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TODAY'S PIRATES:

BIOPIRACY, BIOTECH, AND THE INTERNATIONAL FRAMEWORKS THAT ARE NOT UP TO THE CHALLENGE.

KATY ROTZIN*

ABSTRACT

This paper analyzes biopiracy and its effects on Indigenous populations through case studies on specific incidences of biopiracy, and an analysis of modern day agro-neocolonialism, seed piracy, and advances in biotech that are changing modern patent landscapes. This paper suggests that current international frameworks are failing to defend against widespread biopiracy due to ineffective cross-cultural application of relevant treaties and differing domestic approaches to intellectual property frameworks. This paper examines the World Intellectual Property Organization, the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, The Convention on Biological Diversity, The Bonn Guidelines, and The Nagoya Protocol. This paper then makes suggestions for the international community as a whole and for the United States on how to protect against future threats of biopiracy, including technological advancements, such as Digital Sequencing Information (DNA sequencing/synthesis) and CRISPR-Cas9.

*Student at University of California, College of the Law, San Francisco. Comparative and International Indigenous Peoples Law, Spring 2023. I would like to thank Professor Lindsay Robertson for making the journey to San Francisco, for teaching me not one but three courses in law school, for inspiring this paper, and for graciously dealing with my many emails.

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INTRODUCTION

Biopiracy is "the unethical or unlawful appropriation or commercial exploitation of biological materials (such as medicinal plant extracts) that are native to a particular country or territory without providing fair financial compensation to the people or government of that country or territory."[1] It is a multi-faceted issue that spans from the simple use of traditional knowledge to large corporate patents that end in multi-million dollar lawsuits to storage of traditional and heirloom seeds in "Doomsday" vaults by billionaires.[2]
It is also a complex crossover between intellectual property, technology, and biology, and is at the heart of the struggle with international Indigenous farming freedom and the protection of traditional knowledge. Due to the complexities and ramifications of biopiracy, international and domestic lawmaking bodies have struggled to control it. Biopiracy's rise to global relevance has come due to interest of the pharmaceutical, beauty, and agriculture industries in the use of Indigenous traditional knowledge. Traditional knowledge is defined by the World Intellectual Property Organization as "knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity."[3] At its core, traditional knowledge reaches much deeper than just the surface level farming practices of a group of people, for many Indigenous groups it is a cultural expression and a way of life[4]

The challenges facing the international community in protecting traditional knowledge become even more complex when viewed through domestic lenses, which vary state-to-state and who often have different definitions of what biopiracy truly is or how to combat it.[5] In many domestic patent systems, nature is not patentable,[6] and so protecting traditional knowledge,

1. *Biopiracy*, MERRIAM-WEBSTER DICTIONARY, www.merriam-webster.com/dictionary/biopiracy.

2. *Traditional Knowledge*, WORLD INTELL. PROP. ORG., http://www.wipo.int/tk/en/tk/%3B; *see generally*, Jennifer Dugan, *Inside the Doomsday Vault*, TIME MAG., https://time.com/doomsdayvault/.

3. *Folklore*, WORLD INTELL. PROP. ORG., https://www.wipo.int/tk/en/folklore.

4. *What is traditional knowledge? When an elder dies, a library burns*, NATIVE SCI., http://www.nativescience.org/html/traditional_knowledge.html.

5. *See generally* Daanyall R. Kumar, *United States Patents, Biopiracy, and Cultural Imperialism: The Theft of India's Traditional Knowledge*, 11 INQUIRIES J. 1, 1 (2019). U.S. Law currently has no direct patent protections against biopiracy. But see, *Rules*, NAT'L BIODIVERSITY AUTHORITY (Apr. 15, 2004), http://www.nbdindia/content/17/20/1/rules.html. India has an autonomous National Biodiversity Authority, which can impose prison sentences for up to five years and fines of up to 20,000 USD for wrongful exportation of biological materials.

6. *See, e.g.*, Diamond v. Diehr, 450 U.S. 175 (2010) (holding that "exluded from such patent protection are laws of nature, natural phenomena, and abstract ideas."). *See also*, Parker v. Flook,

which is often passed through oral history and relies solely on nature in its primary form, is difficult, if not impossible. Though many domestic systems have allowed for the patenting of variations on nature through gene editing technology, like CRISPR-Cas9.[7] These allowances have opened the door to large companies and international conglomerates amassing thousands of patents for commercial products at the expense of Indigenous groups.[8] Historically, Indigenous groups have not viewed their traditional knowledge as something to be commercialized.[9] Profits have never been the focal point of Indigenous communities and the socioeconomic values around traditional knowledge differ from Western commercialized medicine.[10]

In fact, these communities view traditional knowledge as communal knowledge, which comes head-to-head with modern day patent and intellectual property frameworks.[11] Despite this, with the rise of Western demands for traditional products, Indigenous communities have been forced to either "evolve" or fall prey to appropriation.[12] At this juncture, with varying approaches domestically, the international community is the strongest contender against biopiracy. While protecting Indigenous traditional knowledge has certainly come to the forefront of the international

437 U.S. 584 (1978); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948). "An idea of itself is not patentable," Rubber-Tip Pencil Co. v. Howard, 20 Wall. 498, 507 (1874).

7. Melody Redman, Andrew King, et al, *What is CRISPR/CAs9*?, 101 ARCH. DIS. CHILD EDUC. PRACT. ED. 213, 213-215 (Aug. 2016), https;//pubmed.ncbi.nlm.nih.gov/27059283/. ("Clustered regularly interspaced palindromic repeats (CRISPR)/Cas9 is a gene-editing technology causing a major upheaval in biomedical research. It makes it possible to correct errors in the genome and turn on or off genes in cells and organisms quickly, cheaply and with relative ease. It has a number of laboratory applications including rapid generation of cellular and animal models, functional genomic screens and live imaging of the cellular genome. It has already been demonstrated that it can be used to repair defective DNA in mice curing them of genetic disorders, and it has been reported that human embryos can be similarly modified.").

8. *See* Molly Bond & Debra Scott, *Digital Biopiracy and the (dis)assembling of the Nagoya Protocol*, 117 GEOFORUM 24-32 (2020), https://sciencedirect.com/science/article/pii/S001671852030227X (stating that the stakes on demarcating material from digital are high; in the age of expanding bioeconomies, the utilisation [sic] of genetic resources is moving to the heart of capital accumulation strategies.").

9. Paul Havemann, *Lessons from indigenous knowledge and culture: learning to live in harmony with nature in an age of ecocide*, STATE OF THE WORLD'S MINORITIES AND INDIGENOUS PEOPLES (2016), https://minorityrights,org/wp-content/uploads/2016/07/Lessons-from-indigenous-knowledge-and-culture.pdf (stating that "discoveries cannot be owned, but most of the products of western scientific knowledge are susceptible to being commodified – owned and traded by investors or corporations – as private intellectual property rights.".

10. *Id*.

11. Marcia Ellen DeGeer, *Biopiracy: The appropriation of Indigenous People's Cultural Knowledge*, 9 NEW. END. J. INT'L & COMP. L. 179, 191 (2002), https://ipmall.law.unh.edu/sites/default/files/hosted_resources/PLANT_PATENT_ARTICLES/BIOPIRACY_AND_INDIGENOUS_knowledge.pdf.

12. Rekha Ramani, *Market Realities v. Indigenous Equities*, 26 BROOK. J. INTL'L. 1147, n.4 (2001).

community in recent years,[13] and effective changes have been made, the current protections against worldwide corporate and individual-funded biopiracy are inadequate to defend against the advancing threat to Indigenous food sovereignty, protection of traditional knowledge, farming freedom, and worldwide agrobiodiversity.

