ability of bioprospectors to secure overly favorable conditions from nations vying for the most attractive, lowest price (Kariyawasam and Guy 2007). The decision also references the tacit understandings of traditional knowledge, but doesn't provide a specific mechanism for its protection.

Decision 391 of the Andean Community is derived from the protections allocated under the Cartagena Protocol on Biosafety, a protocol to the Convention on Biological Diversity. The Cartagena Protocol was adopted in 2000 and entered into force on September 11, 2003 to provide further protection of living modified organisms (LMOs). The effects of the

implementation of the Cartagena Protocol include increased national legislation to restrict access of third parties to a nation's biological resources, such as the regulations provided under Decision 391.

Because products derived from genetic resources are often necessary inputs to the development of new drugs, pharmaceutical industries must be willing to pay those who maintain natural ecosystems. Access and benefit sharing legislature must provide standard guidelines for state-to-state as well as state-to-community benefit sharing through the use of PIC and MAT. Case by case, non-generalized standards for MAT may be too complex and unfamiliar for pharmaceutical companies and foreign investors to pursue and will thereby encourage non-compliance.

As a response to criticisms of the CBD's lack of specific regulations regarding ABS, the 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 was adopted on October 29, 2010 and will come into effect ninety days after the ratification of 50 nations. The protocol was designed to implement the third objective of CBD – "the fair and equitable sharing of benefits arising from the utilization of genetic resources" – and effectively implement articles 8(j) and 15.

Citing signatories' commitment to uphold the ideals, objectives, and specific articles of the CBD, the Nagoya Protocol commits to use access and benefit sharing as a tool to conserve biodiversity and the use of genetic resources. Additionally, the benefits derived from the use traditional knowledge associated with genetic resources is specifically stated to be part of the scope of the protocol in Article 3.

The key consideration to be made in observation of the Nagoya Protocol is the requirements of researchers and developers to obtain PIC do not come directly from the Protocol but from the implementation of its requirements into national legislations. This remains consistent with the CBD's established notion of state's holding sovereign rights over their genetic resources and also allows for proper sanctions to be administered for noncompliance under the PIC guidelines.

The implementation into national law is extremely important to the access of traditional knowledge because the wording under Article 7 of the protocol leaves the issue of PIC for "access to traditional knowledge associated with genetic resources" up to interpretation. It calls for "prior informed consent *or* approval and involvement of these indigenous and local communities." As the regulations of PIC under the Bonn Guidelines are quite clear, the additional option regarding access to traditional knowledge leaves room for ambiguities and discrepancies over ABS. Under the protocol, PIC of the indigenous for access to their genetic resources is only needed in the case where a nation has granted sovereignty to an indigenous group, leaving a large number of excluded communities. They will not be able to control who comes into their communities to take what – that will be up to a national office to decide.

What the Nagoya Protocol clarifies are the steps needed to ensure PIC and MAT once implemented into national law. Article 6 – Access to Genetic Resources – states the need for source nations to provide transparency and predictability of the access permit application process, the due process for applicants without discrimination, a cost-effective permit allocation process, and clear rules and procedures for determining MAT.

Additionally, the Protocol provides the infrastructure for developing nations to clearly state their national ABS legislation and for developed nations to comply through the ABS

Clearing House Mechanism (CHM) as administered by the CBD Secretariat (Buck and Hamilton 2011). As nations began to develop individualized access legislation such as the regulations in Costa Rica, Brazil, and the Andean Community of Nations, the obvious impediment to R&D was the complicated process of determining each individualized set of regulations for ABS. By creating the Clearing House Mechanism, the Nagoya Protocol has ensured greater compliance through a more streamlined process.

Although there is common consensus the Protocol cannot retroactively force nations to comply with its regulations, there was no agreement as to whether future buyers of samples extracted from source nations will be responsible for benefit sharing, even though they will be involved in a third party transaction. For instance, if biological researchers from Company X extract samples from a source nation and sell to Company Y, not only would Company X need to apply for proper permits and negotiate ABS agreements, but would Company Y need to as well?

