

PIRACY BY PATENTS: HOW UNITED STATES PATENT LAW ENABLES BIOPIRACY

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I. INTRODUCTION

Like the original explorers of the Americas, American biopharmaceutical companies enrich themselves by stealing from indigenous communities. Now,

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however, this theft is accomplished through United States patent law.¹ Under current United States patent law, companies can use traditional knowledge from indigenous peoples and local communities to create new drugs and profit from that knowledge without the consent of the source community and without ever returning any monetary benefits to those communities.² This practice is known as biopiracy, and it is enabled by patent law because new “modern knowledge” can be patented, but there are no laws to provide the same protection for the traditional knowledge of indigenous peoples and local communities.³ A broader definition of biopiracy includes “any unauthorized acquisition or transport of genetic material or live flora and fauna . . .” for commercial purposes.⁴

Biopharmaceutical drug companies often begin their engagement in biopiracy by bioprospecting—a method of natural resource exploitation that targets the genetic and biochemical information from plants, animals, and microorganisms.⁵ To begin bioprospecting, researchers often first look at the knowledge that is already available through indigenous people and local communities.⁶ By using the traditional knowledge of these communities, the biopharmaceutical firms are able to reduce the time and costs required for drug development.⁷ Once the company develops a successful drug, the inventors obtain a patent on the drug so they can have the right to exclude others from producing and selling it.⁸

1. See Megan Dunagan, *Bioprospection Versus Biopiracy and the United States Versus Brazil: Attempts at Creating an Intellectual Property System Applicable Worldwide When Differing Views are Worlds Apart—and Irreconcilable?*, 15 L. & BUS. REV. AM. 603, 620 (2009); see also STEPHANIE HOWARD, INDIGENOUS PEOPLE’S COUNCIL ON BIOCOLONIALISM, LIFE, LINEAGE AND SUSTENANCE 11 (2001), http://www.ipcb.org/pdf_files/LifeLineageandSustenance.pdf [<https://perma.cc/3PUB-4TLF>] (explaining that applying for a patent is the most common and effective route to claim ownership over plants used by indigenous communities).

2. Aman Gebru, *The Global Protection of Traditional Knowledge: Searching for the Minimum Consensus*, 17 J. MARSHALL REV. INTELL. PROP. L. 42, 43 (2017).

3. Aman K. Gebru, *International Intellectual Property Law and the Protection of Traditional Knowledge: From Cultural Conservation to Knowledge Codification*, 15 ASPER REV. INT’L BUS. & TRADE L. 293, 293 (2015) [hereinafter *International Intellectual Property Law*].

4. Larry Rohter, *As Brazil Defends its Bounty, Rules Ensnare Scientists*, N.Y. TIMES (Aug. 28, 2007), <https://www.nytimes.com/2007/08/28/science/28biop.html> [<https://perma.cc/T4JY-NUDM>].

5. Aman Gebru, *Intellectual Property and Bioprospecting: A Model Legal Framework*, 19 N.C. J.L. & TECH. 257, 259 (2017) [hereinafter *Intellectual Property and Bioprospecting*]; *Edmonds Inst. v. Babbitt*, 42 F. Supp. 2d 1, 6 (D.D.C. 1999); see also Dunagan, *supra* note 1, at 619-20 (defining bioprospecting as a step towards biopiracy as only one perspective of the definition of bioprospecting).

6. *Intellectual Property and Bioprospecting*, *supra* note 5, at 257, 259.

7. *Id.*

8. *Id.* at 259-60; 35 U.S.C. § 154.

The biopharmaceutical companies earn billions in annual profits from their protected invention while the people who provided the traditional knowledge on which that research is based, receive no compensation.⁹ The knowledge provided by indigenous people and local communities are considered to be part of the public domain because it was developed over generations.¹⁰ This means inventors can use the traditional knowledge without any legal requirement to provide attribution or benefits to the source communities.¹¹

As the demand for these resources has increased, other countries have taken measures to protect the traditional knowledge and resources of their indigenous groups and local communities.¹² This has led to a protectionist trend which effectively protects indigenous groups from exploitation, but slows the innovation of new drugs by foreign companies.¹³ American biopharmaceutical companies benefit from using traditional knowledge, and society benefits from access to new drugs.¹⁴ To continue this access, however, it is necessary to enact laws that will protect the rights of indigenous communities in other nations and ensure they receive some of the profits while still allowing foreign companies to bioprospect in those biodiversity-rich areas. The United States needs to alter its patent laws to require the disclosure of use of traditional knowledge in patent applications and enact legislation which recognizes indigenous communities' traditional knowledge as prior art to ensure continued collaboration with biodiversity-rich nations and to facilitate the development of new drugs.

II. HISTORY AND LEGAL BACKGROUND

A. Why Biopharmaceutical Companies Rely on Traditional Knowledge

The use of traditional knowledge in the initial stages of biopharmaceutical research reduces the time and cost of developing products.¹⁵ This practice is called “ethnopharmacology” or “ethnomedicine,” and more companies have adopted this approach because of the increase in efficiency.¹⁶ A 2004 study analyzing the role

9. Samuel Lim, *An Equitable Approach to Traditional Knowledge Protection*, 53 N.Y.U. J. INT'L L. & POL. 135, 141 (2020); *Intellectual Property and Bioprospecting*, *supra* note 5, at 260.

10. *Intellectual Property and Bioprospecting*, *supra* note 5, at 260.

11. *Id.*

12. *Id.*

13. *Id.*

14. *See id.* at 259, 274.

15. Aman Gebru, *Patents, Disclosure, and Biopiracy*, 96 DENV. L. REV. 535, 550 (2019) [hereinafter *Patents, Disclosure, and Biopiracy*].

