THE NECESSITY OF MOVING FROM BIOPIRACY TO COLLABORATION

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Early exploitation of Indigenous communities' traditional medical knowledge involved theft of natural resources. Today, this knowledge is exploited through biopiracy: the use of traditional medical knowledge by third parties to obtain intellectual property rights in pharmaceuticals based on that knowledge. Many scholars have rightly argued traditional medical knowledge and Indigenous communities themselves should be protected from this exploitation. However, existing literature on biopiracy largely glosses over a crucial topic: how traditional medical knowledge is used by third parties in their scientific research. This Comment fills that gap.

Through an examination of how traditional medical knowledge is used in scientific research—specifically ethnopharmacology, natural products chemistry, and drug discovery and development—this Comment argues that protecting traditional medical knowledge does not substantially impede innovation. This Comment then discusses why existing intellectual property regimes do not effectively protect traditional medical knowledge without modification. Although current patent and trade secret laws could be modified to cover traditional medical knowledge, such modification for traditional medical knowledge is a practically impossible. The best mechanism to protect traditional medical knowledge is defensive protection. Through a combination of documenting knowledge, imposing patent disclosure requirements, and requiring access and benefit-sharing agreements, Indigenous communities can obtain control over their knowledge. This de facto right in their knowledge would allow Indigenous communities to collaborate with the scientific community rather than endure continued exploitation.

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I. INTRODUCTION

William Dampier was a late seventeenth- and early eighteenth-century naturalist who lived for a short time in the Bay of Campeche in eastern Mexico.[1] He used the earnings from his work as a logger to fund his scientific research until a hurricane tore through the Caribbean in 1676.[2] After the hurricane, Dampier lost his job and needed a new source of income to continue his true passion, scientific research.[3] So, Dampier became a buccaneer and recorded his observations of any plants, animals, and cultures he encountered on his journeys.[4] In 1697, Dampier published these notes in *A New Voyage Round the World*, with a first volume in 1697 and a second volume in 1699.[5]

The success of his books brought Dampier acclaim throughout the scientific community, leading to his selection as commander of a first-of-its-kind

1. Dampier was one of the greatest naturalists at the time, and he inspired the writings of Daniel Defoe and Jonathan Swift. SAM KEAN, THE ICEPICK SURGEON 11–12 (1st ed. 2021). Charles Darwin was also a fan and was particularly inspired by Dampier's work on his famous 19th century *HMS Beagle* expedition. *Id.*; *Scientist of the Day—William Dampier*, LINDA HALL LIBRARY (June 8, 2021), https://www.lindahall.org/about/news/scientist-of-the-day/william-dampier.

2. Dampier's detailed description of this hurricane was significant for meteorology as the first of its kind. KEAN, *supra* note 1, at 12–14.

3. *Id.* at 14.

4. *Id.* at 14–16. Buccaneers often kept journals of their travels which they would later publish; Dampier kept some of the best journals. *Id.* Dampier kept his journal in a bamboo tube sealed with wax to protect it from damage. Jess Romeo, *William Dampier, Pirate Scientist*, JSTOR DAILY (Sept. 19, 2021), https://daily.jstor.org/william-dampier-pirate-scientist.

5. Romeo, *supra* note 4; *Scientist of the Day–William Dampier*, *supra* note 1.

government-sponsored expedition to the western coast of Australia, known at the time as New Holland.[6] On this journey, Dampier recorded detailed observations of not only the natural world but also food and cuisine from different cultures.[7] Throughout his travels, Dampier ate with local residents and wrote down his observations of their customs and practices.[8] Dampier's books likely contained the first English-language recipe for guacamole as well as the first English-language uses of the terms "chopsticks," "barbeque," "tortilla," and "soy sauce."[9] The colonial era adventures of William Dampier were prologues to modern biopiracy.

The exploits of Manuel Incra Mamani and Charles Ledger have more in common with modern biopiracy than any of Dampier's deeds. Their story begins with the cinchona tree.[10] Native to South America, the cinchona tree's bark is the only natural source of quinine, a treatment for malaria.[11] An Indigenous treatment using cinchona tree bark as an anti-malarial likely predates use by Jesuit missionaries in the seventeenth century.[12] In colonial times, malaria tore through human civilization, leaving a global trail of bodies in its wake.[13] Because quinine was the best treatment at the time, cinchona trees became highly sought-after resources.[14] European nations sought to grow their own cinchona trees by stealing the seeds from South American nations.[15] All European smuggling attempts failed until Charles Ledger hired Manuel Incra Mamani, a Bolivian Indian, to steal the seeds in the nineteenth century.[16] Mamani stole forty pounds of seeds from a species of cinchona tree that contained more quinine than other species and delivered them to Ledger, who went on to sell the seeds to Dutch planters.[17] When Ledger sent Mamani back to procure more seeds, Mamani was apprehended and charged with smuggling.[18]

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6. Romeo, *supra* note 4. Dampier published *A Voyage to New Holland* in two volumes in 1703 and 1709 from his notes on this expedition. *Scientist of the Day—William Dampier*, *supra* note 1.

7. Luke Fater, *The Pirate Who Penned the First English-Language Guacamole Recipe*, GASTRO OBSCURA (July 26, 2019), https://www.atlasobscura.com/articles/first-food-writer.

8. *Id.*

9. *Id.* CAPTAIN WILLIAM DAMPIER, A NEW VOYAGE ROUND THE WORLD: VOL. I 203 (1703) ("[T]he fruit is as big as a large Limon. It is of a green colour till it is ripe, and then it is a little yellowish. They are seldom fit to eat till they have been gathered 2 or 3 days; then they become soft, and the Skin or Rind will peel off. The substance in the inside is green, or a little yellowish, and as soft as butter. Within the substance there is a Stone as big as a Horse-Plumb. This Fruit hath no taste of it self, and therefore *'tis usually mixt with Sugar and Lime-juice, and beaten together in a Plate; and this is an excellent Dish*.") (emphasis added).

10. Louis Werner, *Quinine's Feverish Tales and Trails*, AMERICÁS, Oct. 2003, at 25.

11. *See id.* at 25 (detailing history of quinine as remedy for malaria).

12. Jane Achan et al., *Quinine, an Old Anti-Malarial Drug in a Modern World: Role in the Treatment of Malaria*, MALARIA J., May 2011, at 1, 1.

13. *See* KEAN, *supra* note 1, at 28 (detailing estimates of human beings killed by mosquito-borne viruses, specifically malaria).

14. *Id.*

15. *Id.*

16. *Id.* at 28–29.

17. *Id.*; Werner, *supra* note 10, at 29.

18. Werner, *supra* note 10, at 29. Mamani was jailed, starved, and beaten for two weeks.

Historians are divided on whether Mamani and Ledger's crimes were justified.[19] Smuggling the cinchona seeds was an act of colonialism—an intrusion on the sovereignty of a country deemed subordinate.[20] However, Peru and Ecuador were hoarding quinine and driving the cinchona trees to extinction.[21] Cinchona trees grown from the smuggled seeds saved innumerable lives, especially in Africa and Asia.[22] The theft of Mamani and Ledger was a turning point in the evolution of biopiracy. Mamani and Ledger stole a physical natural resource; modern biopiracy involves the theft of something far less tangible—knowledge itself.

A story about the hoodia cactus involves the theft of knowledge. The San people live in the Kalahari Desert in South Africa and use the hoodia cactus as a source of food and water.[23] The cactus suppresses hunters' hunger and thirst, allowing them to complete long journeys.[24] The South African Center for Scientific and Industrial Research (CSIR) used this knowledge about the hoodia cactus to begin developing an obesity treatment derived from P57, the molecule in the cactus responsible for suppressing appetite.[25] Recognizing the value of P57, CSIR obtained patent protection; Pfizer and Phytopharm obtained licenses from CSIR to develop a marketable obesity treatment.[26]

Widespread media attention about these licensing agreements alerted the San people to CSIR's unauthorized use of San knowledge.[27] Accused of biopiracy by the San, CSIR asserted that it had always intended to share the benefits from the invention with the San people;[28] however, one of CSIR's licensees claimed that CSIR led them to believe that the San people "were extinct."[29] Once alerted to CSIR's activities, the San communities formed the South African San Institute, which negotiated a benefit-sharing agreement with CSIR.[30] After these negotiations, the San people eventually received royalties and shared benefits from sales of P57.[31] In addition, CSIR formally acknowledged the role the San people's

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KEAN, *supra* note 1, at 29. A few days after his release, Mamani died from his injuries. *Id.*

19. *See* KEAN, *supra* note 1, at 29 (discussing competing views of whether lives saved justify crimes).

20. *See id.* (discussing exploitative nature of Dampier's actions).

21. *Id.*

22. *Id.*

23. *Case Study: Hoodia Cactus (South Africa)*, CASE W. RSRV. UNIV. (Oct. 20, 2006, 1:15:19 PM), https://case.edu/affil/sce/authorship-spring2004/hoodia.html.

24. *Id.*

25. *Id.*; *Leveraging Economic Growth Through Benefit Sharing*, WORLD INTELL. PROP. ORG. [WIPO] (Sept. 16, 2015), https://www.wipo.int/ipadvantage/en/details.jsp?id=2594.

26. *Leveraging Economic Growth Through Benefit Sharing*, *supra* note 25.

27. *Case Study: Hoodia Cactus (South Africa)*, *supra* note 23.

28. *Id.*

29. *Id.*

30. The Institute recognized that reversing existing research, patents, and licensing agreements was not practical, so they focused on a realistic goal of receiving benefits from CSIR's research and commercialization. *Leveraging Economic Growth Through Benefit Sharing*, *supra* note 25.

31. *Id.*

traditional knowledge played in their P57 research program.[32]

Both the act of piracy by William Dampier to fund his scientific research and the act of smuggling by Charles Ledger and Manuel Incra Mamani to traffic natural resources are precursors to modern biopiracy. The hoodia cactus story illustrates that pharmaceutical companies and researchers develop many new drugs from chemical compounds found in natural resources without compensating the Indigenous communities that first discovered the resources' utilities.[33] Indigenous communities around the world have developed their own cultures, practices, and knowledge systems, which include how to use natural resources to treat illnesses within their communities.[34] These practices and knowledge systems are often referred to as traditional knowledge.[35] Ultimately, outsiders to the community recognized the value of this knowledge.[36] Pharmaceutical companies, academic researchers, and other scientists began using traditional medical knowledge to produce new inventions beneficial to society.[37] Such innovation is often undertaken without the consent of the Indigenous communities who hold the traditional medical knowledge.[38] This is biopiracy.[39]

Indigenous communities need effective mechanisms to safeguard their knowledge and protect themselves from exploitation.[40] Positive protection would give Indigenous communities themselves intellectual property rights, through patents and trade secrets, in their knowledge and the ability to control the use of their knowledge.[41] Existing intellectual property laws do not sufficiently protect traditional medical knowledge as patents or trade secrets because they fail to contemplate for prior involuntary public disclosure of traditional medical knowledge.[42] Indigenous communities are unlikely to receive intellectual property

32. *Id.*

33. *See* KEAN, *supra* note 1, at 30 (discussing continued practice of biopiracy in modern times).

34. RYAN ABBOTT, DOCUMENTING TRADITIONAL MEDICINAL KNOWLEDGE 3 (2014), https://www.wipo.int/export/sites/www/tk/en/resources/pdf/medical_tk.pdf.

35. *See id.* (describing breadth of content that comprises traditional knowledge).

36. *See* Janna Rose, *Biopiracy: When Indigenous Knowledge is Patented for Profit*, THE CONVERSATION (Mar. 7, 2016, 7:32 PM), https://theconversation.com/biopiracy-when-indigenous-knowledge-is-patented-for-profit-55589 (describing widespread practice of biopiracy in pharmaceutical, agricultural, and other industries).

37. Ryan D. Levy & Spencer Green, *Pharmaceuticals and Biopiracy: How the AIA May Inadvertently Reduce the Misappropriation of Traditional Medicine*, 23 U. MIAMI BUS. L. REV. 401, 406–07 (2015).

38. Rose, *supra* note 36.

39. *Id.*

40. The necessary protection could be positive or defensive. WORLD INTELL. PROP. ORG., INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND TRADITIONAL CULTURAL EXPRESSIONS 22 (2020) [hereinafter IP AND GR, TK AND TCE]. Positive protection allows people to acquire and assert intellectual property rights in their traditional knowledge and traditional cultural expressions, while defensive protection prevents people outside of the community from acquiring these rights. *Id.*

41. *Id.*

42. But the laws can be modified. See *infra* Part IV for a discussion of the suitability of patent and trade secret protection for traditional medical knowledge.

rights in their traditional medical knowledge because existing frameworks would need to be modified.

Without positive protection for their traditional medical knowledge, Indigenous communities would require mechanisms to prevent third parties from using the knowledge or to bargain with third parties who want to use the knowledge. Defensive protection provides an avenue for communities to accomplish this goal.[43] Ensuring Indigenous communities can leverage their knowledge for their own benefit would allow them to engage with the scientific community through collaboration rather than continued exploitation. Furthermore, documentation of traditional medical knowledge would allow Indigenous communities to challenge or prevent third parties from acquiring intellectual property rights—especially patent rights—based on the documented traditional medical knowledge.[44] Requirements for patent disclosure[45] and for access and benefit-sharing agreements[46] would help prevent third parties from exploiting traditional medical knowledge if they lack consent from the Indigenous community who developed the knowledge. These mechanisms would ensure that communities can protect themselves from biopiracy.

