BIOPIRACY AND INTERNATIONAL LAW: HOW INTERNATIONAL INTELLECTUAL PROPERTY REGULATION ENCOURAGES THEFT

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INTRODUCTION

Since the beginning of civilization, explorers have sought out the novel and exciting, appropriating such discovery for their own ends. During Charles Darwin's five years aboard the Beagle, he collected and sent back to England millions of fossils and specimens. He collected lizards from Argentina, finches from Ecuador, and parrot fish from the Pacific ocean, among many other specimens. Darwin was not the first explorer to venture out in search of new discoveries, and he will not be

the last. Today, however, it is not just scientists and researchers who are in search of biological specimens, but multinational corporations in the business of developing pharmaceuticals and chemical products. And it is not just fossils and new species that they are interested in. Rather, they are interested in the genetic material found in plants and animals, material that can be used to develop commercial products. They are interested in the knowledge of traditional communities, knowledge as to the practical uses of such indigenous materials. And, sometimes, they are interested in the indigenous people themselves, people whose blood and genes may be useful in studying some disease or cure.[1]

Bioprospecting is a term for exactly that kind of practice. It is exactly what its name implies; simply, it is the search for biological resources that might prove profitable in some capacity. Biopiracy is a similar term with a more negative connotation that is, in truth, closer to the practices our friend Darwin was participating in. Biopiracy is, to put it broadly and simply, the harvesting of biological resources

[1] *See* Christopher Hunter, *Sustainable Bioprospecting: Using Private Contracts and International Legal Principles and Policies to Conserve Raw Medicinal Materials*, 25 B.C. Envtl. Aff. L. Rev. 129, 139 (1997) (describing an attempt in 1989 by U.S. scientists to patent the blood of the Hagahai tribe of Papua New Guinea).

without the consent of those who own them.[2]

This paper examines how biopiracy is aided by current international patent regulation. Part I discusses the issues created by biopiracy. Part II discusses international patent regulation and how it affects the practice of biopiracy. Part III provides a map of solutions that have been undertaken or suggested with regards to mitigating biopiracy. And finally, the conclusion recommends a possible approach in dealing with biopiracy.

I. The Effects of and Problems with Biopiracy

Bioprospecting can be an extremely profitable business; multinationals have made millions of dollars in products developed from genetic resources.[3] The practice typically involves one of two scenarios, with interrelating issues, the main one of which is that of fair compensation.

A. Biopiracy and Fair Compensation

[2] No concrete legal definition of biopiracy exists, although legal scholars are often eager to devise their own. One legal article, quoting an entry on the web site www.answers.com, defines biopiracy as "the commercial development of naturally occurring biological materials, such as plant substances or genetic cell lines, by a technologically advanced country or organization without fair compensation to the peoples or nations in whose territory the materials were originally discovered." Kari Moyer-Henry, *Patenting Neem and Hoodia: Conflicting Decisions Issued by the Opposition Board of the European Patent Office*, 27 Biotechnology L. Rep. 1, 1 (2008).

[3] Lakshmi Sarma, *Biopiracy: Twentieth Century Imperialism in the Form of Intellectual Agreements*, 13 Temp. Int'l & Comp. L.J. 107, 112 (1999).

As mentioned already, bioprospecting generally falls into one of two scenarios. In the first scenario, a product is derived solely from the genetic resources of a country. For instance, Amylin Parhamceuticals developed a drug to treat diabetes from the venom of a Gila lizard, while the National Cancer Institute developed a chemotherapy from the the bark of the Pacific yew tree.[4] The problem with this practice is that multinationals usually appropriate such resources without compensation to the host country those resources are from. In the 1960s, Eli Lilly earned several million dollars on cancer-fighting alkaloids that it developed from the rosy periwinkle, without providing any compensation to the periwinkle's native

[4] Hunter *supra* note 1, at 132. Another interesting issue, which is outside the scope of this article, is that of marine genetic resources. Access to marine resources, due to the huge expense of collecting them, have so far belonged mainly to developed countries. The issue here is not so much about that taking of indigenous knowledge and resources, but about the ownership of the resources themselves. When resources are found in the high seas, seabed, ocean floor, and subsoil beyond any country's national jurisdiction, no one nation can asset sovereign rights over the resources. Consequently, developed countries prefer a "first come, first serve" treatment of marine resources, while developing countries prefer a broader view where the resources are property of all countries. See generally Kirsten E. Zewers, *Bright Future for Marine Genetic Resources, Bleak Future for Settlement of Ownership Rights: Reflections on the United Nations Law of the Sea Consultative Process on Marine Genetic Resources*, 5 Loy. U. Chi. Int'l L. Rev. 151 (2008) for an in-depth discussion of marine genetic resources.

Madagascar.[5]

Furthermore, sometimes it is not just products derived from genetic research that are at issue, but genes themselves. Various groups, in an attempt to study diseases such as cancer and leukemia, have sought out indigenous groups for blood samples.[6] Many times, the groups were not compensated for their help, not even with the results of the testing.[7] The United States government has held that a researcher need not obtain the consent of a patient or subject to develop a commercial product from his or her genes.[8] Furthermore, the researcher need not obtain consent to patent any isolated genes, DNA fragments, proteins, or other genetic material he considers of interest.[9] Proponents of this practice argue that the groups have no claim to any genes once they are extracted.[10] They are not, obviously, excluded from the use of the genes in their own bodies, and they

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[5] Greg Venbrux, *When Two Worlds Collide: Ownership of Genetic Resources Under the Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 6 U. Pitt. J. Tech. L. & Pol'y 5, 5 (2005); Hunter *supra* note 1, at 130.

[6] Marina L. Whelan, *What, if any, are the Ethical Obligations of the U.S. Patent Office?: A Closer Look at the Biological Sampling of Indigenous Groups*, 14 Duke L. & Tech. Rev. 1, 7-10 (2008).

[7] *Id.* at 8.

[8] Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 Yale J. Health Pol'y, L. & Ethics 403, 409 (2005).

[9] Whelan *supra* note 6, at 11.

[10] *Id.* at 16.

gave tissue voluntarily, even if, in some cases, they didn't know that their DNA might be patented.[11] However, the United Nations supports the opposite view, one where "individuals should have property rights in their biological material and should not be forced to comply with the whims of researchers."[12] Furthermore, it seems arrogant to dismiss so casually profound ethical issues a person might have over his own bodily material.