I. A BRIEF HISTORY OF BIOPIRACY

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Not surprisingly, biopiracy origins start in a similar place as the destruction of Indigenous food systems — with the arrival of settlers to uncolonized lands. One of the first examples of bioprospecting[14] to be written about was in the 1570s when the Spanish physician Francisco Hernandez led the first scientific colonial expedition to Mexico and Central America to collect plants that might cure illnesses abroad.[15] During his three year trip, he relied on traditional Indigenous knowledge from healers, leaders, and botanists about herbal remedies and then exported the plants back to Spain.[16] Following this, settlers around the globe were quick to find other goods — coffee, cotton, and spices to name a few — that local inhabitants used for traditional purposes and export them for commercial purposes.[17] In fact, the looting of India's subcontinent of their spices, which sold for high prices back in England, is arguably the reason that to this day the East India Company (founded in 1600) is still known as one of the largest corporations of its kind in history.[18]

The building blocks of modern day biopiracy have been in the works for hundreds of years, and the problem has only grown with the arrival of complex economic and justice systems that have protected the colonization of nature and left the discoverers with no method of redress. Indigenous groups are systematically left out of intellectual property frameworks due to lack of access to legal information and have also "had no practical

13. *See, eg. Traditional Knowledge and Intellectual Property – Background Brief,* WORLD INTELL. PROP. ORG. (2016), https;//www.wipe.int/pressroom/en/briefs/tk_ip.html.

14. Bioprospecting can be defined as "searching for substances that are produced by living organisms and may be of medicinal or commercial value." *Bioprospecting,* MERRIAM-WEBSTER DICTIONARY, https;//merriam-webster.com/dictionary/bioprospect.

15. Teo Ballve, *Bioprospecting and Biopiracy in the Americas,* N. AM. CONG. ON LATIN. AM. (Sept. 4, 2007), https;//nacla.org/news/bioprospecting-and-biopiracy-americas.

16. *See* Ballve *supra* note 15.

17. Dave Roos, *How the East India Company Became the World's Most Powerful Monopoly*, HISTORY.COM (Oct. 30, 2002), https://www.history.com/news/east-india-company-england-trade.

18. *Id.*

opportunity to participate in the development of national or international intellectual property systems" until very recently.[19]

Now with robust patent, licensing, copyright, and trademark protections in the US and other Western nations, Indigenous populations are faced with the growing problem of watching their traditional medicines become protected intellectual property in lucrative trade industries — specifically pharmaceuticals, though the market has grown to beauty products, biotech, and agriculture. In 2021, the herbal supplement market reached 151.9 billion USD,[20] and the pharmaceuticals industry was estimated to be worth 1.42 trillion USD.[21]According to the US National Institute of Health, consulting with Indigenous populations doubles the success rate of finding plants that are commercially viable for these markets.[22] On the whole, though, Indigenous communities have not seen any of this profit that they contributed to making.[23] As an example, in the years of 1994-1998, researchers from the University of Wisconsin obtained a patent on brazzein, a sweet berry protein native to Gabon, claiming they had discovered it.[24] This berry had been in use by the native populations of Gabon for centuries, but none of the Indigenous groups, or the country, saw the benefits of the patent.[25]

In recent years, the incredibly strong lobbying efforts of biotech and pharmaceutical companies have incentivized the taking of traditional knowledge by making it a lucrative business.[26] The monopolies that these

19. Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L. 919, 939 (1996).

20. *Dietary Supplements Market Size, Share & Trends Analysis Report by Ingredient, By Type, By End-iser, By Distribution Channel, By Form, By Application, By Region, And Segment Forecasts, 2023-2030*, GRAND VIEW RSCH., https;//www.grandviewresearch.com/industry-analysis/dietary-supplements-market.

21. *Revenue of the worldwide pharmaceutical market from 2001 to 2022*, STATISTA (2023), https;//www.statista.com/statistics/283102/pharmaceutical-market-worldwide-revenue-since-2001/.

22. *See* Roos, *supra* note 17, at 5.

23. Christopher Hunter, *Sustainable Bioprospecting: Using Private Contracts and International Legal Principles and Policies to Conserve Raw Medicinal Materials*, 25 J. OF ENV'T AFF. 129, 146 (1997), https://core.ac.uk/download/pdf/71459977.pdf ("Beneath the fraying of interests is the "reality that while [biodiversity] resources are predominantly located within the territories of the South, the profits derived from their use are almost exclusively reaped by the industrialized North.") (quoting Susan H. Bragdon, *National Sovereignty and Global Environmental Responsibility: Can the Tension Be Reconciled for the Conservation of Biological Diversity?*, 33 HARV. INT'L L.J. 381, 381-82 (1992)).

24. Someschwar Singh, *Rampant Biopiracy of South's Biodiversity*, THIRD WORLD NETWORK (July 20, 2000), http://www.twn.my/title.rampant.htm.

25. *Id*.

26. *See generally*, Olivier Wouters, PhD, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutal and Health Product Industry in the United States, 1999-2018*, 180(5) JAMA INTERNAL MED., 688 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054854/.

corporations and certain conglomerates create on intellectual property rights can make it difficult for Indigenous communities to enter the market with their own products and occasionally bars them from using the resources at all without running aground of patent protections or licensing agreements.[27]

II. CASE STUDIES ON CORPORATE BIOPIRACY

A. The Neem Tree and Biopiracy in India

One of the hallmark cases of biopiracy comes from the saga surrounding the neem tree *(Azadirachta indica)*, which is native to India.[28] The neem tree is known as being one of the most versatile plants found in human history, boasting a plethora of uses such as the curing of leprosy and other skin diseases, antiseptic, fuel, timber, and agriculture to name just a few.[29] For centuries, the neem tree was virtually ignored by Western practitioners, because the practices of Indian doctors were looked down upon; however, when it was discovered that the tree was a natural pesticide it became a patent battleground.[30] In 1985, the United States Patent and Trademark Office (USPTO) awarded a patent to a US timber importer named Robert Larsen for the extraction method of neem oil that would survive long journeys and act as a natural pesticide on US crops.[31] This patent was then transferred to a chemical company called W.R. Grace Co. (Grace) in 1988.[32] Grace and the USDA then filed for a patent with the European Patent Office (EPO).[33] While the patent award did not prohibit Indian farmers from using neem or continuing their own harvesting techniques, Grace began to buy up large portions of neem seeds, build processing plants, and export the oil to the US.[34] Concerns arose that the neem seeds would be bought in such large quantities that it would wipe out the Indian market.[35] The patent was then challenged on the ground that there was a "prior art."[36] because this practice of harvesting neem

27. *See* Shauenberg, *infra* note 75-55, at 15.

28. *See Introduction to the New Tree*, NEEM FOUND., https://neemfoundation.org/about-neem/introduction-to-neem-tree/.

29. *See* Vandana Shiva, *The Neem tree – a case history of biopiracy*, THIRD WORLD NETWORK, https://www.twn.my/title/pir-ch.htm.

30. Kurt Kleiner, *Pesticide tree ends up in court*, NEW SCIENTIST (Sept. 15, 1996), https://neemfoundation.org/about-neem/introduction-to-neem-tree/.

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. Under current USPTO requirements, patents must meet certain criteria to be accepted: utility, patent eligible subject matter, novelty, statutory bar, non-obviousness, enablement. See, 35 U.S.C. § 101-3, 112. Under "novelty" anything that has a "prior art" will be barred from

oil had been going on for centuries in India.[37] Grace's argument hinged on the point that this patent was a new innovation on the prior art.[38] On the challenge by the Indian government, the EPO overturned the patent, identifying the lack of novelty, and the possibility of a prior art.[39]

While the case of the neem tree ended in what some would call a net win, being in the top ten most biodiverse nations in the world,[40] India has become a lightning rod for biopiracy activity. In 1997, the USPTO granted a patent on basmati rice lines and grains for a novel method of cooking starch called Ricetec.[41] Most World Trade Organizations reject plant-variety patents,[42] but the US is unique and allows patents of this genre under certain circumstances.[43] Indian farmers expressed concern that the Ricetec patent was "attempting to gain exclusive control on its development and propagation through a legal process that threatens the traditional rights of the original possessors of the resource."[44] The Indian government challenged the patent

patentability. See, 35 U.S.C. § 301. "Prior art consist[s] of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent" before the patent claim was filed. See also, Graham v. John Deere Co., 383 U.S. 1, at 17-18 (stating that "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined").

37. *See* Shiva, *supra* note 29, at 3.

38. *See* Kliener, *supra* note 30, at 2; *see also*, Art. 124(1), R. 141, Information on Prior Art, EUR. PAT. CONVENTION, https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/r141.html (last visited Sept. 15, 2023) ("An applicant claiming priority within the meaning of Article 87 shall file a copy of the results of any search carried out by the authority with which the previous application was filed together with the European patent application, in the case of a Euro-PCT application on entry into the European phase, or without delay after such results have been made available to him").