Overall, the Nagoya Protocol strengthens a nation's sovereign claim over its biological resources. While giving power to developing countries, this may remove control from indigenous communities. Payment for conservation services will be collected by national governing bodies and in an effort to ensure revenue generation. Centralized governments may be less inclined to allocate secure property rights to indigenous groups based on the fear they will not want to collaborate with researchers and generate revenues for the nation. Similar trends of recentralized property rights are being observed in other proposed payment for ecological service agreements such as an international proposal for tropical forest protection (Phelps, Webb, and Agrawal 2010).

It remains to be seen if the Nagoya Protocol will have any effect on bioprospecting agreements. After a surge in interest in ethnobotanical research in the 1990s, complicated and

restrictive access laws discouraged pharmaceutical companies to pursue bioprospecting agreements. If the CHM of the Nagoya Protocol is effective, allowing for more streamlined R&D, there is expected to be renewed interest in the field of ethnobotany as a tool for pharmaceutical development. It took three years from the time of adoption to the time of implementation of the Cartagena Protocol of the CBD, so a similar time lapse may be expected in the ratification process of the Nagoya Protocol. As of December 1, 2011, no nation has ratified the agreement.

Sanctions

TRIPS and CBD have been implemented as international standards for the protection of IPR and biodiversity, but what will ensure compliance with their regulations? On an international scale there is no sovereign governing body to impose sanctions on any nation in violation of a cross-state treaty. When two treaties contain mismatched regulations, there is no authority to prioritize one agreement over another. Countries are left to police themselves and violations often go unpunished. In many cases, agreed upon economic sanctions are the penalties for noncompliance. Economic heavyweights like the European Union and the United States, among others, can use their influence to force noncompliant nations into abiding by the regulation of a treaty. For instance, after lobbying for many of the provisions contained within TRIPS, the United States wanted to ensure the compliance of other nations. However, when it comes to CBD, developing nations are the driving force and do not have the political or economic powers of developed nations to force compliance.

The mechanism for US-based trade sanctions comes from the special 301 section of the US Trade Act that labels nations as non-compliant with IPR standards. Currently eleven Latin American nations are under review. Argentina, Chile, and Venezuela are listed on the Priority Watch List, while Bolivia, Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, and Peru are listed on the Watch List. Listed with each country is a description of their weaknesses in national patent legislature or enforcement. In addition, the US recommends to many of these nations not only that they remedy existing problems under TRIPS, but also enact TRIPS-Plus provisions in an effort to provide increased protection. The United States encourages Argentina, Brazil, Chile, Ecuador, and Mexico to provide for "protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test and other data generated to obtain marketing approvals for pharmaceutical products" (USTR 2011).

Some national sanctions of compliance with ABS legislation have included fines, seizure of illegal material and products, prohibition of distribution, prohibition from the collection of future samples and invalidation of patents (Larson 2007, Kariyawasam and Guy 2007). Additionally, companies that violate access laws and create patents based on the resources found can be forced to lose the profits gained from any procurement of a legal patent based on stolen goods (Larson 2007). Because of the huge amount of capital pharmaceutical companies manage and spend each day, flat rate fines may not be a substantial punishment. Instead, creating more severe sanctions encourages compliance with the law from the very first steps in the R&D process.

National Implementation of Intellectual Property Law in the Andean Community

The Andean Community of Nations has enacted national and regional initiatives into its legislation to protect its own natural resources. Laws on the books don't always signify compliance, especially in a region of the globe with as much political turmoil as Latin America has experienced. However, legal interest demonstrates the Andean Community's commitment to uphold the protections they enacted. 1338 preliminary references were sent to the judges of the Andean Tribunal of Justice in 2007. Of these, 1303 concern violations of intellectual property rights (Helfer and Alter 2011). This prosecution of violators not only demonstrates the legal standing of IPR in the Andean Community, but the citizens interest in prosecuting those that violate their terms.

Legislation enacted by the Andean Community encouraged its member nations to enact further legislation into their own national laws. Of the five nations, Peru took the greatest initiative to create *sui generis* regulations. Transparency and education were lofty goals for the Peruvian program, the National Institute for Defense of Competition and Protection of Intellectual Property, as they enacted consumer protection laws and educated their citizens of possible unlawful market practices (Helfer and Alter 2011).