In the second scenario, a product is derived using the genetic resources of a country, along with the traditional knowledge of indigenous peoples in regards to those resources. Many times, indigenous communities aid corporations in finding and identifying genetic resources, yet they compensated no more than the host country.[13] Of prescription drugs made using plant material, seventy-four percent come from knowledge derived from indigenous communities.[14]

A famous example of this "genes plus knowledge" scenario is that of India's neem tree. For centuries, Indian villagers around the tree have attributed all manner of uses to neem tree oil, which is sometimes called "the curer of all ailments."[15] American and Japanese companies have since taken samples of the

[11] *Id.*
[12] *Id.* at 15.
[13] Sarma *supra* note 3, at 113.
[14] Venbrux *supra* note 5, at 5.
[15] Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 Colo. J. Int'l Envtl. L. & Pol'y 219, 226 (2008).

neem tree, extracted the active compounds, and developed products ranging from pesticides to toothpaste.[16] This case has been publicized by NGOs and mentioned in numerous articles on biopiracy; it remains illustrative of many issues found in biopiracy, and will be a useful example to turn back to during the course of this paper.

The use of genes plus knowledge presents an issue in regards to compensation that is not found in the use of genes alone. In cases where a multinational negotiates with the government to gain access to resources, indigenous communities may be left out of the process. A government of a country may not be acting in the interest of indigenous communities, and may do little to protect traditional knowledge when there is economic gain to be made.[17]

Even if a multinational decides to compensate the communities themselves, acting so directly may also present problems. First, when knowledge is shared by several communities, it may be hard to know which ones to compensate.[18] And once one indigenous community is identified as the source of

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[16] *Id.* at 227.

[17] Eugene Ho, *Biopiracy ant Beyond: A Consideration of Socio-cultural Conflicts with Global Patent Policies*, 39 U. Mich. J.L. Reform 433, 461 (2006).

[18] George Frisvold, *Bioprospecting and Biodiversity Conservation: What Happens When Discoveries are Made?*, 50 Ariz. L. Rev. 545, 552 (2008).

knowledge and compensated, it may exclude other communities with the same knowledge from obtaining benefits.[19] Second, the practice of rewarding one community may very well discourage communities in a given region from sharing knowledge with one another, in the hopes that they would some day benefit from being the only holders of such knowledge.[20]

And third, it may be difficult to decide how much and what kind of compensation is due. For example, the USDA, while collecting plants in certain environments, used traditional knowledge to prioritize certain plants; it did not, however, actively search for those plants.[21] If one such plant ended up leading to a profitable venture, how much should the knowledge holders be compensated? How much, exactly, did their knowledge aid in developing a final product? This is a common quandary in bioprospecting. Furthermore, compensation need not just be monetary; technology transfers, training and job opportunities may be better methods for certain communities.[22] Also, some communities may not want compensation, but are still offended by the private ownership of knowledge they consider belongs to the public good.[23]

[19] Ho *supra* note 17, at 461-62.
[20] *Id.* at 463.
[21] Frisvold *supra* note 18, at 558.
[22] *Id.* at 551-52.
[23] Dorothy E. Schmidt, *Postcard From the Reality-based Universe: "Wish You Were All Here!" A Mediatation on the Relationship*

The neem example provides a prime example of how difficult it is to provide compensation to knowledge holders. In that case, the uses of neem were known to millions of people; compensating each person individually would be an impossible task. Furthermore, there is the issue of how much compensation would be adequate. The use of neem bark to repel insects, for instance, might be common knowledge, but it was the efforts of the multinationals that extracted the active ingredient from the bark and developed it into a commercial product.

Fair compensation is important for a couple of reasons, not just for fairness' sake, but also because of bioprospecting's potential to widen already existing wealth gaps. Multinationals are largely residents of developed countries, while the genetic resources they are interested in are largely found in developing countries. Nearly eighty percent of raw genetic material used in biotechnology are from developing countries.[24] Not only would biopiracy involve the appropriation of resources without compensation, residents of host countries might have to make royalty payments on products developed from their own genetic resources, and possibly their own traditional knowledge. Some argue that allowing biopiracy allows the rich to get richer and

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Between Science, Intellectual Property Law, and the Rights of Indigenous Populations in Plant Genetic Resources, 38 Envtl. L. 315, 333-34 (2008).

[24] Venbrux *supra* note 5, at 5.

the poor to get poorer.

Of course, there are counters to this argument. While some argue that it is only fair to provide compensation to the host country or indigenous population, others argue that such an argument is a simple matter of developing countries "clamoring" for the wealth of developed countries.[25] And as a further counter-argument, developed countries often accuse developing countries of piracy when it comes to royalties lost for chemicals and pharmaceuticals; however, they do not take into account the contributions of developing countries to the development of those products.[26]

The lack of fair compensation is not the only issue that biopiracy presents. There are other, arguably smaller, problems that biopiracy may cause.

B. Other Considerations

Other problems with biopiracy are environmental, commercial, and moral in nature.

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[25] See Jim Chen, *There's No Such Thing as Biopiracy. . . and it's a Good Thing Too*, 37 McGeorge L. Rev. 1, 26-28 for just such an argument; *see also* Sarma *supra* note 3, at 112 (noting that developing countries want to "jump on the bandwagon" in terms of sharing in the profits made by multinationals).

[26] *See* Ketih Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-so-Brave) New World Order of International Intellectual Property Protection*, 6 Ind. J. Global Legal Stud. 11, 49 (1998) (estimating royalties lost by the US as $2.5 billion a year for pharmaceuticals, but positing that when developing country contribution is taken into account, the US would owe developing countries $5.1 billion).

One issue is the effect on the genetic resource itself. Genetic resources do tend to be, after all, finite resources. Whether or not bioprospecting would deplete a genetic resources is undecided; while some claim it will, others claim that multinationals partaking in bioprospecting have an interest in sustaining the genetic resource. Environmental effects or not, biopiracy can have a very real effect on the commercialization of a genetic resource.

The mass commercialization of a once free resource may turn that resource into an expensive commodity, effectively pricing it out of the range of those who once relied on it. To turn back to our example of the neem tree, since the patenting and commercialization of neem-based products, prices for neem seeds have skyrocketed from 300 rupees per ton to 3000 rupees per ton, thereby excluding it from the use of many traditional farmers.[27]

One final problem with biopiracy lies in the value, or lack thereof, that it places in traditional knowledge. Some argue that biopiracy marginalizes, or outright ignores, traditional knowledge as a valuable resource by allowing it to be commercialized by outside interests.[28]

While the degree to which biopiracy problems are valid concerns is debated, it is clear that such problems do exist.

[27] Aoki *supra* note 26, at 51-52; Ho *supra* note 17, at 465.
[28] Schmidt *supra* note 23, at 336.

Common notions of decency dictate that a country's resources should not be stolen, and yet such theft occurs without punishment where modern bioprospecting is concerned. It occurred in the case of the neem tree, where foreign companies were allowed to steal common knowledge about neem properties and price neem seeds out of the range of traditional public consumption. And it occurs because the current international framework for intellectual property allows it to.