39. PTI, *India wins neem patent*, THE TIMES OF INDIA (Apr. 1, 2005), https://timesofindia.indiatimes.com/business/international-business/India-wins-neem-patent/articleshow/1067104.cms; *see also* Tanya Saraswat, *India: The Neem Patent Case*, MONDAQ (Feb. 23, 2023), https://www.mondaw.com/india/patent/1286020/the-neem-patent-case.

40. India is well known for megafauna, species richness, and is ranked especially high in the biodiversity of reptiles and birds. *See generally, The 10 Most Biodiverse Countries in the World,* WORLDATLAS, https://www.worldatlas.com/nature/the-10-most-biodiverse-countries-in-the-world.html.

41. U.S. Patent no. 5,663,484 ("Patent 484").

42. Le Quang Vinh, *How did India win in the legal battle against biopiracy regarding basmati hybrid ride variety patented by the USPTO and valuable lessons for Vietnam*, BROSS & PARTNERS, https://www.lexology.com/library/detail.aspx?g=3b46692a-8b13-416a-b35d-f766f69a52e2 (last visited Sept. 28, 2023).

43. There are three kinds of patents offered protection in the USPTO system: (1) utility patent, (2) plant patent, and (3) plant variety protection certificate (PVP) based on the UPOV Convention. *See, Patent Process Overview*, USPTO, https://www.uspto.gov/patents/basics/patent-process-overview (last visited Sept. 28, 2023).

44. Uzma Jamil, *Biopiracy: The Patenting of Basmati Rice by Ricetec* (Comission on Environmental, Economic, and Social Policy – South Asia and Sustainable Development Policy

and a senior USPTO officer reexamined certain claims, throwing out fifteen[45] of the twenty on the grounds that the rice grains were prior art already in use in India for centuries.[46] While heralded as another win, many commentators have expressed ongoing concern that the entire patent was not withdrawn based on a lack of novelty.[47]

The story has repeated itself many times in India over the years — a multinational corporation appropriates a product without giving fair compensation to the Indigenous population and is able to lock down an entire market.[48] Many biodiverse and developing nations lack the requisite protections to defend against this appropriation from well-funded Western corporations, and, thus, this story seems doomed to repeat itself again and again.

B. The Hoodia Cactus plant and biopiracy in Africa

The Hoodia cactus plant (*Hoodia gordonii*) of the Kalahari Desert is known for its appetite suppressing capabilities.[49] The plant will allow a user to go several days without needing food.[50] The San community in South Africa had been using Hoodia for generations to survive bouts of famine as well as long hunts that required being away from food sources for days at a time.[51] In 1996, the South African Council for Scientific and Industrial Research (CSIR) obtained a patent on P57, an isolated compound of the Hoodia that directly suppresses appetite, and granted development rights to a UK-based pharmaceuticals company, Phytopharm.[52] The patent was then transferred to Pfizer for twenty-five million dollars and the drug then gained international fame.[53]

The San People launched a lawsuit based on a lack of fair compensation for the use of their traditional knowledge, which had spawned yet another

Institute, Working Paper No. 37, 1998), https://sdpi.org/sdpiweb/publications/files/W37-Biopiracy.pdf.

45. Claims 1-7, 10 and 14-20 were rejected, while 8, 9, 11-13 remained. *See Basmati rice <<biopiracy>> patent struck down by us patent office*, PUBLICEYE (Apr. 1, 2001), https://www.publiceye.ch/en/media-corner/press-releases/details/basmasti-rice-biopiracy-patent-struck-down-by-us-patent-office/.

46. *Id*.

47. *See* Jamil, *supra* note 44, at 9.

48. *See* Shauenberg, *infra* note 75-77, at 15.

49. *See Hoodia Cactus*, BIOEXPLORER, https://www.bioexplorer.net/plants/flowers/hoodia-cactus/ (last visited Sept. 17, 2023).

50. *Id*.

51. *Id*.

52. *Id*.

53. *Id*.

Western pharmaceutical success, without their permission.[54] The only reason they became aware of the drug was due to media outlets' excessive coverage of the multi-million dollar sale.[55] When asked about the claims from the San people, the CEO of Phytopharm, Richard Dixey, stated that CSIR had led Phytopharm to believe that the San were extinct.[56]

Due to criticism by non-governmental organizations for not obtaining prior-informed consent, the pharmaceutical companies set up a "San-Hoodia Benefit-Sharing Trust" which entitled the San to milestone payments and a share in the royalties.[57] This was viewed as a win by the San, but there are many who thought the artful backtracking by the pharmaceutical companies was not enough and merely a band-aid on a growing problem, especially since the Hoodia was just one instance of biopiracy that was caught and "adequately" compensated for.[58]

Being defined as a biodiverse and underdeveloped country, Africa, too, has been a target of expansive and biopiracy since the late nineties and early 2000s.[59] In 2006, The African Centre for Biosafety reported to the Convention of Parties (COP) for the Convention on Biological Diversity that over thirty instances of biopiracy from Africa alone had taken place from the 1990s into the early 2000s without fair compensation or benefit-sharing.[60] Some of these instances included antibiotic development from Giant Land Snails in Western Africa, drug addiction treatment from Kombo Butter in Central and West Africa, and cosmetics from the Kokori Fruit in Nigeria.[61] Many of these patents were noted to be from powerful US-based companies and universities like Bayer, Merck, Option Biotech, Unilever, Rutgers, and Pfizer.[62] The unequal power dynamics between small groups and multinational, multi-billion dollar corporations leaves little to no bartering power in Indigenous populations' hands.

54. *See Hoodia Cactus*, *supra* note 49. .

55. *Id*.

56. *Id.* CSIR later claimed that they had plans to give some monetary reward to the San People, though this was not effectuated until after the international community responded to the piracy.

57. *Sharing the Secrets of the Hoodia: San to Reap Financial Benefits of Traditional Knowledge*, CULTURAL SURVIVAL (Mar. 24, 2003), https://www.culturalsurvival.org/news/sharing-secrets-hoodia-san-reap-financial-benefits-traditional-knowledge.

58. *Id.*

59. *This Is What It's All About: Protecting Biodiversity in Africa*, WORLD BANK (Feb. 14, 2019), https://www.worldbank.org/en/news/feature/2019/02/14/biodiversity.

60. *See* Jay McGowan, *Out of Africa: Mysteries of Access-Benefit Sharing*, THE EDMOND INST. AND THE AFR. CTR. FOR BIOSAFETY, https://healingmaps.com/wp-content/uploads/2022/04/out-of-africa-jaymcgowan.pdf.

61. *Id.* at 12.

62. *Id*.

In some circumstances, artful, if not crafty, wording in these patent applications masked the taking of traditional knowledge as well. Egypt's adaption of the French code serves as an interesting example. In 2004, The Dior Group filed for a patent in the US and EU on Okoumé resin found in Gabon, Cameroon, and the Congo, for use in mascara and skin products.[63] Indigenous group's traditional knowledge of Okoumé already extended to multi-purpose uses on the skin and Dior was aware of this, but in their patent application stated, "okume [sic] resin was used in Gabon to make torches used during initiation ceremonies. That use which persists to the present day in villages, is extended in towns during family gatherings. In missionary stations, it is used as a substitute for incense. In *folk medicine*, it is used to bring abscesses to a head and in the treatment of wounds where it activates healing."[64] Under the guise of "folk medicine," Dior was effectively able to mask the true use of the product by the Indigenous populations for skin application, and was able to secure a patent on the resin.[65] Dior, who's sales in 2004 (the year the patent was taken out) totaled 13.4 billion euros, which was four times Gabon's GDP that year, has control over global brands and after this okoumé resin began to invade the market.[66]

C. Conclusion on country-related biopiracy

Neem, hoodia, and okoumé resin are only a few examples of biopiracy. In 1997, after a year-long battle with the Indian government, the USPTO withdrew a patent on turmeric for its healing properties.[67] In 2008, the US-based cosmetics company, Mary Kay, attempted to obtain a patent on the Australian Kakadu plum *(Terminalia ferdinandiana)* — a potent source of Vitamin C — which would have locked out Indigenous producers from the Australian market.[68] More recently, certain instances of biopiracy have gone unstudied and unnoticed. There is concern that underdeveloped and highly biodiverse nations lack the relevant IP frameworks to compete with Western countries and are being systematically taken advantage of, though the relevant information on the biopiracy is lacking.[69] For example, Haiti, the second

63. *See* McGowan, *supra* note 60.