However, just as the Andean Community was beginning to stand strong to the patent protection of pharmaceutical corporations provided by TRIPS, the US began to interfere. In the early 1990s, there was conflict over "pipeline patents" – medicines patented in foreign nations before 1992, during which time it was impossible to apply for patent protection in Andean Community nations (Helfer and Alter 2011). The sub-regional organization of states argued by recognizing those patents they were disrupting the rights of their citizens to access to medicines.

Although there was some conflict with Ecuador allowing the pipeline patenting of 23 pharmaceuticals to such companies such as Pfizer and Novartis, these were overturned by the Andean Community in 1996, and no additional pipeline patents were granted. The Andean Community strongly supported their stance.

The support of this subregional body has provided resources and legal standing for indigenous communities to dispute patents. One such dispute occurred over a Peruvian plant known as *maca*. Maca is a small root vegetable hailed for its properties that can combat fatigue, infertility, symptoms of menopause, and sexual dysfunction and has been used by indigenous living in the Andes for thousands of years. Scientists hope after building upon their preliminary studies, the maca root will provide an answer to some types of cancer. One pharmaceutical company, PureWorld, Inc., has four worldwide patents on the maca plant on varieties of the root vegetable, an extraction process, and the extract itself of the very same chemical compounds the indigenous peoples of Peru use (Larson 2007). Peruvian law states patents cannot be held on parts of plants due to the lack of novelty and although reference to indigenous Peruvian knowledge of the uses of the plant were cited in the patent application, intellectual property right protection was still granted to PureWorld, Inc. (Larson 2007). The recognition of the indigenous community's right to their intellectual property regarding maca is helping the group stand up to international pressures and request the patent be overturned.

The Andean Community's stance on bioprospecting and ABS agreements is strong, but has not deterred prospectors. Kina Biotech is a research institute of Spain that sought to use bioprospecting to search for useful compounds they would then sell to third party clients. In accordance with the goals outlined by CBD, Kina Biotech created an access and benefit sharing agreement amongst themselves, the Peruvian government and the Aguaruna tribe. The program

included collaboration between Kina Biotech, national, and indigenous researchers from the Aguaruna tribe and established monetary benefit sharing through milestone payments and royalties from future revenue generation as well as nonmonetary benefits of training in the collaborative process (Lizarzaburu 2004). The corporation recognizes both the ownership over genetic resources through benefit sharing mechanisms as well as the intellectual property of indigenous communities as any third party to buy samples from the lab must enter into a knowledge license agreement directly with the indigenous community, in this case, the Aguaruna peoples of Peru. This process of obtaining PIC and MAT was streamlined due to the regulations of Decision 391, which required specific stipulations to be met in order to proceed. Clear transparent rules made the process simple and easy to follow.

Access Legislation in Brazil

Many Latin American nations look to their sovereignty over their resources as an instrument to generate revenues and increase their economic wealth. Under the Convention on Biological Diversity and the newly adopted Nagoya Protocol, nations have the right to restrict access of their genetic resources to outside research parties, whether the research has commercial or simply academic intentions. In Brazil, the National Council for Scientific and Technological Development oversees scientific research in the country and fights to protect its natural resources. In 2000, the nation halted all exports of biological samples and instigated a new administrative body, the National Council of Genetic Resources, to determine controlled access to samples (Revkin 2002). The moratorium was supported by indigenous shamans who met in

early December 2001, calling for the ban of shipments until an equitable system of benefit sharing was developed.

History shows countless reasons for Brazil's insecurities regarding biopiracy. As early as the 19th century, Sir Henry Wickham extracted rubber trees, and sent them to be planted in Malaysia, and farmed for commercial exploitation under the British crown. In the 1970s, Brazilian viper venom was used in the pharmaceutical drug Capoten, known generically as captopril, to counter hypertension and congestive heart failure without any sharing of benefits from its producer, Bristol-Myers Squib pharmaceutical corporation, back to the Brazilian people (Rohter 2007).