II. International Regulation of Intellectual Property Law

The link between biopiracy and intellectual property is as follows. When a multinational develops a product from a country's resources, it will obtain a patent on it. A patent grants the patent holder a temporary monopoly. For some certain length of time, generally a few decades, the holder may exclude other parties from making, using, selling, offering for sale, or importing the patented product within the jurisdiction that the patent was granted. Allowing multinationals to obtain patents on products developed using a country's resources and knowledge is thus providing commercial incentive to commit biopiracy. However, patent laws for each nation are varying and limited to the jurisdiction of that nation. For example, a patent in the United States for a pesticide derived from neem would not be enforceable in India, although it would preclude Indian parties

from importing a substantially similar pesticide into the United States, thereby excluding it from a lucrative market.

While patent laws vary from nation to nation, in the last few decades various countries have moved towards creating a more unified global system for the recognition of intellectual property rights. While a completely unified system is still a long way off, if it is possible at all, several attempts have been made to provide some form of cohesion. This part of the paper will describe the history of such unification attempts, discuss the involvement of the World Trade Organization in such matters, and analyze how this facilitates biopiracy.

A. International Treaties Regarding Intellectual Property

Like much of international law in general, international intellectual property law is regulated largely by voluntary agreements between member countries. The first real discussion of global patent rights culminated in the Paris Convention for the Protection of Industrial Property, enacted in 1883.[29] While not a regulatory framework, it does establish some general propositions for its member states.[30] First, each member state

[29] Amy E. Carroll, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 Am. U. L. Rev. 2433, 2455 (1995).

[30] There are currently 173 nations that are party to the Paris Convention. WIPO Administered Treaties Page, http://www.wipo.int/treaties/en (follow "Paris Convention" hyperlink).

must grant a foreign property holder the same rights as a national property holder.[31] This way, a patent applicant will not be discriminated against on the basis of his nationality.[32] Second, the agreement standardizes a right of priority for patent applicants. To put it simply, if an applicant files for a patent in several countries, a right of priority allows subsequent applications in other countries to be regarded as if they had been filed on the same day as the first application.[33] And third, the agreement recognizes that different countries have different needs, and thus have the right to maintain their own IP systems.[34] More specifically, the grant of a patent in one country does not oblige any other member country to grant a patent for the same invention.[35] And conversely, a patent cannot be refused, invalidated or otherwise terminated in any member country on the ground that a patent for the same invention has been refused, invalidated or terminated in any other country.[36]

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[31] Paris Convention for the Protection of Industrial Property art. 2, Mar. 20, 1983 (hereinafter "Paris Convention").

[32] WIPO Intellectual Property Handbook: Policy, Law and Use 242 (2006), http://www.wipo.int/about-ip/en/iprm/pdf/ch5.pdf#paris (positing that discrimination would have been a problem without this provision) (hereinafter "WIPO IP Handbook").

[33] This is provided that the applicant act promptly: within 12 months of the first application for patents and utility models, and 6 months for industrial designs and marks. Paris Convention art. 4.

[34] Sarma *supra* note 3, at 119

[35] Paris Convention art. 4bis.

[36] Paris Convention art. 4bis.

The next important international agreement was the Patent Corporation Treaty (PCT) of 1970. The treaty allows its member states to file an "international patent," which would file the application in several countries simultaneously.[37] However, the task of granting patents remains exclusively in the hands of the patent offices of the countries where protection is sought.[38] The PTC functions in three general phases: a filing phase, an international phase, and a national phase. In the filing phase, an applicant files an application with either the national patent office of the Contracting State of which the applicant is a national or resident, or with the International Bureau of WIPO in Geneva.[39] In the international phase, an International Searching Authority (ISA) then conducts a search of relevant patents and technical literature, culminating in a report which is then published along with the patent application.[40] And in the national phase, that national patent offices that the applicant applies to will determine whether or not to grant the patent in

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[37] Zewers *supra* note 4, at 168.

[38] WIPO IP Handbook supra note 32, at 277.

[39] Protecting your Inventions Abroad: Frequently Asked Questions about the Patent Cooperation Treaty 5 (http://www.wipo.int/pct/en/treaty/about.htm) (hereinafter "Protecting Your Inventions Abroad").

[40] *Id.* at 9, 11. The national Offices of Australia, Austria, Canada, China, Finland, Japan, the Republic of Korea, the Russian Federation, Spain, Sweden and the United States of America, along with the European Patent Office, are designated ISAs. *Id.* at 8-9.

their states.[41]

While it is still ultimately left to the individual nation to determine if the patent should be granted or not, the process under the PCT facilitates things in several ways. First, applicants have more time than in a non-PCT process in which to seek protection in different countries.[42] Second, the international search report reduces the workload of the national patent office.[43] And third, publication of the report allows third parties to better formulate a well-founded opinion on the invention and provides notice to the world of the application.[44]

In 2000, the Patent Law Treaty was enacted. It was further able to harmonize global IP law, establishing formal procedures such as the requirements to obtain a filing date for a patent application and the form and content of a patent application.[45]

Several other small agreements exist that attempt to

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[41] Protecting your Inventions Abroad *supra* note 39, at 15.
[42] *Id.* Applicants have 18 months more than if they used the traditional method of filing a patent with one country, then subsequently filing them with others. *Id.*
[43] *Id.* at 16.
[44] *Id.*
[45] WIPO IP Handbook *supra* note 32, at 301.

harmonize worldwide intellectual property regulation.[46] However, the most important agreement in existence right now, especially in regards to substantive provisions, is the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").

B. TRIPS and the WTO

TRIPS is primarily a trade agreement, and as such is administered by the World Trade Organization. More and more, commodities being traded are not just tangible goods, but the intellectual property they entail. Studies estimate that in the United States, over fifty percent of exports within the last decade were dependent on intellectual property.[47] And with the weak protection offered by previous treaties concerning intellectual property, it was inevitable that nations would enact a stronger agreement in order to protect their exports.

Negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994, TRIPS first and foremost contains requirements that member states must meet in

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[46] *See* Berne Convention for the Protection of Literary and Artistic Works 1886, WIPO Copyright Treaty 1996, Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure Apr. 28, 1977, Madrid Agreement Concerning the International Registration of Marks Apr. 14, 1891, Strasbourg Agreement Concerning the International Patent Classification Aug. 27, 1675.

[47] Thomas G. Field, *What is Intellectual Property?, Focus on Intellectual Property* 2 (2006), http://usinfo.state.gov/products/pubs/intelprp/.

terms of copyrights, trademarks, patents, and other facets of intellectual property law.[48] And unlike the previous treaties discussed, TRIPS details civil, criminal, and border enforcement provisions its member states must implement, and subjects its member states to binding, enforceable dispute settlement in a formal adjudicatory process.[49]

The regulations found in TRIPS are meant to provide a minimal framework of intellectual property protection, with member states providing stricter regulation if they wish to do so.[50] However, there is much debate as to whether TRIPS is really an adequate "minimal" framework, or if it is too much for some of its member states to implement. To comply with TRIPS, developing countries must establish administrations and methods that can enforce intellectual property and prosecute infringers, something they may not be economically equipped to do.[51]

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[48] Agreement on Trade-Related Aspects of Intellectual Property Rights Dec. 8 1994 (hereinafter "TRIPS").