64. *Id.*

65. *Id.*

66. *Id.*

67. *See* K.S. Jayaraman, *US patent office withdraws patent on Indian herb*, NATURE (Sept. 4, 1997), https://www.nature.com/articles/37838.

68. *See* Alecia Wood, *How the Kakadu plum industry is being shaped by Indigenous-led business*, GOURMET TRAVELER (July 4, 2022, 6:01PM), https://www.gourmettraveler.com.au/news/food-news/kakadu-plum-19149.

69. *See Sri Lanka – Protecting Intellectual Property Systems*, INT'L. TRADE ADMIN. (Dec. 12, 2022), https://www.trade.gov/country-commercial-guides/sri-lanka-protecting-intellectual-property ("The government has taken steps over the last five years to integrate relevent [sic] offices

most biodiverse island in the Caribbean, has had a stunted IP framework since it ratified The Convention on Biological Diversity and there is little literature on their systems.[70] Haiti has been in a comprehensive and interminable state of crisis, leaving government systems in disarray, and it appears Western pharmaceutical companies have preyed on the disaster. A recent study revealed that 85.1% of the relevant patents being taken on the island are linked to US, French, and Canadian-based pharmaceutical companies.[71] Several of these patents are on endemic species to the island.[72]

Thus, despite certain wins, the market tends to expand for these Indigenous-found products regardless of patent losses and successes and more companies find ways to take advantage of the resources. As of today, W.R. Grace Co. has a total of forty-nine patents on different forms of neem and led to the price of neem in India skyrocketing.[73] Hence, the problem is much deeper than just patent jargon and court wins or losses — the problem is that multinational corporations are able to take the knowledge gained over centuries by Indigenous groups and then monopolize the industry oftentimes without fair compensation or prior-informed consent.

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and streamline IP protection activities, however local agent of U.S. brands still criticize that enforcement of IP protection is lacking."). *See Haiti – Protecting Intellectual Property Systems*, INT'L TRADE ADMIN. (Aug. 8, 2022), https://www.trade.gov/country-commercial-guides/haiti-protecting-intellectual-property, [https://perma.cc/CX5G-JPJ7] (stating that "[w]eak enforcement mechanisms, inefficient courts and judges' limited knowledge of commercial law comprise effective statutory [IP] protections").

70. *See* Roberto Louis Forestal, *Automated patent landscaping and legal geography analysis to spot biopiracy activities in the island of Hispaniola*, 72 WORLD PAT. INFO J. (2023), https://www.sciencedirect.com/science/article/abs/pii/S0172219023000042 ("Existing regulations on accessing and conserving biological resources do not offer explicit protection for traditional knowledge. Thus, assessing how a given patented product is linked to traditional knowledge of specific endemic plants on the island may be difficult. Third, the current patent regime and scarcity of patent information make it even more challenging to admit that tacit traditional knowledge from local communities is a victim of biopiracy activity.").

71. *Id.* at 8 (Results showing that "85.1% of the patented technologies are mainly developed by foreign pharmaceutical and biotechnology applicants in developed countries like the United States, France, and Canada. An explanation for this growing trend in patent applications is likely due to market changes driven by increased demand for biodiversity-based products and services. As a result, biotech and pharmaceutical companies tend to appropriate biodiversity materials, some through official agreements and others through backdoor means.").

72. *Id*. at 2. Endemic species found under patents included: Herodotia, Eupatorina, Sarcopilea, Haitia, and Tortuella.

73. *Patent on Neem*, NEEM FOUND., https://perma.cc/D9ZB-9LEB ("Further these cases demonstrate the potential of IPR in creating awareness, enthusiasm in scientists, entrepreneurs, organizations and society and increased investments in research and development of products which compete in the marketplace. This is evident from upward trend of patents filed globally on neem from 1994-96 onwards, intense patent debate period, and commercial product available in markets from neem."). *See also* Shiva, *supra* note 28, at 7 ("Over the last 20 years the price of neem seed has gone up from []300[rupees] a ton to current levels of []3000-4000[rupees] a ton.").

III. SEED PIRACY, MARKET MONOPOLIZATION, AND AGRICULTURAL NEOCOLONIALISM

In the past, the focus of biopiracy has been on *corporations* taking the knowledge of Indigenous groups for commercial purposes, but the new pioneers of biopiracy are different and require different controls. Many of these corporations, which were once spread out and diversified, are merging to create super-conglomerates, which carry knowledge and thousands of patents with them, making it harder not only for Indigenous people to retain their knowledge and break into the market but to even launch a successful campaign against the corporations at all.[74] In 2019, PepsiCo sued a potato farmer, Haribhai Devjibhai Patel, from the Western Indian province of Gujarat for planting a patented potato variety called FC5.[75] PepsiCo sued for 140,000 USD; Patel makes 3,500 USD a year.[76] The suit was dropped after protests from Indian farmers, but there are still major international concerns about the patent power held by large corporations and their control over the future of farming freedom.[77]

The concern is not misplaced either. Four players control 50% of the seed business — Bayer, Corteva, ChemChina, and Limagrain.[78] Many major seed producers place limits on how farmers can use varieties they purchase.[79] Buyers must sign agreements that prohibit them from saving or using the seeds again the next season or producing derivatives.[80] This forces them to return to the major corporations every year to purchase seeds and creates an unwilling reliance on the seed giants for continued existence.[81] For example, in India over 80% of all cotton grown is Monsanto GMO Bt cotton, which was introduced in 2002.[82] In perhaps an ironic turn of events, many

74. *See* Charli Shield, *Who Controls the World's Food Supply ?*, DEUTSCHE WELLE (Apr. 8, 2021), https://www.dw.com/en/agriculture-seeds-seed-laws-agribusiness-climate-change-food-security-seed-sovereignty-bayer/a-57118595.

75. *See* Tim Shauenberg, *Patents on plants threaten farmers*, DEUTSCHE WELLE (Sept. 3, 2019). The FC5 variety was developed by PepsiCo. Though the patent was eventually overturned in 2021 due to the fact the Indian patent system does not allow patents on seed varieties. *See* Summit Khana, Mayank Bhardwaj, *India revokes patent for PepsiCo's Lay's potatoes*, REUTERS (Dec. 3, 2021, 11:01 AM PST), https://www.reuters.com/markets/commodities/india-revokes-patent-pepsicos-lays-potatoes-2021-12-03/.

76. *Id*.

77. *See* Khana, *supra* note 75, at 1.

78. *See* Shield, *supra* note 74.

79. *Id.*

80. *Id*.

81. *Id*.

82. *See Genetically modified cotton: How has it changed India?,* RSCH. OUTREACH (Jan. 25, 2021), https://researchoutreach.org/articles/genetically-modified-cotton-how-changed-india/; *see also* Ian Plewis, *Adopting Hybrid Bt Cotton: Using Interrupted Time-Series Analysis to Assess Its*

grassroots movements are further alleging that not only are super-corporations the problem, but billionaire moguls like Bill Gates, who is claimed to be leading the way in seed piracy, agro-neocolonialism, and the spread of unsustainable farming technology.[83] The Green Revolution, which began in the early 1960s, pushed for the production of more food via advanced farming methods, genetically modified crops, and pesticide use, but was also the backdrop for Indigenous seeds (specifically in Mexico and India) to be taken and placed into international seed vaults.[84] After the seeds were removed, they were replaced with chemical monocultures of wheat, rice, and other grains — the Indigenous populations had no say or choice in the matter.[85]

The impact of this was significant, causing a loss "of distinct Indigenous crops from cultivation and also . . . extinction."[86] This is especially relevant since in the 20th Century, 75% of agrobiodiversity has been lost and seed diversity is paramount to restoration [87]

The Indigenous seeds, rich in diversity, were eventually moved into the Consultative Group of International Agriculture Research (CGIAR), which is a conglomeration of fifteen different agricultural research centers, who are funded almost entirely by The Bill and Melinda Gates Foundation (the Foundation) with help from some Western governments, as well as The World Bank.[88] Since 2003, CGIAR has received 720 million from Gates alone and 1.4 billion was pledged in 2022.[89] CGIAR now owns the world's largest and most diverse seed bank at the expense of Indigenous farmers across the globe.[90] Seed sovereignty groups are claiming that CGIAR is disguised as a

Effects on Famers in Northern India, 9 UNIV. OF MANCHESTER REV. OF AGRARIAN STUD. 4, 23 (2020), https://ideas.repec.org/a/fas/journal/v9y2019i2p4-23.html.