Brazil has been criticized as being overzealous in terms of their rights of access and penalties for infringement. An American scientist, Dr. Joseph M. McCann, was placed under house arrest while the police investigated his samples although he had attained the proper permits (Revkin 2002). Dr. Marc van Roosmalen, a world-renowned primatologist and naturalized Brazilian citizen, was sentenced to 16 years in a notoriously harsh Brazilian prison on charges of biopiracy (Rohter 2007). Brazil claims it is simply trying to protect its resources and has the authority to incarcerate for the violation of their national laws, but the scientific community is outraged at such harsh measures. Signatures of 287 scientists were collected at an international biology conference shortly after the ruling to protest the "trend of government repression of scientists in Brazil" (Rohter 2007).

"Research needs to be stimulated, not criminalized," states Enio Candotti, the president of the Brazilian Society for the Progress of Science (Rohter 2007). The draw of the biodiversity of the Amazon attracts biologists and other scientists from all parts of the world leading to the spread of many benefits discussed under the Bonn Guidelines. The harsh sanctions are not only

slowing scientific research from international sources, but Brazil's own scientific bodies as well. A professor from the State University of Santa Cruz in Bahia, Brazil had hoped to use equipment in New York to complete his doctoral research, but due to the exportation ban was unable to do so (Revkin 2002). The head of the herbarium at the National Museum in Rio de Janeiro, Ruy Valka Avles, states that in the face of such strict legislation, "either you give up your research or work clandestinely" (Margolis 2005).

In the case of the Kraho Indians of Brazil, although the Federal University of Sao Paulo sought to create mutually agreed terms with the indigenous group, their agreement wasn't sufficient. The lead university researcher, Eliana Rodrigues, claimed to have spent months developing an ABS agreement between the university and the perceived leaders of the Kraho to share any profit with the indigenous group. Instead of praise for the agreement that was forged in 1999, before any regulations of the Nagoya protocol, the university was asked for $8 million dollars in damages by the Brazilian government on behalf of the Kraho Indians. Rodrigues states, "We tried to do things the right way and instead of helping us it only brought us a lot of problems" (Jones 2002).

One native Brazilian scientist in Sao Paulo was researching the larva of a species of Amazon butterfly that release a toxic goo causing numbness and paralysis. It was of particular pharmaceutical interest because the researcher believed the toxin might contribute to arthritis. Long after the larva had finished their metamorphosis and were no longer of use to the researcher, the delayed authorization from the Brazilian government finally arrived (Rohter 2007). As threats of extinction loom over a number of diverse species, this delay may signify the inability of researchers to catalogue and record data before it's too late. As research proposals

can take years to be approved (Revkin 2002, Rohter 2007), many scientists may be running out of time.

Other environmentalists claim Brazil has every right to demonstrate severe sanctions in the violation of access laws. To pharmaceutical companies and other corporations most fines are insignificant in cost and the only substantial punishment may be significant jail time as a deterrent to illegal access and biopiracy. Scientists complain the laws against biopiracy are too vague and too harsh, leaving biopiracy sanctions in the hands of those that do not understand the research process and are paranoid in their assumptions that every researcher is trying to steal their genetic resources.

These restrictions not only impede scientists but also the transfer of benefits from future ABS agreements. If researchers can't gain any sort of access to genetic resources and traditional knowledge even with PIC and MAT, benefits cannot be shared from developed to developing source nations. In fact, scientific research permits have become so strict that "as a result, biologists say, in many tropical regions it is easier to cut a forest than to study it" (Revkin 2002).

IPR and Public Health

Because patent law restricts access to the innovations of pharmaceutical companies, there are often many people denied new medicines because of domestic price and availability. To address this issue, the WTO adopted the Doha Declaration, which addresses the implementation of TRIPS in a way that supports benefit sharing of necessary medicines. The emphasis of the

Doha Declaration is that the provisions defined by TRIPS should not interfere with a nation's actions regarding the public health of their citizens.

