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Genetic Source Disclosure in the United States

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REQUIRING GENETIC SOURCE DISCLOSURE IN THE UNITED STATES

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Abstract

Bioprospecting and biopiracy are an increasing problem, particularly for developing nations. Large companies, usually from developed nations, gather biological samples to use in research, and often patent the results without sharing profits with the nations from which the biological samples were taken. The Convention on Biological Diversity (CBD) attempted to address these issues by stating that natural resources belong to the source nations, and entities wishing to use those resources should obtain prior informed consent before using them. The CBD, however, lacks an enforcement mechanism. Other nations and organizations have proposed amendments to Agreement on Trade-Related Aspects of Intellectual Property Rights and the Patent Cooperation Treaty to bring these laws more in line with the spirit of the CBD, but there has been little progress made on these proposals. This article provides a proposed genetic source and prior informed consent disclosure that the U.S. can implement that will not significantly upset the current patent regime, bring the U.S. into closer harmony with the CBD, and make the U.S. a model for other nations to implement similar legislation.

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According to professor Laymert Garcia, "biopiracy has two degrees." First, biopirates take advantage of a lack of regulation and patent biological substances, without either referencing the local culture or community from which the substance originated or compensating the local culture or community for its contributions. Second, biopirates get a patent for something indigenous populations are already freely using. Even though patents have legal value only in the country in which the patent was granted, usually most of the world ends up recognizing the patent rights. In other words, biological researchers take natural resources from underdeveloped countries without permission and without compensating the nation for their contribution to scientific advancement. Further, those resources often result in patents, effectively stopping that source country from utilizing its own natural resources and technological advances to its advantage.

To combat biopiracy--the smuggling of genetic resources into the hands of corporations from developed nations who then claim ownership of these resources--and regulate bioprospecting--the search for beneficial biological resources throughout the world by sampling--many nations


2 Id.

3 Id.

4 Id.
have implemented legislation requiring researchers to obtain prior informed consent (PIC) from the source nation and local authorities before commencing any research or sampling.5 Usually included in the PIC agreement is some provision regarding sharing profits or other benefits obtained from the research undertaken.6 The Convention on Biological Diversity (CBD) furthered the individual nations’ efforts by requiring all parties to the agreement obtain PIC.7

The United States in not a member of the CBD and, therefore, is not required to obtain PIC before commencing research on biological resources from another nation.8 Further, the United States has no provision requiring those applying for patents to disclose the source of any biological materials used in deriving the invention.9 In essence, companies in the United States can engage in biopiracy, patent any invention or discovery resulting from the research on stolen biological resources and innovations, and prohibit other nations from utilizing their own resources.10

To date, many scholars have analyzed the provisions of the CBD, and even reconciled the seeming inconsistencies between the CBD, to which the U.S. is not a party, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), to which the U.S. is a

5 See infra II.A. Biopiracy and bioprospecting are often used interchangeably to refer to the same acts. Bioprospecting is considered a more “politically correct” term, and is often used when large companies who engage in biopiracy try to put a positive spin on their actions. However, bioprospecting can also refer to the hunt for new genetic resources and natural compounds that are not currently being used by indigenous cultures.

6 Id.

7 Id.

8 Id. For a list of CBD signatories, see http://www.bdx.net/sd/biodiversity/2001/sdnpweb/sdi/international_day/biodiversity/2001/SIGNATORIES%20OF%20THE%20CBD.htm.

9 See infra II.B.

10 See infra III.A.
party.\textsuperscript{11} There has also been much discussion on whether or not the U.S. can or should ratify the CBD. On the one side, some argue that the U.S., as a powerful leader nation, should ratify the CBD because it has an obligation to act in a responsible and respectful manner toward other nations and set an example for other countries to do the same. On the other side, it is argued that complying with the CBD would not only require significant changes to the patent system, but also disregard the competitive market advantages the current regime bestows upon the inventors who put time and money into research and development. There is little discussion, however, of the possibility of bringing U.S. policy more in line with the spirit of CBD without overhauling the entire patent system. This Article will fill the gap by proposing a genetic source/PIC disclosure requirement that is easily workable into the United States’ current patent regime.

Part I of this Article will consider the harms of biopiracy and bioprospecting on local peoples, including both economic and ecological harm. Part II of this Article will introduce the concept of PIC, briefly covering its evolution from the medical realm to the international level, and consider the CBD’s PIC requirement. Part II will also look at the state of American patent laws as they pertain to genetic source disclosures. Finally, Part III will propose a model disclosure provision complementary to the current U.S. patent regime that will bring the U.S. closer to complying with the disclosure requirements of the CBD.

I. THE PROBLEM: BIOPROSPECTING/BIOPIRACY DRAINS GENETICALLY RICH NATIONS OF VALUABLE RESOURCES AND ECONOMIC POTENTIAL

Bioprospecting and biopiracy have been a plague on developing nations for decades. The tropics and other biologically diverse areas are goldmines of potential economic gain.\textsuperscript{12} That potential makes

\textsuperscript{11} See generally, \url{http://www.wto.org/english/theWTO_e/countries_e/usa_e.htm} (showing WTO agreements and other treaties the U.S. is part of).

\textsuperscript{12} Norman Myers, \textit{What's Biodiversity Worth?}, available at \url{http://www.populationpress.org/publication/2002-12-myers.html}. 
genetically-rich nations especially alluring to biopirates and bioprospectors looking for a quick penny. This section will first look at the problem of biopiracy and bioprospecting by reviewing a few case studies. It will then review in more detail the most significant harms (and limited benefits) to not only developing countries, but also the world as a whole, caused by biopiracy and bioprospecting.

A. A Couple of Tales: Prospectors and Pirates

In the 1950s, the pharmaceutical company Eli Lilly & Company isolated vinca alkaloids from the rosy periwinkle plant. These compounds led researchers to develop vincristine, an anti-cancer agent used to battle childhood leukemia, and vinblastine, used to fight Hodgkin's Disease. Originally, Eli Lilly relied on various developing countries for its supply of rosy periwinkle, but eventually dealt exclusively with Madagascar, where rosy periwinkle was cultivated on large plantations run by the French. It takes about 15 tons of rosy periwinkle leaves to make only one ounce of vincristine or vinblastine, so the French had lots of business. Using the Madagascar-grown rosy periwinkle, Eli Lilly made over $100 million annually from the sale of vincristine and vinblastine, and continues to make large profits.

13 History, Eli Lilly and Company, available at http://www.lilly.com/about/history/
Madagascar, however, saw no significant money. Eventually the Madagascar people living near the plantations got tired of seeing the rosy periwinkle, a valuable commodity, being stripped from the nation with nothing to show in return. They overthrew the French and took control of the supply themselves, thus somewhat rectifying the social injustice.

Similarly, in the 1980s, the United States Department of Agriculture sent bioprospectors to Australia to collect samples of smokebush. Smokebush contained a compound that, once isolated, is used to make concurvone, a drug that appears to stop HIV replication in vitro. Once aware that the U.S. was taking smokebush plants out of Australia, the Australian government halted all export of the plant and charged the Western Australia Department of Conservation and Land Management (CALM) to investigate smokebush collecting activities and biopirating rings. Although concerned with missing out on profits, the Australian government was also concerned with conserving the plant species and

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18 Christopher Hunter, Comment: Sustainable Bioprospecting: Using Private Contracts and International Legal Principles and Policies to Conserve Raw Medicinal Materials, 25 B.C. ENVTL. AFF. L. REV. 129, 130 (1997). The amount of profit Eli Lilly made from vincristine and vinblastine was way in excess of what the people of Madagascar saw for their work and contribution to the development of these drugs.

19 Hunter, supra note 15.

20 Id.


making sure it was not harvested to extinction. In an effort to conserve Australia's natural resources, the National Cancer Institute, the U.S. laboratory researching smokebush and the resulting drug concurvone, entered into an agreement with Australia in which NCI guarantees a share of resulting concurvone profits to all local communities with which NCI works in collecting smokebush.

Despite its vast harms, biopiracy does, in some instances, prove valuable to both the source nation, and human society as a whole. Consider the story of the neem tree. Natives in India had been using the berries from the neem tree for thousands of years as an insecticide, fungicide and contraceptive. In 1985, however, an American timber importer obtained a patent on a new method to extract the potent compounds from the neem berry, and sold that patent to chemical and materials giant W.R. Grace a few years later.

While a clear cut example of biopiracy, India, in actuality, received many benefits. The natives’ method of extracting the compounds from the neem berry, though effective, was not very efficient. The new method created a highly purified pesticide, oil, and

24 Hunter, supra note 15 at 140. The investigation actually uncovered a smuggling operation and apprehended a collector, or biopirate, sent by the laboratory processing the smokebush trying to take samples of the plant out of Australia in 1992.