83. *See* Vandana Shiva, *One Empire Over Seed: Control Over the World's Seed Banks*, ORGANIC CONSUMERS (OCT. 27, 2020), https://organicconsumers.org/one-empire-over-seed-control-over-worlds-seed-banks/#footnote5; *see generally*, *Gates to a Global Empire*, NAVDANYA INT'L, https://navdanyainternational.org/wp-content/uploads/2021/02/1-SECTION-1-SEED-BG-REPORT.pdf.

84. *See* VANDANA SHIVA, THE VIOLENCE OF THE GREEN REVOLUTION: THIRD WORLD AGRICULTURE, ECOLOGY, AND POLITICS (1991)*; see generally, Svalbard Seed Vault*, NORWEGIAN MINISTRY OF AGRIC. AND FOOD, https://www.seedvault.no/.

85. *Id.* at 16.

86. *See* Ann Raeboline, Lincy Eliazer Nelson, Kavitha Ravichandran, et al., *The impact of the Green Revolution on Indigenous crops of India*, J. OF ETHNIC FOODS (Oct. 1, 2019), https://journalofethinicfoods.biomedcentral.com/articles/10.1186/s42779-019-0011-9.

87. *See What's Agrobiodiversity?*, FAO, https://www.fao.org/3/y5609e/y5609e.pdft.

88. *OPEN LETTER | 'One CGIAR with Two Tiers of Influence?*, IPES FOOD (July 21, 2020), https://www.ipes-food.org/pages/OneCgiar.

89. *CGIAR Welcomes Bill & Melinda Gates Foundation's 1.4 Billion Pledge to Climate Adaptation*, CGIAR (Oct. 11, 2022), https://billion-pledge-to-climate-adaptation/.

90. *CGIAR Genebank Platform*, CGIAR., https://www.cgiar.org/the-genebank-platform/ (last visited Sept. 18, 2023).

global-research partnership to alleviate food insecurity, but is operating similarly to the initial Green Revolution, which was simply agricultural neocolonialism.[91]

Under the project Gates Ag One,[92] the Foundation seeks to merge the fifteen research centers together into one seed collective.[93] CGIAR, and another arm of the Foundation called DivSeek,[94]are currently mapping the genetics of the seeds they have, patenting their findings,[95] and monopolizing the information and licensing of the seeds. Hence, the concern is that patent power over the most diverse collection of seeds in the world (many of which were actively stolen from Indigenous populations) will be in the hands of one foundation.

The Seed Freedom Movement[96] has actively protested CGIAR and Gates Ag One, asking them to return the stolen seeds to the Indigenous populations to no avail. The Movement has argued that the loss of seed diversity is contributing to food insecurity and the loss of farming freedom, which is vital for the future of worldwide farming and food production.[97] It is further alleged that Green Revolution technology (or agroneocolonialism) is replacing sustainable Indigenous farming practices.[98] Green Revolution technology has been shown to develop poisonous superweeds, cross pollination between GMO-altered species to other plants creating invasive species,[99] groundwater pollution, high costs, shortages of supplies, and reliance on "Big Ag" for fertilizers, seeds, and infrastructure.[100]

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91. Agricultural neocolonialism is defined generally as "imposing uniform rules on a global scale ultimately forcing the industrial farming that dominates Europe and the U.S. onto parts of the world where food is still largely produced by smaller-scale, more sustainable farms." *See* Shield, *supra* note 74, at 15.

92. *Our Purpose*, GATES AG ONE, https://www.gatesagone.org/our-purpose/.

93. *See* Shiva, *supra* note 84, at 16.

94. *See Harnessing Crop Diversity*, DIVSEEK INT'L, https://divseekintl.org/harnessing-crop-diversity/.

95. *See* Shiva, *supra* note 84, at 16.

96. *See Seed Freedom*, NAVDANYA INT'L, *https://navdanyainternational.org/key-issues/seed- freedom/.*

97. *Id.*

98. *See* Shiva, *supra* note 84, at 16.

99. *See generally, Katie Mantell, Mexico confirms GM maize contamination*, SCI. DEV. NET., (2003), https://www.scidev.net/global/news/mexico-confirms-gm-maize-contamination/ [https://perma.cc/9QH2-9XDZ]; *see also,* John Paull, *Genetically Modified Organisms (GMOs) as Invasive Species*, 4 J. OF ENV'T. PROT. AND SUSTAINABLE DEV. 31, 31 (2018), https://orgprints.org/id/eprint/33327/1/Paull2018GMInvasiveSpeciesJEPSD.pdf (framing GMOs as an invasive species because "[t]he evidence is that GMOs are invasive species, they are unwelcome by consumers, peaceful coexistence with non-GM varieties is a fiction, and GMOs [must be] appropriately managed as a biosecurity issue.").

100. Aristidis M Tsatsakis, Muhammad Amjad Nawaz, Demetrios Kouretas, et al., *Environmental impacts of genetically modified plants: A review*, 156 ENV'T. RSCH. 818, 833

In 2017, CGIAR, DivSeek, and Gates Ag One lost the support of The International Treaty on Plant Genetic Resources for Food and Agriculture due to the fact that the existence of the conglomeration threatens Indigenous farmers worldwide.[101] This was a strong statement since the Treaty was a large point of support for the Foundation though it did not deter CGIAR or subsidiaries.[102] In 2022, a Memorandum of Understanding was signed between the two organizations in agreement of a common goal for greater access-benefit sharing with developing countries.[103] Despite this, there is a common thread amongst smaller organizations, who would like the Foundation and its funded subsidiaries to be removed from their localities. In 2020, the Southern African Faith Communities' Environment Institute asked the Foundation to stop funding "Green Revolution" technology throughout Southern Africa, because it was degrading local, holistic approaches to farming and increasing food insecurity.[104] Perhaps somewhat unsurprisingly, in November 2022 the Foundation rebranded the African arm of its project,

(2017), https://pubmed.ncbi.nlm.nih.gov/28347490/(finding that "The current state of knowledge reveals that GM crops impart damaging impacts on the environment such as modification in crop pervasiveness or invasiveness, the emergence of herbicide and insecticide tolerance, transgene stacking and disturbed biodiversity…").

101. *See "DivSeek initiative" loses support of the International Treaty on Plant Genetic Resources for Food and Agriculture*, INT'L PLAN. COMM. FOR FOOD SOVEREIGNTY (Feb. 28, 2017), https://www.foodsovereignty.org/divseek-initiative-loses-support-international-treaty-plant-genetic-resources-food-agricul- ture/#_ftn11.

102. The Gates Foundation still funded multiple projects after 2017. For example, from 2017-2020 the Foundation gave twenty million to the The Golden Rice Foundation, and from 2018-2023 gave thirty-four million to AGGRi Alliance (Accelerated Genetic Gain in Rice in South Asia and Africa) and is funding other projects currently. *See, e.g.*, Vandana Shiva, *One Empire Over Seed: Control Over The World's Seed Banks*, NAVDANYA INT'L., https://navdanyainternational.org/wp-content/uploads/2021/02/1-SECTION-1-SEED-BG-REPORT.pdf.

103. *DivSeek signs MOU with International Treaty*, DIVSEEK INITIATIVE (June 6, 2022), https://divseek- intl.org/news-mou-itpgrfa/.

104. *Open letter to the Bill and Melinda Gates Foundation from the SAFCEI and faith community representatives from the African continent*, SAFCEI (2020), https://safcei.org/wp-content/uploads/2020/09/Gates-Foundation-appeal-from-SAFCEI-African-faith-Leaders-September-2020.docx.pdf [hereinafter, "Open Letter"].

moving from "Alliance for a Green Revolution in Africa"[105] (AGRA) to "Sustainably Growing Africa's Food Systems" (AFSA).[106]

The main problem remains untreated. Groups are concerned there is a lack of control over the conglomeration and many large seed industries have aligned themselves with Gates Ag One, making them a strong and highly powerful organization.[107] In some instances, seed banks are popping up in an attempt to stop corporations from effectively monopolizing the agri-seed business, but it will take many more of these to stop the monopolization.[108] The only opportunity to change the current trajectory may be through treaties and other international legal protections.