[49] Paul E. Salmon, *A Short Guide to International IPR Treaties, Focus on Intellectual Property* 16 (2006), http://usinfo.state.gov/products/pubs/intelprp/.

[50] TRIPS Part I, Art 1; Jerome H. Reichman & Rochelle C. Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 Duke L.J. 85, 88 (2007).

[51] *See* Venbrux *supra* note 5, at 5 (noting that countries "must establish industrial property registries, develop enforcement mechanisms, combat piracy, and prosecute criminals," a venture that, for example, would cost Bangladesh an estimated annual $1.1 million); Sarma *supra* note 3, at 127 (stating that developing countries would be forced to expand patent protection for the benefit of multinationals).

Developing countries are still struggling to adjust to minimum TRIPS standards,[52] as evidenced by the fact that developing countries have called for amendments to TRIPS several times.[53]

While some claim that countries do not have to join TRIPS, developing countries are forced to join under enormous pressure in order to export goods to lucrative markets.[54] If a country wants to be a part of the WTO, they must become a party to TRIPS.[55] Pressure is not just found in coercing nations into joining the treaty, but is inherent in the creation of the treaty itself and in negotiations for amendments. Such pressure is found in most international treaties, insofar countries in economic power can use their gravitas to force provisions that are more favorable to them.[56] Furthermore, pressure in the form of trade sanctions and economic benefits is not uncommon in the global community, even outside of the TRIPS context. In 1991, a

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[52] Reichman & Dreyfuss supra note 50, at 85.

[53] The first to do so was Columbia in 1999, suggesting that patents should have to comply with the CBD to be valid. Ho *supra* note 16, at 453-54.

[54] Sarma *supra* note 3, at 109, Aoki *supra* note 26, at 20, Schmidt *supra* note 23, at 350; see also Ho *supra* note 17, at 511 (noting also the tendency of developing countries to corporate with another country that can control its credit).

[55] Salmon *supra* note 49, at 16.

[56] *See* Sarma *supra* note 3, at 125-26 (stating that the views of developing countries are often ignored during negotiations); Aoki *supra* note 256, at 20 (positing that the notion of a true consensus is a myth); Ho *supra* note 17, ay 512 (claiming that the lack of negotiation power on the part of developing countries is widely acknowledged).

United States Trade Representative threatened India, China, and Thailand with trade sanctions for failure to respect U.S. intellectual property.[57]

Although there is an imbalance of power among the states that are party to TRIPS, TRIPS remains the most comprehensive international instrument on intellectual property law, and is the principal means of international IP regulation among its member states. The major reason this is true is because, as stated to above, TRIPS is enforceable under WTO Dispute Settlement Proceedings. However, even the settlement proceedings reflect power imbalances. The cynical even claim that the majority of disputes never even reach the WTO, and are instead squashed by the threat of unilateral trade sanctions on the part of more powerful parties.[58]

While a full discussion of TRIPS is outside the scope of this paper, we will turn to two issues: what TRIPS requires in a patentable invention, and its effect on biotechnology.

i. Patentable subject-matter: the three pre-requisites

It has already been established through our discussion o international treaties that every nation has the power to decide

[57] Stefan Kirchanksi, *Protection of U.S. Patent Rights in Patents Developing Countries: U.S. Efforts to Enforce Pharmaceutical in Thailand*, 16 Loy. L.A. Int'l & Comp. L.J. 569, 569 (1994).

[58] *See* Ho *supra* note 17, at 484 (accusing the United States of doing this very thing).

whether to grant or deny a patent, and thus each nation has its own laws regulating the granting of patents. TRIPS provides some requirements, many of which corroborate with the requirements already in place in most developed countries. The requirements are minimal and able to be interpreted in several ways.

According to TRIPS, patents can be granted "for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[59] In order words, inventions must be novel, non-obvious, and useful, characteristics already required in many jurisdictions.

These requirements put limits on what can be patented. In regards to genetic resources, objects that occur in nature are generally not considered novel or non-obvious. And in regards to products developed from genetic resources, if such products were developed from indigenous knowledge, they arguably should not be patentable because such knowledge is not new. These two propositions, however, do not always held true, something that is shown by a comparison of the patent law systems of two member states, namely the laws enacted by the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO).

a. Patentable subject-matter under U.S. Law

[59] TRIPS Part II Sec. 5 Art. 27 P. 1.

The three TRIPS requirements are already found in United States patent law, which requires novelty, non-obviousness, and utility for an invention to be patentable. However, United States patent law goes much further than TRIPS in defining what those three requirements truly mean.

The requirement of novelty is described by statute using very technical means. A patent is not novel if:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
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> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
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> . . .
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> (f) he did not himself invent the subject matter sought to be patented[60]

So, if the subject matter is known to others, it cannot be patented. As an example, the use of aloe vera plant in sunburn treatments would most likely fail the novelty requirement, as aloe is known to the public as having cooling effects. However, the statute does not take most foreign activity into account. For instance, while the use of neem oil was widely known and in practice in India for ages, such use would not be taken into

[60] 35 U.S.C. § 102.

consideration under United States patent law.[61] Foreign activity must be published in order to be a factor in a US novelty analysis. This is problematic due to the fact that common knowledge is usually not published, and the knowledge of indigenous populations is rarely documented.[62]

Generally, objects found in nature are not considered novel, and are unable to be patented.[63] However, in the landmark case *Diamond v. Chakrabarty*, the Supreme Court ruled that "anything under the sun made by man" is patentable, and allowed for a patent on a new bacterium genetically engineered to degrade crude oil.[64] So a scientist can patent neither a new species that he has discovered in some isolated jungle, nor a strand of DNA that is found in another human being. A scientist can, however, patent a new species if it is one that he has genetically engineered,[65] or a strand of DNA that he has isolated.[66]

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[61] Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 IDEA 371, 371 (1997)

[62] Sarma *supra* note 3, at 130, Moyer-Henry *supra* note 2, at 5.

[63] Restaino *supra* note 19, at 4, Chen *supra* note 25, at 15.

[64] 447 U.S. 303, 309 (1980). See also Zewers supra note 4, at 160-61 for more examples of court decisions on patents on DNA.

[65] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (rejecting the proposition that an organism is unpatentable just because it is a product of nature); U.S. Patent No. 4,736,866 (describing a mouse engineered for the study of cancer).

[66] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001); *also In re Bergstrom*, 427 F.2d 1394, 1401 (C.C.P.A. 1970) (holding that isolated hormones were not naturally occurring and were this patentable), Restaino supra note 19, at 6 (explaining the USPTO's decision to allow patents on isolated

In addition to being novel, inventions must also be non-obvious. To determine if an invention is non-obviousness, the patent office looks at all inventions, technology and information that are known to the public ("prior art"), and determines whether the invention "would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[67]

Finally, an invention must be useful.[68] To be useful, a patent must be "specific, substantial, and credible."[69] For example, a strand of DNA whose only use is as a general genetic research tool has no utility other than one common to all DNA strands, and thus cannot be patented.[70]

b. Patentable subject-matter under European Law

In Europe, patents may be obtained either through the national offices of each country, or through the EPO. For simplicity's sake, this paper will focus only on the laws of the EPO.

