

**BIOPIRACY:
IS THERE A NEED FOR A MORE EXTENSIVE DEFINITION OF
“NOVELTY” WITHIN THE CONTEXT OF US PATENT LAWS?**

NOTE

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I. INTRODUCTION

A patent is the grant of a property right to the inventor of an invention, which is issued by the United States Patent and Trademark Office (“the US PTO”).¹ The right conferred by the patent grant is, in the language of the statute and of the grant itself, “the right to exclude others from making, using, offering for sale, or selling the invention in the United States or importing the invention into the United States.”² What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention.

Consequently, U.S. patent legislation legally grants a monopoly to inventors. Nonetheless, the term “invention” leaves space for lawfully taking and patenting knowledge from undeveloped countries outside of the United States. This shortfall is mainly due to the meaning of “novelty” under United States (“U.S.”) patent legislation.

Bioprospecting is generally defined as the search for useful organic compounds in nature, commonly involving the collection and examination of biological samples (such as plants, animals, microorganisms, etc.) for sources

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¹ See <http://www.uspto.gov/patents/index.jsp>.

² Patent Act, 35 U.S.C. § 154(a)(1) (2011).

of genetic or biochemical resources.³ This search, which is sometimes conducted with the “assistance” and “resources” of undeveloped countries, is intended to conclude with the grant of an exclusive patent, without compensation to the source-country of knowledge.

Our objective is to discuss the importance of expanding the meaning of “novelty” within the context of U.S. patent legislation and to further continue efforts towards developing better means to share the benefits of patents with source-countries of knowledge.

II. PATENTS FRAMEWORK AND LAWS

The Constitution of the United States of America gives Congress the power to enact laws relating to patents. In § 8 of Article I, the Constitution declares that the “Congress shall have the [p]ower . . . [t]o promote the [p]rogress of [s]cience and useful [a]rts by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries.”⁴

Under this power, Congress enacted the first patent law in 1790 and has, from time to time, enacted other laws relating to patents. These patent laws underwent a general revision that came into effect on 1953, and is codified as Patent Act in Title 35 of the United States Code.⁵

Three sections of the Patent Act plainly enumerate the elements of patentability: [1] novelty and [2] utility, in § 101⁶ and [3] non-obviousness in § 103⁷. Novelty is further defined in § 102⁸ within the context of exclusions to patentability.

³ Montana State University <http://serc.carleton.edu/microbelife/topics/bioprospecting>. See also “bioprospecting,” Oxford Dictionaries. April 2010. Oxford University Press. 6 October 2011 <<http://oxforddictionaries.com/definition/bioprospecting>>.

⁴ U.S. Const. art. I, § 8.

⁵ Additionally, on November 29, 1999, Congress enacted the American Inventors Protection Act of 1999 (AIPA), which further revised the patent laws. See Public Law 106-113, 113 Stat. 1501 (1999).

⁶ 35 U.S.C. § 101 (2011). – Inventions patentable: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

⁷ 35 U.S.C. § 103 (2011). (Conditions for patentability; non-obvious subject matter).

⁸ 35 U.S.C. § 102 (2001). – Conditions for patentability; novelty and loss of right to patent: A person shall be entitled to a patent unless—

(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

(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

A. Novelty

In simple words, “novelty” is one of the doors that must be opened for a person to be entitled to a patent. If the invention is known or used by others in the United States of America (“U.S.A.”), or patented or described in a printed publication anywhere, it is not entitled to a U.S. patent grant.

Accordingly, under U.S. patent provisions; this *geographical constraint* could preclude a patent from being issued on an invention. Thus, it leaves space for knowledge from other countries that not been published in printed media to be patented under U.S. patent laws.

1. Novelty and Patents in Foreign Countries

The U.S. geographical constraint contrasts with other foreign patent legislation. For instance, the European Patent Convention (“E.P.C.”) considers also the “novelty” and “utility” elements for patentability. However, it differs from the U.S. patent laws within the framework of a provision that describes “state of the art” as “everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor’s certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor’s certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in

(1) an application for patent, published under section 122 (b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language;

[1] or

(f) he did not himself invent the subject matter sought to be patented, or

(g)

(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person’s invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or

(2) before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

filing of the European patent application.”⁹ This means that under the E.P.C. there is no geographical limitation as to the availability of prior knowledge (or “art”); hence, “prior art or knowledge” anywhere – published or not – precludes patentability because of the absence of “novelty”. As a result, “novelty” is a term reserved for true unavailability of knowledge or art.