27 Id. at 21.

28 Id.
fertilizer. The shelf life of the neem berry products was also increased from weeks to years. Further, the patent obtained in this case was on an extraction method, and not on the product itself, so natives would still be able to utilize their local resource and sell the traditional neem products – just as long as they stuck to the traditional, less efficient means of production.

The case of the neem tree, however, is rare. Locals are often prohibited from utilizing their resources, and the large, patent-holding companies come in with teams preaching jobs for locals who will help the global community by taking part in the creation of the next wonder-drug. Some also claim that such developing nations benefit economically through increased exports as a result of increased demand for whatever the biological source may be in the given situation.

Plants are not the only biological sources developed nations use in research and discovery. Indigenous peoples themselves also provide valuable resources. As a prime example, in 1983, bioprospectors searching remote jungles of Melanesia came across the Hagahai tribe. The Hagahai tribe consisted of about 300 people. After over five years

29 Id.
30 Id.
31 Id.
34 Hunter, supra note 15 at 139.
35 Hunter, supra note 15 at 130.
of research on the Hagahai tribe, the researchers isolated a cell line from the blood of 24 Hagahai tribe members that they thought might be valuable in the diagnosis and treatment of leukemia.\textsuperscript{36} The U.S. researchers were quick to patent the “discovery” and begin profiting while the tribe received nothing.\textsuperscript{37}

Some may argue that the tribe could benefit, should a member of the tribe ever be diagnosed with leukemia. The chance of that the chance of receiving benefits, however, would be low. Not many natives in developing countries have the means to receive medical care; rarer still would be the means to obtain expensive testing and/or treatment for many diseases. For example, during the avian influenza (bird flu) outbreak in the early 2000s, many scientists and researchers obtained virus samples from Indonesia and Thailand – two countries on the front line of the growing pandemic.\textsuperscript{38} Those samples were then sold to other researchers without permission.\textsuperscript{39} All the research was not in vain, however, and vaccines to fight the avian influenza were quickly developed, though Thailand and Indonesia saw little of that vaccine. Even Thai Health Minister Mongkol Na Songkhla did not receive a vaccination.\textsuperscript{40} Why? In his words: “It’s too expensive for me.”\textsuperscript{41}

\begin{flushright}
\textsuperscript{36} Olivier Cassar, et al., \textit{Human T-Cell Leukemia Virus Type 1 Molecular Variants, Vanuatu, Melanesia}, 11 EMERGING INFECTIOUS DISEASES 5 (2005).


\textsuperscript{39} Id.

\textsuperscript{40} Id.

\textsuperscript{41} Id.
\end{flushright}
With potentially beneficial species dying off at an alarming rate,\(^42\) and improvements in technology allowing biological samples to be accurately and rapidly analyzed for beneficial chemical compounds, the biopiracy and bioprospecting businesses have become quite lucrative.\(^43\) In 2002, it was estimated that the annual market value of biological research specimens in the United States was, conservatively, between $30 and $60 million.\(^44\) In 2000, the estimated cost of research and development for a new drug, prior to getting FDA approval, was over $800 million.\(^45\) Given the investments pharmaceutical companies make, the researchers’ willingness to recruit bioprospectors and biopirates to sneak samples out of biodiverse countries becomes more understandable.\(^46\)

**B. The Consequences: Poor, Naked and Angry**

Situations such as these are playing out in many nations throughout the world, with the greatest amount of bioprospecting and


\(^44\) Id.


\(^46\) RAFI COMMUNIQUE RURAL ADVANCEMENT, *supra* note 43. For example, Monsanto, Inc., asked employees traveling to exotic places to pick up samples along the way. See also Harriet Upton, *Origin of Drugs In Current Use: The Cyclosporin Story*, 2001, available at http://www.world-of-fungi.org/ Mostly_Medical/Harriet_Upton/Harriet_Upton.htm. (Swiss pharmaceutical company Sandoz, Ltd. would give employees on vacations or business trips baggies to collect soil samples for analysis. Interesting to note, the fungus *Tolypocladium inflatum*, used to make the immunosuppressive cyclosporin, was isolated from two samples Sandoz employees obtained – one from Norway and one from Wisconsin.)
biopiracy being done in developing nations—especially countries near the equator, which are rich in biodiversity with naturally varying landscapes.\textsuperscript{47} Costa Rica, for example, though covering only .03% of the Earth's surface, is home to almost 5% of the world's species.\textsuperscript{48} With an estimated species count of 500,000, Costa Rica is one of the top 20 countries with the greatest biodiversity in the world.\textsuperscript{49} Indonesia, straddling two distinct biogeographic regions, is also an extremely biodiverse nation.\textsuperscript{50} Conservation International considers Indonesia to be one of seventeen “megadiversity” countries, with two of twenty-five of the world’s “hotspots.”\textsuperscript{51} Indonesia also houses over 10% of the world's species of flowering plants.\textsuperscript{52} These two countries, and countries in similar situations, may not be strong economic or international powers, but they are the richest nations in terms of indigenous knowledge and biodiversity.

Because developing countries, like Costa Rica and Indonesia, do not have the economic resources to fully utilize their own biodiversity, they are at the mercy of developed countries, who exploit the natural

\begin{itemize}
\item \textsuperscript{47} Hunter, supra note 15, at 130.
\item \textsuperscript{48} Instituto Nacional de Biodiversidad, \textit{Biodiversity in Costa Rica}, 2009, available at \url{http://www.inbio.ac.cr/en/biod/bio_biodiver.htm}.
\item \textsuperscript{49} \textit{Id.}
\item \textsuperscript{51} Conservation International, \textit{Sundaland}, available at \url{http://www.conservation.org/explore/priority_areas/hotspots/asia-pacific/Sundaland/Pages/default.aspx}. See also, Conservation International, \textit{Hotspots Defined}, available at \url{http://www.conservation.org/explore/priority_areas/hotspots/Pages/hotspots_defined.aspx}, describing a “hotspot” as an area with greater than .05% of the world's species of vascular plants and has to have lost more than 70% of its original habitat.
\item \textsuperscript{52} Hunter, supra note 15.
\end{itemize}
resources to their own benefit. Biopiracy results in no profits for the developing nation, but even in cases where an agreement or negotiated compensation is reached, the profits to a company of using the biological resource far outweigh any benefit bestowed on the developing country. In 1991, for example, Merck & Co. entered into an agreement with the Instituto Nacional de Bioversidad (INBio) of Costa Rica in which Merck agreed to pay INBio approximately $1 million in exchange for extracts and samplings from plants and insects.\footnote{UN Department of Economic and Social Affairs, Division for Sustainable Development, CSD-6 Follow-up: Multi-Stakeholder Review of Voluntary Initiatives and Agreements for Industry, available at http://www.un.org/esa/sustdev/mgroups/viaprofiles_Merck_INBio_Agreemen.html.} Merck's profits for that year were approximately $8.6 billion.\footnote{RAFI COMMUNIQUE RURAL ADVANCEMENT, supra note 43.}

Not only are the victims of bioprospecting and biopiracy not compensated, but many times compounds or derivatives isolated from the developing nation's resources are patented in developed countries, such as the U.S.\footnote{Mark A. Urbanski, \textit{Note: Chemical Prospecting, Biodiversity Conservation, and the Importance of International Protection of Intellectual Property Rights in Biological Materials}, 2 \textit{BUFF. JOUR. INT'L L.} 131, 135 (1995).} This essentially and effectively inhibits the developing country from using its own resources in a productive and innovative fashion. In his article “Biopiracy or Bioprivateering?” Richard Stallman identifies three ways in which patent monopolies on the biodiverse resources harm the developing source nations: (1) the patent holder raises the price so high that citizens in the developing county do not have the economic means to access the resource, (2) the patent holder can enforce its patent rights at any time, blocking local production of the resource, and (3) if the resource is an agricultural variety, the patent holder can halt breeding of the particular variety.\footnote{Richard Stallman, \textit{Biopiracy or Bioprivateering?}, available at http://www.stallman.org/articles/biopiracy.html.}
The first and second forms of monopoly listed above are, for the most part, self-explanatory. The patent holder is acting as a patent holder and controlling his or her product. The third sort of monopoly power listed above, the patent holder’s ability to halt breeding of a particular agricultural variety, may need some explanation. Growers may work years to develop a plant with any variety of wanted attributes. For example, if a grower notices a particular need for a bean plant that is unappetizing to caterpillars, survives in dry climates, and whose beans have a higher-than-usual protein content, the grower can work at breeding a plant that fits those specifications. In exchange for the plant’s development, that grower may then obtain a plant patent on that specific plant, provided the qualifications of 35 U.S.C. § 161, and the rest of the Patent Act, are met.\(^57\) Should another grower develop the same plant, the plant patent holder may enforce his or her patent, and stop others from growing the patented plant variety. While, on a positive note, the patent holder is compensated for the time and money invested in developing a very marketable (and profitable) plant variety, there are instances when society, as a whole, may benefit from the specific plant but is, in essence, blocked from breeding that particular variety.