Patent legislation has caused restricted access to medicine in developing nations with limited financial means. For instance, in Argentina, with the acceptance of patent legislation, pharmaceuticals increased in price by 273% while consumption decreased by 45% (Elisabetsky and Costa-Campos 1996). The nation had to spend an additional US $209 million each year in order to provide the medicines while their tax revenue from pharmaceuticals decreased by US $2.4 billion each year (Elisabetsky and Costa-Campos 1996). Similar price hikes due to patent legislation have also been seen in other Latin American nations (Chaves and Oliveira 2007).

The most effective way to drive down patent protected prices of monopolistic pharmaceutical firms is to introduce competitors to the market. In the US, if just one generic form of a patented drug is produced, the price of the pharmaceutical drug will drop by 60% (Creese and Quick 2001). If ten competitors have entered the market, the price will drop to 29% of its original price under patent (Creese and Quick 2001). A group of developing nations including the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela prepared a document detailing possible amendments to TRIPS to allow for the provision of health care, which were addressed in the implementation of the Doha Declaration. Meanwhile, pharmaceutically strong nations, including the US and Switzerland, argued against allegations that patents were an obstacle blocking access to medicines (Abbott 2002).

The final text of the Doha Declaration both recognizes the necessity of patent protection for continued developments in the field of medicine while, at the same time, recognizes the effect patent protect creates on prices. Paragraph 5(b) of the Declaration states that "Each

Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." Additionally, nations are allocated the right to suspend patent protection in the time of a national emergency or epidemic.

A compulsory license is an economic tool that gives the right for other pharmaceutical firms to create generic versions of patented medicine. This type of license requires the payment of a royalty fee to the patent holding company, but the overall effect is the price of medicines decreased with increased competition in the market. The licenses may be authorized because high prices are not in the public interest. Increasing competition in the market will allow consumers a choice, eliminating the monopolistic effects of patent legislation.

Seventy five percent of all pharmaceutical sales are of drugs produced by North America, Europe, and Japan. These companies wield tremendous resources as the annual market for all pharmaceuticals was $650 billion in 2006 and with a growth rate of 7%, is predicted to reach $900 billion in 2011 (Smith *et al.* 2009). These corporations will not transfer patented materials without a legal battle, even after the publication of the Doha Declaration.

If developing nations don't have the authority to require developed nations like the United States to acknowledge contributions of traditional knowledge to pharmaceutical production, they could grant a compulsory license to any pharmaceutical known to originate in traditionally derived knowledge. Compulsory licenses are not limited to just one nation so any nation with a claim to the traditional knowledge can grant this type of license to avoid the payment of outrageously high prices.

Compulsory licensing will slowly transition research objectives away from what is most profitable to what is most socially beneficial, by making the two objectives one in the same. Currently, if a pharmaceutical corporation develops a new compound, patents it, and puts it on

the shelves, they can set their own profit margins and generate substantial revenue, regardless of how many people their pharmaceutical will aid. As compulsory licensing removes this monopolistic price setting effect, corporations will generate revenues based on the amount of their product sold, not just the price at which it is sold. By encouraging corporations to pursue research in areas where they will be able to sell a large quantity of their products, pharmaceutical companies will begin explore chemical compounds that will cure the ailments that effect the greatest number of people in society. As these socially beneficial products are developed and sold at competitive pricing, more and more people will be aided by the developments of pharmaceutical corporations.

Further conflict involving compulsory licensing enters international debates when the question of whether patented products under a compulsory license can be sold and imported into another foreign country. Article 31(f) of TRIPS states compulsory licenses are only valid for predominantly domestic production, however this statement becomes invalid if the country of import doesn't recognize the patent or if it holds its own compulsory license for the medicine's importation. By allowing these loopholes, the WTO made it possible for nations with insufficient manufacturing capabilities to still receive off-patent drugs through the use of compulsory licensing. However, because the article states 'predominantly' domestic production this restricts the flow of compulsory licensed drugs and disallows the exploitation of economies of scale, in which it is easier to produce one good in bulk in one location rather than have a separate facility in each nation producing the same good. This was addressed when the first ever amendment to TRIPS – the Protocol for the Amendment of the TRIPS Agreement 2005 – was authorized (World Trade Organization 2005). This amendment allowed those nations without adequate manufacturing capacities to import generic medicines from those that do. In Latin

America, only Brazil has substantial capacity to produce generic pharmaceuticals (Smith *et al.* 2009).