This Comment will identify and critique legal frameworks for protecting traditional medical knowledge and argue that these frameworks are necessary to allow Indigenous communities to engage with the scientific community through collaboration rather than exploitation. Systems of positive protection—existing patent and trade secret laws—should be made more inclusive of traditional medical knowledge in order to sufficiently protect it. Forms of defensive protection—such as documentation, patent disclosure requirements, and access and benefit-sharing agreements—could be effective tools for protecting the interests of Indigenous communities, but these communities remain vulnerable without widespread international and national frameworks of defensive protection. Incorporated in this critique is a discussion of how pharmaceutical research uses traditional medical knowledge and how protecting this knowledge would affect scientific research and innovation. Part II discusses the nature of traditional medical knowledge and why such knowledge should be protected. Part III explains how scientists use traditional medical knowledge in research. Part IV describes why existing patent and trade secret systems of positive protection are ineffective for traditional medical knowledge. Part V discusses the efficacy of different approaches to defensive protection of traditional medical knowledge: documentation of knowledge, patent disclosure requirements, and access and benefit-sharing agreements.

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43. IP AND GR, TK AND TCE, *supra* note 40, at 22 (describing different approaches to protecting Indigenous communities' knowledge).

44. See *infra* Section V.A for a discussion of how systems of documenting traditional medical knowledge can be used to protect Indigenous communities' interests in their knowledge.

45. See *infra* Section V.B for a discussion of how national patent disclosure requirements can be used to encourage transparency in the use of resources and to prevent third party misappropriation of traditional medical knowledge.

46. See *infra* Section V.C for a discussion of how access and benefit-sharing agreements can be used to protect the interests of Indigenous communities in their traditional medical knowledge.

II. TRADITIONAL MEDICAL KNOWLEDGE: PROVEN VALUE BUT UNPROTECTED

Traditional medical knowledge is valuable both to its Indigenous creators and to the world at large. This knowledge should be protected and preserved. Traditional medical knowledge forms an important part of the identity and heritage of an Indigenous community.[47] A community's traditional knowledge arises out of the accumulated experiences of that community and its holistic relationship with its surrounding environment.[48] Traditional knowledge reflects a community's culture and beliefs and is valuable to the community for preserving that culture.[49] This knowledge includes any medical practices—collectively known as traditional medical knowledge—developed by that community.[50] Traditional medical knowledge comprises any therapeutics derived from plants, animals, or minerals for treating illnesses, as well as any spiritual or physical therapies.[51]

Traditional medicines remain a large part of health care in places like China and sub-Saharan Africa.[52] In addition to their use as alternative medicines, traditional medicines are recognized as an efficient way to search for new and better pharmaceuticals.[53] Scientists have long exploited traditional medical knowledge to promote research into natural product chemistry and develop new pharmaceuticals.[54] Relationships between traditional practices and pharmaceutical

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47. *See* ABBOTT, *supra* note 34, at 5 (explaining impact that traditional medical knowledge has on a community's economy which helps shape its identity); WIPO, BACKGROUND BRIEF NO. 6: INTELLECTUAL PROPERTY AND TRADITIONAL MEDICAL KNOWLEDGE (2015) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_6.pdf [hereinafter BACKGROUND BRIEF NO. 6] (detailing social, cultural, and scientific value that traditional medical knowledge brings to Indigenous communities).

48. Mindahi Crescencio Bastida-Muñoz & Geraldine A. Patrick, *Traditional Knowledge and Intellectual Property Rights: Beyond TRIPS Agreements and Intellectual Property Chapter of FTAS*, 14 MICH. ST. J. INT'L L. 259, 261 (2006); Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 446–447 (2006).

49. ABBOTT, *supra* note 34, at 6.

50. This knowledge includes practices developed and improved over generations. ABBOTT, *supra* note 34, at 3. As defined by the World Health Organization, traditional medicine is "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences [I]ndigenous to different cultures" to maintain health and help prevent, diagnose, and treat both physical and mental illnesses." *Traditional, Complementary and Integrative Medicine*, WORLD HEALTH ORG., https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab_1 (last visited Jan. 13, 2022).

51. ABBOTT, *supra* note 34, at 3.

52. Daniel Bennett, *The Tension Between Traditional and Western Medicine*, UNIV. OF S. CAL. SCHAEFFER: THE EVIDENCE BASE (July 11, 2017), https://healthpolicy.usc.edu/evidence-base/the-tension-between-traditional-and-western-medicine/.

53. *See* Gelvina Rodriguez Stevenson, *Trade Secrets: The Secret to Protecting Indigenous Ethnobiological (Medicinal) Knowledge*, 32 N.Y.U. J. INT'L L. & POL. 1119, 1131 (2000) (describing increased research emphasis placed on Indigenous ethnobiological knowledge due to its efficiency); Bhushan Patwardhan, *Ethnopharmacology and Drug Discovery*, 100 J. ETHNOPHARMACOLOGY 50, 51 (2005) (describing positive trend of research using traditional and integrative health sciences).

54. Thanh-Hoang Nguyen-Vo et al., *Plant Metabolite Databases: From Herbal Medicines to Modern Drug Discovery*, 60 J. CHEM. INFO. & MODELING 1101, 1102 (2020); Daniel A. Dias

uses of medicinal plants can inspire drug research.[55] Many modern drugs and vaccines originated as traditional medicines and were developed without the consent of the Indigenous community holding the knowledge.[56] This exploitation of traditional medical knowledge is biopiracy and has its origins in colonialism.[57]

Many industries, such as the pharmaceutical and agricultural industries, have reaped the benefits of biopiracy.[58] These benefits concentrate power in wealthy countries with high technological capabilities at the expense of countries rich in coveted traditional resources[59] and must be shared with the Indigenous communities which cultivated the knowledge. Addressing biopiracy requires the assistance of developed nations because the intellectual property laws protecting inventions that use traditional medical knowledge are largely enforced in those nations.[60] Developed countries prefer strong intellectual property laws that incentivize innovation[61] and allow them to reap immediate benefits because innovators within their borders possess the majority of protected intellectual property.[62] However, developing countries hold most traditional knowledge within their borders.[63] These countries are disadvantaged by intellectual property laws that do not extend protection to traditional knowledge because their valuable knowledge and resources are not protected.[64]

In general, traditional medical knowledge should be protected to prevent biopiracy, respect the autonomy of Indigenous communities, and preserve Indigenous cultures. Proponents of protecting traditional medical knowledge argue that biopiracy should be prevented because it is morally offensive to exploit Indigenous communities and their resources.[65] Biopiracy-related patents often protect inventions derived from a community's genetic resources.[66] These genetic resources include parts of biological materials such as plants, animals, or

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et al., *A Historical Overview of Natural Products in Drug Discovery*, 2 METABOLITES 303, 310 (2012).

55. Nguyen-Vo et al., *supra* note 54, at 1102.

56. ABBOTT, *supra* note 34, at 10; Michael Heinrich et al., *A Perspective on Natural Products Research and Ethnopharmacology in Mexico: The Eagle and the Serpent on the Prickly Pear Cactus*, 77 J. NAT. PRODS. 678, 678 (2014).

57. Rose, *supra* note 36; *see also* Daniella Silva, *Biopiracy: The Largely Lawless Plundering of Earth's Genetic Wealth*, LANDSCAPE NEWS (Dec. 15, 2020), https://news.globallandscapesforum.org/48905/biopiracy-the-largely-lawless-plundering-of-earths-genetic-wealth/ (describing misappropriation of genetic resources and traditional knowledge through intellectual property system).

58. Rose, *supra* note 36.

59. *Id.*

60. Ho, *supr*a note 48, at 438–39.

61. Rodriguez Stevenson, *supra* note 53, at 1126.

62. Most intellectual property protection is issued to inventors in developed countries. Rodriguez Stevenson, *supra* note 53, at 1126. Developed countries argue that promoting innovation requires strong intellectual property laws because scientific and technological advances bolster a country's international competitiveness. *Id.*

63. Ho, *supr*a note 48, at 446.

64. *Id.*

65. *Id.* at 435–36.

66. *Id.* at 448.

microorganisms that contain valuable genetic information—like the plants used in traditional medicines.[67] Because of these resources' value, proponents argue that protecting traditional medical knowledge safeguards the rights of, and shows respect for, the Indigenous communities.[68] Opponents counter that intellectual property systems are not intended to profess moral values and instead exist for the purpose of promoting innovation.[69]

In addition to moral arguments, proponents insist that protection for traditional medical knowledge would safeguard the communities' cultures and interests because the knowledge has intrinsic value to those communities.[70] Because traditional knowledge is a part of a community's identity, communities should have a right to that identity and the ability to exert control over its use—commercial or otherwise.[71] Through this right, Indigenous communities can obtain monetary compensation for their community through instruments like access and benefit-sharing agreements.[72] Although Indigenous communities have at times received compensation for uses of their knowledge, that compensation often is only offered after scientific research institutions or corporations are compelled to do so. For example, only when a corporation receives bad publicity for its biopiracy will it choose to compensate the Indigenous community to rehabilitate its reputation.[73] Supporters of intellectual property rights for traditional medical knowledge argue that protection and compensation are fair to communities who have expended time and effort developing this valuable asset.[74]

Proponents of protecting traditional medical knowledge also argue that such protection conserves natural resources and preserves the knowledge itself.[75] Communities can conserve the natural resources centered within their culture by protecting these resources and knowledge from further exploitation.[76] Yet, not all Indigenous communities wish to commercialize their traditional knowledge.[77] Some argue that traditional medical knowledge is sacred and should not be

67. IP AND GR, TK AND TCE, *supra* note 40, at 18.

68. WIPO, *The Protection of Traditional Knowledge: Updated Draft Gap Analysis*, para. 76, WIPO Doc. WIPO/GRTKF/IC/37/6 (July 20, 2018) [hereinafter *Updated Draft Gap Analysis*].

69. David R. Downes, *How Intellectual Property Could be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENV'T L. 253, 261 (2000).

70. *Updated Draft Gap Analysis*, *supra* note 68, para 76.

71. Ameera Haider, *Reconciling Patent Law and Traditional Knowledge: Strategies for Countries with Traditional Knowledge to Successfully Protect Their Knowledge from Abuse*, 48 CASE W. RSRV. J. INT'L L. 347, 355 (2015).

72. *Id.* at 354; Downes, *supra* note 69, at 257.

73. *See* Ho, *supra* note 48, at 459 (explaining that compensation is often only negotiated after negative publicity and tends to provide miniscule percentage of profits).

74. Haider, *supra* note 71, at 354.

75. *Updated Draft Gap Analysis*, *supra* note 68, at para. 76.

76. *See* Rodriguez Stevenson, *supra* note 53, at 1120–21 (explaining that intellectual property rights create incentives to defend natural resources and provide protection from further exploitation).

77. *See* Ho, *supra* note 48, at 459 (explaining that many groups find it morally offensive and improper to patent sacred knowledge).

commercialized.[78] Because this sacred knowledge transcends monetary incentives, some believe that Western intellectual property values are incompatible with their own community's cultural values.[79] Due to this clash in values, some communities believe that applying intellectual property laws to Indigenous communities would amount to imposing Western values on those communities.[80] Any effort to protect traditional medical knowledge would need to allow Indigenous communities to decide how best to manage their own knowledge and account for the diverse beliefs among the communities themselves.[81]

Outside of Indigenous communities, opponents of protection for traditional medical knowledge argue that protection is unnecessary and would impede innovation.[82] Critics of efforts to protect traditional knowledge argue against specific protection for traditional knowledge because they believe that existing intellectual property systems already protect it.[83] This assertion may be theoretically true but is practically unachievable.[84] Western countries frame the problem as a misunderstanding of existing intellectual property laws.[85] They argue that individuals within an Indigenous community who help develop a particular traditional medicine are inventors under existing intellectual property systems, even if the knowledge is held communally by the Indigenous community.[86] Opponents also argue that current intellectual property systems are sufficient because they incentivize developing innovative uses of natural resources by *anyone*, including Indigenous communities.[87]

The final argument against protecting traditional medical knowledge is that such protection would unreasonably impede the development of new pharmaceuticals.[88] Opponents contend that intellectual property protection serves a

78. *See id.* at 448 (explaining that traditional knowledge has spiritual value and some Indigenous groups find it improper to attribute authorship to such knowledge).

79. *See id.* at 459 (explaining that Western solution to provide monetary compensation fails to acknowledge sacred status of traditional knowledge); *see also* Rodriguez Stevenson, *supra* note 53, at 1120 (describing incompatibility of intellectual property laws with Indigenous cultures).

80. Rodriguez Stevenson, *supra* note 53, at 1121.

81. *See id*. (suggesting that Indigenous communities may have better chance of protecting knowledge by bringing misappropriation of trade secret action than by protecting knowledge with patents).

82. Ho, *supra* note 48, at 437; Rodriguez Stevenson, *supra* note 53, at 1126.

83. *See* Ho, *supra* note 48, at 449 (stating that some patent proponents argue the patent system works because it eventually corrected the error).

84. *See, e.g.*, *id.* at 449, 526 (describing multiple scenarios in which acquiring patent for traditional knowledge is difficult or impossible).