Blocking local access to genetic resources is a particular problem with the AIDS pandemic in many developing countries.\(^58\) In the 1970s, for example, scientists isolated mycobacterium from Uganda. The mycobacterium displayed autoimmunosuppressant properties and was subsequently patented as a treatment for HIV/AIDS.\(^59\)

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\(^{57}\) 35 U.S.C. § 161 states “[w]hoever invents or discovers and asexually reproduces any distinct new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor…”


\(^{59}\) U.S. Patent No. 6,210,684 (filed May 16, 1995).
treatments cost around $25,200 a year for the lifesaving cocktails, while the average individual in Africa spends only around $10 a year for all medical treatment, including treatment for TB and malaria. Even if developing countries had the technology to begin utilizing their own natural resources to develop HIV/AIDS treatments for themselves, the patent owners would enforce their monopoly rights and prevent any such drug research and development from taking place. Without getting any compensation for the resources being taken out of the country for research and development, and having to buy back any of the patented results of that research, developing countries will continue to lose valuable resources and lucrative exports.

In addition to the economic loss countries face as a result of biopiracy, over-harvesting and over-sampling of promising resources has resulted in near extinction for some. Brazil recently created a list of endangered medicinal plants in a large conservation effort. One particular plant on the list, the jaborandi tree, was nearly cultivated to extinction after pilocarpine, an alkaloid used to treat glaucoma, was isolated from its leaves. Similarly, Espinheira Santa, a small shrub

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62 To combat this problem, various health organizations have partnered with drug companies and developed plans allowing developing countries to get very needed medicine for a rational cost. See, for example, Joint United Nations Program on HIV/AIDS ([www.unaids.org](http://www.unaids.org)), President's Emergency Plan for AIDS Relief ([http://www.pepfar.gov/](http://www.pepfar.gov/)), and AIDS Healthcare Foundation ([www.aidshealth.org](http://www.aidshealth.org)).


64 Hunter, *supra* note 15 at 141.
from Brazil, was nearly eradicated when pharmaceutical companies discovered its antacid and antiulcerogenic effects.\textsuperscript{65}

Biopiracy and the ecological problems it creates contribute to the more overwhelming problem of declining biodiversity on a worldwide level. The Earth has experienced five major extinctions since its creation, the most recent including the extinction of the dinosaurs,\textsuperscript{66} and scientists believe the Earth is now experiencing a sixth, human-induced massive extinction.\textsuperscript{67} Scientists estimate that over 50\% of the world's species will disappear within the century, and humans, in various capacities, are responsible for that horrific figure.\textsuperscript{68}

Compounding biopiracy’s over-harvesting effects is the fact that tropical rainforests, home to most of the world’s biodiverse populations, are being destroyed by locals for wood, hunting and cash crops.\textsuperscript{69} In fact, it is estimated that as much as 90\% of current tropical deforestation is to accommodate the farming of cash crops, such as oils (like palm oil), coffee and sugar.\textsuperscript{70} These crops are then sold on the international market to generate income for the developing nations.\textsuperscript{71} Some argue that this destruction of rainforests actually reflects an under-exploitation of the


\textsuperscript{70} Id.

\textsuperscript{71} Id.
forests’ resources, and, in that sense, biopiracy and bioprospecting should actually serve to create value in the rainforests, thus protecting them from rapid deforestation. However, because the funds from pharmaceuticals and other results of biopiracy “revert in only small measure to developing countries,” it is unlikely they will discontinue harvesting their local rainforests and growing cash crops for international markets. Further, what small incentives developing nations receive in exchange for industrialized nations prospecting in their biodiversity is not enough for the large conservation (and, in many cases, restoration) efforts needed. Without greater profit sharing between developing nations and the large companies that exploit their resources, deforestation will continue and no one will profit (financially, ecologically or medicinally) from the rainforests’ natural biodiversity.

II. THE SOLUTION: PRIOR INFORMED CONSENT AND DISCLOSURE OF SUCH CONSENT ON PATENT APPLICATIONS

In response to the increased bioprospecting and biopiracy, each developing nation seeks a way to manage access to its genetic resources, plant-based or otherwise. One solution that has emerged is the concept of prior informed consent and genetic source disclosure on patent applications. This section will briefly introduce the concept of prior informed consent (PIC) as it developed first in the medical field and evolved into the governmental regulation arena. It will then look briefly at the Convention on Biological Diversity (CBD) and its PIC/source disclosure requirements and conclude in discussing situations under which U.S. patent applicants may be required to disclose their biological sources or any PIC agreements.


74 Id.
A. The Evolution of Prior Informed Consent

Prior informed consent, as it is known today, originated in response to the Nuremberg Trials in the 1940s.\textsuperscript{75} Karl Brandt, the WWII senior medical official of Nazi Germany, was tried and convicted for various medical crimes against prisoners of war and against humanity.\textsuperscript{76} In particular, Brandt was charged with over twelve accounts of medical experimentation, including testing the effects of treatments for “high altitude conditions, freezing, malaria, poison gas, sulfanilamide, bone, muscle, and nerve regeneration, bone transplantation, saltwater consumption, epidemic jaundice, sterilization, typhus, poisons, and incendiary bombs.”\textsuperscript{77} These charges were in addition to those relating to the killing of Jews for anatomical research and euthanizing ill and/or disabled civilians in Nazi-occupied areas.\textsuperscript{78}

The Nuremberg Code, outlining necessary procedures and ethical requirements for research involving human subjects, was developed in response to Brandt’s actions and the outrage society experienced.\textsuperscript{79} In summary, the Nuremberg Code contains two basic and distinct elements for informed consent: (1) the patient must give voluntary consent, free from “force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion,” and (2) the experimenter must disclose the “nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards

\textsuperscript{75} Deborah Mascalzoni, Andrew Hicks, Peter Pramstaller, Matthias Wjst, Informed Consent in the Genomics Era, PLOS MEDICINE, September 2008, Volume 5, Issue 9, pgs 1302-1305.


\textsuperscript{77} Id.

\textsuperscript{78} Id.

\textsuperscript{79} Mascalzoni, supra note 75.
reasonably to be expected; and the effects upon [the patient’s] health or person” as a result of participating in the experiment. In this regard, the Nuremberg Code, and its requirement of prior informed consent, was not intended to completely prevent researchers from exploiting humans in their studies, but more so intended to make sure that any exploitation was moral, ethical and legal.

The concept of informed consent soon made its way from human experimentation to medical treatments in general. Prior to this transition, doctors were considered to have a therapeutic privilege, allowing doctors to withhold information from patients when the doctor believed it was in the patient’s best interest. Injured patients and the families/survivors tried contesting that immunity, but prior to the concept of informed consent, were forced to bring actions under the tort of battery. Salgo v. Stanford University was the first case to actually articulate the concept of informed consent in a malpractice context. While the court still found the therapeutic privilege applied, the case is considered a turning point by many because of the argument that “in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent.” The case law following Salgo continued to place patients’ rights before a doctor’s therapeutic privilege, with some victories, but it was not until 1972 that

85 Id.
the concept of informed consent was fully accepted and looked at from a patient’s perspective rather than a doctor’s.86

Today, there are many rules, regulations and guidelines that physicians must adhere to when obtaining informed consent. Before treating a patient, particularly if the treatment involves surgery, invasive procedures or new or experimental medicines, doctors are required to obtain the patient’s informed consent. The American Medical Association lists six topics of conversation a patient and doctor must have before a patient is able to give informed consent: (1) the diagnosis, (2) nature and purpose of proposed procedure, (3) risks and benefits of proposed procedure, (4) any and all alternatives, (5) risks and benefits of alternatives, and (6) risks and benefits of not receiving the proposed procedure.87 This list closely mirrors the guidelines in the Nuremberg Code.

The concept of prior informed consent then quickly made its way into state sovereignty rights and relations between the states.88 States began using prior informed consent to control the movement of hazardous materials and waste into and out of the state.89 The Commission for Environmental Cooperation is an organization currently coordinating hazardous waste movement across the entirety of North American.90 The commission recognized that the transport of hazardous

86 Oliver, supra note 82 at 1182-1183.
89 Id.
waste within the United States, Canada and Mexico was based on the concept of prior informed consent (PIC), and laid out basic ground rules for transport between the countries. PIC, it stated, “is achieved through a government-to-government export notice and consent process.”