16. *Id.* at 549-50.

of traditional knowledge in modern medicine found that the use of traditional knowledge increased the probability of getting a “preliminary hit” from 6% without relying on traditional knowledge, to 25% with use of traditional knowledge.¹⁷ Another study found that 80% of plant-derived compounds tested were used for the same ethnomedical purposes as the developed drug.¹⁸ The usefulness of traditional knowledge in the initial stages of drug development has been repeatedly proven.¹⁹ “The trial and error from the centuries-old use of biodiversity resources by communities has been serving as a diverse pool upon which biopharmaceutical firms build to develop modern drugs.”²⁰

Evidence of this success can be found in the attempt to find a cure for acquired immunodeficiency syndrome (AIDS).²¹ In search for a cure, a New York researcher conducted a field study in the Belize rainforest.²² He compared a random collection of plant species with plants used by the local community for medicinal purposes.²³ Out of twenty plants gathered based on the local people’s knowledge, five of them killed the AIDS virus.²⁴ Out of eighteen plants collected randomly, only one killed the AIDS virus.²⁵ Although the plant itself requires more development for it to be used as a drug, the knowledge provided by the local community facilitates the research that leads to the innovation.²⁶

B. Consequences of Not Protecting Traditional Knowledge

Traditional knowledge is disappearing at a rapid rate.²⁷ Research conducted from 2000-2009 found that traditional knowledge from an Amazonian community was being lost at a rate that ranged from 9% to 26% with most of the loss happening

17. *Intellectual Property and Bioprospecting*, *supra* note 5, at 268 (defining “Preliminary hit”) (“[T]he compound that is selected from a large number of compounds because of either its phenotype or process which is relevant for the disease being researched.”).

18. *Intellectual Property and Bioprospecting*, *supra* note 5, at 268; Daniel S. Fabricant & Norman R. Farnsworth, *The Value of Plants Used in Traditional Medicine for Drug Discovery*, 109 ENV’T HEALTH PERSPS. 69, 72 (2001).

19. *Intellectual Property and Bioprospecting*, *supra* note 5, at 268.

20. *Patents, Disclosure, and Biopiracy*, *supra* note 15, at 550.

21. *Intellectual Property and Bioprospecting*, *supra* note 5, at 268.

22. *Id.* at 269.

23. *Id.*

24. *Id.*

25. *Id.*

26. *See id.*

27. *Id.* at 261.

in communities living closer to cities.²⁸ As urbanization of rural communities increases, the rate at which traditional knowledge disappears will also increase.²⁹ Two major reasons traditional knowledge is being lost at this rate: the use of oral transmission, instead of written documentation, among indigenous peoples and local communities, and the protectionist trend which restricts access to traditional knowledge.³⁰

Almost 200 countries have agreed to increase access to traditional knowledge and genetic resources by signing the Convention on Biological Diversity (CBD).³¹ However, in response to the absence of legal protection for traditional knowledge in other nations, megadiverse countries are participating in a protectionist trend.³² The rising protectionist trend in megadiverse countries limits access to the traditional knowledge that has proven to be valuable for biopharmaceutical research.³³ An increase in restrictions will decrease opportunities to collaborate in bioprospecting and will slow down innovation because megadiverse countries make up almost 70% of the world's diversity.³⁴ If the protectionist trend continues, it will be difficult to maintain bioprospecting relationships with megadiverse countries.³⁵ This trend would be less problematic if the restrictive measures of the megadiverse countries would lead to the creation of new products based on their own traditional knowledge.³⁶ These countries, however, usually do not have the capacity to use their traditional knowledge to create and produce new products.³⁷ By failing to protect traditional knowledge, the United States is making it more challenging for its researchers to access essential resources in biodiverse countries.³⁸

C. United States Patent Law

Patents protect the inventor's right to "exclude others from making, using,

28. *Id.* at 269.

29. *Id.*

30. *Id.* at 270.

31. *Id.* at 272; *see generally* I.L.M. Content Summary art. 1, June 5, 1992, 31 I.L.M. 818.

32. *Intellectual Property and Bioprospecting*, *supra* note 5, at 272 ("Megadiverse" refers to countries that are "host to a disproportionately high level of biological diversity.").

33. *Id.*

34. *Id.*

35. *Id.* at 273.

36. *Id.*

37. *Id.*; *but see* Dunagan, *supra* note 1, at 622 ("[M]any developing countries [are] striving for their own development and commercialization of traditional medicines and local resources in the local setting . . .").

38. *See Intellectual Property and Bioprospecting*, *supra* note 5, 273.

offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”³⁹ There are five major requirements for patentability: (1) patentable subject matter, (2) utility, (3) novelty, (4) nonobviousness, and (5) enablement.⁴⁰ The invention must be something that is covered by a category of patentable subject matter.⁴¹ In *Diamond v. Chakrabarty*, the Supreme Court defined patentable subject matter very broadly, determining that Congress intended “anything under the sun that is made by man” to be patentable.⁴² The Court, however, explained that this does not mean there are no limits to what can be patented.⁴³ “[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter.”⁴⁴ The Court determined that a unique bacterium was patentable because it was not naturally occurring and was the result of Chakrabarty’s work.⁴⁵ The relevant distinction is between “products of nature, whether living or not, and human-made inventions.”⁴⁶

Nonobviousness requires the invention to be sufficiently different from prior art that it would not be obvious to a person of ordinary skill in that field.⁴⁷ In determining nonobviousness, the Supreme Court requires courts to ask: “whether the improvement is more than the predictable use of prior art elements according to their established functions.”⁴⁸ “Nonobvious” is not defined uniformly in the global context. Western countries generally follow the definition of nonobvious used by the United States while developing countries largely reject this definition.⁴⁹

To satisfy the novelty requirement, the invention cannot be known or used by others and cannot be patented or described in a printed publication in any country.⁵⁰ If the inventor discloses the invention to the public before the patent is filed, it will not meet the novelty requirement and the patent can be denied.⁵¹ Further,

39. 35 U.S.C. § 154.

40. *Patent*, LEGAL INFO. INST. (Aug. 19, 2022, 8:40 PM), <https://www.law.cornell.edu/wex/patent> [<https://perma.cc/3LT5-SNZA>]; *see also* 35 U.S.C. §§ 101-03, 112.

41. *Patent*, *supra* note 40.

42. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

43. *Id.*

44. *Id.*

45. *Id.*; Dunagan, *supra* note 1, at 606.

46. *Diamond*, 447 U.S. at 313.

47. 35 U.S.C. § 103.

48. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007).

49. *See* Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 445 (2006).

50. *Patent*, *supra* note 40; 35 U.S.C. § 102.

51. *Intellectual Property and Bioprospecting*, *supra* note 5, at 330; *see generally* World Intellectual Property Organization, U.S. PAT. AND TRADEMARK OFF. (Aug. 26, 2021, 4:27

the invention cannot be prior art.⁵² Prior art refers to “any publicly accessible knowledge prior to the filing of a patent.”⁵³ This includes any printed document anywhere in the world, but does not include information shared orally unless it is made available to the public.⁵⁴ Under this definition, the United States grants patents on inventions based on knowledge used in other countries as long as that knowledge is not documented or “otherwise available to the public.”⁵⁵

Previously, other developed nations agreed with the United States standards for novelty and supported United States courts when they held that isolated and purified genes and gene sequences should be considered patentable because they satisfy the novelty requirements of a chemical compound.⁵⁶ Support for this application of the novelty requirement has shifted, however, because gene patents have become an impediment to genetic testing and further gene research.⁵⁷ This shift from other nations could potentially lead to restrictions in patents for “genetically engineered equivalents” of plants whose medicinal use became known through traditional knowledge.⁵⁸

D. Plant Patent Act

Under the Plant Patent Act, an inventor can obtain a patent on a discovered and asexually reproduced new variety of a plant.⁵⁹ The act sets forth limitations on plant patentability, but also weakens the requirements of the Patent Act and expands what can be patented.⁶⁰ The Plant Patent Act only requires the plant to be new and distinct to be patentable, eliminating the requirement in the Patent Act that inventions have utility.⁶¹ Additionally, the Plant Patent Act loosened the requirement for specificity in the description.⁶² The Act no longer requires the description to provide enough detail to allow others to reproduce the newly discovered plant.⁶³ These lax requirements make it easier for inventors of asexually

PM), <https://www.uspto.gov/ip-policy/patent-policy/world-intellectual-property-organization> [<https://perma.cc/H5JL-FHG9>].

52. 35 U.S.C. § 102.

53. *International Intellectual Property Law*, *supra* note 3, at 301; 35 U.S.C. § 102 (a)(1).

54. Ho, *supra* note 49, at 532; *see* 35 U.S.C. § 102.

55. Ho, *supra* note 49, at 532; 35 U.S.C. § 102(a)(1).

56. Ho, *supra* note 49, at 530.

57. *Id.* at 531.

58. *Id.*

59. 35 U.S.C. § 161.

60. Dunagan, *supra* note 1, at 607.

61. *Id.*

62. *Id.*

63. *Id.*

produced plants to obtain patents on plants.⁶⁴ Equating the discovery of a plant with the invention of a plant demonstrates the United States' loose patent requirements for natural substances.⁶⁵

III. WHY PATENT LAW NEEDS TO CHANGE

A. Issues with Disclosure

Although United States patent law requires some disclosure, research has found that patent applicants withhold information from the Patent Trademark Office.⁶⁶ This is caused by the disproportion of information available to the patent applicant and the examiner.⁶⁷ The inventors have done an extensive amount of research and know all the sources of information they have used, but the patent examiners are not experts of every invention they examine.⁶⁸ This issue is exacerbated in products that are based on traditional knowledge because traditional knowledge is not as accessible as other sources inventors rely on.⁶⁹ Unlike Western societies that document knowledge, indigenous peoples and local communities primarily transfer their knowledge through oral traditions.⁷⁰ Even if the traditional knowledge is documented, it is usually in local languages that patent examiners do not understand.⁷¹

B. Issues with Conflicting International Treaties and Regulations

1. World Intellectual Property Organization Approach

In contrast to the lack of protection of traditional knowledge under United States patent law, the World Intellectual Property Organization (WIPO) considers biopiracy a trade abuse and a threat to biodiversity.⁷² The WIPO is an agency of the United Nations with 193 member states.⁷³ The mission of WIPO “is to lead the

64. *Id.*

65. *See id.* at 607–08; *see also* Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 *COLO. J. INT’L ENV’T L. & POL’Y* 219, 239 (2008) (“In the United States, it is possible to patent naturally occurring chemicals if their structures have not been published before.”).

66. *Patents, Disclosure, and Biopiracy*, *supra* note 15, at 548.

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.* at 548–49.

71. *Id.* at 549.

72. Dwyer, *supra* note 65, at 232, 243.

73. *Inside WIPO*, WORLD INTELL. PROP. ORG. (Sept. 7, 2022, 12:34 PM), <https://www.wipo.int/about-wipo/en/> [<https://perma.cc/647B-L33C>].

development of a balanced and effective international [intellectual property] system that enables innovation and creativity for the benefit of all.”⁷⁴ It is a forum where “members negotiate the changes and new rules needed to ensure that the international [intellectual property] system keeps pace with the changing world.”⁷⁵

In 2000, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC Committee) to focus on the demands of developing nations for the protection and preservation of their traditional knowledge.⁷⁶ The IGC Committee is expected to assist in developing international legal instruments to combat biopiracy.⁷⁷ The IGC Committee has sought measures to protect traditional knowledge by requiring “disclosure of the use of [traditional knowledge] before patent authorities” and “the consideration of legal and ethical aspects in the patent systems.”⁷⁸ Additionally, the IGC Committee encourages members to use patent law to avoid appropriation of traditional knowledge and recognizes the need to improve cooperation between patent offices.⁷⁹ The WIPO approach acknowledges the need for a change in patent law because in some nations, inventors can profit from their inventions without any obligation to first obtain permission from the source community where the traditional knowledge originated.⁸⁰

2. The United Nations Convention on Biological Diversity

The CBD is an international convention meant to be used for “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.”⁸¹ The Convention has been ratified by 196 nations.⁸² The United States has signed the CBD but has not ratified it.⁸³

The CBD promotes the idea that each state has sovereignty over its genetic

74. *World Intellectual Property Organization*, *supra* note 51.