The greatest flaw with the use of compulsory licensing is many developing nations rely on the support of other nations through foreign direct investment. It is the fear of the elimination of this revenue stream and the economic sanctions that their nations may face if they grant compulsory licenses that in many cases keeps them from doing so (Abbott 2002). This effect has been demonstrated in trade agreements, where a developing nation will agree to restrict compulsory licensing as a TRIP-Plus provision, in order to enter into a free trade agreement with the US. It is therefore easier in many cases for developing nations to reach agreements with patent holding corporations instead of challenging their legal standing through the licensing process (Abbott 2002).

Compulsory licensing is one method of ensuring the equitable sharing of pharmaceutical innovations with the world, but as these are restricted by free trade and other bilateral agreements, further steps have to be taken to ensure equitable benefit sharing. To utilize traditional knowledge in R&D only to restrict the indigenous groups' access to the medicines produced seems immoral to some, but pharmaceutical companies operate under the morality of the legal system – any decision supported by its legality is permitted. Therefore proper mechanisms of benefit sharing must be incorporated into national legislation and the international intellectual property regime.

Solutions

Registries of Traditional Knowledge

Restricted access and undefined benefit sharing mechanisms create uncertainty at an international scale that will need resolution. One proposed solution is to have national registries of traditional knowledge. A database system would allow for a simple assessment of a novelty claim as well as provide legal standing for traditional knowledge, as it would be presented in a written form rather than oral preservation (de Carvalho 2007). The World Intellectual Property Organization (WIPO) recognizes the legal standing of an indigenous knowledge database as evidence of prior art (WIPO 2011). Therefore international patent offices could be required to screen incoming patent applications through the database before approval in order to ensure the novelty of the new innovation and have its patent recognized under international IPR legislation.

If patent applicants were required to disclose the geographic origin of any biological resources used in the pending application, monitoring the use of traditional knowledge could be more easily identified based on region. Because traditional knowledge is based on the biodiversity of the region, it could easily be recognized through the application of geographic indicators. Geographic indicators provide legal IPR protection over a good that is only authentic if developed in a given regions such as wine grown in a specific region or art produced by a specific indigenous tribe. Geographic indicators, a tool already recognized internationally by TRIPS could easily be applied in the case of the use of biological resources of traditional knowledge and provide further protection of their rights.

The function of the database would only prohibit others from placing patent protection over previously developed innovations; it would not provide patent protection to traditional

knowledge. If a pending patent were to be denied due to the existence of the same innovation in a traditional knowledge database, this would not require a corporation to cease production of the patent pending good. Because the traditional knowledge is not itself patented, its use cannot be controlled in the open market. Therefore, it is extremely important that access to search an indigenous database be extremely limited in order to protect it from theft and common use.

An ethnobotanical database has the potential to further streamline pharmaceutical R&D. An indigenous community would only codify their knowledge into a database if they receive some sort of benefit from the access of their knowledge. In this way, pharmaceutical companies would pay to access specific entries of a database, with those funds reaching the indigenous community as a monetary benefit, whether any marketable products come from the pharmaceutical research or not. If an innovation were developed based on the traditional knowledge a pharmaceutical company would have to enter into an ABS agreement with the holders of the rights to the knowledge before applying for any patent. If a company failed to do so an indigenous community could repeal the approved patent due to its lack of novelty using far less resources than they would have had to before their knowledge was codified and easily accessible in patent law. Additionally, if the knowledge used was native to many different tribes, ABS agreements would be more effectively forged, as all indigenous groups would be tied to the specific database entry and therefore easily identifiable.