The EPO was created in 1977, and is based upon the European Patent Convention (EPC), signed in 1973 and most recently

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DNA molecules, because even though the isolated molecule has the same sequence as a naturally occurring gene, the molecule cannot exist in an isolated state in nature).

[67] 35 U.S.C. §103(a).

[68] 35 U.S.C. §101.

[69] Michele Westhoff, *Gene Patents: Ethical Dilemmas and Possible Solutions*, 20 No. 4 Health Law. 1, 5 (2008).

[70] *In re Fisher*, 421 F.3d 1365, 1379 (Fed. Cir. 2005).

modified in 2000.[71] The EPC lays out the rules and procedure for applying for a European patent. Similar to U.S. patent law, the EPC designates the three subject-matter requirements under TRIPS, although with small differences. The EPC requires novelty,[72] an inventive step,[73] and industrial application.[74] The inventive step is akin to the U.S.'s non-obviousness requirement, while industrial application parallels utility.

The key way in which the EPO's analysis differs from that of the USPTO is in its approach to novelty. Unlike the United States, Europe takes foreign prior art into consideration when determining the novelty of an invention.[75] So in our earlier example of the neem tree, common knowledge in India would be relevant in determining novelty in Europe.[76] For this reason, patents for neem-derived products have been unsuccessful in obtaining patents under the EPO, although they have obtained them in the United States.

ii. Further considerations and exceptions

Of course, even if an invention is novel, non-obvious, and

[71] European Patent Convention (hereinafter "EPC"), 13th Edition, 2000 http://www.epo.org/patents/law/legal-texts/epc.html.
[72] EPC art. 54.
[73] EPC art. 56.
[74] EPC art. 57.
[75] Guidelines for Examination in the European Patent Office 240, 2007 http://www.epo.org/about-us/publications/procedure/guidelines-epc2000.html.
[76] Moyer-Henry supra note 2, at 5-6 (discussing the patenting of the neem plant).

useful, TRIPS deems that member states may decline to patent: "(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[77] In addition, member states may decline to patent inventions in order to "protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."[78] The EPO also includes an similarly-worded exception for inventions against public morale, although the United States does not.[79] The EPO also allows concerned citizens to challenge an invention as being against ordre public through judiciary action.[80]

Of course, these provisions are not compulsory, and in the case of the EPO, how heavily they weigh is left to the discretion of the patent examiner. So, even if a patent on genetic sources could be considered against ordre public, the government of a nation can still grant it.

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[77] TRIPS Part II Sec. 5 Art. 27 P. 3.
[78] TRIPS Part II Sec. 5 Art. 27 P. 2.
[79] EPC art. 53.
[80] Lydia Nenow, *To Patent or Not to Patent: The European Union's New Biotech Directive*, 23 Hous. J. Int'l L. 569, 585-86 (2001).

TRIPS also includes situations where, even if a patent is granted, third parties may be excepted from having to pay royalties or licenses for the use of the invention. Article 30 states:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.[81]

While ambiguous, the article may be read to apply to several scenarios, such as for research, experimentation for testing, and education.[82] Furthermore, TRIPS Article 8 allows exemptions to protect health, and has been used to facilitate access to medicines in developing countries.[83]

iii. The effect of TRIPS on bioprospecting

As seen in the discussion above, while TRIPS provides some guidelines as to the what may be patented, it leaves much of the analysis up to its member states. And while TRIPS allows member states to exclude certain subject-matter, its weak stance towards such exclusions means that states aren't likely to subscribe to them if it is in their best interests not to do so.

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[81] TRIPS Part II Sec. 5 Art. 30.

[82] Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-use Exemption*, 76 N.Y.U. L. Rev. 1623, 1690(2001).

[83] *Id.*

Developed countries, as homes to the bioprospectors and inventors in question, tend to favor stronger intellectual property rights, and use several arguments to support their position.

The most common argument in support of strong IP rights is that, at least theoretically, stronger intellectual property protection creates incentives for additional invention.[84] More specifically, a limited monopoly over an invention provides an economic incentive to the inventor. However, there has always been a debate among academics as to whether it actually does so.[85] Furthermore, whether or not patents actually increase innovation is very much dependent on what kind of industry or technology the patent is in. In terms of bioengineering, biologists were attempting to identify genes, such as in the Human Genome project, long before they knew genes would be patentable.[86] And

[84] Venbrux supra note 5, at 5; *see* Westhoff *supra* note 69, at 6 (explaining that granting a monopoly gives the inventor the opportunity to recover research and development costs and make a profit), Kirchanksi *supra* note 57, at 571-72 (explaining the unproven belief that stronger patent protection gives the best incentive to invent).

[85] *See* A. Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 Duke L.J. 831, 837 (stating the difficulty groups have had in determining if the patents system really does offer proper incentive); *see generally* Mark D. Janis, Patent Abolitionism, 17 Berkeley Tech. L.J. 899 (2002) (discussing arguments both for and against the abolition of the patent system).

[86] Andrews & Paradise *supra* note 8, at 406; Westhoff supra note 69, at 7 (claiming that genetic research was taking place before genetic materials were patentable).

some have distinguished, for instance, between the development of drugs and the discovery of genes. The argument is that new drugs are financed by mostly private funds, while gene discovery is financed by mostly public funds, hence a greater need for commercial incentive in the former case.[87]

To further counter the argument for strong IP rights over products derived in bioprospecting, the rational in patent law behind granting temporary monopolies is that patent holders are required to fully disclose their inventions. The full disclosure of such information is of benefit to society and justifies the monopoly. Some argue that biotechnology inventions add too little to public knowledge to justify such a monopoly.[88] This is especially true in cases such as the neem tree, where the uses are already a matter of public knowledge, albeit foreign public knowledge.