75. *Id.*

76. Dwyer, *supra* note 65, at 243.

77. *Id.*

78. *Id.* at 244.

79. *Id.*

80. Dunagan, *supra* note 1, at 609.

81. *Convention on Biological Diversity, Key International Instrument for Sustainable Development*, UNITED NATIONS (Aug. 19, 2022, 8:39 AM), <https://www.un.org/en/observances/biological-diversity-day/convention> [<https://perma.cc/EQW3-JGVJ>].

82. *Id.*

83. Dunagan, *supra* note 1, at 610.

resources.⁸⁴ The CBD maintains that “[s]tates have . . . the sovereign right to exploit their own resources pursuant to their own environmental policies.”⁸⁵ Because of this sovereign right, the CBD encourages the sustainable use of genetic resources and a dispersion of bioprospecting profits to the developing country which provided access to the resources.⁸⁶ The CBD calls for the recognition of traditional knowledge by requiring each “contracting party” to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities . . . and promote their wider application with the approval and involvement of the holders of such knowledge . . . and encourage the equitable sharing of the benefits arising from the utilization of such knowledge.”⁸⁷

Although the CBD is a conservation agreement, its goal of benefit sharing with developing countries is relevant to the patent law issue.⁸⁸ The CBD creates a link between benefit sharing and intellectual property by encouraging its members to utilize patent rights that do not conflict with the objectives of the Convention.⁸⁹ The CBD encourages members to “cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to [the Convention’s] objectives.”⁹⁰ The CBD’s governing body, the Conference of Parties, has also encouraged members to require disclosure of the source of traditional knowledge in patent applications.⁹¹

The CBD’s requirements and recommendations provide a clear link between biodiversity conservation and patent law.⁹² An important accomplishment of the CBD is the incorporation of the Bonn Guidelines into domestic laws by certain countries.⁹³ The Bonn Guidelines encourage “appropriate and concrete measures to defend [traditional knowledge] . . . and call for implementation of access and benefit-sharing agreements.”⁹⁴ However, a noticeable weakness of the CBD is the lack of enforceability and a lack of liability rules.⁹⁵ Additionally, the CBD does

84. Dwyer, *supra* note 65, at 236.

85. *Id.* at 236, n.142.

86. *Id.* at 236.

87. Dunagan, *supra* note 1, at 610 (citing I.L.M. Content Summary, *supra* note 31, at art. 1).

88. Jay Erstling, *Using Patents to Protect Traditional Knowledge*, 15 TEX. WESLEYAN L. REV. 295, 302 (2009).

89. *See id.*

90. I.L.M. Content Summary, *supra* note 31, at art. 16.

91. Erstling, *supra* note 88, at 303.

92. *Id.* at 303-04.

93. Dwyer, *supra* note 65, at 237.

94. *Id.*

95. *Id.*

not provide clear guidelines on what activities require prior consent, what information must be disclosed, and which party is required to provide the information.⁹⁶

3. Trade Related Aspects of Intellectual Property Rights

The Trade-Related aspects of Intellectual Property Rights (TRIPS) is the United States' preferred intellectual property agreement and is a victory of the United States over developing countries.⁹⁷ Its purpose is to “reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”⁹⁸ Patent regulations under TRIPS favor the interests of pharmaceutical industries because it lacks regulations to protect biodiversity and traditional knowledge.⁹⁹ The TRIPS Agreement's position on patents is similar to the patent system used in the United States and financially benefits the United States more than other nations.¹⁰⁰

The only section of the TRIPS Agreement that includes a policy comparable to the CBD's effort to promote national sovereignty on patent rights is opposed by the United States and other industrialized nations.¹⁰¹ Article 27, paragraph three, of the TRIPS Agreement explains which inventions governments are allowed to exclude from patenting.¹⁰² Industrialized nations argue that this section of TRIPS provides nations with too much power to determine their own restrictions for patents and will lead to a variation in the “intellectual property regime.”¹⁰³

Similarly, researchers and scientists argue that granting this power to each individual nation harms the scientific field because it leads to criminalizing research instead of encouraging it.¹⁰⁴ Researchers who bioprospect in these developing nations claim the restrictions imposed by developing countries to prevent biopiracy are excessive and have created unwarranted paranoia about science.¹⁰⁵

96. *Id.*

97. *Id.* at 238; Dunagan, *supra* note 1, at 623.

98. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 1197 [hereinafter Agreement on Trade].

99. Dunagan, *supra* note 1, at 624; Dwyer, *supra* note 65, at 238.

100. Dunagan, *supra* note 1, at 624.

101. *Id.* at 623; *see* Agreement on Trade, *supra* note 98, at art. 27, ¶ 3.

102. *Background and the Current Situation*, WORLD TRADE ORG. (Nov. 2008), https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm [<https://perma.cc/4LHE-F9SU>]; Agreement on Trade, *supra* note 98, at art. 27, ¶ 3.

103. Dunagan, *supra* note 1, at 623.

104. *Id.* at 624.

105. *Id.*

In contrast, developing countries argue that the TRIPS Agreement should be amended to require patent applicants to disclose the country of origin of the resources and traditional knowledge used, evidence that the inventor received prior informed consent, and evidence that applicants have engaged in fair and equitable benefit sharing.¹⁰⁶ If the TRIPS Agreement is amended in the way the United States and other industrialized nations propose, there will be almost no protections left for developing nations to shield their traditional knowledge and resources from biopiracy.¹⁰⁷

C. Protectionist Policies in Other Nations

In response to the lack of adequate protection by international regulations, developing countries have enacted their own restrictions to prevent biopiracy.¹⁰⁸ The signing of the CBD “[s]timulated a wave of national legislation having the effect . . . of restricting, rather than facilitating, access to genetic resources in the developing world, pending the industrialized world’s adoption of a meaningful benefit-sharing measure.”¹⁰⁹ Brazil, India, and Peru are examples of developing nations that have used protectionist rules to stop the theft of resources when international regulations fail to provide sufficient protection.¹¹⁰

1. Brazil

Brazil’s history of biopiracy and the refusal of other nations to recognize the theft as biopiracy has led to an increase in the nation’s regulation of patents.¹¹¹ One of the most significant examples of biopiracy in Brazil is the unauthorized removal of rubber seeds from Brazil by a British explorer.¹¹² During the Industrial Revolution in Europe and North America, the value and demand for rubber increased drastically.¹¹³ At the time, most rubber was being produced from trees in the Amazon allowing cities along the Amazon River to flourish from the profits of the

106. *Background and the Current Situation*, *supra* note 102 (“Prior informed consent” is a term used in the CBD).