85. *Id.* at 438.

86. *See* Downes, *supra* note 69, at 258 (explaining that individuals in Indigenous communities may be singled out as informal creators or inventors and recognized as having intellectual property rights over knowledge).

87. *See id.* at 257 (stating argument that current intellectual property rights create incentives for innovative uses of biodiversity, which holders of traditional knowledge can participate in).

88. Ho, *supra* note 48, at 440. Protection may impede research but *unreasonably* is an extreme descriptor. Intellectual property licensing is common in scientific research. Licensing traditional medical knowledge would hardly impose an unreasonable burden on researchers and institutions. *E.g.*, Federico Caviggioli et al., *The Licensing and Selling of Inventions by US*

social good by commercially valuing underused natural resources and knowledge.[89] Many innovations, like scientific discoveries and natural phenomena, are already excluded from intellectual property protection and reside in the public domain; [90] traditional medical knowledge should be treated no differently. These opponents also argue that protecting traditional medical knowledge is unnecessary because existing incentives in scientific communities promote the preservation of traditional medicinal knowledge.[91] However, advocates counter that intellectual property protection for traditional knowledge would strengthen traditional medical knowledge systems and promote further innovation within Indigenous communities.[92] These advocates argue that protecting traditional medical knowledge allows continued development and exchange of this knowledge.[93] Protecting traditional medical knowledge would allow Indigenous communities to collaborate with scientists and others in academia, industry, or elsewhere as equals rather than exploitable resources.[94]

III. SCIENTIFIC RESEARCH: EXPLOITING TRADITIONAL MEDICAL KNOWLEDGE

If the goal of protecting traditional medical knowledge is to allow Indigenous communities to engage with the greater scientific community to leverage that knowledge to benefit their communities, then discussing how academic scientists and pharmaceutical companies use traditional medical knowledge is beneficial. Such a discussion could also dispel arguments that protecting traditional medical knowledge would unreasonably impede scientific research. Traditional medical knowledge is often used as inspiration for new research projects or clues to solve research questions.[95] Protecting traditional medical knowledge would not foreclose *any* use of the knowledge in scientific research, just unauthorized uses.[96] Scientists would only need to obtain licenses or other permission to use the knowledge, just like any other protected intellectual property they may wish to use.[97]

Scientists generally use traditional medical knowledge in three different stages of scientific research: (1) ethnopharmacology, (2) natural products

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Universities, TECH. FORECASTING & SOC. CHANGE, Oct. 2020, at 1.

89. Ho, *supra* note 48, at 455–56.

90. Downes, *supra* note 69, at 259–60.

91. *Id.* at 260 (listing publication, citation, academic tenure, prizes for academic achievement or demonstrations of skill at public competitions, and awards of research grants as incentives).

92. *Updated Draft Gap Analysis*, *supra* note 68, at para. 76.

93. *Id.*

94. *See* William N. Hait & Paulus Stoffels, *A Primer for Academic Entrepreneurs on Academic-Industrial Partnerships*, NATURE COMMC'NS, Oct. 2021, at 1, 2–3 (explaining that collaboration with academia and industry leads to good-faith negotiations, and companies may ask for rights to sub-license if intellectual property protections exist).

95. See *infra* Section III.A for a discussion of examples of traditional medical knowledge being used to inspire research.

96. See *infra* Section IV for a discussion of how protection of traditional medical knowledge would not prohibit scientific innovation.

97. See *infra* Section IV.C for a discussion of how the permission could be obtained.

chemistry, and (3) drug discovery and development.[98] Ethnopharmacological research, including reverse ethnopharmacology, is an ideal starting point for this discussion because it studies how cultures have historically used traditional medicines;[99] reverse ethnopharmacology studies correlations between traditional medicines and their biomedical uses to guide drug discovery research.[100] Natural product chemists isolate active ingredients in plants or other organisms and develop methods to prepare natural products for further study in drug development research.[101] Drug discovery and development research performed by medicinal chemists transforms traditional medicines into pharmaceutical treatments.[102]

A. Ethnopharmacology: Finding Correlations

Ethnopharmacological research translates traditional medical knowledge into inspiration for new pharmaceuticals.[103] Fundamentally, ethnopharmacology studies the development of traditional medical knowledge.[104] The field focuses on how communities create medicines from naturally occurring genetic resources like plants, animals, and fungi.[105] Ethnopharmacological researchers use anthropological and comparative methods to analyze traditional uses of particular medicinal plants.[106] These findings have been used in drug discovery to identify potential new treatments from natural sources based on the traditional medicinal uses of those natural sources.[107] This use of natural sources and related traditional knowledge often results in new drugs with improved efficacy and safety.[108] Traditional medical systems like Ayurveda in India and traditional Chinese medicine are rich sources for inspiration.[109] For example, arteminisin, extracted from the Chinese medicinal herb *qing hao*, or *Artemisia annua*, has inspired structural derivatives that have been used as anti-malarials.[110]

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98. Daniel S. Fabricant & Norman R. Farnsworth, *The Value of Plants Used in Traditional Medicine for Drug Discovery*, 109 ENV'T HEALTH PERSPS. 69, 69 (2001).

99. WILLIAM C. EVANS, TREASE AND EVANS PHARMACOGNOSY 69–74 (16th ed. 2009).

100. See *infra* Section III.A for a discussion of how ethnopharmacology and reverse ethnopharmacology use traditional medical knowledge in its research.

101. See *infra* Section III.B for a discussion of how natural product and synthetic chemists use traditional medical knowledge.

102. See *infra* Section III.C for a discussion of how medicinal chemists performing drug discovery and development use traditional medical knowledge.

103. *See* Heinrich et al., *supra* note 56, at 678 (discussing how ethnopharmacological research into medicinal plants used by Indigenous and local communities led to development of many medicines today).

104. *See* Marco Leonti et al., *Reverse Ethnopharmacology and Drug Discovery*, 198 J. ETHNOPHARMACOLOGY 417, 418 (2017) (explaining that ethnopharmacology uses anthropological concepts and tools to assess most culturally accepted uses of medicinal plant species).

105. Marco Leonti & Laura Casu, *Traditional Medicines and Globalization: Current and Future Perspectives in Ethnopharmacology*, FRONTIERS IN PHARMACOLOGY, July 2013, at 1, 1.

106. Leonti et al., *supra* note 104, at 418.

107. *Id.*; Nguyen-Vo et al., *supra* note 54, at 1103.

108. Leonti et al., *supra* note 104, at 418.

109. Patwardhan, *supra* note 53, at 50–51.

110. Leonti & Casu, *supra* note 105, at 4. Other pharmaceuticals with origins as traditional

Despite a wealth of available information, ethnopharmacological information can be difficult to use in drug discovery because traditional uses of plants in Indigenous cultures do not always parallel their pharmaceutical uses.[111] By analyzing correlations between traditional and biomedical uses of medicines, reverse ethnopharmacology translates ethnopharmacological information into useful data for drug discovery.[112] For example, traditional remedies used as antidotes to treat toxins or animal bites often result in pharmaceutical treatments for skeletomuscular disorders.[113] Likewise, there is a higher probability of discovering potential cancer drugs from traditional remedies for bacterial or viral infections.[114] There are other significant correlations between some traditional uses of medicines and the eventual biomedical use of the medicines' corresponding natural product.[115]

Anticancer treatments are of special interest to ethnopharmacological research. Although Indigenous communities rarely identify traditional medicines as cancer treatments, isolated active compounds in traditional medicines can be cancer treatments.[116] For example, the Madagascar periwinkle was traditionally used to treat diabetes, but its active ingredient was eventually marketed as an anticancer drug.[117] In addition, natural products in traditional medicines treating gynecological disorders are often developed into anticancer treatments.[118] Ethnopharmacological research can lead to better pharmaceuticals through examining time-tested traditional medicinal systems.[119] Information about which traditional medicines are more likely to become successful treatments for a given condition can point chemists toward the plants or natural products that should be isolated and studied.[120]

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medicines include atropine, codeine, morphine, and pseudoephedrine. Fabricant & Farnsworth, *supra* note 98, at 70–71.

111. *See, e.g.*, Leonti et al., *supra* note 104, at 418 (using Madagascar periwinkle as an example of traditional medicine to treat diabetes becoming pharmaceutical drug to treat cancer).

112. *Id.*; Nguyen-Vo et al., *supra* note 54, at 1103 (using term reverse pharmacognosy to describe reverse ethnopharmacology).

113. Leonti et al., *supra* note 104, at 419–22.

114. *Id.* at 422.

115. *See id*. at 421 (showing a highly significant association between biomedical indications and ethnomedicinal citations).

116. *See id.* at 418 (explaining that natural products like plant metabolites can be developed into anticancer remedies but that cancer is generally poorly recognized in ethnomedicinal systems).

117. *Id.*

118. *See id.* at 422–23 (illustrating how several natural products traditionally used as women's medicine have been developed into anticancer treatments).

119. *See* Heinrich et al., *supra* note 56, at 678 (explaining that ethnopharmacological research into medicinal plants used by Indigenous and local communities led to development of many medicines today).

120. *See id.* at 679–80 (discussing International Collaborative Biodiversity Groups which sought to investigate biological targets for potential pharmaceutical use).

B. Natural Product Chemistry: Finding the Active Ingredient

Natural product chemistry—the isolation, characterization, and synthesis of natural products—links ethnopharmacology and drug development.[121] Traditional medical knowledge and ethnopharmacological research can direct natural product chemists to which natural products to study; natural product research can direct medicinal chemists to which compounds to develop into marketable treatments.[122] Natural products are a class of chemical compounds that include any active ingredients[123] in traditional medicines.[124] These compounds are produced by a living organism's secondary metabolism which encompasses biological processes that respond to an organism's environment but are not essential for an organism to live.[125]

To study a natural product, chemists first identify and acquire the organism—commonly a plant for traditional medicines—which contains the target natural product.[126] Next, chemists extract crude mixtures of natural products using different solvents[127] and determine any bioactivity[128] which these mixtures may possess.[129] If any crude mixtures are bioactive, the extract is purified to isolate the individual natural products.[130] Finally, any isolated natural product is characterized to determine its chemical structure and bioactivity.[131] This is a time-consuming and labor-intensive process but a necessary foundation for future research.[132]

For organic chemists, synthesizing isolated natural products is an exciting

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121. *See, e.g.*, *id.* (describing different natural products research and ongoing ethnopharmacological research efforts).

122. *See id*. (outlining various projects of International Collaborative Biodiversity Groups).

123. *Drugs@FDA Glossary of Terms*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (last visited Mar. 8, 2022).

124. *See* Bawnha Chopra & Kumar Dhingra, *Natural Products: A Lead for Discovery and Development*, 35 PHYTOTHERAPY RSCH. 4660, 4660 (2021) (explaining that several natural products were used as traditional medicine in China, India, and many other countries).

125. Dias et al., *supra* note 54, at 306.

126. *See* Atanas G. Atanasov et al., *Natural Products in Drug Discovery: Advances and Opportunities*, 20 NATURE REVS. DRUG DISCOVERY 200, 201 (2021) (explaining that natural products-based drug research begins with screening extracts to identify certain target extracts, which are then isolated).

127. A variety of solvents are used because the chemical compounds have different solubilities in different solvents. *Solubility*, MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/solubility (last visited Sept. 27, 2022).

128. *See Bioactive Compound*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/bioactive-compound (last visited Mar. 8, 2022) (defining bioactive compound as "[a] type of chemical found in small amounts in plants and certain foods").

129. Atanasov et al., *supra* note 126, at 201.

130. *Id.* at 201–02.

131. *See id.* (explaining metabolomic process to distinguish different compositions in crude mixtures to characterize them at molecular level and to understand their mechanisms of action).

132. *See id.* (detailing many steps of metabolite profiling and highlighting usefulness in understanding molecular mechanisms of natural products).

challenge.[133] The natural products' biological properties and potential uses catalyze these synthetic efforts.[134] As a field of organic chemistry,[135] the synthetic preparation of natural products from simpler and readily available starting materials is called total synthesis.[136] Natural product chemists can assist biochemists and medicinal chemists by preparing complex molecules for their biomedical research.[137] Synthetic chemists provide biological researchers with any natural products required for their research and develop larger-scale syntheses for those natural products with proven utility.[138] Total synthesis is propelled by synthesizing newly isolated natural products and improving existing synthetic methods and strategies.[139] Synthetic chemists also design and prepare complex molecules structurally similar to or mimicking isolated natural products that are used in the same way as natural products.[140]

Natural products and their structural derivatives serve an important role in modern drug discovery and development.[141] Their structures often have known biological importance and are easily modified.[142] Natural products inspire new pharmaceuticals because their origin as traditional medicines suggests that they may be more effective and safer in ways that conventional synthetic medicines may not be.[143] From 1981 to 2019, 53.1% of total new drugs were natural products

133. *See* K.C. NICOLAOU & E.J. SORENSEN, CLASSICS IN TOTAL SYNTHESIS: TARGETS, STRATEGIES, METHODS 9 (5th ed. 2008) (explaining that natural products have fascinated and challenged synthetic organic chemists since they started assembling complex molecules from simple starting materials).

134. *See id.* at 2 (highlighting biological properties of many natural products and opportunities for probing biological questions as reasons to receive training in synthetic chemistry).