Another example is the Japan Patent Law which also requires “novelty” and “utility” for patentability and excludes geographical limitations to the availability of prior knowledge (or “art”).¹⁰ Similar to the E.P.C., the Japan Patent Law (“J.P.L.”) considers “prior art or knowledge” anywhere – published or not – as deterrence to patentability because of the absence of “novelty”.

So, based on the different definitions of “novelty”, patents granted by the US PTO can lawfully benefit from prior knowledge elsewhere (outside the United States, if not made public in printed media), while the rest of the countries considers as a limitation to patentability any “prior art or knowledge” available, within or outside their countries. By these means, the U.S. statutory definition of novelty certainly puts US patents applications in a better position than those applications in foreign countries.

III. BIOPROSPECTING VERSUS BIOPIRACY

Bioprospecting begins when firms from developed countries, such as multinational corporations based in the United States, interact with aboriginal or indigenous cultures in developing countries. The firms learn the “traditional knowledge” of these cultures, especially as that knowledge is applied to biotechnology.¹¹

⁹ European Patent Convention, art. 52(1), Oct. 5, 1973, 1075 U.N.T.S. 199. European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. An invention shall be considered to be new if it does not form part of the state of the art, *id.* at Art.54(1). The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application, *id.* at Art.54(2).

¹⁰ Tokkyohō [Tokkyohō] [Pat. L.] 1959 § 29, no. 1 (Japan). – Conditions for Patentability: An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention, except if one of the following applies prior to the filing of the patent application; (i) inventions that were publicly known in Japan or a foreign country, (ii) inventions that were publicly worked in Japan or a foreign country, or (iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country. (See http://www.wipo.int/clea/docs_new/pdf/en/jp/jp006en.pdf for a non-official translation of the law. At October 29, 2011 no official translation exist).

¹¹ See Jonathan B. Warner, *Using Global Themes to Reframe the Bioprospecting Debate*, 13, IND. J. GLOBAL LEG. STUD. 645 (2006).

Biopiracy, on the other hand, has emerged as a term to describe the ways that firms from the developed world claim ownership of, or otherwise take unfair advantage of, the genetic resources and traditional knowledge and technologies of developing countries. This knowledge is then appropriated by that firm under the developed country's intellectual property laws (generally by means of patents), to the exclusion of the indigenous cultures from which that knowledge originated, without compensation to the indigenous groups who originally developed such knowledge.

It can be fairly expected that, under the generous provisions of the US patent laws (where "novelty knowledge" can be easily found outside the U.S.), U.S. firms would be searching for traditional knowledge with the "assistance" and "resources" of undeveloped countries, with the ultimate purpose of obtaining a U.S. patent. Nevertheless, the difference between "bioprospecting" and "biopiracy" rests in the willingness of the firms learning the "traditional knowledge" to not only conserve and promote sustainability of biological diversity but also to equitably share the benefits of bioprospecting.

A. Traditional Knowledge (T.K.)

The World Intellectual Property Organization ("W.I.P.O.") defines T.K. as a form of knowledge which has a traditional link with a certain community; it is knowledge which is developed, sustained and passed on within a traditional community, and is passed between generations, sometimes through specific customary systems of knowledge transmission. It is the relationship with the community that makes it "traditional" since it is being created every day and evolves as individuals and communities respond to the challenges posed by their social environment.¹²

1. 1992 Convention on Biological Diversity ("C.B.D.")