Another argument for stronger IP rights is that it can expand investment within a country's jurisdiction.[89] For example, after Singapore enacted stronger intellectual property legislation, foreign countries started to enter into joint ventures with domestic companies.[90] While it is unclear if

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[87] Hunter *supra* note 1, at 406.
[88] Andrew Torrance, *An Extinction Bar to Patentability*, 20 Geo. Int'l Envtl. L. Rev. 237, 251-52 (2008).
[89] Venbrux *supra* note 5, at 5.
[90] *Id.*

patents provide incentives to inventors, the limited monopoly it provides, along with the higher profits that tend to come with it, is certainly attractive to investors.[91]

It is also clear that stronger IP protection may help to subsidize research and development.[92] The field of biotechnology is inherently risky. Research is time consuming and marked by numerous dead-ends; for every drug or product that makes it onto the market, there are countless others that fall to the wayside during the research process.[93] Patent protection, and the monopoly it provides, is incentive for companies to push countless years and dollars into research that may or may not pay off.[94]

The common theme in the above arguments seem to be more economic than anything else. And sure enough, when discussing intellectual property rights on a global level, developed countries often cite the royalties and profit lost from infringing goods.[95] Stronger IP rights mean more economic compensation; furthermore, the practice of obtaining royalties and licenses provide countries with a two-fold method of maintaining a competitive edge in global trade. One, foreign

[91]Kirchanksi *supra* note 57, at 572.
[92] Ho *supra* note 17, at 516.
[93] Nenow *supra* note 80, at 570.
[94] *Id*.
[95] Kirchanksi *supra* note 57, 575.

manufacturers that must pay royalties must increase the price of their goods to cover such royalties.[96] And two, manufacturers that do not pay royalties have no access to protected technology, thereby decreasing their quality of goods.[97] Both options mean that competitors will have less attractive products.

However, the economic incentives that patent law creates must be balanced by moral obligations to society. Developing countries have an interest in not having to pay expensive royalties on products derived from their own resources and knowledge, especially when they have insufficient funds to do so.[98]

One case where this is especially true is in the case of medicine and vital treatments derived from genetic resources. Here, patent monopolies allow patent holder to charge higher prices, precluding patients of limited means from medical care.[99]

However, as already stated, TRIPS does allow a government the ability to make, use, or sell the patented invention without permission from the patent owner under various circumstances.[100] This provision has been applied to medicine in several

[96] *Id.*
[97] *Id.*
[98] *Id.* at 576-77.
[99] Ho *supra* note 17, at 516; but see G. Chandrashekhar, *Taking Stock of Threats to Intellectual Property*, Bus. Line 11 (April 26, 2007) (making the argument that the high cost of medicine is due to high tariffs and taxes).
[100] TRIPS Part II Sec. 5 Art. 31

situations, most notably in the case of providing cheap, generic antiviral medications to AIDS patients worldwide.[101]

The practice of patenting genes themselves also calls for more relaxed IP protection. In the case of products such as drugs, researchers can always "invent around" drugs, developing different ones that perform the same function.[102] They cannot invent around genes.[103] Typically, only one gene can be used in a genetic test; no other gene will work.[104] A scientist who studies a gene may need to obtain licenses from several patent holders for different fragments of the gene.[105] And a scientist who wants to study a genetic disease would have to obtain licenses from the patent holder of that gene and any mutations thereof.[106] In this way, a patented gene's availability is severely restricted. This is problematic from an investment standpoint as well; an investor may not want to put money into studying a disease if it

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[101] Richard Parker, *AIDS Solidarity as Policy: Constructing the Brazilian Model*, NACLA Rep. on Americas 20 (July 1, 2008)(discussing Brazil's role in the movement towards universal access to drugs), John Boscariol, *Canada Is First To Grant WTO Compulsory Licence For Export Of Generic Drug*, Mondaq Bus. Briefing (Apr. 17, 2008) (noting Canada's grant of a compulsory license to a generic drug manufacturer pursuant to a plan negotiated under the WTO).

[102] Hunter *supra* note 1, at 406-07.

[103] *Id.*

[104] Westhoff *supra* note 69, at 8.

[105] *Id.* at 7.

[106] *Id.* at 7.

involves genes that will have to be licensed.[107] And while patents may provide economic benefits to patent holders, they may preclude the more altruistic among us from conducting their own research and giving the results away for free.[108] Some argue, however, that patents have no effect on research, citing a survey of United States scientists that claimed that "'the patent status of the requested material had no significant effect'" on why those materials were restricted."[109]

One tricky situation occurs when a company takes out a patent that it does not intend to use.[110] One company holds patents of genes that can potentially be used to test for breast cancer, and, in a pro-life stance, has stated that it will use its patent to forbid prenatal testing for breast cancer.[111] And even when testing is allowed, and a researcher is able to license the patents for all the genes he needs, such patents can render the cost of the test prohibitive.[112] Such medical testing

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[107] Gitter *supra* note 82, at 1668.
[108] Schmidt *supra* note 23, at 332.
[109] Gregory Ellis, *Emerging Biotechnologies Demand Defeat of Proposed Legislation That Attempts to Ban Gene Patents*, 15 Rich. J.L. & Tech. 1, 27 (2008), available at http://law.richmond.edu/jolt/v15i1/article1.pdf.
[110] *See* Andrews & Paradise *supra* note 8, at 409 (describing an example of a company that filed a patent for a genetic test to determine the effectiveness of an asthma drug).
[111] *See id.* at 411 (attempting, in passing, to make an argument that such a practice interferes with a women's constitutional right to privacy).
[112] Ellis *supra* note 109, at 27.

may, however, still fall under the TRIPS exception for compulsory licensing. This proposition has yet to be tested, but many have proposed exceptions for medical tests involving gene patents.[113] An increase in patents on research tools such as gene sequences makes it impossible for many scientists to use such tools to develop commercial products.[114] Many scientists are taking steps against this even without resorting to legal instruments, by publishing their research results immediately and precluding others from obtaining patents.[115]

While medicine derived from genes and genetic resources may be granted compulsory licenses under certain circumstances, what about other products? A compulsory license would certainly not be given for cosmetics made using the oil derived from neem seeds, and products such as anti-itching and burn medications would most likely still be enforced under valid patents. While it's clear that few would advocate the use of compulsory licenses for such products, there is still an underlying issue of fairness involved. We have already discussed the

[113] Ho *supra* note 17, at 516; *see* Andrews & Paradise *supra* note 8, at 412 (noting that Congress enacted a statute allowing licensed medical physicians to use patented medical or surgical procedures), Westhoff *supra* note 69, at 10 (suggesting the patents on genes used in diagnosing a genetic disorder or pre-natal screening should not be enforced against healthcare professionals).

[114] Ho *supra* note 17, at 517.

[115] *Id.* at 519.

commercialization of the neem seed; when a corporation uses the resources and traditional knowledge of a culture, should they be able to profit without providing fair compensation?

Of course, intellectual property may be used to protect traditional knowledge.[116] An example of this occurred in India, where an indigenous tribe gained IP rights on a plant it used to combat stress.[117] We may see more of this as cultures become more and more globalized; however, given the fact that most indigenous peoples are largely unaware of and unconcerned with intellectual property rights, such an approach would probably not be presently feasible.

With all these issues involved in the patenting of genes and genetic material, the question remains as to what can be done in on international level regarding intellectual property regulation. It is important that the communities that aid in the development if genetic products are treated fairly and with respect, yet a truly international IP framework seems to be a long way off. There is only so much WTO, or any other international system, may be able to do, if it wished to do so. In an attempt to devise a solution, next we will turn to other

[116] *See* Chen *supra* note 25, at 35 (citing a WIPO study that found that at least 28 developing countries were interested in exploring the role of intellectual property in protecting traditional knowledge).