135. Organic chemistry as a field studies natural or human-made carbon-containing compounds; organic chemists develop and probe these compounds through synthesizing new ones or improving ways to make known ones. *See Organic Chemistry*, AM. CHEM. SOC'Y, https://www.acs.org/content/acs/en/careers/chemical-sciences/areas/organic-chemistry.html (last visited Mar. 8, 2022) (describing organic chemistry as "the study of the structure, properties, composition, reactions, and preparation of carbon-containing compounds.").

136. NICOLAOU & SORENSEN, *supra* note 133, at 2.

137. *See id.* at 3 (highlighting beneficial impact and applications of organic synthesis to biology and medicine).

138. *Id.* at 9.

139. *See id.* at 7 (explaining that total synthesis is driven by continuous discovery of novel and complex structures from nature and by need to improve ability to synthesize organic molecules in more efficient ways).

140. *See id.* at 12–13 (detailing how new molecular designs are frequently based on structures of natural products and numerous clinically useful drugs were discovered through this approach).

141. Chopra & Dhingra, *supra* note 124, at 4660; *see also* David J. Newman & Gordon M. Cragg, *Natural Products as Sources of New Drugs Over the Nearly Four Decades from 01/1981 to 09/2019*, 83 J. NAT. PRODS. 770, 770–71 (listing numerous articles demonstrating significant role of natural products in drug discovery and development process).

142. Nguyen-Vo et al., *supra* note 54, at 1102; Dias et al., *supra* note 54, at 304.

143. *See* Atanasov et al., *supra* note 126, at 200 (explaining that natural products are structurally optimized by evolution, that their use in traditional medicine may provide insights regarding efficacy and safety, and that natural products cover wider area of chemical space

or structurally derived from natural products.[144] From 1981 to 2019, for new anti-infective treatments, 37.3% of all new drugs were related to natural products.[145] That percentage increases to 65.6% for new small-molecule anti-infective treatments.[146] Natural products and natural product derivatives made up 48.6% of all new anticancer treatments.[147] For new small molecule anticancer treatments, 64.3% originated as natural products.[148] This trend continued from 1946 to 1980, when natural products and their derivatives contributed to 64.9% of all new anticancer treatments.[149] Natural products continue to become new drugs to treat cancer, infectious diseases, and other illnesses.[150]

Natural products research remains a priority for the National Institutes of Health, with many funding opportunities available for researchers.[151] Academic institutions continue to perform natural products research;[152] however, many pharmaceutical companies have reduced—or even eliminated—in-house natural products research departments.[153] Partnerships between academia and industry allow these companies to use academic expertise in natural products chemistry to develop new pharmaceuticals.[154] An increased prevalence of these collaborative efforts not only helps develop new technologies faster but also raises routine legal questions because companies often seek intellectual property rights in or licenses to use the new technologies.[155] These collaborations are crucial to developing new

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compared with typical synthetic medicines).

144. Newman & Cragg, *supra* note 141, at 775 (showing radar plot of percentages for new drugs based on type of drug).

145. *Id.* at 786 (showing percentages for new drugs from 1946 to 1980 based on type of drug and class of disease).

146. *Id.* (adding percentages presented in Table 7 for drug classes N, ND, S/NM, S*, and S*/NM).

147. *Id.* at 791 (showing percentage breakdown of all anticancer treatments from 1946 to 1980 by drug type).

148. *Id.* (showing percentage breakdown of small molecule anticancer treatments from 1946 to 1980 by drug type).

149. *Id.* at 793 (showing percentage breakdown of all anticancer treatments from 1946 to 1980 by drug type).

150. Atanasov et al., *supra* note 126, at 200.

151. *Natural Products Research—Information for Researchers*, NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH, https://www.nccih.nih.gov/grants/natural-products-research-information-for-researchers (last visited Jan. 5, 2022).

152. *See, e.g.*, *Natural Products and Bioactive Compounds Conference*, GORDON RSCH. CONF., https://www.grc.org/natural-products-and-bioactive-compounds-conference/2022/ (last visited Jan. 13, 2022) (detailing research conference devoted to natural products with academic and industry speakers).

153. This reduction is caused by perceptions that (1) drug development of natural products is a slow process, (2) all the low-hanging-fruit discoveries have already been made, (3) natural product synthesis is difficult, (4) getting natural products is difficult, and (5) structure-based drug design is better. John A. Beutler, *Natural Products as a Foundation for Drug Discovery*, CURRENT PROTOCOLS PHARMACOLOGY, Sept. 2009, at 1–4.

154. *See* Quentin Michaudel et al., *Academia—Industry Symbiosis in Organic Chemistry*, 48 ACCTS. CHEM. RSCH. 712, 712–13 (introducing examples of academic and industrial collaboration).

155. *See* Hait & Stoffels, *supra* note 94, at 2–3 (describing methods by which companies

marketable technologies through pharmaceutical drug discovery and development.[156]

C. Drug Discovery and Development: Finding New Treatments

Drug discovery and development together make up the final step to transform traditional medicines into marketable pharmaceuticals.[157] Drug development is the entire process by which a chemical compound is approved for public use as a drug.[158] This process narrows a large field of potential drugs through multiple steps to determine which drug, if any, are safe and effective for public use.[159] In contrast, drug discovery is only the first step of drug development.[160] In drug discovery, medicinal chemists ascertain potential new drugs, known as drug candidates, through either traditional screening methods or structure-based drug discovery.[161] Only a small number of compounds make it through drug discovery and progress to the second step of drug development, in which promising drug candidates undergo preclinical trials to determine appropriate dosage amounts and any disqualifying toxicity.[162]

Any compounds that successfully make it through preclinical testing undergo clinical trials, the third stage of drug development.[163] During clinical trials, remaining drug candidates are administered to human subjects to determine the drug candidate's safety, efficacy, final dosage, side effects, and adverse reactions.[164] In the fourth stage, government agencies, like the U.S. Food and Drug Administration (FDA), review applications for successful drug candidates seeking approval for public use.[165] If approved by the FDA, the drug can be marketed to the general public.[166] In the fifth and final stage, government agencies continually monitor any problems with the drug during its lifetime on the market and

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can sub-license ideas).

156. *See id.* at 3 (explaining that partnership between academia and industry provides scientists with opportunity to see work become lifesaving products for people around world).

157. *See* BACKGROUND BRIEF NO. 6, *supra* note 47 (discussing commercialization of traditional medicine).

158. Lorrene A. Buckley et al., *Drug Development 101: A Primer*, 39 INT'L J. TOXICOLOGY 379, 379 (2020).

159. *The Drug Development Process*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process.

160. *Id.* at 380.

161. *Step 1: Discovery and Development*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-1-discovery-and-development (Jan. 4, 2018).

162. *Id.*; *Step 2: Preclinical Research*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research (Jan. 4, 2018).

163. *Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (Jan. 4, 2018).

164. *Id.*

165. *Step 4: FDA Drug Review*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review (Jan. 4, 2018).

166. *Id.*

implement any necessary public safety measures.[167] Out of all the stages, drug discovery, the first stage, is when traditional medical knowledge has the most impact on the long drug development process.[168] Two types of drug discovery—classical drug discovery and structure-based drug design—are discussed below.

1. Classical Drug Discovery: Looking for a Needle in a Haystack

Medicinal chemists have historically used classical, also called traditional, drug discovery to identify drug candidates in the first stage of drug development.[169] In this process, thousands of compounds are screened to determine their relevant physicochemical[170] and absorption, distribution, metabolism, excretion, and toxicity (ADMET)[171] properties, and to evaluate their potential as a drug candidate.[172] A good drug candidate is potent,[173] chemically stable,[174] and able to permeate through the body's various systems until selectively binding to an intended location in the body.[175] Any good drug candidate, including natural products, undergoes a series of small structural modifications to further optimize these properties.[176] These structurally modified compounds, including natural product derivatives, often result in better drug candidates and, eventually, better drugs.[177]

The process to optimize the properties of drug candidates is labor intensive

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167. *Step 5: FDA Post-Market Drug Safety Monitoring*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring (Jan. 4, 2018).

168. *E.g.*, Dias et al., *supra* note 54, at 304.

169. *See* DRUG DISCOVERY AND DEVELOPMENT: FROM TARGETS AND MOLECULES TO MEDICINES 11–12 (Ramarao Poduri ed., 2021) (overviewing process of drug discovery by medicinal chemists).

170. Physicochemical properties are those that are physical or chemical like molecular weight, boiling point, melting point, and density. *Physico-chemical Properties*, NAT'L CHEM. EMERGENCY CTR., https://the-ncec.com/en/regulatory-compliance/environmental-chemistry-and-toxicology/expertise-in-environmental-chemistry-and-toxicology/physico-chemical-properties (last visited Sept. 26, 2022).

171. ADMET, as a term of art, describes properties which measure how a compound interacts with the body. ConnectedLab Staff, *The Role of ADME & Toxicology Studies in Drug Discovery & Development*, THERMO FISHER SCI.: THE CONNECTED LAB (Mar. 10, 2020), https://admin.acceleratingscience.com/connectedlab/the-role-of-adme-toxicology-studies-in-drug-discovery-development.

172. Maria Batool et al., *A Structure-Based Drug Discovery Paradigm*, 20 INT'L J. MOLECULAR SCIS. 2783, 2783 (2019).

173. Chopra & Dhingra, *supra* note 124, at 4672.

174. Franz F. Hefti, *Requirements for a Lead Compound to Become a Clinical Candidate*, 9 BMC NEUROSCIENCE, S7 (2008).

175. Drug permeability measures the ability of a compound to travel across membranes in cells and is key for distributing drugs to the intended organs within the body. Jianling Wang & Suzanne Skolnik, *Permeability Diagnosis Model in Drug Discovery: A Diagnostic Tool to Identify the Most Influencing Properties for Gastrointestinal Permeability*, 13 CURRENT TOPICS MED. CHEMISTRY 1308, 1308 (2013).

176. Atanasov et al., *supra* note 126, at 211.

177. Chopra & Dhingra, *supra* note 124, at 4672.

and costly.[178] Drug development is a risky endeavor for pharmaceutical companies.[179] Developing a pharmaceutical using classical drug discovery can take up to fourteen years and cost over $800 million.[180] A drug company can invest up to $19 million just to perform preclinical efficacy trials in the second stage of drug development.[181] Increased risk and cost lead to higher pharmaceutical prices for consumers.[182]

To minimize these costs, pharmaceutical companies look to traditional medical knowledge as a starting point for new drugs.[183] A compound found in a traditional medicine is more likely to be safe and effective due to better physicochemical and ADMET properties.[184] Structural features commonly found in natural products isolated from traditional medicines can lead researchers to better drug candidates.[185] Using traditional knowledge can guide researchers to potential drugs, reducing the total labor and cost of the drug discovery process.[186] However, pharmaceutical companies also rely on a newer method of drug discovery.

2. Structure-Based Drug Design: Creating a Key for a Lock

Structure-based drug design is a modern method of drug discovery.[187] This method was developed to address problems with and costs of classical drug discovery.[188] Screening thousands of compounds, as required in classical drug discovery, is costly and often unsuccessful because the process involves trial and error.[189] Pioneers of structure-based drug discovery sought to develop a new technique to assemble potential drug candidates piece by piece through their understanding of how a proposed drug's structure would interact with biological receptors.[190] This method of rationally designing drugs is more tailored and cost

178. *See, e.g.*, Patwardhan, *supra* note 53, at 50 (discussing issues faced by pharmaceutical industry in recent years surrounding drug development and discovery).

179. *Id.*

180. Batool et al., *supra* note 172, at 2783.

181. *Id.*

182. Patwardhan, *supra* note 53, at 50.

183. ABBOTT, *supra* note 34, at 11; *see* BACKGROUND BRIEF NO. 6, *supra* note 47 (defining traditional medical knowledge); Atanasov et al., *supra* note 126, at 212.

184. ABBOTT, *supra* note 34, at 10.

185. *See, e.g.*, Nguyen-Vo et al., *supra* note 54, at 1102 (discussing benefits of using natural products in traditional Chinese medicines).

186. *See* ABBOTT, *supra* note 34, at 10 (outlining benefits of using traditional knowledge in drug discovery).

187. Amy C. Anderson, *The Process of Structure-Based Drug Design*, 10 CHEMISTRY & BIOLOGY 787, 787 (2003).

188. *Id.*; Batool et al., *supra* note 172, at 2783–84; *see* BARRY WERTH, THE BILLION DOLLAR MOLECULE: ONE COMPANY'S QUEST FOR THE PERFECT DRUG (1st ed. 1994) (recounting efforts of Joshua Boger and Vertex to create first marketable drug developed using structure-based drug design).