Within the past two decades, prior informed consent has expanded from states and local territories to the national and international level in various contexts. Even more recently, discussions over prior informed consent have centered largely around access to genetic resources, particularly when these resources are used at the expense of one nation to benefit and enrich another.

**B. The Convention on Biological Diversity – A Model**

In 1992, the Convention on Biological Diversity concluded in Rio De Janeiro, resulting in the Convention on Biological Diversity (CBD) document, registered with the United Nations Treaty Series in December, 1993. In the preamble, the CBD recognizes that conserving biological diversity is important on an international level, and

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92 Id. Like a doctor’s discussion with a patient, the export notice must contain certain information before the nation receiving it can make an informed decision. The export notice must contain: (1) the time period covered by the notice, (2) type and amount of waste, (3) number of shipments, (4) type of container, (5) recipient name and address, and (6) method of transportation.

93 IUCN Project, supra note 88 at 2. Local, national and international communities are looking to prior informed consent to regulate activities such as “logging, mining, resettlement, dam building and access to genetic resources.”

94 Id.

humankind has a common responsibility for conserving that diversity.\textsuperscript{96} This duty gives rise to the CBD’s three main objectives: (1) “conservation of biological diversity,” (2) “sustainable use of its components,” and (3) “fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including appropriate access to genetic resources.”\textsuperscript{97}

In furthering these objectives, the CBD included Article 15 regarding access to genetic materials. Section 5 of Article 15 requires that “access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.”\textsuperscript{98} The CBD, however, does not indicate what constitutes PIC. Rather, that decision is left to the individual member countries, whose policies regarding PIC can vary in the details, but overall contain the same basic elements.

The Phillipines' Indigenous People's Rights Act of 1997, for example, states that access to genetic and biological resources will only be granted with free and prior informed consent of the relevant communities as is customary with the relevant laws.\textsuperscript{99} “Free and prior consent” is defined as permission granted after full disclosure of the “intent and scope of the activity, in a language and process understandable to the community.”\textsuperscript{100} Similarly, Costa Rica's Biodiversity Law of 1998 requires that local communities grant prior informed consent, and that consent must be approved by the Technical Office, before any bioprospecting or related activities occurs.\textsuperscript{101} An application for PIC must contain: (1) name and complete identification

\textsuperscript{96} Id. at Preamble.
\textsuperscript{97} Id. at Article I. Objectives.
\textsuperscript{98} Id. at Article 15, Section 5.
\textsuperscript{100} Id. at Chapter II, § 3(g).
\textsuperscript{101} Biodiversity Law, Chapter 5, Section I, Article 63 (1998). (Costa Rica)
of the interested manager or, if not the same as the interested party, the name and complete identification of the official and the power (s)he possesses, (2) name and complete identification of the responsible professional/researcher, (3) exact location and identification of items subject to research and an indication of ownership or possessor of the property, (4) chronogram of the scope of research and possible environmental impacts, (5) purpose/objective of research, (6) written declaration that above statements have been made under oath, and (7) place for notifications.  

As part of the access arrangement, however, access applicants must enter into a benefit-sharing agreement and identify conservation methods that will be taken to preserve the species being researched and limit disruptions to the ecosystem.

It is not just developing nations that are taking part in the CBD. The United Kingdom, for example, has been a leading force in nation-state compliance with the CBD and role model for other developed nations. In 1994, in response to the CBD and its obligations as a signatory party, the UK developed *Biodiversity: the UK Action Plan*. The Plan describes, in great detail, the ecological problems the UK faces, putting it in a global context, and then continues to create a plan the UK can follow to fulfill its obligations under the CBD, both in its own country and worldwide. The Plan specifically lays out individual

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102 Biodiversity Law, Chapter 5, Section II, Article 72 (1998). (Costa Rica)


action plans for conservation within habitats, conservation outside natural habitats, promoting and developing sustainable use of resources, and supporting overseas biodiversity.\textsuperscript{107} Similarly, the European Communities, through a 1998 directive, encourages disclosing the geographical origin of genetic material in certain situations.\textsuperscript{108}

Many other nations, large and small, have enacted, or are proposing, similar legislation and directives, giving local communities the right to grant or deny access to the nation’s genetic and biological resources.\textsuperscript{109} The nations seem to be on further agreement in that each provision for prior informed consent includes at least the five w's: who, what, where, when and why of the research. All parties to the Convention, therefore, must, at a bare minimum, submit the five w's to the source country, and thus obtain prior informed consent before starting any research on or gathering of biological resources.\textsuperscript{110}

\textbf{C. Assessment of the CBD}

To many, the CBD appears to be a large step in the right direction. Some scholars, however, have pointed out flaws in the CBD’s functioning and implementation. First, while some proponents view the CBD as returning rights in local resources to the indigenous people, it actually puts the ownership of those resources in the hands of the nation-states.\textsuperscript{111} There have been attempts to rectify this perceived weakness,

\begin{itemize}
\item \textsuperscript{107} Id. at Section 2, Chapters 4-6, 8.
\item \textsuperscript{109} See the Organization of African Unity Model Legislation on Community Rights and on Access to Biological Resources (1998) and the Thai Traditional Medicinal Intelligence Act (1999).
\item \textsuperscript{110} For a list of parties and signatories to the CBD, see \url{http://www.cbd.int/convention/parties/list/}.
\item \textsuperscript{111} Rebecca M. Bratspies, \textit{Symposium: Lands, Liberties and Legacies: Indigenous Peoples and International Law: Theoretical Approaches to International Indigenous Rights: The New Discovery Doctrine: Some Thoughts on Property}
including the 2002 Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization. These Guidelines, however, are just that – guidelines. They are recommendations, not mandates. Despite the weakness that the CBD invests legal rights in the nation-states and not the indigenous people, the CBD is may still be considered beneficial to indigenous people. The vesting of rights to the nation-states can still be used to oppose Section 27.3(b) of TRIPs, which requires TRIPs member nations to recognize plant and genetic resource patent rights. CBD nation-states can point to the CBD and show that the genetic resources are “common property of the people of [the nation].” As property of the nation-state, genetic resources are treated similarly to oil and uranium, and nation-states can therefore protect genetic resources as other tangible resources.

Another danger of the CBD investing rights in local resources to the nation-states as a whole is the danger that the majority culture will not actually protect the interests of smaller, localized, minority cultures. The majority culture could be swayed by large investments, the spur of


Id. at 329. See also Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization, available at http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf, which states in Section C, paragraph 31that, in respecting the “legal rights of indigenous and local communities associated with the genetic resources being accessed..., the prior informed consent of indigenous and local communities...should be obtained.”


Id.

Bratspies, supra, note 111 at 329.

Id. at 330.
tourism, and other luring offers by developed nations seeking to exploit local resources and, in cases, commodify the minority cultures.\textsuperscript{117}

Another weakness critics of the CBD point out is the lack of a dispute resolution or enforcement mechanism.\textsuperscript{118} It is carried out through member-states enacting their own legislation, and there are few guidelines in place to make sure national legislation is enacted as required under the treaty. As a result, nation-states do not have a strong obligation to perform under the treaty, and nation-states attempting to enforce their rights under the treaty have little recourse.\textsuperscript{119} After considering the development of the CBD, summarized in the previous section, the appearance of this weakness should not be a surprise. The CBD was most concerned with preservation and equitable sharing of resources; there was little worry about implementation during drafting. The CBD is an idealistic document.

In response to the lack of enforcement and implementation under the CBD, members have started calling for action. In 2002, the World Summit on Sustainable Development reinforced a goal laid for the CBD.\textsuperscript{120} Through the CBD, and other environmental protection mechanisms, the world, as a whole, was to achieve a “significant reduction of the current rate of biodiversity loss as a contribution to poverty alleviation and to the benefit of all life on earth” by the year 2010.\textsuperscript{121} The goal year has just started, so it is yet to be seen how close

\textsuperscript{117} Id.


\textsuperscript{119} Id.

\textsuperscript{120} \textit{Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP7)}, Kuala Lumpur, Malaysia, 9-20 February 2004, IUCN, available at \url{http://cmsdata.iucn.org/downloads/2004_feb_cop7_follow_up_wssd.pdf}.