107. Dunagan, *supra* note 1, at 623-24.

108. *Intellectual Property and Bioprospecting*, *supra* note 5, at 260.

109. *Id.* at 272 (quoting CHARLES MCMANIS, *BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY, AND TRADITIONAL KNOWLEDGE* 5 (2007)).

110. Dunagan, *supra* note 1, at 621; see Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection*, 7 J. INT’L ECON. L. 371, 380 (2004).

111. Dunagan, *supra* note 1, at 629.

112. John Tustin, *Traditional Knowledge and Intellectual Property in Brazilian Biodiversity Law*, 14 TEX. INTELL. PROP. L.J. 131, 133-34 (2006).

113. *Id.*

rubber boom.¹¹⁴ As the profitability from rubber became evident, a British botanist was commissioned to send seeds from the Amazon to London and then to a British colony to establish the first rubber plantation.¹¹⁵ Rubber then flooded the international market and Brazil's monopoly on natural rubber was destroyed.¹¹⁶ The wealth that was causing Brazilian cities to flourish was now being directed to Britain instead.¹¹⁷

A more recent example of biopiracy in Brazil is the unauthorized taking of venom from a Brazilian viper to create Captopril, a blood pressure medicine.¹¹⁸ The pharmaceutical company, Squibb (now part of Bristol-Myers Squibb), used the viper venom to develop the drug which at one point became their largest selling product.¹¹⁹ In 1991, the medicine brought in \$1.6 billion in revenue for Squibb.¹²⁰ No royalties were ever paid to Brazil.¹²¹ Addressing the loss of potential revenue from pharmaceuticals due to the delay in development of their own genetic patrimony, the Brazilian Environment Ministry stated, “[b]ecause of past errors, captopril is not Brazilian.”¹²²

Brazil adopted the TRIPS Agreement in 1997, but the country continued to enforce its own patent regulations.¹²³ Brazil's patent regulations included a provision that would only allow patents on products that were manufactured in Brazil.¹²⁴ This regulation allowed Brazil to better protect its resources and increase its own production of drugs because they now had more control over how Brazilian resources would be used.¹²⁵

In 2001, the United States Trade Representative filed a complaint arguing

114. *Id.*

115. *Id.* at 134; Larry Rohter, *As Brazil Defends its Bounty, Rules Ensnare Scientists*, N.Y. TIMES (Aug. 28, 2007), <https://www.nytimes.com/2007/08/28/science/28biop.html> [<https://perma.cc/7QBK-Z3B2>].

116. Tustin, *supra* note 112, at 134; Rohter, *supra* note 115.

117. Tustin, *supra* note 112, at 134.

118. Paulo Prada, *Poisonous Tree Frog Could Bring Wealth to Tribe in Brazilian Amazon*, N.Y. TIMES (May 30, 2006), <https://www.nytimes.com/2006/05/30/business/worldbusiness/30frogs.html#:~:text=If%20a%20plan%20initiated%20by,from%20a%20poisonous%20tree%20frog> [<https://perma.cc/U8ZY-5HFD>].

119. *Id.*

120. *Id.*

121. Dunagan, *supra* note 1, at 622.

122. Prada, *supra* note 118.

123. Dunagan, *supra* note 1, at 616.

124. *Id.*

125. *Id.* at 627.

that certain provisions of Brazil's patent regulations violated the TRIPS Agreement.¹²⁶ Despite the pressure, Brazil did not change its policy and the United States eventually withdrew its complaint.¹²⁷ The removal of the complaint was not motivated by respect for Brazil's natural resources and sovereignty in enacting patent laws.¹²⁸ Instead, the removal was an attempt to avoid bad publicity for the United States.¹²⁹ Under the production requirements of the Brazilian law, the drugs could be produced at a lower cost, so continuing with the complaint would mean the United States was advocating for something that would result in more expensive drugs.¹³⁰ This would make drugs less accessible and cast the United States in a negative light.

2. Peru

Peru has also experienced the consequences of biopiracy and has created measures to protect the traditional knowledge of its indigenous groups.¹³¹ Peru enacted the first law protecting traditional knowledge in the world.¹³² It is a megadiverse country, has more than 4,000 known medicinal plants, and is home to more than forty-four indigenous groups.¹³³ In 1986, Loren Miller, a bioprospector, obtained a United States patent on the ayahuasca plant, a plant which has been used in Peru for religious and healing ceremonies for centuries.¹³⁴ After a request for reexamination was filed by indigenous groups, the United States Patent Trade Office (USPTO) rejected the Miller patent in 1999 on grounds of novelty.¹³⁵ However, the patent was reinstated on appeal after Miller was given the opportunity to submit additional evidence of the plant's patentability, and the opposing parties were precluded from any involvement in the reexamination process.¹³⁶ The

126. *Id.* at 617.

127. Barbara Crossette, *U.S. Drops Case Over AIDS Drugs in Brazil*, N.Y. TIMES (June 26, 2001), <https://www.nytimes.com/2001/06/26/world/us-drops-case-over-aids-drugs-in-brazil.html> [<https://perma.cc/NH72-VZAS>].

128. Dunagan, *supra* note 1, at 628.

129. *Id.* at 627-28.

130. *See id.* at 628.

131. Daniel S. Sem, *Co-Developing Drugs with Indigenous Communities: Lessons from Peruvian Law and the Ayahuasca Patent Dispute*, 23 RICH. J.L. & TECH. 1, 16 (2016).