How would the case proceed if a patent application was based in traditional knowledge, but the party applying for the patent had no such knowledge? Independently acquired inventions would be subject to some sort of modified patent, one that would ensure that the indigenous community would be undisturbed in the commercialization process, but wouldn't provide benefits to the community, as there would be no compensation required. For instance, if a

chemical compound in an Amazonian plant were to be discovered as pharmaceutically viable independent of the use of indigenous knowledge, there would be increased demand for samples to be extracted from the plants. Increased demand for the plant would have resonating effects to those communities that use the medicinal plants and increased harvest may impede on their rights to access.

Databases of this sort have been put into practice in certain locations. Peruvian Law No 27,811 established in 2002 encourages the protection of traditional knowledge through national registries of three classification levels – one that includes knowledge in the public domain, another that is reserved for confidential knowledge, and a third that registers information in accordance with indigenous peoples' practices and customs (Kariyawasam and Guy 2007). In order to use any of the information protected under this law, bioprospectors must obtain a license agreement with the Peruvian government to establish proper payment methods for the adequate distribution of benefits (Kariyawasam and Guy 2007).

This solution addresses, multiple holders of traditional knowledge as well as clear and transparent mechanisms for ABS of pharmaceutical companies. Its use is already recognized by international IPR organizations allowing for easy implementation. The difficulty of implementing such a database lies in the manner in which traditional knowledge is understood. Indigenous medicinal techniques are not only based in the techniques pharmaceutical companies view as useful, but also in their connection to interpersonal relations and local values that shamans view as inextricably linked to therapeutic success or failure (Brown 2003). This makes indigenous knowledge hard to codify into a database. Additionally, many indigenous groups simply will not share their information with outsiders so the introduction of their communal knowledge into a database will never occur.

Indigenous Autonomy over Genetic Resources

Secure property rights for indigenous communities can be allocated by the national government. Decentralization efforts will remove control over local biological resources from the national government and grant it to local organizations. Because the benefit sharing mechanisms of the Nagoya Protocol reference domestic law as the indicator of the beneficiaries, secure tenure of indigenous groups will help to ensure proper benefit sharing. If PIC is required from the indigenous community itself for any bioprospecting agreement to receive approval, giving property rights to the indigenous provides legal means for local communities to restrict access.

Globally, 8.3% of forest area is under the control of communal governing bodies and indigenous associations (Agrawal 2011). Because each area is unique, it is logical to include local leaders in the ABS negotiating processes with the legal assistance of an ombudsman provided by national government. In this way, local practices and customs can be observed and benefits will be received on a regional scale. This will enable indigenous communities to allocate their resources in their own terms.

Autonomy over resources not only creates a system of proper benefit sharing, but also creates a greater incentive of preservation of local lands. Indigenous with secure tenure rights were able to drive out industrial timber interests from their forests in Costa Rica (Silva 1997) and the Yanomami and Ye'kuana communities were able to do the same in Venezuela (Colchester 2000), demonstrating the power these communities have to protect their lands. Encouraging the decentralization of authority of genetic resources and tracts of diverse lands, will entrust conservation efforts to those who might care the most. This creates a system of development

based on the understanding of local knowledge and practices, which will lead to proper benefit sharing and greater conservation efforts.

Collaborative Efforts

Indigenous autonomy may be an effective means of protecting local regions, but the involvement of the national government is important for the maintenance of regulatory power over biological resources. Because CBD recognizes a nation's sovereignty over biological resources, they have been given an internationally recognized power to regulate access. If this power is totally decentralized to local communities, regional authorities may not have the power to restrict access of resourceful corporations.

Promoting collaborative efforts to ensure biological protection may be the most effective way to manage ABS regulations, but these will come with their own set of complications. Latin America is historically a region of unstable governments and of militaristic *coup d'états*, the most recent of which occurred in 2009 in Honduras. With changing governance, amendments to national constitutions, and a highly variable legislative body, many local communities distrust their national governments. Therefore, if benefits being paid to national government are expected to reach local communities, local groups will approach ABS agreements with suspicion. This amount of distrust will create roadblocks for successful research endeavors.