\textsuperscript{121} Id.
the world will come to reaching that goal, but annual monitoring of the progress of the CBD toward attaining that goal has reflected significant forward movement. The 2005 *Indicators for Assessing Progress Toward the 2010 Target: Coverage of Protected Areas* shows that the number of protected areas, worldwide, has been increasing.\(^\text{122}\) Further, since the implementation of the CBD, the total land coverage of protected sites has risen to about 12% of the Earth’s land surface.\(^\text{123}\) The report indicates that this increase reflects “one of the largest conscious changes of land use” seen to date.\(^\text{124}\)

As further evidence of the CBD’s positive impact, nations, including the U.S., have indicated frustration at developing nations’ unwillingness to share genetic material, and many scholars have expressed their fears of potential harms that sovereign ownership of genetic resources will cause society as a whole.\(^\text{125}\) Further, and as mentioned in the previous section, many member nations to the CBD have already implemented their own domestic laws regarding preserving natural resources and requiring prior informed consent before such resources are removed from the country.\(^\text{126}\) Several nations, again including the U.S., have also spoken up against the time and effort they must expend, and red tape they must cut, in order to even obtain minute genetic samples from CBD nations. While not a party, the U.S. and its companies must still interact

\(^{122}\) *Indicators for Assessing Progress Towrads the 2010 Target: Coverage of Protected Areas*, Note by the Executive Secretary, Subsidiary Body on Scientific, Technical and Technological Advice, 10\(^{th}\) Meeting, Bangkok, 7-11 February 2005, UNEP/CBD/SBSTTA/10/INF/12, 1, available at [http://www.cbd.int/doc/meetings/sbstta/sbstta-10/information/sbstta-10-inf-12-en.pdf](http://www.cbd.int/doc/meetings/sbstta/sbstta-10/information/sbstta-10-inf-12-en.pdf). There are currently more than 100,000 sites, and the total area of those sites totaled over 20 million squared kilometers as of 2004.

\(^{123}\) *Id.* at 2.

\(^{124}\) *Id.*


\(^{126}\) See, *infra*, Section II.B.
and cooperate with member-nations. The CBD has also had a large consciousness-raising effect on U.S. society, and companies may have to take that into consideration when developing new products. If it gets out that the company acted inequitably in obtaining resources or compensating source nations, consumers may react negatively.

D. The U.S.: Lack of a Model

At this point, the U.S. is not a party to the CBD, and therefore does not have to abide by its guidelines. Furthermore, U.S. patent law contains no independent requirement of disclosure of genetic resources or prior informed consent. Any source disclosure would arise only as a consequence of other statutory disclosure requirements. There are two main areas in U.S. patent law exist where such a situation could occur: first, to satisfy a section 112 requirement, and second, as part of a plant patent application.

1. Section 112 Disclosure

As part of the patent application process, applicants must complete a section called the specification. The specification is basically a written description of what the applicant is attempting to patent, including the best mode for making, utilizing or carrying out the invention. Section 112 of the Patent Act governs what disclosures must be made in the specification:

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

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In other words, should access to the genetic source be required to (1) enable another to make and/or use the invention, (2) disclose the best mode, or (3) meet the statutory written description requirement, then the genetic source must be disclosed.

The enablement requirement of Section 112 requires that the inventor provide sufficient information to enable someone to make and/or use the invention. The court in *In re Wands* considered a patent application enabling if a person having ordinary skill in the art (PHOSITA) could make and use the invention without undue experimentation. Similarly, the best mode requirement of Section 112 requires the inventor to provide the best way to make and use the invention known to the inventor at the time of filing – an enablement-plus requirement of sorts. If knowledge of the biological source or country of origin of any biological product used is necessary for meeting either of these requirements, that information must be disclosed in the patent application.

As for the written description requirement, the USPTO views the requirement as a timing mechanism. Anything claimed after the initial filing date not included in the original written description is not entitled
to the benefit of the earlier filing date. The written description also illustrates that the inventor was “in possession” of the invention at the time of filing. If the source of biological material is important to make sure future claims are not outside the realm of the written description, or to put the inventor in possession of the invention, the information should be disclosed.

2. Plant Patent Disclosures

Patents for plants are governed by two provisions. First, the Plant Patent Act grants patent rights for asexually reproducing plants. Second, the Plant Variety Protection Act provides sui generis protection for specific instances of sexually reproducing plants. Both provisions for plant patents require disclosure of genetic resources in some form.

While patents filed under the Plant Patent Act are not subject to the same 112 disclosure requirements as other inventions, the United States Patent and Trademark Office (USPTO) does offer some guidance as to what should be disclosed in the written description. As part of the background of the invention and description of relevant prior art, the USPTO recommends including the genealogy parent plant(s), or the supposed parent plant(s) should the actual parent plant(s) be unknown.

134 Id.
136 35 U.S.C. § 161 et seq. Section 161 states: “Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.”
137 7 U.S.C. § 2401 et seq.
138 35 U.S.C. § 162, stating “[n]o plant patent shall be declared invalid for noncompliance with section 112 of the title if the description is as complete as is reasonably possible.”
The genealogy of a plant is the genetic make-up of the plant, and would not necessarily reflect or indicate the plant’s nation of origin.

The particular information of the plant being patented is also required in the written description.\textsuperscript{140} The USPTO requires not only the physical attributes of the plant, but also the genus, species and genealogical information if known.\textsuperscript{141} Anything that sets the plant apart from the prior art should be disclosed.

Similarly, the Plant Variety Protection Act (PVPA) requires the disclosure of the genealogy when known.\textsuperscript{142} The PVPA goes a step further than the Plant Patent Act however, by requiring a sample of the seed to be deposited in the public repository.\textsuperscript{143}

Both the Plant Patent Act and PVPA require some sort of genetic disclosure of the plant for which patent protection is thought, and disclosure of the parent plant(s) genealogies, in the case of the Plant Patent Act, is recommended. Outside the realm of plant patents, disclosure of genetic resources or sources of biological materials is only required to the extent such a disclosure is pertinent to meet one of the Section 112 disclosure requirements of enablement, best mode, or written description.

\textbf{III. WORKING THE GENETIC SOURCE/PIC DISCLOSURE SOLUTION INTO U.S. LAW}

There has been little discussion to date regarding specifically how a genetic source disclosure can be worked into existing U.S. patent law. The issue of requiring genetic source/PIC disclosure is usually considered from an international perspective. Leading proposals for change to international law include amending TRIPs or the Patent Cooperation Treaty (PCT), or enacting the Mandatory Disclosure

\textsuperscript{140} \textit{Id.}
\textsuperscript{141} \textit{Id.}
\textsuperscript{142} 7 U.S.C. § 2422(2).
\textsuperscript{143} 7 U.S.C. § 2422(4).
Proposal by the European Union. The TRIPs proposal would require the source of an invention, proof of attainment of PIC, and a fair benefits-sharing agreement before a patent is issued. The PCT proposal would require disclosure of genetic sources on patent applications, but the patent would only be invalidated for non-compliance if it is shown the information was withheld for fraudulent purposes. The third, and last, main international proposal – the Mandatory Disclosure Proposal by the European Union – would also require genetic source disclosure of those sources the inventor knew or should have had reason to know. Patent proceedings will stop and no patent will issue if the applicant refuses to disclose this information. After the patent issues, however, any sanctions or punishments for non-compliance or supplying false information would lie outside patent law.

As far as proposals for U.S. law specifically are concerned, such limited proposals are mostly based on the doctrine of fraudulent procurement.

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145 Id. at 147. The proposed TRIPs amendment was advanced by Brazil and India, with help from other bio-rich nations. Out of the three proposals, the TRIPs proposal for requiring genetic source disclosure would offer the most protection and impose the most stringent obligations.
146 Id at 148. Switzerland was the main instigator of the proposed PCT amendment. While not as stringent as the proposed TRIPs amendment, it still imposes significant obligations on patent applicants.
147 Id at 149. The European Union’s proposal is the least restrictive of the three. While it requires genetic source disclosure, and applications not supplying that information will be barred from further review, it does not call for the invalidation of patents that do issue.
148 Id.
149 Id.
Patent applicants have a duty to provide full and complete information on applications in order for examiners to best review the application. Failure to supply information necessary to the final patentability determination (such as that information that would affect novelty, etc.) may result in patent invalidity. When the failure to supply information relates to only non-essential matters, and the patent issues, the fraudulent misinformation results in patent non-enforceability.

This same concept of fraudulent procurement has been suggested as a not-so-invasive way to implement a genetic source disclosure requirement in the U.S. Genetic source information, such as the country of origin, PIC and any benefit sharing agreements, would be suggested, though not required as an essential element for patentability. In other words, that information, when the patent applicant knows it, or should reasonably know it, must be disclosed. Failure to do so would be considered fraudulent procurement of the patent, and, if issued, the patent would not be enforced.