132. Susanna E. Clark et al., *The Protection of Traditional Knowledge in Peru: A Comparative Perspective*, 3 WASH. U. GLOB. STUD. L. REV. 755, 773 (2004).

133. *Id.* at 770.

134. Sem, *supra* note 131, at 12.

135. *Id.* at 18-19.

136. *Protecting Traditional Knowledge: Ayahuasca Patent Dispute*, CENT. FOR INT'L

USPTO found that ayahuasca was patentable under the Plant Patent Act because it was found in a cultivated area, and it could be reproduced asexually.¹³⁷ Despite its use in other countries, the USPTO granted Miller the right to “exclude others from asexually reproducing the [plant] or selling or using the plant so reproduced” for two years based on the plant’s distinguishable characteristics such as leaf size and shape.¹³⁸

Peru’s measures to protect traditional knowledge are meant to promote equity and to provide a tool in the creation of sustainable livelihoods for indigenous communities.¹³⁹ Peruvian legislation protects traditional knowledge by granting indigenous groups rights in their traditional knowledge.¹⁴⁰ The law states that the collective knowledge is “inalienable and inalienable” because it is part of the cultural heritage.¹⁴¹ To access the traditional knowledge, interested researchers must first obtain prior informed consent from representative organizations of the indigenous group.¹⁴² If access is granted for the purposes of commercial or industrial use, a license agreement must be signed ensuring equitable distribution of the benefits derived from the use of the traditional knowledge.¹⁴³ Disobeying the provisions of the law by benefitting from traditional knowledge without consent and benefit sharing can lead to criminal charges.¹⁴⁴

In addition to legislation, Peru created the National Institute for the Defense of Free Competition and the Protection of Intellectual Property (INDECOPI) to promote consumer protection and fair competition in Peru.¹⁴⁵ The organization’s

ENV’T L. (Aug. 19, 2022, 8:59 PM), <https://www.ciel.org/project-update/protecting-traditional-knowledge-ayahuasca/> [<https://perma.cc/MT2T-5PSM>]; Glenn Wiser, *U.S. Patent and Trademark Office Reinstates Ayahuasca Patent*, CENT. FOR INT’L ENV’T L. 12 (Jun. 25, 2001), <https://www.ciel.org/wp-content/uploads/2015/06/PTODecisionAnalysis.pdf> [<https://perma.cc/KV79-7MV9>].

137. HOWARD J. LOCKER, U.S. DEP’T OF COM. PAT. AND TRADEMARK OFF., NOTICE OF INTENT TO ISSUE REEXAMINATION CERTIFICATE 2 (2001), https://www.ciel.org/wpcontent/uploads/2015/06/PTO_Examiner_Transcript.pdf [<https://perma.cc/M8FK-JEU4>]; 35 U.S.C. § 161.

138. LOCKER, *supra* note 137, at 3; 35 U.S.C. § 163.

139. Clark et al., *supra* note 132, at 770.

140. Ley No. 27811, 10 Aug. 2002, Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos [Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Regarding Biological Resources], EL PERUANO (Peru).

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*

145. Tiffany N. Palmer et al., *Millennial Demand for Alternative Medicine and Its Effects on Biopiracy*, 9 LANDSLIDE 26, 29 (2017).

view is that “the State exercises sovereign rights over its genetic resources, while indigenous peoples have rights over the collective knowledge they have created, developed, and preserved over the centuries.”¹⁴⁶

Additionally, Peru has a National Commission against Biopiracy which monitors patent applications for biopiracy and commences the process to invalidate those patents when necessary.¹⁴⁷

3. India

In India, in addition to legislation, the government has created a different tool to combat biopiracy.¹⁴⁸ In the 1990s, thousands of patent applications involving traditional Indian medicine were filed.¹⁴⁹ Some were invalidated after lawsuits, but without evidence of prior use, it was difficult to invalidate many of the patents.¹⁵⁰ In response to this challenge, the Indian government created a “massive electronic repository of herbal prior art” called the Traditional Knowledge Digital Library (TKDL).¹⁵¹ The TKDL is now more than 34 million pages long and has been translated into numerous languages.¹⁵²

To test the effectiveness of the TKDL, researchers examined whether there were any changes in patent applications after the creation of the TKDL.¹⁵³ The researchers found that codifying the “traditional herbal formulations” shifted patent applications away from pure herbal formulations and toward combinations of herbs and synthetic compounds.¹⁵⁴ The new inventions being patented were less similar to the prior art.¹⁵⁵ By making it difficult to obtain a patent on traditional herbal formulations, the TKDL inspired new research because patents on combinations of herbs, rather than traditional herbs, were more likely to be approved.¹⁵⁶

146. *Id.*

147. *Id.*

148. See Carmen Nobel, *Bio-Piracy: When Western Firms Usurp Eastern Medicine*, FORBES (Apr. 21, 2014, 10:43 AM), <https://www.forbes.com/sites/hbsworking-knowledge/2014/04/21/bio-piracy-when-western-firms-usurp-eastern-medicine/?sh=446769224ade> [<https://perma.cc/6VN5-9APL>].

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.*

154. Prithwiraj (Raj) Choudhury & Tarun Khanna, *Information Provision and Innovation: Natural Experiment of Herbal Patent Prior Art Adoption at the United States and European Patent Offices* 5 (Harvard Bus. Sch., Working Paper No. 14-079, 2018).

155. *Id.* at 1.