189. WERTH, *supra* note 188, at 186.

190. Essentially, structure-based drug design is creating a key to open a lock in which known tumblers of the lock need to be touched for it to open. *Id.* at 30–31. The key is designed

effective.[191]

Unlike classical drug discovery, which begins with thousands of different drug candidates, structure-based drug design begins with the selection of a drug target: a specific biomolecule, such as a protein, to which the drug will bind.[192] An optimal drug target is one essential to a particular biological pathway associated with the disease to be treated.[193] Once a suitable drug target is identified, researchers must determine the structure of the target's binding pocket.[194] The structures of many drug targets are known today, permitting structure-based drug design to become more prevalent.[195]

Once the drug target structure is determined, drug candidates are designed and tailored for their ability to bind the target.[196] Through computer algorithms and programs, researchers can virtually bind proposed molecules to the target site and assess their binding ability before actually synthesizing the compounds in a laboratory.[197] Any synthesized compounds undergo biological screening to determine their potential as safe and effective drugs.[198] Promising drug candidates then undergo preclinical and clinical trials just like candidates in classical drug discovery.[199]

Structure-based drug design addresses the problems and high costs of classically screening drug candidates.[200] Rationally designed drugs can be more effective, safer, and have fewer side effects.[201] Because structure-based drug design begins with the structure of a drug target,[202] traditional medical knowledge is less likely to reduce the costs and labor required by this method. However, traditional medical knowledge provides a wealth of information about known, effective treatments and could be used to determine which disease to study or which biomolecule to target.[203]

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specifically to position the tumblers where they need to be. *Id.* at 30–31.

191. *E.g.,* Batool et al., *supra* note 172, at 2783–84.

192. *Id.* at 2784; Anderson, *supra* note 187, at 787.

193. *E.g.*, Anderson, *supra* note 187, at 787–88.

194. A binding pocket is a crevice or cavity on the surface of or within a biomolecule that allows a drug to bind the biomolecule. Antonia Stank et al., *Protein Binding Pocket Dynamics*, 49 ACCTS. CHEM. RSCH. 809, 809 (2016); Batool et al., *supra* note 172, at 2786.

195. *See* Batool et al., *supra* note 172, at 2783–84 (stating that structures of over 100,000 drug targets are known today).

196. *E.g.*, Anderson, *supra* note 187, at 790.

197. *E.g.*, Batool et al., *supra* note 172, at 2787–88.

198. NICOLAOU & SORENSEN, *supra* note 133, at 13; *e.g.*, Batool et al., *supra* note 172, at 2788.

199. *E.g.*, Batool et al., *supra* note 172, at 2784.

200. WERTH, *supra* note 188, at 29.

201. *Id.* at 29–30.

202. Anderson, *supra* note 187, at 787.

203. *See* Dias et al., *supra* note 54, at 306 (discussing examples of traditional medical knowledge that led to pharmaceuticals).

IV. POSITIVE PROTECTION OF TRADITIONAL MEDICAL KNOWLEDGE

Although traditional medical knowledge is theoretically entitled to protection under existing intellectual property systems, this knowledge is practically excluded from protection.[204] Intellectual property laws determine who possesses rights to innovative knowledge, like traditional medical knowledge, through patent or trade secret protection.[205] These intellectual property rights economically reward inventors with a return on their investment, thus incentivizing innovation and invention.[206] This economic aspect of intellectual property is at odds with traditional knowledge, which is often treated within an Indigenous community as innovation uncoupled to a property interest.[207]

Applying existing intellectual property laws to traditional knowledge is challenging because communities often cannot identify a specific individual who invented the traditional medical knowledge and is entitled to an intellectual property right.[208] Additionally, only traditional medical knowledge that has not been publicly disclosed can be protected under existing intellectual property laws.[209] This is a fundamental problem in current intellectual property systems.[210] This requirement is often too difficult for traditional medical knowledge to meet because the knowledge has already been disseminated by others outside of the Indigenous community itself.[211] As a result, Indigenous communities have limited and ineffective options under existing intellectual property laws to protect and preserve their traditional medical knowledge.[212] Existing intellectual property systems, like patents and trade secrets, would need to be modified to effectively protect traditional medical knowledge.[213]

A. Patent Protection: The Impossible Dream

Patent laws commonly protect innovations using traditional medical knowledge, but existing patent laws fail to adequately protect traditional medical knowledge itself.[214] Patent protection is a quid pro quo between an inventor and society; the inventor receives protection in exchange for their public disclosure of

204. *Updated Draft Gap Analysis*, *supra* note 68, para. 40.

205. Downes, *supra* note 69, at 256; BACKGROUND BRIEF NO.6, *supra* note 47.

206. Bastida-Muñoz & Patrick, *supra* note 48, at 262.

207. Haider, *supra* note 71, at 351–52.

208. *See* Murray Lee Eiland, *Patenting Traditional Medicine*, 89 J. PAT. TRADEMARK OFF. SOC'Y 45, 57 (2007) (explaining some difficulties with determining inventorship in traditional medicine).

209. *Updated Draft Gap Analysis*, *supra* note 68, at para. 40.

210. *See id.* at para. 86 (explaining gap in protection for disclosed, non-confidential traditional knowledge).

211. *Id.* at para. 86.

212. *E.g.*, *id.* para. 88 (explaining difference in timeframes between most intellectual property protections and preservation of traditional knowledge).

213. *See, e.g.*, Rodriguez Stevenson, *supra* note 53, at 1140–42 (describing how communal values hinder patent opportunities for Indigenous communities).

214. *See, e.g.*, Eiland, *supra* note 208, at 57 (discussing hurdles to patenting traditional medicine).

the invention.[215] This trade-off funnels information into the public domain so that others can use the knowledge while also economically rewarding—through patent rights—those who exerted time and effort to develop the invention.[216] Traditional medical knowledge is difficult to protect in the existing U.S. patent system for three reasons: (1) traditional medicines are naturally occurring; (2) the knowledge is publicly available and included in the body of prior art examined to determine patentability; and (3) the utility of the traditional medicine may not be sufficiently provable.[217]

An invention must first consist of proper subject matter; it must be a process, machine, manufacture, or composition of matter.[218] In addition, this requirement bars traditional medical knowledge from patent protection because natural phenomena, which include living organisms and traditional medicines derived from them, are excluded from protection.[219] Indigenous communities, who often use the actual plant as the medicine, cannot obtain traditional protection this way.[220] To circumvent this prohibition, pharmaceutical companies will isolate the active ingredient in the plant and often optimize the structure of the drug candidate before seeking patent protection; this allows them to patent either the structurally optimized drug itself or the process of creating or using the drug.[221] Indigenous communities, in contrast, are only able to patent the process of using a traditional medicine to treat an illness.[222] This refusal to grant patents for natural phenomena is confined to the United States—natural products are protected in other nations—but nevertheless impactful to Indigenous communities.[223]

Second, an invention must be novel over existing prior art.[224] Previously publicly disclosed traditional medical knowledge cannot meet this requirement because those disclosures are prior art.[225] While countries differ in defining prior

215. Haider, *supra* note 71, at 351–52.

216. Ho, *supra* note 48, at 443.

217. BACKGROUND BRIEF NO.6, *supra* note 47.

218. 35 U.S.C. § 101 ("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 therefor, subject to the conditions and requirements of this title.") (emphasis added).

219. As required under 35 U.S.C. § 101, something must be new to be patented. *Id.* Traditional medicines are not; they are newly discovered natural phenomena. *See* Ho, *supra* note 48, at 445–46 (discussing requirements for obtaining patent for natural products).

220. *E.g.*, BACKGROUND BRIEF NO. 6, *supra* note 47.

221. *Id.*; *see also* Lindsey M. Round, *USPTO Guidelines: Effects on Natural Product Pharmaceuticals*, 34 SYRACUSE J. SCI. & TECH. L. 103, 107–08, 113 (2017) (discussing how plants are excluded from protection, but products derived or isolated from plants are not).

222. Round, *supra* note 221, at 105.

223. *Id.* at 113.

224. *See generally* 35 U.S.C. § 102. Prior art includes all the evidence that an invention or part of an invention were previously known. *What is Prior Art?*, EUR. PAT. OFF., https://www.epo.org/learning/materials/inventors-handbook/novelty/prior-art.html (last visited Sept. 26, 2022). Any type of description of the invention can be prior art, not just printed publications or commercial sales of an invention. *Id.*

225. *E.g.*, BACKGROUND BRIEF NO. 6, *supra* note 47.

art, the general concept of novelty is the same.[226] To be protected as novel, an invention cannot have been previously disclosed to the public in a single reference containing every element of the claimed invention.[227] Traditional medicines are generally not considered novel because they have been used for generations, are known throughout the local community, or are documented in publicly available sources.[228] Without a specific exception for traditional medical knowledge and Indigenous communities, the communities are barred from protecting their knowledge even if they did not consent to the public disclosure of their knowledge.

Related to novelty, an invention must also be nonobvious over the prior art.[229] This requirement can be difficult for traditional medical knowledge to meet because of the scope of prior art references. To satisfy the nonobviousness requirement, an inventor must make an inventive step that is not obvious to another inventor who possesses ordinary skill level in the same field.[230] Establishing an inventive step can be difficult for Indigenous communities because traditional medical knowledge often evolves over generations with no single or clear inventive step.[231] Also, for purposes of determining novelty and obviousness of inventions derived from misappropriated traditional medical knowledge, the inclusion of traditional medical knowledge as prior art is challenging because Indigenous communities often do not have documented proof of their knowledge.[232] Because of this challenge, Indigenous communities may not be able to easily challenge patents and applications by other inventors who use their traditional medical knowledge without consent.

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226. *Id.*

227. *See* 35 U.S.C. § 102 ("*A person shall be entitled to a patent unless* (1) *the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public* before the effective filing date of the claimed invention; or (2) *the claimed invention was described in a patent* issued under section 151, *or in an application for patent published or deemed published* under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.") (emphasis added); DONALD S. CHISUM, 2 CHISUM ON PATENTS § 3.01 (2021); Rodriguez Stevenson, *supra* note 53, at 1136.

228. BACKGROUND BRIEF NO. 6, *supra* note 47; Rodriguez Stevenson, *supra* note 53, at 1142–43.

229. *See, e.g.*, 35 U.S.C. § 103 ("A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that *the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains*.") (emphasis added).

230. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW: CASES AND MATERIALS 512–13 (7th ed. 2017). Nonobviousness is considered the ultimate requirement for patentability because it requires inventors to contribute something new to the field that deserves patent protection. DONALD S. CHISUM, 2 CHISUM ON PATENTS § 5.01 (2021). The "inventive step" is a term that refers to that new contribution. Rodriguez Stevenson, *supra* note 53, at 1136–37.

231. Rodriguez Stevenson, *supra* note 53, at 1146.

232. *Id*.

Finally, an invention must also be useful to be patentable.[233] This requirement is a low bar which traditional medical knowledge would likely clear. To satisfy this requirement, an invention must (1) achieve a beneficial purpose, (2) be credibly operable, and (3) have specific utility for a particular purpose.[234] To have a beneficial purpose, an invention must have some positive use for society.[235] A traditional medical treatment would certainly meet this requirement. Operability of an invention generally only becomes an issue when someone tries to patent an implausible invention like a perpetual motion machine, which traditional medical knowledge clearly is not.[236] Specific utility requires that the invention have a known use in the present, not just some hypothetical future use.[237] Therapeutic inventions face a heightened standard of proof for specific utility.[238] In these situations, an inventor must show that the invention is effective, using proof that would convince a person skilled in the same field of invention.[239] This requirement could bar Indigenous communities from obtaining patents when they cannot sufficiently prove that their traditional treatment is effective.

To protect traditional medical knowledge through patents, existing laws would need to be modified to account for the unique character of traditional medical knowledge. At a minimum, these laws should recognize community-owned inventions and create an exception that would exclude publicly disclosed traditional medical knowledge from use as prior art against applications by Indigenous inventors. Opponents of tailored patent protection for traditional medical knowledge argue that amending laws is unnecessary because inventions by third parties using traditional medical knowledge would likewise not qualify because these inventions are also not novel.[240] Even so, it would be difficult and time-consuming for Indigenous communities to prove that an invention is not novel because these communities tend to preserve traditional knowledge orally, and a challenge to an invention's novelty requires written documentation.[241]

Moreover, third party patent rights in traditional medical knowledge can affect Indigenous communities' use of their own knowledge. A patent owner does not receive an exclusive right to use their invention, but instead a right to exclude others, including Indigenous communities, from using or practicing an invention.[242] This right to exclude can prevent Indigenous communities from using

233. *See* 35 U.S.C. § 101 ("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 therefor, subject to the conditions and requirements of this title.") (emphasis added).

234. DONALD S. CHISUM, 2 CHISUM ON PATENTS § 4.01 (2021).

235. *Id.*; Rodriguez Stevenson, *supra* note 53, at 1137.

236. MERGES & DUFFY, *supra* note 230, at 195.

237. *Id.* at 215.

238. DONALD S. CHISUM, 2 CHISUM ON PATENTS § 4.04(2) (2021).

239. *Id.*

240. Ho, *supra* note 48, at 449.

241. *Id*.

242. *See id*. at 443–44 (discussing how patent owner only has right to exclude not right to use an invention).

their knowledge in their own community or elsewhere.[243] As a result, Indigenous communities need mechanisms—namely, defensive protection—to prevent third parties from obtaining patents for the community's knowledge when they do not have feasible positive protection for their traditional knowledge.[244] With patent protection, Indigenous communities could use their knowledge to collaborate with the scientific community rather than continue to be exploited. Absent such measures, Indigenous communities would remain at the mercy of pharmaceutical biopiracy without control over their own knowledge.