IV. EXAMINING WHERE THE CURRENT INTERNATIONAL LEGAL FRAMEWORKS FOR INTELLECTUAL PROPERTY PROTECTIONS SUCCEED AND FAIL IN DEFENDING INDIGENOUS GROUPS AGAINST BIOPIRACY

On the whole, the international community has been more apt to do damage control than to take preemptive protective measures against biopiracy. Up until the enactment of the Convention of Biological Diversity in 1993, traditional knowledge was essentially unprotected, but even with enactments of the Treaty and those that followed, biopiracy and agro-neocolonialism has still exploded. Some scholars have attributed this to the lack of progress once a certain treaty is ratified and that progression is slowed further by certain strategic ambiguities within the treaties that are allowing new frontiers of biopiracy to explode.[109] Many current international agreements are failing to keep pace with technological advancements and are ill-equipped to manage domestic laws, international agreements, and where

105. Timothy Wise, Jomo Kwame Sundaram, *AGRA Gets Make-Up, Not Make-Over*, INTER-PRESS SERV. NEWS AGENCY (Nov. 29, 2022), https://www.ipsnews.net/2022/11/agra-gets-make-not-make/; *see* Tracy Keeling, *African farmers to UK: stop funding 'climate-stupid' agriculture on our continent*, THE CANARY (Sept. 12, 2022), https://www.thecanary.co/global/world-analysis/2022/09/12/african-farmers-to-uk-stop-funding-climate-stupid-agriculture-on-our-continent/ ("Millions of African people have demanded that the UK and others cease funding an agricultural initiative on the continent. They say that the Alliance for a Green Revolution in Africa (AGRA) locks farmers into dependence on corporations and environmentally destructive practices. Instead, farmers, along with faith leaders and other civil society organizations (CSOs), have urged funders to redirect financing to initiatives that are ecologically sound and offer self-sufficiency for people").

106. *Our Strategy*, AGRA, https://agra.org/.

107. *See Gates Ag One: The Recolonisation of Agriculture*, INDEP. SCI. NEWS (Nov. 16, 2020), https://www.independentsciencenews.org/commentaries/gates-ag-one-the-recolonisation-of-agriculture/ (last visited Oct. 18, 2023). Companies that have aligned themselves with Gates Ag One include Monsanto, Bayer, and Dupont.

108. *Id*.

109. *See* Bond & Scott, *infra* notes 196–97, at 26.

they intersect.[110] Some of the agreements are in direct contradiction with one another, and oftentimes where one agreement succeeds, it begins to fail as time passes. This is especially relevant in the age of ever-expanding bioeconomies.[111] Below examines the five most relevant international accords on intellectual property frameworks and the use of traditional knowledge.

A. World Intellectual Property Organization (WIPO)

Established in 1967, the World Intellectual Property Organization (WIPO) "is a global forum for intellectual property services, policy, information, and cooperation"[112] operating under the United Nations. WIPO currently has 193 member states, and functions cross-culturally making IP access easier and more understandable to those who may have no background in it.[113] WIPO is also the primary forum for negotiating the protection of traditional knowledge, which has been defined widely as, "a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity"[114] WIPO is also aware that protecting traditional knowledge is a difficult task — knowledge that is informal, oral, or passed down over generations is oftentimes not afforded protection.[115] These barriers to protection come through established legal precedents. For example, in most patent systems nature is not protectable nor are the traditional uses of the resources.[116]

To address the systemic barriers that Indigenous groups face for protection of traditional knowledge, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).[117] The IGC was created to develop legal instruments dedicated to giving traditional knowledge legal protections.[118] There are two kinds of legal protections being sought by the IGC: 1) "Defensive protection [which] aims to stop people outside the community from acquiring intellectual property rights over traditional knowledge," and 2) "Positive protection [which] is the granting of rights that empower communities to promote their traditional

110. *See* Bond & Scott, *supra* note 9, at 26.

111. *Id*.

112. *About WIPO*, WIPO, https://www.wipo.int/about-wipo/en/ (last visited Sept. 19, 2023).

113. *Id*.

114. *Traditional Knowledge and Intellectual Property – Background Brief*, WIPO, https://www.wipo.int/pressroom/en/briefs/tk_ip.html.

115. *Id*.

116. *See, e.g.*, Diehr, 450 U.S. 175 at 185*; see also* Bilski v. Kappos, 561 U.S. 593, 601 (2010), Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

117. *Intergovernmental Committee (IGC)*, WIPO, https://www.wipo.int/tk/en/igc/.

118. *Id.*

knowledge, control its uses and benefit from its commercial exploitation."[119] [119]119 Another key aim of the IGC is the defensive protection of genetic resources, especially relevant now that seed piracy is rampant through Digital Sequencing Technology and CRISPR.[120] At the forty-sixth and forty-seventh IGC meetings digital technology and genetic manipulation was discussed.[121] The draft articles also seek to protect Indigenous cultural expressions/folklore and protect traditional knowledge against misappropriation.[122] The articles, if passed, would likely be an effective way to prevent some international biopiracy by enacting stronger protections than what is currently available.

1. Ongoing negotiations slow WIPO progress and allow biopiracy to carry on.

The IGC is clearly on the right path and aimed squarely at the correct problems, in fact it is one of the only forums that is openly trying to control new advances on gene and gene editing technology,[123] but unfortunately has gotten very little done in the way of implementation. The IGC's negotiations started in 2009 and are still ongoing due to the lack of agreement from different nations on how to approach the problem and diverging views on what should be and can be protected.[124] In December of 2022 and March of 2023, the IGC met to discuss the draft articles of the treaty and will meet again June 5th-9th, 2023 in Geneva, Switzerland.[125] Due to these disagreements, at this juncture every proposed legal instrument is as the name implies, just a proposition with no legal force behind it.[126] The difficulty is that when there are so many contributing voices, an instrument may never be signed and the negotiations could, potentially, go on for another sixteen years. While negotiations continue to take place, biotech advances, the intellectual property

119. *See Intergovernmental Committee (IGC), supra* note 117.

120. *See* Redman & King, *supra* note 7, at 3.

121. *See* Martin Michaus, *The 46 Session IGC/WIPO The Protection of Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions*. (TK/GR/TCE) (Draft of an International Instruments), INT'L ASSOC. FOR THE PROTECTION OF INTELL. PROP. (Mar. 24, 2023), https://www.aippi.org/news/the-46-session-igc-wipo-the-protection-of- traditional-knowledge-genetic-resources-and-traditional-cultural-expressions-tk-gr-tce-draft-of-an-international-instruments/.

122. *See* Intergovernmental Committee (IGC), *supra* note 117.

123. *See* Michaus, *supra* note 121.

124. *See* Catherine Saez, *Disclosure, Sanctions - Still to be Overcome in WIPO Genetic Resources Negotiations*, INTELL. PROP. WATCH (June 28, 2018), https://www.ip-watch.org/2018/06/28/disclosure-sanctions-still-overcome-wipo-genetic-resources-negotiations/.

125. *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Forty-Seventh Session*, WIPO, https://www.wipo.int/meetings/en/details.jsp?meeting_id=75419.

126. *Id*.

system awards patents, copyrights, and trademarks, and traditional knowledge gets swept away. It would be useful for the IGC to agree on a placeholder agreement for some minimal protections while talks continue, otherwise the instrument they eventually sign may only be a band aid on a problem that is bleeding out.

B. The World Trade Organization and Trade-Related Agreement on Intellectual Property Rights (TRIPS)

Under the World Trade Organization (WTO), one of the foremost agreements in intellectual property rights is the Trade-Related Agreement on Intellectual Property Rights (TRIPS). TRIPS came into force on January 1, 1995 and is the most comprehensive trade agreement on IP[127] and followed the Paris Convention and the Berne Convention.[128] The WTO website states that "[the Agreement] plays a central role in facilitating trade in knowledge and creativity, in resolving trade disputes over IP, and in assuring WTO members the latitude to achieve their domestic policy objectives. It frames the IP system in terms of innovation, technology transfer and public welfare."[129] The Agreement was created to address the changing patterns of information in an ever-globalized society where knowledge flows freely across borders without restraint.[130] A key aim of the Agreement was to establish minimum levels of required IP protections since both the Paris Convention and the Berne Convention had failed to provide uniform international IP requirements.[131] The Agreement required members to establish minimum standards for use, availability, and scope of the seven forms of IP,[132] and "spells out permissible limitations and exceptions in order to balance the interests of intellectual property with interests in other areas."[133] Though over

127. *TRIPS — Trade-Related Aspects of Intellectual Property Rights*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/trips_e.htm.