Recently, international attention has turned to intellectual property laws to preserve, protect, and promote T.K. Accordingly, in 1992, the C.B.D. recognized the value of T.K. in protecting species, ecosystems and landscapes; incorporating language regulating access to it and its use. It soon became apparent that implementing these provisions would require that

¹²W.I.P.O. Booklet No. 2 Intellectual Property and Traditional Knowledge. <http://www.google.com/search?client=safari&rls=en&q=Intellectual+Property+and+Traditional+Knowledge&ie=UTF-8&oe=UTF-8> (One of a series of Booklets dealing with intellectual property and genetic resources, traditional knowledge and traditional cultural expressions/folklore).

international intellectual property agreements be revised to accommodate them.

The C.B.D. was drafted in response to shared concerns of international organizations and governments, with the objective of developing strategies for the conservation and sustainable use of biological diversity as well as providing means for equitable sharing of benefits of bioprospecting (i.e., compensating source countries). The treaty set new standards that more than 190 member countries¹³ are expected to follow when engaging in bioprospecting. Nonetheless, there is a level of distrust regarding the success potential since C.B.D., although a legal document; is a voluntary treaty among member countries. Therefore, it does not incorporate means to effectively enforce its provisions.

2. The case of INBio - Costa Rica

An example of the standard of conduct in dealing with biological diversity of undeveloped countries is the biodiversity prospecting agreement between Merck Pharmaceutical Ltd. and the National Biodiversity Institute of Costa Rica ("INBio"), a non-profit, public interest organization established by

¹³ C.B.D. member countries: (Andorra, Holy See, Iraq, Somalia and U.S.A. are not members) Afghanistan, Albania, Algeria, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, Central African Republic, Chad, Chile, China, Colombia, Comoros, Congo, Cook Islands, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Democratic Republic of the Congo, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, European Community, Federated States of Micronesia, Fiji, Finland, France, Gabon, Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hungary, Iceland, India, Indonesia, Ireland, Islamic Republic of Iran, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kiribati, Kuwait, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, Monaco, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norway, Oman, Pakistan, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, The former Yugoslav Republic of Macedonia, Timor-Leste, Togo, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Tuvalu, Uganda, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Yemen, Zambia, Zimbabwe. See <http://www.cbd.int/information/parties.shtml>.

the Costa Rican government. In pursuing the search for wild species with medicinal, veterinarian, or agricultural potential, in 1991 INBio granted Merck the right to evaluate commercial prospects of a limited number of plant, insect, and microbial samples collected in Costa Rica's eleven (11) conservation areas. In return, Merck paid INBio \$1 million over two years, and provided equipment for processing samples and scientific training.¹⁴

By means of such bioprospecting agreements like this that have been negotiated since then, Costa Rica is now earning revenues from resources for which it previously received nothing (because there was no market at all). In addition, besides sharing the economic benefits of the intellectual property rights, Merck contributed to the sustainability and development of the Costa Rican economy by providing technical training and equipment to its people.

IV. CONCLUSION

Is there a need for a more extensive definition of "novelty" within the context of the U.S. patent legislation? Or, would it be enough to pursue more effective ways to enforce C.B.D. internationally?

Maybe, expanding the meaning of "novelty" is the easiest way to deter biopiracy, and pursue the fair use of TK and biodiversity of undeveloped countries. However, the United States must have had strong reasons for not yet ratifying the C.B.D. (which had been ratified by countries that deal the "more extensive definition"). In my opinion, the reasons relate to the enormous economic interest contained in the statutory definition of "novelty".

This being said, at this moment in history what U.S. firms must strive for is to not fall in biopiracy conduct but instead to assume a leadership role within the true meaning of bioprospecting. The ultimate incentives of the firms learning the "traditional knowledge" should not be a patent grant *per se*. It should entail the conservation and promotion of sustainable biological diversity, as well as the equitably distribution of the benefits of bioprospecting.

In any case, we should not forget that the First Amendment of the U.S. Constitution¹⁵ ensures access to information, by fostering creativity and freedom of expression; inevitably resulting in technological and scientific advancement. Bioprospecting must be construed as means of a contribution to the sharing of such information (including T.K.).

¹⁴ Elissa Blum, *Making Biodiversity Profitable: A Case Study of the Merck/INBio Agreement*, 35 ENVIRONMENT 4, 40 (1993).

¹⁵ "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances." U.S. Const. amend. I.