B. Trade Secret Protection: A Flawed Alternative

Trade secret protection is an alternative—albeit an ineffective one—to patent protection, due to the widespread public availability of traditional medical knowledge.[245] Compared to patent protection, trade secret protection has fewer substantively restrictive requirements.[246] For knowledge ineligible for patenting, trade secret protection is often the only remaining option.[247] Information is a trade secret if it is (1) valuable, (2) a secret, and (3) subject to reasonable security measures to maintain secrecy.[248]

To be valuable, knowledge needs to be commercially or economically valuable to its owner.[249] Information is a trade secret only if it remains a secret, but this requires only reasonable efforts to keep a secret, not absolute secrecy.[250] Trade secret owners can seek remedies against any party who obtains their secret by improper means, i.e., misappropriating the trade secret.[251] Courts often look to the conduct of the parties and industry norms when determining if a trade secret has

243. *See* Rodriguez Stevenson, *supra* note 53, at 1148 (mentioning how patent held by researchers from Colorado State University for male sterile plants used by the traditional Bolivian Apelawa people effectively limits these Indigenous peoples' use of their native plants).

244. See *infra* Part V for a discussion of the types of defensive protection for traditional medical knowledge that would prevent third parties from gaining positive protection for an Indigenous community's knowledge.

245. *See* Eiland, *supra* note 208, at 75 (discussing how trade secret protection laws could replace or augment patent protections).

246. Deepa Varadarajan, *A Trade Secret Approach to Protecting Traditional Knowledge*, 36 YALE J. INT'L L. 371, 375 (2011).

247. Rodriguez Stevenson, *supra* note 53, at 1154.

248. *See, e.g.*, UNIF. TRADE SECRETS ACT § 1(4) (UNIF. L. COMM'N 1985) ("Trade secret means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) *derives independent economic value, actual or potential, from not being generally known* to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the *subject of efforts that are reasonable under the circumstances to maintain its secrecy*.") (emphasis added).

249. Knowledge needs to have actual, potential, or unrealized value to fulfill this requirement. Rodriguez Stevenson, *supra* note 53, at 1158.

250. *Id.* at 1155–57.

251. *See, e.g.*, UNIF. TRADE SECRETS ACT § 1(2) (UNIF. L. COMM'N 1985) (defining misappropriation as someone acquiring a trade secret having reason to know that the secret was improperly acquired, unauthorized disclosure of the secret, or use of the secret without the owner's consent).

been misappropriated.[252] The minimal requirements for trade secret protection and the remedies available to trade secret owners make trade secret protection attractive for traditional medical knowledge. However, most traditional medical knowledge is not eligible for protection using patents.

Traditional medical knowledge is difficult to protect under existing trade secret law for Indigenous communities who are unable to meet the requirements.[253] Although traditional medical knowledge has potential commercial value, the knowledge is often no longer secret because it has been published or otherwise disclosed.[254] Similar to patent protection, once a traditional medicine becomes known to the Indigenous community at large or to the general public, the knowledge is no longer a trade secret and cannot be protected accordingly.[255] Because large amounts of traditional medical knowledge have become public knowledge, Indigenous communities can have difficulty demonstrating that they took reasonable steps to keep their knowledge secret.[256] However, traditional medical knowledge held only by healers of a community is more amenable to trade secret protection.[257] Even though some knowledge may be protectable, trade secret protection is ill-suited for protecting the bulk of knowledge held by Indigenous communities.[258]

The policy rationale behind trade secret laws is attractive for traditional medical knowledge, but the laws do not promote collaboration between parties. Proponents of trade secret protection for traditional medical knowledge argue that the laws promote trust because the laws regulate how information is shared between parties who are distrustful of each other.[259] This argument is compelling, especially considering the painful legacy of biopiracy. However, protecting traditional medical knowledge under trade secret law impedes the flow of information to the scientific community because the Indigenous community would need to keep the knowledge secret.[260] Protecting traditional medical knowledge another way would allow for new research that could benefit society.[261] If collaboration between Indigenous communities and the scientific community is a goal for protecting traditional medical knowledge, other protection mechanisms are more appropriate than trade secret law.

V. DEFENSIVE PROTECTION OF TRADITIONAL MEDICAL KNOWLEDGE

Without effective means to obtain positive protection in their traditional medical knowledge, Indigenous communities need real solutions—defensive

252. Rodriguez Stevenson, *supra* note 53, at 1156.
253. BACKGROUND BRIEF NO. 6, *supra* note 47; Eiland, *supra* note 208, at 75.
254. Rodriguez Stevenson, *supra* note 53, at 1164.
255. BACKGROUND BRIEF NO. 6, *supra* note 47.
256. Eiland, *supra* note 208, at 74–76.
257. BACKGROUND BRIEF NO. 6, *supra* note 47.
258. Eiland, *supra* note 208, at 76.
259. Varadarajan, *supra* note 246, at 375–76.
260. Eiland, *supra* note 208, at 76.
261. *Id*.

protection—to protect their interests in and ownership of this knowledge.[262] These protective measures include documentation of traditional medical knowledge, patent disclosure requirements, and access and benefit-sharing agreements. Documenting traditional knowledge can help Indigenous communities prevent others from gaining patent rights to inventions with origins as traditional medicines, but documentation is far from a panacea.[263] Other mechanisms, like requirements in patent applications to disclose an invention's origin in traditional knowledge, can help acknowledge the interdependency of these new pharmaceuticals and traditional medical knowledge.[264] Access and benefit sharing agreements ensure not only that scientific research can be performed but also that Indigenous communities are compensated for their knowledge and contributions.[265] International agreements and national laws have begun to encourage and require prior informed consent in access and benefit sharing agreements,[266] but more widespread adoption and enforcement of these laws would be necessary for more uniform and effective protection of the interests of Indigenous communities.

A. Documenting Traditional Medical Knowledge: Creating Prior Art

Documentation can prevent the exploitation of traditional medical knowledge; however, it does not provide Indigenous communities with actual intellectual property rights in their knowledge.[267] This process of identifying, collecting, recording, and organizing traditional knowledge creates a database to maintain, use, and disseminate the knowledge.[268] Documentation allows Indigenous communities to preserve and protect their knowledge.[269] However, if the documented knowledge becomes widely available to the public, Indigenous communities' control over the knowledge is difficult to maintain.[270] A main benefit of documentation to an Indigenous community is its ability to prevent others from acquiring intellectual property rights in traditional knowledge;[271] however, documentation's effectiveness as a tool can be impacted by how databases are created and maintained.

Documentation has been used as an effective tool to prevent third parties from

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262. Katie Bates, *A Penny for Your Thoughts: Private and Collective Contracting for Traditional Medicinal Knowledge Modeled on Bioprospecting Contracts in Costa Rica*, 41 GA. L. REV. 961, 995 (2007).

263. Seemantani Sharma, *Traditional Knowledge Digital Library: "A Silver Bullet" in the War Against Biopiracy?*, 17 J. MARSHALL REV. INTELL. PROP. L. 214, 230–31 (2017).

264. Chidi Oguamanam, *Patents and Traditional Medicine: Digital Capture, Creative Legal Interventions, and the Dialectics of Knowledge Transformation*, 15 IND. J. GLOB. LEG. STUD. 489, 517 (2008).

265. Bates, *supra* note 262, at 996.

266. Oguamanam, *supra* note 264, at 517–18.

267. WORLD INTELLECTUAL PROPERTY ORGANIZATION, DOCUMENTING TRADITIONAL KNOWLEDGE – A TOOLKIT 7 (2017) [hereinafter TOOLKIT].

268. *Id.* at 9.

269. *Id.*

270. *Id.*

271. ABBOTT, *supra* note 34, at 32.

obtaining intellectual property rights in traditional medical knowledge.[272] The Traditional Knowledge Digital Library (Library) in India offers an example of how documentation can be used as defensive protection.[273] The Library was created as a response to questionable traditional knowledge-based patents on turmeric, basmati, and neem filed in U.S. and European Patent Offices.[274] The Indian government created the Library to document traditional Indian Ayurvedic medical knowledge.[275] The Library aims to make the publicly available Ayurveda easily searchable for patent examiners to identify prior art and reject patent applications that misappropriate traditional medical knowledge as obvious or not novel.[276]

The Indian government has granted access to the Library to patent offices in India, Europe, Australia, Canada, Japan, and the United States.[277] The government restricted access to the database to prevent mismanagement in a way that would facilitate misappropriation through any widespread access.[278] Although the Library provides valuable information to patent examiners, the Indian government controls the database.[279] Such a database would not be ideal for protecting traditional knowledge of contemporary Indigenous communities because the communities would still not have control over their own knowledge.

As seen in the Traditional Knowledge Digital Library, this problem of access to and control of documented traditional medical knowledge must be addressed so such databases may become effective tools for Indigenous communities.[280] If the documented knowledge becomes widely available, the knowledge joins the public domain preventing anyone—Indigenous communities and third parties alike—from receiving intellectual property rights in that knowledge.[281] Widespread public availability of traditional medical knowledge also offers opportunities for third parties to use the knowledge without consent of the Indigenous community who have lost control over their knowledge.[282] Databases closed to the public can provide control; however, restricted databases can stifle collaboration and prevent Indigenous communities from advancing and commercializing their knowledge especially when they are not maintained by the community.[283] Regardless of the type of database, prior informed consent of the Indigenous community is crucial to protecting the interests of the community. Efforts to document traditional knowledge must be undertaken with the consent of the community holding that knowledge.[284]

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272. *Id.*
273. *Id.* at 33.
274. Oguamanam, *supra* note 264, at 498–99.
275. ABBOTT, *supra* note 34, at 32–33.
276. Oguamanam, *supra* note 264, at 499; TOOLKIT, *supra* note 267, at 22.
277. TOOLKIT, *supra* note 267, at 22.
278. Oguamanam, *supra* note 264, at 500–01.
279. *Id.* at 499.
280. ABBOTT, *supra* note 34, at 32–33.
281. *Id.*
282. *Id*.
283. Sharma, *supra* note 263, at 224.
284. *Id*.

The design of traditional medical knowledge databases can lessen their efficacy as defensive protection. Databases of traditional medical knowledge can be created and maintained by different entities: Indigenous communities, external collaborators, or government organizations.[285] Databases held by Indigenous communities themselves ensure that a community maintains sole control over its knowledge.[286] However, compiling a database can be expensive and logistically difficult for a community to do on its own.[287] Therefore, external collaborators, often universities, corporations, or non-governmental organizations, commonly create databases.[288]

While some of these databases are created in collaboration with Indigenous communities, others are created using public knowledge.[289] The databases can be used to preserve or facilitate new research based on the knowledge.[290] Governments, like India's, can set up databases of traditional knowledge to prevent misappropriation of registered knowledge developed within each country's borders.[291] A database would be most effective when it contains publicly unavailable knowledge and gives an Indigenous community the power to control access to the database.

Documentation of traditional medical knowledge would best serve as defensive protection against exploitation of that knowledge. Databases of documented traditional knowledge can be used as prior art to challenge granted patents and patent applications as obvious or not novel.[292] In countries limiting challengeable prior art to written material, databases can be a tool to record orally held traditional knowledge as written records.[293] Documentation would also promote innovation and collaboration between Indigenous communities and scientists because the databases offer troves of information useful in developing new pharmaceuticals. Indigenous communities could use access to their restricted databases as a bargaining tool to leverage the value of their knowledge for the community's benefit. Documentation has the potential to be an effective tool for protecting traditional medical knowledge, but without other protective measures, Indigenous communities are still at the mercy of biopiracy.

B. Patent Disclosure Requirements: Imposing Obligations

Requirements to disclose what traditional medical knowledge was used in an invention are another tool that could be an effective defensive protection for traditional medical knowledge. General disclosure requirements are common in

285. ABBOTT, *supra* note 34, at 35.

286. *Id*.

287. *Id*.

288. *Id*.

289. Databases of publicly available knowledge are only valuable to Indigenous communities as challengeable prior art because the communities cannot restrict access to knowledge to which the public already has unrestricted access. *Id.* at 35–36.

290. *Id.* at 35.

291. *Id.* at 36.

292. TOOLKIT, *supra* note 267, at 22.

293. *Id*.

national patent laws.[294] Inventors often must provide a written description and an enabling description as part of the quid pro quo of patent protection.[295] This technical disclosure requirement promotes innovation by incentivizing the disclosure of information that may have otherwise remained secret.[296] Patent applicants have a duty to disclose any information relevant to determining if an invention is patentable. However, disclosing information related to the use, origin, or source of traditional knowledge contained in the invention is not generally covered by that duty because this information is not usually determinative of whether an invention is patentable.[297] Patent disclosure requirements vary in their policy objectives, imposed obligations, covered traditional knowledge, and consequences for noncompliance.

Countries can have different motivations in and objectives for implementing patent disclosure requirements.[298] Some disclosure requirements aim to prevent misappropriation of traditional knowledge by allowing countries to monitor how parties seeking patent protection use traditional knowledge.[299] This monitoring is enhanced via greater patent transparency by increased online availability and searchability of published patents and patent applications and their related traditional knowledge.[300] Other disclosure requirements prevent exploitation of traditional knowledge when coupled with requirements for prior informed consent of the Indigenous community for inventions with traditional medical knowledge origins.[301] With such consent provisions, disclosure requirements are a tool to guarantee that Indigenous communities benefit from inventions that use their knowledge.[302]

A lack of binding requirements at the international level for such disclosures limits the effectiveness of implemented national laws.[303] The Bonn Guidelines

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294. *See* Aman Gebru, *Patents, Disclosure, and Biopiracy*, 96 DENV. L. REV. 535, 540 (2019) (discussing how quid pro quo of patent system necessitates disclosure obligations). These requirements impose a duty to disclose information material to patentability on patent applicants. *Id*. 540–42.