In this final section, a proposal for a disclosure requirement compatible with the current U.S. patent regime is offered. The proposed requirement will consider what needs to be disclosed under what circumstances and to what degree, and what the consequences will be for withholding disclosure. The result of the proposed requirement is a regime similar to that relying on the theory of fraudulent procurement, but incorporates elements of the PCT proposal and European Union proposal as well. The arguments for and against requiring source/PIC disclosure will then be considered, and a hypothetical situation will be played out to illustrate the proposed disclosure requirement and how it achieves the benefits discussed. Finally, this section will highlight the differences between this proposal and the proposed TRIPs amendment,


\[Id at 398.\]

\[Id at 399.\]

\[Id.\]
PCT proposal, and the E.U.’s Mandatory Disclosure Proposal and explain why domestic legislation, as opposed to international agreement, is ideal.

A. Proposed Disclosure Requirement

Most of the arguments for a disclosure requirement center around ethical and moral treatment of source countries and the indigenous peoples that naturally utilize their local resources. The CBD also recognizes local control of resources and the rights of indigenous people to their own resources.\textsuperscript{154} The CBD goes further to acknowledge the economic rights of source countries and indigenous peoples to shared benefits resulting from their contribution to research. The proposed model of source/PIC disclosure reflects these concerns.

1. What Should Be Disclosed

When filing a patent application resulting from research on biological materials sampled from a source country, applicants should be required to disclose the country from which the raw materials originated and, if that nation requires prior informed consent before utilizing its resources, the completed PIC agreement. Should a PIC agreement not be reached, the patent applicant should be required to show a good faith attempt to reach agreement and provide an explanation as to why an agreement was not made. By requiring the source disclosure, patent examiners will be able to more accurately assess whether or not the resulting invention meets the 112 novelty requirements.\textsuperscript{155} Requiring PIC agreement disclosure addresses the more moral concerns fueling the acceptance of a disclosure requirement and ensures that the U.S. and its researchers and inventors treat developing countries equitably.


\textsuperscript{155} For example, if a patent is based on the antacid properties of an herb found in Africa, and natives of Africa have been using the herb as an antacid for centuries, the patent examiner should conclude that the subject of the patent is not novel.
While required, this information would not be considered necessary in order for the patent to issue. The results of non-disclosure of the genetic source and PIC information are discussed below.

2. When Should Source/PIC Disclosure Be Required

These disclosures should be required whenever the invention being patented resulted from research on a biological source, or the invention was in anyway furthered by such research. Requiring disclosure if a biological source was used in any portion of research again furthers the equitable purposes of the disclosure.

As for the time to make the disclosure, the information should, hypothetically, be provided with the initial patent application. However, it may sometimes be unrealistic for a researcher to have that information when a patent application is first filed. It makes sense, therefore, to require as complete disclosure as possible upon initial filing, but the disclosed information should be amendable up to issuance of the patent.

3. How Much Has to Be Disclosed

With respect to increased burden on the patent applicant, the opponents of required disclosure have some valid points. Researchers or patent applicants may not always know where their resources came from. This is particularly true when working in a lab, where outside companies stock the supplies and a hierarchy of administration oversees stocks and any special orders. In consideration of this hardship, source and PIC disclosure should only be required to the best knowledge of the applicant. A reasonable amount of good-faith investigation into the source of materials used will, of course, be expected, just as a reasonable search into prior art is expected.156 The applicant, however, will not be required to personally verify source/PIC information reasonably and reliably obtained from superiors or suppliers.

4. Consequences for Mistaken Disclosure or Withheld or Falsified Disclosure

156 See MPEP § 1.56.
If the source country or PIC disclosure made by an applicant is found to be incorrect or otherwise inadequate, the patent should not be automatically invalidated. If the mistaken disclosure is found during the prosecution, the applicant should be given a specified time in which to obtain the correct disclosure information and participate in PIC agreement negotiations. The applicant should make good faith efforts with the source country to obtain PIC, even if it means coming to an agreement different than the nation's standard agreement. The failure to reach an agreement, however, if negotiating is done in good faith, should not result in an invalid or unenforceable patent. If the patent applicant refuses to comply with the disclosure requirements, or fails to do so within the specified time, the patent should not issue.

If the incorrect disclosure is discovered after the patent successfully issues, the consequences should depend on the situation under which the incorrect disclosure was made. If the patent holder can show that, at all times during the prosecution, the information disclosed was reasonable and reliable, and no situation arose which would cause the patent holder to question that information, the patent should still be valid. The patent holder should then be given a specified time during which to obtain the correct information. The patent holder should consult with proper individuals, whether they be suppliers or other researchers, to determine the proper country, when possible, and obtain proper PIC. A good faith effort should be undertaken to reach some form of PIC agreement with the source country, should the standard PIC agreement fail. If the source country cannot be ascertained, or a PIC agreement reached, within the specified time, the patent should still be valid.

If the incorrect disclosure information was merely a result of inadequate investigation or pure ignorance, the applicant should be given a specified amount of time to determine the source country and obtain a PIC agreement. The same good faith effort to obtain PIC, as mentioned above, should be undertaken. If the source country cannot reasonably be determined in the specified time period, or a PIC agreement reached, the patent should still be valid, but a financial penalty should be imposed.
Finally, if the applicant purposefully falsified the source/PIC disclosure, whether the intent was to deceive the USPTO into issuing the patent or not, the patent should be declared invalid and a financial penalty imposed.

While the above-proposed scheme is not perfect, and many aspects, such as the specified time period for obtaining correct disclosure information, may need some trial and error before final implementation, the proposal provides a starting point from which a more comprehensive and detailed disclosure requirement can be built.

B. The Pros of the Proposed Genetic Source and Prior Informed Consent Disclosure and a Response to Objections

1. The Pros

First, disclosures will help to enforce the novelty requirement. The U.S. patent regime places high value on the novelty requirement. Oftentimes when biopirates and bioprospectors hunt the jungles and ecosystems for useful biological specimens, their hunts are aided by indigenous people's use of various local resources in natural treatments. Use of a biological source among indigenous peoples should qualify as prior art when prosecuting patents, and at the very least block the patent from issuing on novelty grounds under Section 112. Allowing companies to patent resulting drugs derived from those specimens, therefore, makes a mockery of the novelty requirement.

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158 See, for example, patent PP5,751, obtained on a variety of the ayahuasca vine collected from the Amazon area. Indigenous people had been using the vine for centuries for medicinal purposes. The earliest recorded use of the plant is from 1858 in Ecuador. See Richard Evans Schultes, Ph.D. F.L.S., An Ethnobotanical Perspective on Ayahuasca, available at http://www.biopark.org/peru/schultes-ayahuasca.html.

Second, patenting biological resources causes definite economic harm to the source countries. U.S. patents confer on the patent holder the right to block import of infringing articles.\textsuperscript{160} The developing source nations, therefore, are effectively stopped from utilizing their own resources for economic advancement. The developing nation, even if it had the means to commercially develop a resulting product from its biological resources, could not export that product, nor could it export the bare source for economic gain when a patent is obtained. Requiring genetic source/PIC disclosure would alert patent examiners to prior uses and raise societal awareness that native cultures are utilizing resources that could, potentially, be beneficial to the world. Source nations, therefore, would be able to use and market their resources appropriately.

Third, as a form of information regulation, a source and PIC disclosure requirement will encourage conservation and ethical treatment of developing nations. Information regulation is a means to alter certain behaviors by requiring disclosure of certain information related to the activity, as opposed to regulating the activity itself.\textsuperscript{161} One example of a law acting via information regulation is the Emergency Planning and Community Right to Know Act.\textsuperscript{162} In the current case, a disclosure requirement will oblige researchers seeking patents to be more aware of where resources come from; research, biopiracy and bioprospecting are not directly prohibited.

The disclosure requirement may also influence researchers to obtain their resources from reliable and reputable handlers to avoid potential downstream difficulties when prosecuting a patent. Bad publicity ruins reputations among consumers. Requiring researchers to disclose PIC will also encourage conservation by putting local

\textsuperscript{160} 35 U.S.C. § 154.
\textsuperscript{162} 42 U.S.C. § 11001, et. seq. The Emergency Planning and Community Right to Know Act was created to improve community access to information on hazardous chemicals released from facilities.
communities, the people who know the natural resources the best, in charge of their use. If a resource is running low, or further removal of a resource will endanger the local ecosystem or biological balance, local communities can withhold their consent and preserve the resource.

2. Responding to Objections

Opponents to including a mandatory source disclosure in U.S. patent law feel such an obligation will place too large a burden on patent applicants. For example, a source may be available in multiple geographic regions, or even one region spanning multiple countries. Requiring research laboratories to retrace the origin of their resources once they reach a patentable result would be both expensive and time consuming. To backtrack sources would also be confusing when one material can be traced back to multiple source locations. In those cases, the decision of which source location to cite will be arbitrary and potentially wrong.