128. *Trade related aspects of IP rights*, USPTO, https://www.uspto.gov/ip-policy/patent-policy/trade-related-aspects-ip-rights.

129. *Id*.

130. *Id*.

131. *See Paris Convention for the Protection of Industrial Property*, WIPO, https://www.wipo.int/treaties/en/ip/paris/("This international agreement was the first major step taken to help creators ensure that their intellectual works were protected in other countries.")(emphasis added); *see Berne Convention for the Protection of Literary and Artistic Works*, WIPO, https://www.wipo.int/trea- ties/en/ip/berne/("It is based on three basic principles and contains a series of provisions determining the minimum protection to be granted, as well as special provisions available to developing countries that want to make use of them.")(emphasis added).

132. The seven forms of IP are: copyrights, trademarks, geographical indications, industrial designs, patents, layout designs for integrated circuits, and undisclosed information (trade secrets). *See* TRIPS, *supra* note 127, at 24.

133. *See* TRIPS, *supra* note 127, at 24.

a decade old at this point, the TRIPS Agreement is widely seen as falling behind — "a floor, not a ceiling" for IP protections."[134]

1. The TRIPS agreement fails to protect traditional knowledge and serves Global North interests over the Global South.

Despite the fact that the Western creators of the TRIPS believed they were aiding developing countries, the TRIPS agreement comes under the heaviest scrutiny from outsiders as the most concerning patent "reform." The three negotiating forces behind the agreement were Keidanren, the Intellectual Property Committee (IPC), and the Union of Industrial and Employees Confederation (UNICE).[135] Each one of these organizations had strong commercial interests — "IPC is a coalition of 12 major U.S. corporations: Bristol Myers, DuPont, General Electric, General Motors, Hewlett Packard, IBM, Johnson & Johnson, Merck, Monsanto, Pfizer, Rockwell, and Warner.[136] Keidanren is a federation of economic organizations in Japan, and UNICE is recognized as the official spokesperson for European business and industry."[137] Concerns arose that the commercial interests would prioritize the Global North over the Global South, who was absent from much of the TRIPS negotiation process. [138] The TRIPS agreement focused on the privatization of the IP system, affirming WTO member patent systems based on private property rights, which successfully negated communal knowledge.[139] Nor does the agreement take into account the varying definitions of comercialization of traditional knowledge.[140] Before TRIPS was enacted, there were no uniform international IP requirements, and states were free to manage their IP, which meant that traditional knowledge could hypothetically be protected.[141] But underdeveloped nations were pressured into signing the agreement to keep pace with developed nation's IP systems at the expense of Indigenous populations and community values.[142] India

134. *See* TRIPS, *supra* note 127, at 24.

135. *See* VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE (1st ed. South End Press 1997).

136. *Id*. at 81.

137. *Id.*

138. *Id.*

139. *Id.* at 25.

140. *See* Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKEFOREST L. REV. 89, 122-23 (1993).

141. *See* James O. Odek, *Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources, 2* J. INTELL. PROP. L. 141, 145-49 (1994).

142. *See* Leanne M. Fecteau, *The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Patent Policy*, 21 B.C. THIRD WORLD L. J. 69, 81 (2001) ("However, these [underdeveloped] countries were economically pressured by developed countries to sign TRIPS, which pre- vents them from passing protectionist laws."); *see also* Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing*

stated that its adoption of TRIPS in 1994 was due to its need "to utilize demanded-for intellectual property rights as a sword and shield against deculturizing [sic] forces of globalization and foreign investment."[143] Thus, it is no surprise that in many scholars' eyes the TRIPS agreement was a failure and has been likened to modern day imperialism.[144] Further, TRIPS has not changed or expanded in any meaningful way since its inception in the mid-nineties, and still stands as a hallmark case of bullying by the West.[145] The agreement preys on the interests of Indigenous populations, but is also in direct conflict with the Convention on Biological Diversity, though they both exist in the same universe as one another and in apparent congruence.

C. The Convention on Biological Diversity (CBD).

Unlike TRIPS, The Convention on Biological Diversity (CBD), amidst an elaborate forty-two article document, espouses the need to preserve and protect Indigenous knowledge."[146] The CBD is under the umbrella of the United Nations and has 196 signatories.[147] The Treaty has three stated aims: 1) to conserve biodiversity, 2) create and effectuate sustainable development, and 3) preserve fair and equitable access to genetic resources.[148] The only UN member states that do not follow the CBD are the United States

Countries Toward the Patentability of Biotechnology, 6 J. INTELL. PROP. L. 41, 53 (1998) (The Global North views patents as a way "to maintain their head start in technology and deny a transfer of technology so that [the undeveloped] can begin their own research and development industries." (quoting Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENV'T. L. & POL'Y 111, 127 (1996)).

143. *See* Ramani, *supra* note 12, at 4 (citing Doris Estelle Long, *The Impact of Foreign Investment on Indigenous Culture: An Intellectual Property Perspective*, 23 N.C. J. INT'L L. & COM. REG. 229, 240 (1998)).

144. *See* Shiva, *supra* note 135, at 25.

145. *See WTO members agree to extend TRIPS transition period for LDCs until 1 July 2034*, WTO (June 29, 2021), https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm (WTO has consistently amended the "transitional period" for Least Developed Countries (LDCs) in continued recognition of their lack of infrastructure and economic needs to create technological bases to host intellectual property frameworks); *See also, Request for an Extension of the Transitional Period Under Article 66.1 of the Trips Agreement*, HAITI ON BEHALF OF THE LDC GROUP FOR THE WTO (Nov. 5, 2012), https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipcw583_e.pdf (Haiti requesting on behalf of the LDCs a delay in the transitional period required by the WTO to allow them more time to enter the TRIPS Agreement).

146. *See Thematic Programmes and Cross-Cutting Issues*, CONVENTION ON BIOLOGICAL DIVERSITY (Apr. 1, 2021) https://www.cbd.int/article/indigenous%26localcommunitiesforbiodiversity.

147. *See List of Parties*, CONVENTION ON BIOLOGICAL DIVERSITY (Apr. 14, 2023), https://www.cbd.int/infor- mation/parties.html.

148. *Text of the Convention*, CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/convention/text/.

(who signed but never implemented) and the Vatican City.[149] The implementation of the CBD's aims are discussed every two years at the COP. The most recent convention COP15 took place in December 2022.[150] Viewed as a grand bargain between wealthy Western states and biodiverse developing nations, the CBD is noted as being hugely important in the protection of biodiversity and genetic resources from biopiracy.[151]

1. The CBD struggles to effectuate its end goal due to contrary domestic and international law frameworks.

The CBD has unique issues to overcome. While signatories are obligated to not act in a way contrary to the instrument, they also maintain sovereignty over their natural resources.[152] Thus, each state is allowed to enact their own policies in regards to their resources and control them in accordance with their legislation. [153] The promise of continued state sovereignty is paramount to cooperation in the international community, as states all value self-determination highly, though oftentimes this can run against international goals.[154] Biodiversity is clearly within the bounds of the state, but also spreads beyond it and so states must be held responsible for trans-boundary effects.[155] But, in this instance, the CBD allows the government of the nation to act in a way that takes advantage of Indigenous groups through bioprospecting by companies and other countries under domestic policy.[156] This is often the case when underdeveloped nations in the Global South see op-

149. *See* Braulio F.S. Dias, *The Slow but Steady Progress in the Implementation of the Biodiversity Agenda*, INT'L UNION FOR THE CONSERVATION OF NATURE (July 31, 2020), https://www.iucn.org/news/world-commission-environmental-law/202007/slow-steady-progress-implementation-biodiversity-agenda.

150. *See COP15 ends with a landmark biodiversity agreement*, UNITED NATIONS ENV'T PROGRAM (Dec. 20, 2022), https://www.unep.org/news-and-stories/story/cop15-ends-landmark-biodiversity- agreement.

151. James Ashworth, *Explained: What is the Convention on Biological Diversity, and What Does it Do*?, NAT. HIST. MUSEUM (Dec. 1, 2022), https://www.nhm.ac.uk/discover/what-is-the-con- vention-on-biological-diversity-and-what-does-it-do.html.