156. Nobel, *supra* note 148.

4. Policies in the United States

i. Bioprospecting in National Parks

In contrast to megadiverse countries, the United States currently has no legislation to directly combat biopiracy. However, the United States has implemented policies restricting bioprospecting in its own national parks.¹⁵⁷ In *Edmonds Institute v. Babbitt*, a United States District Court held that national parks could enter into agreements with bioprospectors seeking to conduct research in national parks.¹⁵⁸ In 1997, Yellowstone National Park entered into a cooperative research and development agreement (CRADA) with a biotechnology company, Diversa Corporation, which would allow the company to collect microorganisms from the national park.¹⁵⁹ The agreement required payment from any of Diversa's marketable findings and was the first time a national park had contracted to benefit financially from a bioprospector's findings.¹⁶⁰ The court held that Yellowstone National Park satisfied the definition of "laboratory" under the Federal Technology Transfer Act, that the CRADA between Diversa and Yellowstone was permissible, and that bioprospecting was not a "sale or commercial use."¹⁶¹

CRADAs are beneficial to national parks because they "allow the Park to share in revenues generated by beneficial development, and thus, provide a valuable source of funding."¹⁶² These types of agreements only permit a bioprospector to use their findings for commercial purposes if they have entered into an agreement with the national park, ensuring that any commercial product will be subject to a payment to the agency.¹⁶³ Upholding this type of agreement has created a direct connection between the national park's financial future and the "commercial, extractive interests within the Park."¹⁶⁴ The court found that Diversa was not making "commercial use" of Park resources because they would be obtaining patents on products created using those resources, not acquiring title to the specimens themselves.¹⁶⁵ The decision in this case demonstrates the court's interest in protecting national park resources while also ensuring there is financial compensation

157. See *Edmonds Inst. v. Babbitt*, 42 F. Supp. 2d 1, 4-5 (D.D.C. 1999).

158. *Id.* at 4; Mike Wood, *Are National Park Resources for Sale?: see generally* *Edmonds Institute v. Babbitt*, 21 PUB. LAND & RES. L. REV. 201 (2000).

159. *Edmonds Inst. v. Babbitt*, 42 F. Supp. 2d 1, 4-5 (D.D.C. 1999).

160. *Id.* at 5.

161. See *Edmonds Inst. v. Babbitt*, 93 F. Supp. 2d 63, 63 (D.D.C. 2000).

162. *Id.* at 71; Wood, *supra* note 158, at 205.

163. *Edmonds Inst.*, 93 F. Supp. 2d at 64; Wood, *supra* note 158, at 204.

164. Wood, *supra* note 158, at 222.

165. *Edmonds Inst.*, 93 F. Supp. 2d at 72.

for the benefits derived from those resources.

ii. State Bioprospecting Laws: Utah

After the decision in *Babbitt*, Utah became the first state to enact bioprospecting legislation.¹⁶⁶ The Utah statute requires registration before engaging in bioprospecting.¹⁶⁷ The registration includes payment of a fee, “notice of the state’s reservation of economic interest,” a signed statement from the person registering stating that the person agrees to negotiate with the state, and the locations where the bioprospecting will occur.¹⁶⁸

The statute protects the state’s economic interests by subjecting the right to bioprospect to the rights the state has to the economic benefit derived from bioprospecting and from any information regarding the genetic properties of materials removed from “a natural environment in the state.”¹⁶⁹ Additionally, a person is prohibited from engaging in bioprospecting in Utah if the person does not agree to negotiate in good faith with the state.¹⁷⁰ To enforce registration, the statute provides that a person found to engage in bioprospecting without satisfying the requirements of this law, can be found guilty of criminal trespass.¹⁷¹ Furthermore, the person may be ordered to pay restitution that is “proportional to the economic interests the state may have.”¹⁷²

The provisions of the Utah statute make clear the state’s economic interests in allowing people to engage in bioprospecting within its borders. Because the United States has not ratified the CBD, there is no requirement of benefit sharing when creating patent rights at the federal level.¹⁷³ The Utah statute provides a connection between benefit sharing and patent rights through its registration and negotiation requirements.¹⁷⁴ Utah has created a regulatory solution for an issue that

166. Emily J. Stolfer, *Bioprospecting Legislation in the United States: What We are Doing, What We are Not Doing, and What Should We Do Next*, 65 CLEV. ST. L. REV. 101, 117 (2017).

167. UTAH CODE ANN. § 65A-14-201 (West 2016).

168. *Id.*

169. *Id.*

170. UTAH CODE ANN. § 65A-14-202 (West 2016).

171. UTAH CODE ANN. § 65A-14-301 (West 2016).

172. *Id.*

173. See William M. Fischer, *The Utah Bioprospecting Act of 2010: (Unintentional) State-Level Implementation of the United Nations Convention on Biodiversity*, 10 J. ON TELECOMM. & HIGH TECH. L. 197, 225 (2012).

174. See § 65A-14-201, 202; Fischer, *supra* note 173, at 214.

does not have an effective federal solution.¹⁷⁵ In doing so, Utah has “unintentionally engaged in back door implementation of the CBD.”¹⁷⁶

IV. WHAT THE UNITED STATES NEEDS TO CHANGE

To continue benefitting from the biodiversity of other countries, the United States needs to take legal action to ensure its relationship with megadiverse countries is not hindered by the lack of respect and the misappropriation for those countries’ traditional knowledge.

A. Disclosure Requirements

First, the United States needs to change its requirements for disclosure of use of traditional knowledge in its patent applications.¹⁷⁷ The United States patent law disclosure requirement is currently too broad and even if an inventor relies on traditional knowledge, they often do not disclose it because there is legal uncertainty about when disclosure is required.¹⁷⁸ A clear legal standard stating the level of reliance that requires disclosure would remove any uncertainty and make it easier for patent officers to determine whether an inventor has failed to disclose relevant information.¹⁷⁹

A possible issue with this disclosure requirement being effective is the asymmetry in knowledge available to the patent officer examining a patent application and the knowledge available to the inventor.¹⁸⁰ It is difficult for a patent application examiner to know how much traditional knowledge an inventor has relied on because traditional knowledge is not easily accessed.¹⁸¹ To enable patent officers to make a more informed determination of patentability for inventions that rely on traditional knowledge, the United States can follow India’s example in the creation and utilization of a TKDL.¹⁸² Use of a TKDL will aid in reducing the gap between the knowledge available to the patent examiner and the inventor applying for a patent.¹⁸³

Documenting traditional knowledge and providing a library of it to patent

175. Fischer, *supra* note 173, at 214-15.

176. *Id.* at 215.