[117] *See* Sarma *supra* note 3, at 128 (describing other examples as well).

agreements that may be relevant to the issue, and then to possible changes that can be made to the current international framework.

C. Other International Agreements

While TRIPS is the leading treaty on international IP regulation, other agreements that have little to do with IP on the surface are also relevant in biopiracy discussions.

i. Convention on Biological Diversity

The Convention of Biological Diversity (CBD) was adopted in 1992 in order to promote the conservation of biological diversity and sustainable development. While it is an environmental treatise, and its purpose is to sustain ecological resources, it does have some application in terms of bioprospecting.

The most relevant provision is Article 8(j), which encourages member states to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities."[118] Furthermore, it goes on to suggest that member states obtain the approval and involvement of such knowledge holders in applying such knowledge in a larger scale,[119] and encourages the equitable sharing of benefits that arise from

[118] Convention on Biological Diversity (hereinafter "CBD") Art. 8(j) June 5 1992.
[119] *Id.*

such knowledge.[120]

Article 16 of the Convention requires that parties provide for and facilitate the transfer of technologies relevant to sustainable use of genetic resources,[121] and grants host countries access to technology made from its genetic resources.[122] While an admirable thought, so far efforts to transfer technology to developing countries have been nonexistent.[123]

One other fact that is worth noting is that the convention recognizes sovereign control over natural resources.[124] This places the responsibility of policing biological resources on national governments.[125] A problem with this is that a developing country may not have an interest in protecting genetic resources or traditional knowledge; on the contrary, poorer countries might be tempted to sell its resources to the highest bidder.[126]

ii. Common System on Access to Genetic Resources (1996)

An interesting agreement to look at is the Common System on

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[120] *Id.*
[121] CBD Art. 16.
[122] *Id.*
[123] Venbrux *supra* note 5, at 5.
[124] CBD Art. 15.
[125] *See* Chen *supra* note 25, at 11-12 (making the argument that environmental depletion is not the fault of multinational companies, but the fault of the national governments that allow such companies to overharvest biological resources), Sarma *supra* note 3, at 120 (stating that governments must control who has access to genetic resources).
[126] Sarma *supra* note 3, at 122.

Access to Genetic Resources. It was adopted by the Andean Pact (Bolivia, Columbia, Ecuador, Peru and Venezuela) in an attempt to centralize and police bioprospecting in their countries.[127] The pact requires bio-prospectors to obtain the prior informed consent of the host country's government in order to gain access to its resources.[128]

There are several criticisms with the system. The largest one is with the high cost of operation.[129] The cost has made it prohibitive to implement in the member countries, and will no doubt dissuade other developing countries from creating such a system.[130] Another is the fact that while a foreign prospector who foregoes the system may have his IP revoked under the member countries' laws, he may still obtain one in his own country.

iii. THE CBD's Bonn Guidelines

The Bonn Guidelines, a document created in order to facilitate the implementation of provisions of the CBD, implements similar measures as the Common System. It suggests that an interested party must obtain prior informed consent from the host country before accessing genetic resources and traditional knowledge.[131] It also suggests that a patent

[127] Common System on Access to Genetic Resources (hereinafter "Common System") 1996.
[128] Venbrux *supra* note 5, at 5.
[129] *Id.*
[130] *Id.*
[131] Ho *supra* note 17, at 474.

application disclose if the genetic resources or traditional knowledge of another country were used,[132] and that parties participate in fair and equitable benefit sharing.[133]

The problem with the CBD and the Common System are that they lack a meaningful enforcing party. While the propositions they stand for are admirable, it is unclear if any one is taking tangible steps to implement them.

IV. Suggestions for a New International Framework

A. Amending TRIPS

Over the years there have been many calls to amend TRIPS. This is most likely due to TRIPS' status as the imminent treaty in international intellectual property, coupled with the fact that it actually has an enforcement mechanism in the WTO's dispute resolution system. However, amending TRIPS would be no small feat. Passing an amendment requires that two thirds of the member states most agree on the proposal.[134] In a highly political process that involves hundreds of parties, it can take years for countries to agree on any modifications.[135]

Furthermore, a common argument made against TRIPS, as well as with international treaties in general, is that the more

[132] *Id.*
[133] *Id.*
[134] *Id.* at 490.
[135] *Id.* at 490-91 (noting the years of negotiation it took before the WTO adopted its first and so far only amendment).

dominant countries, in addition to having more pull in negotiations, can bypass unfavorable agreements and enact their own bilateral and multilateral trade agreements.[136] If the power players do not agree with a provision, it will most likely not get passed.[137]

Still, that has not prevented certain parties from suggesting amendments to TRIPS. One approach such parties advocate is to amend TRIPS to promote CBD goals of benefit-sharing and informed consent.[138] Such an amendment would enact provisions similar to the Common System or the Bonn Guidelines, and would define patent requirements in a way that would limit patents based on the traditional knowledge of other countries.[139] A patent would have to disclose the origin of the resource, include evidence of prior informed consent from the resource's country, and include evidence of benefit-sharing.[140] Being able to enforce CBD goals through TRIPS is an attractive prospect,

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[136] *See id.* at 499-500 (accusing the US, EU and Japan of doing this very thing).

[137] Krishna Srinivas, *Traditional Knowledge and Intellectual Property Rights: A Note on Issues, Some Solutions and Some Suggestions*, 3 Asian J. WTO & Int'l Health L. & Pol'y 81, 83 (2008) (noting that when the US and EU both object to an amendment, its chances of passing are zero, despite protracted negotiations).

[138] Ho *supra* note 17, at 477.

[139] *See id.* (suggesting that not doing this makes TRIPS complicit in biopiracy).

[140] Ho *supra* note 17, at 488; *see also* Zewers *supra* note 4, at 167 (discussing the debate of a disclosure requirement).

and groups have already drafted a potential amendment, named article 29bis, that details disclosure, informed consent, and benefit-sharing provisions.[141]

Of course, the drawbacks to such a system have already been discussed, in that it is expensive to administer, making it a poor choice for countries with fewer resources. It places a burden on both the patent applicant and already burdened patent offices. It is often not clear from a patent application whether the invention uses genetic resources.[142] A patent examiner may not know when he has to research the possibility of third country genetic resources in a patent application, and may waste time researching issues in a patent application that may or may not be relevant.[143] A partial implementation might be more feasible; for example, many countries already have disclosure of origin requirements.[144]

Another proposed solution would be for TRIPS to make patents void based on moral grounds. This is already an option under TRIPS, although some would call to make it compulsory. Doing so would present several challenges. For one, morality is a subjective concept that may differ between cultures. Determining what is moral can be an ambiguous question with

[141] Srinivas *supra* note 137, at 81.
[142] *Id.*
[143] Ho *supra* note 17, at 489.
[144] Srinivas *supra* note 137, at 81.

several answers; an international treaty is no place in which to regulate the nuances of morality. And even if morality were not a controversial matter, patent examiners are not trained or qualified to make assessments of ethical grounds.[145] Other fields of law may be better at policing the morality of products placed into commercial stream than patent law.[146]

At least one scholar has also argued for the expansion geographic indicators, which are used to identity the geographic origin of a good. Under TRIPS Article 22, member countries are prohibited from registering a good that misrepresents its geographic origin.[147] Geographic indicators under TRIPS, however, are largely confined to wine and spirits.[148] It has been suggested that geographic indicators could also be used to disclose the origin of genetic products.[149] This would be similar in effect to requiring a disclosure of origin in a patent application, as discussed already, and as such has the same advantages and disadvantages. Furthermore, as the use of geographic indicators has more to do with preventing misrepresentation to the consumer, they may not function as a useful tool for preventing biopiracy.