Some also argue that adding a biological source/PIC disclosure requirement in the U.S. will violate treaties that the U.S. is already party to, such as TRIPs. The specific sections of the TRIPs agreement at issue are Articles 27 and 29.


165 Carvalho, supra note150.

166 Id. at 379. See also, TRIPs Articles 27, 29, 32 and 62, available at http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5. Article 27 involves patentable subject matter; and Article 29 involves conditions on patent applications. Article 62, involving the acquisition and maintenance of IP rights, is also occasionally listed as a point of discontent, and there are also potential issues with Article 32, involving revocation and forfeiture of patents, though they have been hazy at best.
patentability.\footnote{Agreement on Trade Related Aspects of Intellectual Property, Article 27.1.} To sum, patents are available for any invention, product or process, in any field, as long as it “new, involves an inventive step, and [is] capable of industrial application.”\footnote{Id. The terms “inventive step” and “capable of industrial application” are interpreted to be synonymous with the conditions of non-obvious and useful in U.S. patent law. See note 5 of TRIPs text available at \url{http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5}.} Opponents to a genetic source disclosure element to patent applications argue such information is an external condition to patentability.\footnote{Carvalho, supra note 150, at 379.} An invention that arises from, essentially, stolen property, whether that be a microscope, test tube, or plant, is still worthy of a patent.\footnote{Id at 380.} The fact that the resources leading up to the invention were stolen does not limit patentability under Article 27.1.\footnote{Id.} Hinging patentability on such a disclosure, therefore, is not consistent with, and would significantly constrict, the patentable subject matter as laid out in Article 27.1. However, article 27.2 of TRIPs states:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect \textit{ordre public} or morality, including to protect human, animal or plant life...or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.\footnote{TRIPs Article 27(2), available at \url{http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5}.}

In other words, it is up to individual member nations to decide whether or not to allow patents on inventions that significantly harm human, animal or plant life or seriously prejudice the environment. Requiring
genetic source/PIC disclosure would be beneficial in complying with this section.\textsuperscript{173}

Similarly, Article 29 of TRIPs sets guidelines for disclosure conditions.\textsuperscript{174} Disclosure must be sufficient for a person skilled in the art to build, use or otherwise carry out the invention.\textsuperscript{175} In general, opponents to a source disclosure requirement argue that a person with ordinary skill in the art does not need to know where genetic sources were obtained in order to carry out the invention.\textsuperscript{176} Requiring that disclosure, therefore, would be inconsistent with Article 29 and impose more disclosure requirements than necessary.

Article 29 must also be read in conjunction with Article 62.\textsuperscript{177} Article 62.1 states that member nations may require “compliance with reasonable procedures and formalities” consistent with the Agreement as a condition of maintaining a patent.\textsuperscript{178} In other words, formal conditions not listed in Article 29 of TRIPs must be reasonable and consistent with the Agreement. “Reasonable,” however, is not defined.\textsuperscript{179} Some nations and scholars have interpreted “reasonable” to mean only procedures and formalities that relate to the substantive requirements of patentability


\textsuperscript{174} TRIPs, at Article 29.

\textsuperscript{175} Id. at Article 29.1.

\textsuperscript{176} Carvalho, supra note 149 at 380.


\textsuperscript{178} TRIPs at Article 62.1

\textsuperscript{179} Connolly-Stone, supra note 173.
(i.e., the substantive requirements laid out in Article 27.1). Others have interpreted “reasonable” to mean conditions and formalities relating to other priority information, such as the identity of inventors, licensees, payment of fees, etc. The genetic source of material and any PIC obtained (or not) will not add anything to the determination of ownership, inventorship or fee payment. Under both interpretations of “reasonable,” a requirement of genetic source/PIC disclosure would violate TRIPs. To sum, it is argued that formal conditions that (1) have nothing to do with assessing novelty/inventiveness, (2) are not related to the issue of ownership, and (3) are not evidence of fee payment have been opposed as being inconsistent with TRIPs.

On the other hand, information relating to the source of genetic material and any PIC agreements (whether obtained or not) may be very relevant to a nation’s right to refuse a patent under Article 27.2.

C. The Adventures of Dr. Inventor – An Illustrative Hypothetical

This section will look at a hypothetical situation in which Dr. Inventor attempts to patent a new drug (WonderDrug) in the United States. This illustration will show how the proposed genetic source/PIC disclosure element to U.S. patent applications will function and achieve the benefits mentioned earlier.

After years and years of research, testing and development, Dr. Inventor comes up with a cure-all medication to be called WonderDrug. Dr. Inventor decides to patent the new miracle medication. On the patent application, in addition to the current requirements, Dr. Inventor realizes he needs to disclose the nations of origin for raw materials used in developing WonderDrug and information regarding PIC negotiations.

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180 Id.
181 Id. at 126-128.
182 Id. at 127.
with the source country or countries. There are a limited number of ways this disclosure could play out.

First, if Dr. Inventor personally gathered the raw materials used in developing WonderDrug, or otherwise specifically knows where the materials came from (i.e., the supply lab keeps records), the genetic source disclosure is easy. Simply state the resources and the respective origins. The PIC disclosure could be just as easy if Dr. Inventor has written documents indicating permission to utilize the resources. Such documents could be personally obtained by contacting the source nation, or a lab supply company may have already negotiated PIC and is able to supply a copy of the paperwork. Attaching the PIC agreement fulfills the requirement. On the other hand, if a PIC agreement is not reached, despite reasonable efforts, Dr. Inventor need only indicate that information and detail the steps taken to try to obtain PIC.

To add a layer of complication, perhaps Dr. Inventor has no idea where the resources used came from. Like many researchers, Dr. Inventor simply went to the lab and got what was needed. In this case, Dr. Inventor must complete a reasonable investigation to determine the source countries for materials used. For example, Dr. Inventor could ask the materials suppliers for the origin, or talk with other researchers utilizing the same resource. Or perhaps a resource or two are only found in a certain region of the world. In this intermediate-case, Dr. Inventor could probably obtain a reasonable guess as to where the raw material came from. By detailing the reasonable investigation undertaken and stating the origins as accurately as possible, Dr. Inventor is able to fulfill the genetic source disclosure requirement.

If, after reasonable investigation, Dr. Inventor is unable to even guess as to where the raw materials used to create WonderDrug originated, Dr. Inventor need only describe the investigation undertaken and state the sources were unable to be determined.

The PIC disclosure can be similarly complicated. If Dr. Inventor cannot determine, with certainty, where the raw materials came from, Dr. Inventor won’t know who to ask for PIC. In this situation, Dr. Inventor
need only state that the source countries were unable to be accurately
determined, and there is therefore no PIC.

In any permutation of the above situations, Dr. Inventor met the
genetic source/PIC disclosure requirement. However, a couple months
after filing the patent application, Dr. Inventor realizes the source of one
of the materials used was incorrect. Dr. Inventor has a duty to correct
that information, just as Dr. Inventor has a duty to correct any mistaken
information on the patent application.

Because Dr. Inventor met all the requirements of patentability,
including the genetic source/PIC disclosure by any above situation, and
Dr. Inventor appropriately amended the application, Dr. Inventor is
issued a patent for WonderDrug. A year later, however, it is brought to
Dr. Inventor’s attention that the supply company who provided one of
the PIC documents relied on in applying for the patent really had not
obtained PIC and merely created the document for business purposes.
Even though the patent has already been issued, Dr. Inventor still has an
obligation to disclose the mistake and would be granted time to rectify
the situation. In this case, Dr. Inventor should attempt to obtain PIC,
despite the fact that consent, at this point, would no longer be prior.
With the time given after disclosing the mistake, Dr. Inventor should
amend his patent to include proper PIC information, as described earlier.

For a slightly different fact pattern, a year after the patent was
issued, the USPTO, somehow, determines that there was incorrect
information in the genetic source/PIC disclosure. Dr. Inventor, however,
realizes the inadvertent mistake. The USPTO grants Dr. Inventor time to
correct the mistake, and Dr. Inventor completes the necessary
investigations and communications to make sure the patent information
is now as accurate as possible.

These first scenarios illustrate the main benefits of a genetic
source/PIC disclosure requirement. The disclosure encourages
international dialogue regarding the use and flow of genetic resources.
Opening these international channels of dialogue will hopefully increase
awareness of biopiracy and bioprospecting, thus promoting ethical
treatment of source nations and conservation of resources.
In the above hypothetical situations, it's been assumed that Dr. Inventor is an ethical, respectful and honest inventor. For this last illustration, it will be assumed that Dr. Inventor is not ethical, respectful or honest. Dr. Inventor did not disclose the source of raw materials used in the development of WonderDrug. Dr. Inventor did not try to find the sources. Dr. Inventor did not disclose PIC information, nor did Dr. Inventor even attempt to communication with source nations about a PIC agreement. Dr. Inventor did not take any advantage of any opportunity during the prosecution to amend the application for WonderDrug, and, should the patent issue, Dr. Inventor has no intention of correcting the information. In this situation, Dr. Inventor violated his duty of candor towards the USPTO, and some form of punishment is warranted. As indicated above, unintentional misinformation can and should be corrected, whether that misinformation is discovered by the inventor or the USPTO. In this last instance, an instance of pure uncooperativeness and deceit, Dr. Inventor should not receive a patent for WonderDrug, or, if the patent has already issued, the patent should be declared invalid.