295. *See, e.g.*, 35 U.S.C. § 112(a) ("The specification shall contain a *written description of the invention, and of the manner and process of making and using it* . . . .") (emphasis added). A written description is a technical description in sufficient detail that a person of ordinary skill in the art would understand that the inventor was in possession of the invention. 3 CHISUM ON PATENTS § 7.04 (2022). An enabling description provides sufficient detail that a person of ordinary skill in the art would be able to make and use the invention without having to perform undue experimentation. *Id*.

296. Gebru, *supra* note 294, at 543–44.

297. Bates, *supra* note 262, at 983–84.

298. WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO], KEY QUESTIONS ON PATENT DISCLOSURE REQUIREMENTS FOR GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE 14 (2d ed. 2020) [hereinafter PATENT DISCLOSURE REQUIREMENTS].

299. Oguamanam, *supra* note 264, at 517–18.

300. PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 15.

301. *Id.* at 8.

302. *Id*.

303. *Updated Draft Gap Analysis*, *supra* note 68, para. 98–100.

encourage contracting parties to the Convention on Biological Diversity[304] to motivate applicants for intellectual property protection to disclose any traditional knowledge origins of their inventions, but the Guidelines stop short of imposing a binding obligation.[305] There is no international standard for these patent disclosure requirements because the necessity and value of disclosure requirements are still debated.[306] A binding international requirement to implement patent disclosure requirements would be a big step towards giving Indigenous communities control over their knowledge.

Countries have taken different approaches to imposing voluntary or mandatory disclosure obligations.[307] For example, the European Union and Germany have implemented voluntary patent disclosure requirements,[308] but Vietnam and Switzerland have imposed mandatory disclosure requirements as a procedural formality subject to fines or other sanctions for noncompliance.[309] A

304. The Convention on Biological Diversity entered into force in 1993; it is a legally binding international treaty seeking to conserve biodiversity, to promote sustainability in biodiversity, and to ensure equitable benefit sharing in the use of genetic resources. Secretariat of the Convention on Biological Diversity, *Convention on Biological Diversity*, U.N. ENV'T PROGRAMME, https://www.cbd.int/undb/media/factsheets/undb-factsheet-cbd-en.pdf (last visited Mar. 7, 2022).

305. *See*, *e.g.*, Convention on Biological Diversity [CBD], *Decisions adopted by the Conference of the Parties to the Convention on Biological Diversity at its Sixth Meeting: Bonn Guidelines on Access and Benefit Sharing as Related to Genetic Resources*, ¶ 16(d)(ii), COP 6 Decision VI/24 (Apr. 2002) [hereinafter *Bonn Guidelines*] ("Contracting Parties with users of genetic resources under their jurisdiction should take appropriate . . . measures . . . to support compliance with prior informed consent . . . [such as] measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of [I]ndigenous and local communities in applications for intellectual property rights;"); Jay Erstling, *Using Patents to Protect Traditional Knowledge*, 15 TEX. WESLEYAN L. REV. 295, 303 (2009) (discussing how Bonn Guidelines encourage disclosure of origins of traditional knowledge for patent application, but have no real ability to ensure applicants have binding obligation to do so).

306. *Updated Draft Gap Analysis*, *supra* note 68, para. 39.

307. PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 20.

308. *See, e.g.*, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, art. 26-27, O.J. (L 216) ("Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto . . . [and] the patent application should, where appropriate, include information on the geographical origin of such material, if known . . . without prejudice to the processing of patent applications or the validity of rights arising from granted patents;"). However, if the patent application is based off of a plant's biological material, the patent application need only include information on the geographical origin. Patentgesetz [PatG] [Patents Act] Dec. 16, 1980, BMJ at art. 34a(1) (Ger.) ("Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents.").

309. *See, e.g.,* Circular [No. 01/2007/TT-BKHCN] ¶23.11 (Sep. 22, 2006) (Viet.)("[A]n application for registration of an invention concerning gene source or traditional knowledge must also contain documents explaining the origin of the gene source and/or traditional knowledge . . . if the invention is directly based on that gene source and/or traditional knowledge. If the inventor or the applicant cannot identify the origin of the gene source and/or traditional knowledge, he/she

number of countries, like India, go further by imposing substantive mandatory requirements where noncompliance can affect whether a patent is granted for an invention.[310] Mandatory disclosure requirements would be preferred because of greater efficacy brought by greater compliance.

In any patent disclosure measure, the requirements are triggered by the degree of relationship between the invention and the traditional knowledge implicated by the invention: the broader scope of relationships triggered, the more effective the requirement.[311] In some instances, the invention must utilize genetic resources or traditional knowledge.[312] However, a broader trigger applies to all inventions derived from genetic resources or traditional knowledge.[313] Broader language covers more inventions, making it a more effective requirement. For example, the Andean Community uses broader language mandating disclosure when the invention "was obtained or developed" using traditional knowledge.[314] Other countries, like Switzerland, use narrower language requiring disclosure when the invention is based on genetic resources or traditional knowledge.[315] Provisions requiring disclosure in patents on derivatives of genetic resources are crucial for protecting traditional medical knowledge.[316]

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shall so declare and bear responsibility for the truthfulness of his/her declaration."); ZGB, CC, CC, June 25, 1954, SR 101, RS 101, art. 49a (Swaz.) ("The patent application must contain information on the source: of the genetic resource [if] the invention is directly based on this resource; of traditional knowledge of [I]ndigenous or local communities of genetic resources [if] the invention is directly based on this knowledge. If the source is unknown to the inventor or the patent applicant, the patent applicant must confirm this in writing.").

310. *See, e.g.*, The Patents Act, 1970, §10(4)(d)(ii) (India) ("Every complete specification shall . . . be accompanied by an abstract to provide technical information on the invention: [p]rovided that . . . [the applicant] disclose the source and geographical origin of the biological material in the specification, when used in an invention.").

311. PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 36.

312. *See, e.g.*, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, United Nations Enviornmental Programme, Oct. 29, 2010, 33 U.N.T.S. 3008 [hereinafter Nagoya Protocol] (using term "genetic resources").

313. PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 37.

314. Andean Community, *Decision 486—Common Provisions on Industrial Property*, art. 26(h) (Sept. 14, 2000), https://wipolex-res.wipo.int/edocs/lexdocs/laws/en/can/can012en.pdf [hereinafter Andean Community Decision] ("The application for a patent shall be filed with the competent national office and shall contain the following: . . . where applicable, a copy of the access contract where the products or processes for which a patent is sought have been *obtained or developed from genetic resources or products derived therefrom* of which any of the member countries is the country of origin; . . . .") (emphasis added).

315. Bundesgesetz über die Erfindungspatente [Patentgesetz, PatG] [Federal Act on Patents for Inventions] June 22, 2007, AS 2008 2551, art. 49a (Switz.) [hereinafter Federal Act on Patents for Inventions] ("The patent application must contain information on the source: . . . of the genetic resource to which the inventor or the patent applicant had access, provided *the invention is directly based on this resource*; . . . .") (emphasis added); PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 38.

316. *See* PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 29 ("From one perspective, the definition of 'derivative' expands the range of biochemicals that would be covered by [access and benefit-sharing] provisions beyond those that are [genetic resources] in a strict sense.").

The Andean Community requires disclosures in patent applications for inventions obtained from genetic resources as well as derivatives of those resources.[317] However, the Andean Community does not define what is considered a derivative, likely in an attempt to avoid limiting what constitutes a derivative under the requirements.[318] Germany takes a different approach to attain a similar goal by requiring disclosures for inventions "based on biological material of plant or animal origin."[319] More effective patent disclosure requirements cover a larger amount of inventions by using broad language.

Patent disclosure requirements also vary in the geographic origin of traditional knowledge which must be disclosed; they are more efficient with a broader geographical scope. For example, Ethiopia only requires the disclosure of traditional knowledge and genetic resources originating within its own borders.[320] In contrast, the Andean Community more broadly requires disclosure for genetic resources and traditional knowledge that originate within any member country's borders.[321] Other broad requirements, like those in Samoa, mandate disclosing of any genetic resources and traditional knowledge used in the invention regardless of where the knowledge originated.[322] Patent disclosure requirements covering a larger scope of geographic origin would be more effective in protecting the interests of Indigenous communities, but countries do not necessarily have the motivation to protect Indigenous communities outside of their borders.

Remedies and sanctions promoting compliance with patent disclosure requirements are crucial to the requirements' effectiveness.[323] In some countries,

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317. *See* Andean Community, *supra* note 314, art. 26(h) ("The application for a patent shall be filed with the competent national office and shall contain the following: . . . where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed *from genetic resources or products derived therefrom* of which any of the member countries is the country of origin; . . . .") (emphasis added).

318. *See* PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 29 ("Indeed, the inclusion of a specific definition of the term 'derivative' in the law is likely to limit the possible range of derivatives that would be covered by a [patent disclosure requirement].").

319. Patentgesetz [PatG] [Patents Act], Dec. 16, 1980, BGBl I at 1981, "as amended," Artikel 4 des Gesetzes, Oct. 8, 2017, BGBl. I at 3546, § 34a(1) (Ger.) [hereinafter Patents Act] ("Where an invention *is based on biological material of plant or animal origin or if it uses such material*, the application should include information on the geographical origin of such material, if known.") (emphasis added).

320. *See* Access to Genetic Resources and Community Knowledge and Community Rights [No. 4.82/2006] art. 2(9) (Feb. 27, 2006) (Eth.) ("'[L]ocal community' means a human population living in a distinct geographical area in Ethiopia as a custodian of a given genetic resource or creator of a given community knowledge . . . ").

321. *See* Andean Community, *supra* note 314, art. 26(h) ("The application for a patent shall be filed with the competent national office and shall contain the following: . . . where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which *any of the member countries is the country of origin*; . . . .") (emphasis added).

322. *See* Intellectual Property Act art. 7 (Oct. 11, 2011) (Samoa) ("An application must contain the following: . . . a statement stating whether or not the invention for which protection is claimed is based on *knowledge available within any local or [I]ndigenous community whether from Samoa or elsewhere*; . . . .") (emphasis added).

323. *See* PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 25 ("In some instances,

failure to disclose mandatory information can result in the patent office halting or rejecting the application.[324] For example, Switzerland will reject applications missing required disclosures.[325] Others, like India and the Andean Community, allow interested third parties to raise issues of noncompliance in administrative proceedings before the patent is granted.[326] The Andean Community allows a third party with a legitimate interest to challenge the invention's patentability within sixty days after the patent application is published.[327] The Andean Community also permits a third party to petition for revocation of a granted patent for a failure to comply with disclosure requirements.[328] Allowing third parties to challenge granted patents would be an effective mechanism because Indigenous communities, as holders of that knowledge, are better positioned to know when traditional medical knowledge is used in an invention.

While patent disclosure requirements do not by themselves entitle Indigenous communities to intellectual property rights in their traditional knowledge, they could be an effective tool in monitoring how traditional knowledge is used in inventions and preventing exploitation, especially if such requirements see widespread national and international adoption.[329] When paired with requirements for prior informed consent and benefit-sharing agreements, patent disclosure requirements would be effective in ensuring that Indigenous communities are not exploited for their traditional medical knowledge. However, patent disclosure requirements must be sufficiently broad to capture downstream derivatives of traditional medicines within their scope to effectively address the use of traditional medical knowledge in pharmaceuticals.[330] Carefully crafted patent disclosure requirements that broadly cover inventions using traditional medical knowledge can be an effective tool to ensure enforcement and to monitor compliance with other laws related to protecting traditional knowledge.

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non-compliance with a disclosure requirement in [access and benefit-sharing] legislation may have consequences . . . for patent examination . . . .").

324. *Id*. at 39.

325. Federal Act on Patents for Inventions, *supra* note 315, art. 59a ("The Institute shall reject the patent application if: . . . the deficiencies . . . have not been remedied.").

326. PATENT DISCLOSURE REQUIREMENTS, *supra* note 298, at 40–41.

327. *See* Andean Community, *supra* note 314, art. 42 ("*Within a period of 60 days following the publication date*, any person having a legitimate interest may file one reasoned opposition contesting the patentability of the invention.") (emphasis added).

328. *See id.* art. 75 ("The competent national authority shall *decree the absolute invalidity of a patent* at any time . . . where: . . . applicable, a copy of the access contract has not been filed where the products or processes to which the patent application relates have been produced or developed with genetic resources or derived products of which any of the member countries is the country of origin; . . . .") (emphasis added).

329. *See* Gebru, *supra* note 294, at 568–69 ("Compliance with the requirement will also have benefits for the source communities . . . . Source communities and countries that engage in protectionism out of fear of biopiracy can be more confident that they can enforce domestic legislation abroad on researchers who gain access to [traditional knowledge] resources.").

330. *See id.* at 569 (explaining how these requirements can incorporate three different levels of reliance on traditional knowledge to impose obligation to disclose).