177. *See Patents, Disclosure, and Biopiracy, supra* note 15, at 535.

178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.*

182. *See Nobel, supra* note 148.

183. *See id.*; *see also Patents, Disclosure, and Biopiracy, supra* note 15, at 548.

officers will deter biopiracy because it will prevent the granting of patents on inventions that have a strong reliance on traditional knowledge without any further innovation.¹⁸⁴ Additionally, it would encourage innovation that could lead to the creation of useful drugs because more effort would be required to get a patent approved for inventions that rely on traditional knowledge.¹⁸⁵ Documentation of traditional knowledge will also benefit the source communities because it will provide a method to preserve knowledge that is being lost at a rapid rate.¹⁸⁶

There is criticism of attempts to document traditional knowledge because documentation will make traditional knowledge more accessible, increasing the risk of unauthorized takings for commercial purposes.¹⁸⁷ Nevertheless, documentation is essential because under the current application of a “prior art” standard, information that is not documented will not be recognized as prior art and will therefore be patentable.¹⁸⁸

B. Modify the Definition of Prior Art

The United States needs to alter its definition of prior art to cover information like traditional knowledge that is known to be used in other countries but has not been formally documented. Expanding prior art to include traditional knowledge will not require additional research by the patent office examiner if the patent applicant is required to disclose the use of traditional knowledge on their own. Using a different standard than other countries in determining what is prior art means that the same invention can be granted a patent in one country and denied a patent in another country.¹⁸⁹ The inventor is able to benefit financially from traditional knowledge in some countries while the country that provided the knowledge is against its use.¹⁹⁰ Expanding the definition of prior art in this manner will combat biopiracy because it will discourage inventors from attempting to obtain patents on pure herbal formulations that have already been in use for centuries.¹⁹¹ It would require them to make an improvement to the item before they are able to obtain a

184. See Prithwiraj (Raj) Choudhury & Tarun Khanna, *Information Provision and Innovation: Natural Experiment of Herbal Patent Prior Art Adoption at the United States and European Patent Offices* 4 (Harvard Bus. Sch., Working Paper No. 14-079, 2018).

185. See *id.*

186. *International Intellectual Property Law*, *supra* note 3, at 329.

187. Javier Garcia, *Fighting Biopiracy: The Legislative Protection of Traditional Knowledge*, 18 BERKELEY LA RAZA L.J. 5, 24 (2007).

188. *Id.* at 14.

189. Ho, *supra* note 49, at 446.

190. See *generally id.*

191. See *generally* Choudhury & Khanna, *supra* note 184.

patent for it.¹⁹²

C. Require Benefit Sharing with Source Community

Additionally, the United States needs to take action to ensure the indigenous communities' traditional knowledge is not only being recognized, but also receiving some of the benefits derived from use of their traditional knowledge. The United States needs to implement a benefit-sharing requirement when granting patents based on traditional knowledge. This would strengthen the relationship between the United States and megadiverse countries, and facilitate research for American bioprospectors.¹⁹³ It would create a win-win solution because the bioprospector can benefit financially from the invention and the local community that provided traditional knowledge can benefit from some of that wealth.¹⁹⁴

The current United States bioprospecting policies requiring monetary benefits to be shared with the state where the bioprospecting occurred, demonstrate the policymakers' recognition that resources taken from a specific land should result in benefits for the nation they were taken from.¹⁹⁵ While engaging in bioprospecting in other nations, the United States should apply the same principles it has applied in its own land and respect foreign nations' restrictions on bioprospecting and their benefit sharing requirements.

D. Enact a Global Solution

Finally, even with local legislation in the United States, it will be difficult for these laws to be effective without a global solution. The United States needs to ratify the CBD so that traditional knowledge is recognized, and individual State sovereignty rights are respected. "Protection of [traditional knowledge] is only effective if it binds industrialized and developing countries alike. This is only possible with a global-scale protection. Only a paramount level of international law can safeguard indigenous communities against a violation of their rights by their own governments or by other States."¹⁹⁶

Ratification of the CBD will provide a necessary global solution so that the same rights are protected by all nations engaging in bioprospecting. Laws in each country can be effective in protecting the traditional knowledge within their own territory but are not effective in controlling the granting of patents outside of their

192. *See id.*

193. *See Stoller, supra* note 166, at 124-25.

194. Nobel, *supra* note 148.

195. *See Edmonds Inst. v. Babbitt*, 93 F. Supp. 2d 63, 71 (D.D.C. 2000); UTAH CODE ANN. § 65A-14-202 (2016).

196. Cottier & Panizzon, *supra* note 110, at 386.

borders.¹⁹⁷ Regulations that are agreed upon internationally should eventually lead to international recognition of standards to protect traditional knowledge.¹⁹⁸

V. CONCLUSION

“Piracy by patents” has earned billions for developed nations and almost nothing for the developing nations who provided the information on which those inventions were based.¹⁹⁹ The value and benefits of traditional knowledge has repeatedly been proven in the creation of new medicines.²⁰⁰ It is imperative to create a system that allows for continuous access to that traditional knowledge while protecting the rights of the indigenous groups that provide the knowledge.

To ensure bioprospectors have access to that knowledge, the United States needs to enact legislation and adopt policies that strengthen the relationship with megadiverse countries by participating in benefit-sharing agreements and increasing the amount of disclosure required in patent applications. Bioprospecting policies in the United States have created a system that ensure any monetary benefit derived from the state’s resources is shared with the state. These regulations on bioprospecting within the United States’ own land echo the demands foreign nations have with regards to benefit-sharing. Innovation based on the natural resources and traditional knowledge of indigenous communities should involve collaboration with the source community, not an unfair taking benefitting only the developed nation.

197. *See generally* Palmer et al., *supra* note 145.

198. Clark et al., *supra* note 132, at 775.

199. *Patents, Disclosure, and Biopiracy*, *supra* note 15, at 537; *see* Garcia, *supra* note 187, at 5; *see also* Prada, *supra* note 118.

200. *Intellectual Property and Bioprospecting*, *supra* note 5, at 268.