Costa Rica developed a streamlined system for access and benefit sharing that has clear rules and benefit sharing mechanisms in place. According to their national Biodiversity Law, prior informed consent must be given to all involved, including indigenous communities, before the start of any bioprospecting activities (Larson 2007). Additionally, monetary benefits must be shared through the agreement in the allocation of 10% of the research budget and up to 50% of

the bonuses made to either the owners of the bioprospected land or, in the case the land is publicly owned, to the National System of Conservation Areas of Costa Rica (Larson 2007).

What is omitted from international and national legal agreements is the influence of civil society. In order to mediate efforts between national and local authorities, non-governmental actors can act as ombudsmen, ensuring both the education of local communities as well as the proper benefit sharing of the local groups with the national government. Government officials should collaborate with grassroots organizations and non-governmental organizations (NGOs). Organizations, artists, unions, and other groups can wield a great deal of power and resources for the aid of indigenous groups (Brown 2003, Silva 1997). ABS negotiations can be extremely technical and confusing for local organizations so NGOs can provide education and could be contracted to administer efforts for the PIC of local communities. If inequitable benefit sharing or improper PIC occurs under the watch of a NGO, it will be subject to external scrutiny by the internationally community, not simply the two parties involved in the agreement. This provides transparency under which ABS agreements will proceed and will leave not only the NGO, but the national government accountable for violations.

Generating Stringent International Standards for Patent Laws

The standards provided by TRIPS only insure that nations will impose minimum patent regulations according to a standard set by the agreement, but it does not spell out what the legislation will actually entail. Although under Article 27, the requirements are defined, national patent laws are still subject to the approval of their independent governments. For instance, in the United States, the novelty requirement as indicated by TRIPS is bypassed through the claim

that only domestic use disqualifies the approval of the application on the basis that it is not new and inventive (Shiva 2001).

Just as the Nagoya Protocol clearly defines mechanisms for national implementation of ABS legislation, a TRIPS amendment is needed to further define the international standards for patent laws as agreed upon by all nations. Current laws favor the US, European Union, and Japan – the driving forces behind the treaty. A review process would include the view of all nations, developed and developing, to ensure patent laws correctly acknowledge *prior art* and could include a mechanism for the acknowledgement of traditional knowledge in the patent application process.

In 2006, Brazil and Peru were among eight developing countries that proposed a further amendment to TRIPS to further protect genetic resources and traditional knowledge. The proposal wishes to include in TRIPS the requirement for patent applications to disclose the geographic origin of innovation derived from genetic resources or traditional knowledge (Intellectual Property Watch 2006). By implementing further regulations, such as this proposal, TRIPS can create a protective system for both patent holders and the holders of traditional knowledge and biological resources.

Additional research

Continued research of indigenous knowledge and how traditional knowledge systems connect with those of modernized science and medicine will be of use not only for scientific advancement, but for benefit sharing as well. With the implementation of the Nagoya Protocol, the ABS negotiation process should become more transparent and streamlined with the help of the Clearing House Mechanism. If this creates an intensified interest in bioprospecting and

marketable compounds are discovered, there should be a renewed interest in ethnobotanical knowledge as a method of pharmaceutical R&D. With increased bioprospecting efforts comes a larger wealth of resources to be shared amongst communities and developing nations, leading to a greater sharing of the world's benefits in money, education, and infrastructure development. Further research may also result in discoveries for some of the most efficacious vaccines known to society if methods of combating diseases like HIV/AIDS or cancer are found amongst the diverse species of the world.

Conclusion

While TRIPS and CBD continue to promote divergent agendas, one to privatize benefits and the other to share them, conflicts will continue to arise. Proponents for the protection of traditional knowledge need to work within the current system to provide legal protection of the work of the indigenous or it will continue to be used without proper repercussion. As access agreements restrict the free use of genetic resources, the trend of biopiracy of the late 20th and early 21st century should begin to decline. Benefit-sharing agreements will provide a stronger footing for developing nations in trade negotiations and economic development. These agreements will provide incentives to protect indigenous knowledge and biodiversity and allow for the compensation of its use. Ultimately, effective and enforced national legislation must be applied in conjunction with the international IPR regime must to provide standard guidelines for access and benefit sharing to diminish conflict and promote the conservation of biodiversity and traditional knowledge.

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