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[145] Ho *supra* note 17, at 533.
[146] *Id.* at 526.
[147] *Id.*
[148] Venbrux *supra* note 5, at 5.
[149] Chen *supra* note 25, at 29.

One last solution in terms of amending TRIPS is to clarify the requirements of novelty, non-obviousness, and utility. Namely, TRIPS can require that countries consider foreign prior art in granting patent applications. In an increasingly global world, the United State's policy of limiting prior art to domestic knowledge makes little sense.[150] With the advent of the internet and increasingly sophisticated methods of communication, common knowledge in foreign countries is exponentially more accessible now then when the United States first drafted patent laws on novelty. Such an amendment, though a small change, would go a long way in protecting traditional knowledge of other cultures.

Similarly, an amendment could require that an inventor actually use or practice the patented invention.[151] This is already a requisite under European patent law, but not under United States law.[152] It would prevent the scenario where a group holds onto a patent for personal reasons, such as an opposition to prenatal testing for breast cancer, to the potential detriment of society.

One important factor to remember while discussing

[150] *See id.* at 29 (noting that the European Union considers evidence of foreign public use), Ho *supra* note 17, at 478 (suggesting that foreign knowledge, both oral and written, should be considered as prior art).
[151] Westhoff *supra* note 69, at 10.
[152] Andrews & Paradise *supra* note 8, at 409.

modifications to TRIPS and other treaties is that the aim of intellectual property regulation is to encourage invention, not to regulate a third country's resources, whether that resource is genetic material or knowledge.[153] Implementing methods and training employees to deal with this issue would increase costs, which would then impact both the inventors and the consumers of their final products.[154] And ultimately, it is up to the country's government to exercise its sovereign rights and protect its biological resources and indigenous populations from exploitation.[155] For these reasons, perhaps better solutions would be found in other methods.

B. Databases

Some communities have started to document and create registries containing plant and animal species in the area and how they are used in indigenous knowledge.[156] India has started a database of its traditional knowledge, perhaps in response to the neem contreversy, and China has begun an electronic library of traditional Chinese medicines.[157] Such an approach is advocated by both developed and developing countries.[158]

[153] *See* Ho *supra* note 17, at 479 (quoting the European Union in stating this very proposition).
[154] *Id.* at 480.
[155] Sarma *supra* note 3, at 117-18.
[156] *See id.* at 128 (noting that some argue that such registries could hamper research into the compounds).
[157] Srinivas *supra* note 137, at 81.
[158] *See* Ho *supra* note 17, at 480 (noting that developing countries

Inasmuch as the databases exist and include the knowledge in question, it would prevent scenarios such as the neem-oil based insecticide obtaining a patent in the United States. As the reader may recall, the United States looks to foreign prior art only if it is published, and inclusion into an electronic database may meet such a requirement.

A difficulty with databases is that many countries do not have the expertise or resources to implement them.[159] Furthermore, such databases may not be readily accessible to other countries, due to logistic or linguistic reasons.[160] And while databases may go some ways in protecting knowledge, they don't necessarily protect the genetic resource itself. For instance, if a multinational discovers a use for a resource that is not cataloged in a database, even if the resource itself is, that use may still be patentable. For these reasons, databases provide only a partial solution to bipiracy.

C. Material Transfer Agreements

Another solution that does not involve international treaties is the use of material transfer agreements (MTAs). MTAs are private agreements between host countries that are willing to provide genetic resources or indigenous knowledge and the

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do not consider this a complete solution).

[159] Srinivas *supra* note 137, at 81.

[160] *Id.*

foreign entity who wishes to buy such assets. It is a contract where biotechnology and biological material are shared for mutual benefit.[161]

One of the more famous examples of an MTA arose between Merck Pharmaceuticals, a multinational corporation, and Costa Rica's Institution Nacional de Biodiversidad (InBio), a non-profit group with authority over Costa Rica's national parks.[162] InBio provided samples of genetic material, while Merck provided an upfront fee of $1,135,000 along with the promise of royalty payments if it were ever to produce a commercially successful product from InBio's resources.[163]

There are, of course, several problems with MTAs. One is their private, and thus voluntary, nature. Few corporations have offered to enter into MTAs, although that may change over time. Furthermore, many developing countries do not have a counterpart to InBio that oversees its natural resources.[164] Even if a corporation did want to enter into an MTA, it might not have a clear party to engage with. And while an MTA such as InBio may benefit the government of a country, it may not adequately compensate indigenous populations for traditional

[161] Hunter *supra* note 1, at 164.
[162] Venbrux *supra* note 5, at 5, Frisvold *supra* note 18, at 550; see also Hunter *supra* note 1, at 159-160 for a more detailed account of what was agreed.
[163] Venbrux *supra* note 5, at 5.
[164] *Id.*

knowledge.[165]

An example of an MTA that did attempt to compensate indigenous populations occurred between Shaman Pharmaceuticals and certain tribes of Peru. Shaman promised to pay royalties to indigenous communities that assisted in identifying and retrieving the genetic sources used in developing new pharmaceuticals.[166]

Conclusion

Biopiracy is a real concern in current times. The depletion of another country's resources and knowledge for the profit of multinational corporations is decidedly unjust, yet it is a practice that is aided by the WTO, TRIPS, and the current international framework for intellectual property regulation. It is important that steps be taken to mitigate the effects of biopiracy. The use of databases and MTAs is a start, but even both of those combined is only a partial solution to the problem. TRIPS must eventually evolve to take biopiracy concerns into consideration, but may do so in small steps; instead of amendments that would be costly and difficult to implement, TRIPS can impose small but effective requirements, such as disclosure of origin and the consideration of foreign

[165] Venbrux *supra* note 5, at 5.

[166] *Id.* Royalties were subject, of course, to a pharmaceutical actually being developed, the likelihood of which is estimated at 1 in 10,000. *Id.*

prior art in novelty analyses. These small steps, combined with the use of databases and MTAs, would go a long way in overcoming the negative effects of biopiracy.