By imposing penalties for not complying with the genetic source/PIC disclosure requirement, inventors have a further incentive to cooperate with foreign nations in their conservation efforts and the opportunity to give back to nations that contribute to innovation.

D. Comparison with International Proposals

As the Dr. Inventor scenarios illustrate, the proposed disclosure requirements, while perhaps requiring a little more work or astuteness on the part of an inventor, would not severely dampen the patentability of inventions within the U.S. The disclosures are, for the most part, an attempt to raise awareness of the issues facing biodiverse nations and enable the USPTO to better analyze the novelty requirement. In contrast, many of the proposed international proposals, however, would require significant overhaul of U.S. patent laws. This last section will take a deeper look at the proposed TRIPs and PCT proposals and the EU’s Mandatory Disclosure Proposal and show that domestic implementation of disclosure requirements will effectuate the policy behind the CBD while maintaining international relations.
1. The International Proposals

The TRIPs proposal is most strongly supported by developing countries, particularly those in extremely biodiverse regions. These nations are also the primary benefactors and signatories of the CBD, and it is therefore not surprising that the proposed TRIPs amendment would include elements directly from the CBD. While a few variations on the exact wording have been proposed, the essential elements are (1) mandatory disclosure of the source of any biological resources used in the invention (i.e., where the resources were obtained), (2) mandatory disclosure of the origin of any biological resources used in the invention (i.e., where the resources are natively found), (3) actual obtainment of PIC from the appropriate authority, and (4) a fair and equitable benefit-sharing agreement between the source nation and the inventor. Without these additional elements, a patent applicant could not receive a patent.

The TRIPs amendment would be hard (and potentially hazardous) to implement for many reasons. First, by hinging patentability on not only the disclosure of genetic sources, but also on the actual negotiation and obtainment of PIC and a fair and equitable benefit-sharing agreement, the TRIPs amendment would call for a significant redrafting of many nations’ patent laws, the U.S. included. Further, as illustrated with Dr. Inventor’s situation earlier, it is not always possible to determine the exact source or origin of resources used during research. The TRIPs proposal would therefore place severe

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184 Carr, supra, note 108 at 139.
185 Id.
186 Id.
limitations on what resources inventors have access to and, as a practical matter, require meticulously detailed notes for any resource used. Finally, the proposed TRIPs amendment could impose a chilling effect on innovation. Investors would be less willing to back research, particularly of the trial-and-error variety, because the lack of cooperation by a stubborn nation in granting consent and entering in a benefit-sharing agreement could halt the commercialization of an invention.  

While the proposed TRIPs amendment would be very restrictive and invasive in nations’ patent law schemes, the proposed PCT amendment would pose few constraints. The PCT amendment would allow, but not require, member nations to require genetic source disclosure. The PCT amendment would allow patent applicants to fulfill that disclosure requirement at the international level or wait until necessary during national-level proceedings. Nations choosing to require disclosure, therefore, would be able to stop processing a patent application until the disclosure was made. If the genetic source is unknown, the applicant need only declare the source is unknown. The Mandatory Disclosure proposal is very similar, except the disclosure requirement would be compulsory for member nations. 

These proposed amendments may be more implementable than the proposed TRIPs amendment because of their practicality and, in the case of the proposed PCT amendment, optional nature. Further, the

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190 Id.
191 Id.
192 Id.
193 Id.
194 Id.
trouble Dr. Inventor had with unknown origins of materials is also avoided in the proposed PCT amendment and Mandatory Disclosure proposal. What these amendments lack, however, is any reference to PIC. Patent applicants may be required to disclose the origin of resources, but there is little good in disclosing the origin if no attempt at PIC or a benefit sharing arrangement is made.

One final problem, seen in each of the three proposals, is of a practical nature. Many nations do not have the resources to determine the accuracy of genetic source or PIC disclosures, and it would just not be feasible to verify the disclosures, particularly those of PIC and benefit-sharing arrangements. The PCT proposal, by making the disclosures optional, would at least allow nations with a clear inability to verify the disclosure refrain from participating in the provision.

2. Domestic Implementation

The genetic source/PIC disclosure proposal presented in this article falls between the two extremes currently being offered on the international level. The proposed TRIPs amendment would make patentability determinations, for all member nations, based on source disclosure, PIC and an executed benefit sharing arrangement. The PCT and Mandatory Disclosure proposals, on the other hand, would only require a genetic source disclosure, and would accept a declaration that the source is unknown. The proposed disclosure requirements in this article would, like the proposed TRIPs amendment, require genetic source and PIC disclosure, but like the PCT and Mandatory Disclosure proposals, would accept a declaration that the source was unknown or PIC was unable to be obtained. Patentability would therefore not turn

\[195\] Carr, supra, note 108, at 148.
\[196\] Infra, III.D.1.
\[197\] Infra, III.D.2.
\[198\] Infra, III.A.
on the disclosures or actual obtainment of PIC or benefit sharing arrangements.\textsuperscript{199}

The proposal in this article, similar to the proposed PCT amendment, would not affect other nations’ patent laws. Many nations have been opposed to the international proposals, and progress has slowed on passing any of the amendments.\textsuperscript{200} If the U.S. could adopt a set of disclosure requirements, perhaps other nations could look to the U.S. as a role model to either (1) implement domestic legislation in their own countries, or (2) compromise and pass an international amendment agreeable to all parties involved.

Finally, the proposal in this article handles the criticism of lack of resources to verify disclosures in two ways. First, the issuance of a patent is not contingent on the disclosures. A patent applicant is allowed to indicate the genetic source is unknown and admit that no PIC agreement was reached, and the invention may still be patentable. The burden on patent examiners to conclusively investigate the disclosures is therefore significantly less than if patentability depended upon affirmative source disclosures and actual PIC obtainment. Second, the proposal works with the current patent regime, which instills a duty of candor and good faith upon patent applicants in dealing with the USPTO. This duty would extend to genetic source/PIC disclosures, and patent agents would be able to reasonably assume, absent glaring errors or evidence to the contrary, that the applicant is acting in accordance with that duty.

\textsuperscript{199} Infra, III.A.

\textsuperscript{200} Developed nations and large IP holding nations are the primary parties against required source/PIC disclosures. See generally, Carr, supra note 108. See also, North-South Coalition Sets Out “Draft Modalities” on TIRPs, International Centre for Trade and Sustainable Development, 17 July 2008, available at \url{http://www.grain.org/bio-ipr/?id=549}. Member nations to the respective treaties have argued about not only the disclosure requirements themselves, but also the appropriateness of the respective international committees as forums for implementing the policy considerations of the CBD.
CONCLUSION

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Biopiracy and bioprospecting continue to put developing countries that are rich in biodiversity at a disadvantage. Researchers essentially steal one of the only viable exports for these nations and proceed to patent the resource, effectively inhibiting the developing nations from utilizing their own natural resources. The Convention on Biological Diversity works to rectify the inequities caused by biopiracy and bioprospecting by requiring researchers to obtain prior informed consent from source countries. Because the U.S. a not a party to the CBD, patent applicants and researchers have no incentive to halt biopiracy and bioprospecting. The U.S. should therefore institute a source/PIC disclosure requirement, requiring patent applicants to disclose the source country and PIC agreement (or evidence of a good faith effort to obtain such an agreement) during the prosecution period. The applicant, however, should only be required to take reasonable steps to obtain reliable source country and PIC information. If the disclosure is later found to be incorrect, a patent holder who, at all times during the prosecution, reasonably relied on the information disclosed, the patent holder should be given a specified amount of time to reasonably obtain correct disclosure information, but the eventual lack of such information should not invalidate the patent. However, if the incorrect information was due to inadequate investigation into the proper source/PIC information, or pure ignorance, the patent holder should be given the same time in which to obtain correct information to maintain patent validity or incur a financial penalty if such information cannot be reasonably ascertained. Finally, if the incorrect information was purposefully given, regardless of any intent to deceive, the patent should be invalidated. Requiring this genetic source and PIC information would bring the U.S. closer to compliance with the CBD, while still performing in accordance with the U.S.‘s obligations as signatories to current international intellectual property treaties.