C. Access and Benefit-Sharing Agreements: Providing Control

Requiring access and benefit-sharing agreements to use traditional medical knowledge would give Indigenous communities control over their knowledge without actual positive protection. Requirements for access and benefit-sharing agreements have been implemented on both the international and national levels.[331] Access and benefit-sharing agreements provide Indigenous communities with advantages from third-party use of their knowledge without having a recognized intellectual property right in that knowledge.[332] These agreements not only allow third parties access to resources and knowledge with consent from an Indigenous community but also require that the communities benefit from that use.[333] Scientists can continue to perform their research and develop commercial products from the knowledge under these agreements with Indigenous communities.[334] Indigenous communities can receive monetary compensation, like royalties and intellectual property ownership, or non-monetary benefits, like skills and other knowledge, as part of an agreement.[335] Requirements for access and benefit-sharing agreements would be the best substitute for positive protection of traditional medical knowledge.

The Convention on Biological Diversity, the Bonn Guidelines, and the Nagoya Protocol on Access and Benefit-Sharing address access and benefit-sharing agreements at the international level. The Convention on Biological Diversity is an initial effort to allow countries to regulate control of genetic resources within its borders, but it does not go far enough.[336] Before the Convention, genetic resources were seen as belonging to all humanity as freely exchanged resources to be used by all.[337] The Convention recognizes that Indigenous communities have a right to give consent before a third party can use the communities' genetic resources.[338]

The Convention also requires that access and benefit-sharing agreements include prior informed consent and mutually agreed terms between an Indigenous

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331. *See Bonn Guidelines*, *supra* note 305 (discussing international requirements for access and benefit-sharing); *see also* Federal Act on Patents for Inventions, *supra* note 315 (discussing national requirements for access and benefit-sharing).

332. Bates, *supra* note 262, at 966.

333. *Id.* at 966.

334. *See* SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, INTRODUCTION TO ACCESS AND BENEFIT-SHARING (2011), https://www.cbd.int/abs/infokit/revised/web/all-files-en.pdf ("Access to genetic resources can lead to benefits for both users and providers. Access and benefit-sharing ensures that the way in which genetic resources are accessed and used maximizes the benefits for users, providers, and the ecology and communities where they are found.").

335. *Id*.

336. Bates, *supra* note 262, at 980–81.

337. *Id.* at 981.

338. *See Bonn Guidelines*, *supra* note 305, art. 15 ("The objectives of this Convention, to be pursued in accordance with its relevant provisions, are 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, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.").

community and a third party.[339] Mutually agreed terms place conditions on the use of the knowledge or resource and stipulate the benefits that the Indigenous community will receive.[340] The Convention requires that contracting parties respect and preserve the traditional knowledge of Indigenous and local communities.[341] However, the Convention lacks true enforcement and effectiveness because it remains subject to national implementing legislation and does not represent any international consensus on whether or how traditional knowledge should be protected.[342]

The Bonn Guidelines, adopted in 2002, are a further step in implementing the objectives of the Convention on Biological Diversity, but are still less effective than a binding international agreement.[343] The Bonn Guidelines encourage countries to develop access and benefit-sharing mechanisms to protect traditional knowledge.[344] While the Guidelines are a first step in implementing the goals of the Convention on Biological Diversity, they are voluntary and negotiated as a non-binding alternative.[345] Nevertheless, the Bonn Guidelines present useful guidance for governments implementing laws requiring access and benefit-sharing agreements, and for institutions and individuals drafting them.[346]

The Bonn Guidelines suggest that prior informed consent in access and benefit-sharing agreements provide for admittance to resources and knowledge

339. *See id.* art. 15 ("Access, where granted, shall be on *mutually agreed terms* and subject to the provisions of this Article. Access to genetic resources shall be subject to *prior informed consent of the Contracting Party providing such resources*, unless otherwise determined by that Party.") (emphasis added).

340. SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 334.

341. *See Bonn Guidelines*, *supra* note 305, art. 8(j) ("Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of [I]ndigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices; . . . .").

342. *See Updated Draft Gap Analysis*, *supra* note 68, para. 58 ("[T]raditional knowledge, . . . is governed by the Convention on Biological Diversity, which requires that a Contracting Party shall: Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of [I]ndigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity . . . ."); Bates, *supra* note 262, at 985–86.

343. *See, e.g.*, Oluwatobiloba Moody, *Addressing Biopiracy Through an Access and Benefit Sharing Regime Complex: In Search of Effective Protection for Traditional Knowledge Associated with Genetic Resources*, 16 ASPER REV. INT'L BUS. & TRADE L. 231, 265–66 (2016) (explaining how Bonn Guidelines attempted to implement Convention on Biological Diversity and why they were made to be non-binding).

344. *See Bonn Guidelines*, *supra* note 305, art. 11 ("The objectives of the Guidelines are the following: . . . [t]o contribute to the development by Parties of mechanisms and access and benefit-sharing regimes that recognize the protection of traditional knowledge, innovations and practices of [I]ndigenous and local communities, in accordance with domestic laws and relevant international instruments; . . . ").

345. Moody, *supra* note 343, at 265–66.

346. SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 334.

with transparent and legal restrictions on access to the knowledge or resource.[347] The Bonn Guidelines recommend clear and certain mutually agreed terms in a written agreement.[348] The terms of the agreement should include (1) the identity and quantity of the resource or knowledge subject to the agreement, (2) any limitations on the use of the knowledge or resource, (3) the rights of the user to transfer the material or knowledge to a third party, and (4) recognition of the rights of the country where the material or knowledge originated.[349]

The Nagoya Protocol on Access and Benefit-Sharing is another step towards protecting traditional medical knowledge, but like the Bonn Guidelines, one that does not go far enough. The Nagoya Protocol provides more clarity and legal certainty than the Convention on Biological Diversity and, unlike the Bonn Guidelines, is binding.[350] The Protocol, signed in 2010, requires countries to take appropriate measures to ensure that Indigenous communities continue to hold their traditional knowledge associated with genetic resources—but *only* in ways that conform with the country's national laws.[351]

The Nagoya Protocol also requires parties to create appropriate measures to ensure that Indigenous communities receive fair benefits from their knowledge.[352] Article 16 requires informed consent of Indigenous communities in agreements for the use of traditional knowledge.[353] Parties also must ensure they obtain informed consent.[354] The Protocol conditions access to and use of the resources and knowledge on the user sharing benefits arising from their use with the community holding the knowledge.[355] On the whole, the Nagoya Protocol allows Indigenous communities to benefit from how others use their knowledge and resources but has limited effectiveness because it relies on national implementation and international

347. *Bonn Guidelines*, *supra* note 305, art. 13.

348. *Id*.

349. SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 334.

350. Moody, *supra* note 343, at 264–67.

351. *See* Nagoya Protocol, *supra* note 312, art. 7 ("In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by [I]ndigenous and local communities is accessed with the prior and informed consent or approval and involvement of these [I]ndigenous and local communities, and that mutually agreed terms have been established.").

352. *Id.* art. 5, para. 5 ("Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with [I]ndigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.").

353. *Id.* art. 16, para. 1 ("Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of [I]ndigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such [I]ndigenous and local communities are located.").

354. *Id.* art. 16, para. 2. ("Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.").

355. SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 334.

support to have widespread enforcement.[356]

These international agreements grant national governments discretion in requiring access and benefit-sharing agreements.[357] This flexibility severely limits the agreements' effectiveness because countries can choose their own instruments to govern access and benefit-sharing agreements.[358] Many countries, especially those with plentiful genetic resources and traditional knowledge, regulate access and benefit-sharing agreements from the perspective of Indigenous communities—holders of traditional knowledge—because they want to benefit from the resources within their borders.[359] Other countries—industrialized countries—implement provisions to ensure that compliance with requirements of access and benefit-sharing agreements benefits users of traditional knowledge.[360] Effective access and benefit-sharing agreement requirements on the international level would need to balance the needs of both types of countries.

As an example of effective national implementation of access and benefit-sharing agreement requirements, Peru is a leader in protecting traditional knowledge by passing laws that protect Indigenous communities' interests in their own knowledge.[361] Peru recognizes that Indigenous communities have a right to control their knowledge and that these rights are inalienable regardless of third-party commercial endeavors.[362] Under Peruvian law, third parties wishing to use an Indigenous community's traditional knowledge must obtain prior informed consent of that community.[363] To obtain consent, a representative for the Indigenous community must inform their community of any third-party negotiations.[364] The community representative must take into account any community concerns in deciding whether to give consent.[365] The inclusion of the community representative is an effective way to respect an Indigenous community and its culture.[366]

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356. *Id.*

357. SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, *supra* note 334.

358. *See id*. ("Many governments around the world have made efforts to implement the [access benefit sharing] provisions of the [Convention on Biological Diversity] at the national level. However, the way in which they do so varies significantly based on individual national circumstances, administrative structures and priorities. As a result, not all countries implement access and benefit-sharing measures to the same extent, or in the same way.").

359. *Id*.

360. *Id*.

361. Haider, *supra* note 71, at 360–61.

362. Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources [No. 27811] arts. 1, 12 (Aug. 10, 2002) (Peru) [hereinafter Peruvian Law No. 27811].

363. *Id.* art. 6 ("Those interested in having access to collective knowledge for the purposes of scientific, commercial and industrial application shall apply for the prior informed consent of the representative organizations of the [I]ndigenous peoples possessing collective knowledge.").

364. *See id.* ("The organization of the [I]ndigenous peoples whose prior informed consent has been applied for shall inform the greatest possible number of [I]ndigenous peoples possessing the knowledge that it is engaging in negotiations and shall take due account of their interests and concerns, in particular those connected with their spiritual values or religious beliefs.").

365. Haider, *supra* note 71, at 363.

366. *Id.*

Peruvian law also requires that Indigenous communities receive a percentage of profits resulting from the use of their traditional knowledge.[367] This provision allows a community to share in the commercialization of their knowledge while retaining bargaining power for future negotiations.[368] Although Peru is able to effectively enforce its laws within its own boundaries, it lacks sufficient international cooperation for global enforcement and widespread effectiveness of the law.[369] Global, uniform protection of Indigenous communities would require coordinated change and implementation on the international and national levels.

Access and benefit-sharing agreements can empower Indigenous communities to benefit from third-party use of their knowledge.[370] However, these agreements would not be effective without legal requirements to enter into access and benefit-sharing agreements. Despite international instruments recommending the use of access and benefit-sharing agreements, widespread benefit to Indigenous communities is unlikely without mandatory requirements for such agreements as a condition on using traditional medical knowledge. Such an obligation to enter access and benefit-sharing agreements would not hinder scientific innovation because access to the valuable knowledge incentivizes entering into the agreements.[371] Scientists and research institutions can easily adapt existing templates for contracts and compensation for raw materials into agreements for traditional medical knowledge.[372] Requirements to enter into access and benefit-sharing agreements would be no different than the necessity to enter into licensing agreements to perform certain research activities. These requirements would not unreasonably impede scientific research.

VI. CONCLUSION

Biopiracy is a surviving relic of colonialism in which Indigenous communities are at the mercy of wealthy nations. Safeguarding traditional medical knowledge protects Indigenous communities and begins to make amends for this painful legacy. Positive protection for traditional medical knowledge—intellectual property rights in traditional medical knowledge—is not viable in existing intellectual property systems absent modification to tailor current laws to consider the unique character of traditional medical knowledge. Patent systems fail to protect traditional medical knowledge, which is often improper subject matter and has been publicly disclosed. Trade secret laws similarly fail to protect publicly

367. Peruvian Law No. 27811, *supra* note 362, art. 8.

368. *See* Haider, *supra* note 71, at 362–63 (explaining how Peru's law mandating a base percentage for any traditional knowledge use is beneficial for Indigenous communities because they will always profit from their licensing efforts).

369. *Id.* at 365; *see* Bates, *supra* note 262, at 977, 979–980 (. . . [C]ountries therefore have attempted to assert sovereign rights-and thereby physical control-over genetic material in their countries, as well as to create barriers to patenting within their borders . . . . [H]owever, international agreements and corresponding national legislation nonetheless fail to protect this knowledge.").

370. Bates, *supra* note 262, at 996.

371. *Id.* at 997.

372. *Id.* at 998.

disclosed traditional medical knowledge. Intellectual property systems would need to be modified to create an exception for Indigenous communities who wish to protect their knowledge that has already been publicly disclosed. Any effort by Indigenous communities to obtain a de jure intellectual property right in their traditional medical knowledge would likely fail under existing patent and trade secret law.

In the absence of effective positive protection, defensive protection of traditional medical knowledge seeks to protect Indigenous communities' interests in their knowledge by preventing others from acquiring intellectual property rights in that knowledge. Documentation of traditional knowledge in databases and patent disclosure requirements can help prevent third parties from exploiting and misappropriating traditional knowledge; however, documentation is not a long-term solution to give Indigenous communities control over their knowledge. A combination of patent disclosure requirements and access and benefit-sharing agreements could be an effective replacement creating a de facto intellectual property right in traditional medical knowledge.

Any effort to protect traditional medical knowledge needs to be crafted and implemented with consideration and input from Indigenous communities themselves. Focusing on fostering collaboration between Indigenous and scientific communities can allow protection for traditional medical knowledge that respects the autonomy of Indigenous communities while still promoting progress and innovation. But collaboration cannot be fostered without international support, national consensus, or widespread implementation of defensive protection measures for traditional medical knowledge.