152. *Id.*

153. *See Article 3. Principle*, CONVENTION ON BIOLOGICAL DIVERSITY (last visited Sept. 17, 2023) https://www.cbd.int/convention/articles/?a=cbd-03.

154. *See* Ricardo Pereira, *Permanent Sovereignty Over Natural Resources in the 21st Century: Natural Resource Governance and the Right to Self-Determination of Indigenous Peoples Under International Law*, 14 MELBOURNE J. OF INT'L L. (2013) https://ssrn.com/abstract=3656492("Permanent sovereignty over natural resources has emerged as a fundamental principle in international law, allowing postcolonial states to assert full sovereignty or 'sovereign rights' over natural resources found within the limits of their jurisdiction.").

155. *See* Christopher J. Hunter, *Sustainable Bioprospecting: Using Private Contracts and International Legal Principles and Policies to Conserve Raw Medicinal Materials*, 25 B.C. ENV'T AFF. L. REV. 129 (1997), http://lawdigitalcommons.bc.edu/ealr/vol25/iss1/4.

156. *See* Hunter, *supra* note 155.

portunities for economic growth through contracts with the Global North.[157] Some commentators have concerns that this has led to underdeveloped and biodiverse nations plundering their own resources in the name of economic survival without focusing on long term sustainability or the implications for biodiversity.[158]

2. The CBD is vague which leaves member states unsure of how to enact effective policies and legislation.

The CBD also lacks a great deal of clarity in its general wording. The three main goals[159] of which it commits itself to are not expounded on and it lacks direction as to how these goals are to be carried out. In fact, many of the hallmark cases of biopiracy took place after the treaty was brought into force in 1993.[160] Further, as evidenced by the incoherent nature of application, member-states were unsure as to how to proceed, which left a somewhat disjoined international framework being applied cross-culturally. In fact, many of the articles of the treaty have not been implemented by member-states at all.[161] Some scholars attribute this to the fact that countries "still lack effective cross-sectoral dialogue and coordination mechanisms, with prevailing sectoral policies and agencies still working in silos, often with conflicting and competing policies . . ."[162] States with larger interests are likely to favor market pressures over successful application of CBD frameworks. The UN itself also seems to be struggling to successfully execute the Conventions goals — In 2010, The CBD launched a "Decade on Biodiversity Program,"

157. *See* Susan H. Bragdon, *National Sovereignty and Global Environmental Responsibility: Can the Tension Be Reconciled for the Conservation of Biological* Diversity?, 33 HARV. INT'L. L. J. 381, 381-82 (1992) ("reality that while resources are predominantly located within the territories of the South, the profits derived from their use are almost exclusively reaped by the industrialized North").

158. *See* Bragdon, *supra* note 157; *See also*, Forestal, *supr*a note 70, at 14. ("As a result, biotech and pharmaceutical companies tend to appropriate biodiversity materials, some through official agreements and others through backdoor means. This is akin to biopiracy activities in that the island of [Haiti's] intellectual property (IP) system [] and legal framework [] do not always support local people in benefiting from endemic plants and their potential uses").

159. *See Strategic Plan For Biodiversity 2011-2020, Including Aichi Biodiversity Targets*, CONVENTION ON BIOLOGICAL DIVERSITY (May 15, 2018), https://www.cbd.int/sp/elements/.

160. *See* McGowan, *supra* note 60, at 11 (Most notable biopiracy incidents in Africa took place from the 1990s to the early 2000s. The Convention on Biological Diversity was signed in 1993); *See also*, Jamil, *supra* note 44, at 9 (Basmati rice patent took place in 2001); *see also*, Jayaraman, *supra* note 67, at 12 (Turmeric patent was granted in 1995).

161. *See* Dias, *supra* note 149, at 27; Forestal *supra* note 70, at 14 (Featuring Haiti as an example of a state's lack of effective implementation of the CBD/Nagoya Protocol. Haiti has not been able to "[d]evelop[] an effective and coherent ABS framework at the international level by fully adopting international accords such as the Convention on Biological Diversity and the Nagoya Protocol.").

162. *See generally*, Forestal, *supra* note 70, at 14.

with five targets that were to be achieved by 2020 and none were achieved.[163] The Targets were stated to have lacked "clearly defined metrics" to gauge success.[164] At COP15 in December of 2022, another landmark biodiversity agreement was reached (the Kunmings-Montreal Global Diversity Framework), which again created "Targets" related to stopping the loss of biodiversity.[165] Digging deeper into the four stated goals, slated to be achieved by 2030, there is again a lack of direction on how states should effectuate them.[166]

While there is political power and willingness to comply behind a treaty with so many ratifications, there will be no true effective implementation until the vagueness is remedied by clearly defined metrics. To be sure, the CBD is a powerful statement, but it lacks the ability to effectuate many of its end goals due to its vagueness and the fact that much of the CBD's end goals seem to run contrary to principles of state sovereignty and the right of self-determination.

D. The Bonn Guidelines.

Due to lack of clarity on the three main principles[167] of the CBD, which allows countries to apply the scope of the treaty in the way they best see fit with no real guidelines, the convention met again in 2004.[168] The Bonn Guidelines were developed at COP6 with the intent to help the signatory governments in "developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit-sharing."[169]Outside of details on genetic resources, the Guidelines were more

163. *See Aichi Biodiversity Targets*, CONVENTION ON BIOLOGICAL DIVERSITY (Sept. 18, 2020), https://www.cbd.int/sp/targets/; *see also, UN report highlights links between 'unprecedented biodiversity loss' and spread of disease*, UNITED NATIONS (Sept. 15, 2020), https://news.un.org/en/story/2020/09/1072292.

164. *See* Gloria Dicke, *Explainer: Why did past targets to protect nature fail over the last decade?*, REUTERS (Dec. 8, 2022), https://www.reuters.com/business/environment/why-did-past-targets-protect-nature-fail-over-last-decade-2022-12- 09/.

165. *See COP15 ends with a landmark biodiversity agreement*, *supra* note 151, at 27.

166. *See Final Text of the Kunming-Montreal Global Biodiversity Framework*, CONVENTION ON BIOLOGICAL DIVERSITY (Dec. 17, 2022), https://www.cbd.int/article/cop15-final-text-kunming-montreal-gbf-221222 (stating that the Agreement does not state how the Goals and Targets are to be implemented internationally, nor is there any current discussion on further guidelines to establish uniform application cross-culturally.).

167. *See* Dicke *supra*, note 165, at 30.

168. *Bonn Guidelines History*, CONVENTION ON BIOLOGICAL DIVERSITY (Aug. 16, 2017), https://www.cbd.int/abs/bonn/.

169. *See Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of Their Utilization*, SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY (2002), https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf.

comprehensive than the CBD, covering improving sustainability in developing countries,[170] technology transfers between nations, and the protection of Indigenous traditional knowledge.[171] Further, under the Guidelines, informed consent was made necessary before accessing genetic resources and even permission to access genetic resources does not necessarily mean that the knowledge associated with the resources comes along with it.[172] Thus protecting much of what traditional knowledge is based on.

1. The Guidelines are suggestions with no binding force on parties.

The trouble with the Guidelines is that following them is completely voluntary. While it details more on how a country who is a party to the treaty might go about effectuating the treaty, it does not require any country to abide by the rules. The Guidelines use of the words "should," "endeavor," and "encourage" are significations of a suggestion, not a binding oath.[173] Nor does it require that member states recognize certain Indigenous groups or categories of traditional knowledge, which, again, leaves groups unprotected.[174] Further, many scholars have noted that applying the Guidelines in any contract-based domestic setting [175] is nearly impossible, or, at the very least, unhelpful, because they are "simply inadequate for tackling certain problems associated with the use of genetic resources which have international dimensions and tend to require international cooperation with regards to jurisdictional and enforcement matters."[176]

E. Nagoya Protocol.

In October of 2010, the Convention met again and agreed to The Nagoya Protocol. The Nagoya Protocol has 139 ratifications, but several large countries have not ratified, including the USA (who never ratified the CBD),

170. *See supra* note 169, at § 11(e).

171. *Id.* § 11(g).

172. *Id.* § 34.

173. *See Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of Their Utilization to the Convention on Biological Diversity*, SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY (2011), https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf [hereinafter, "Nagoya Protocol"].

174. *Id*.

175. *See* Paul Kuruk, *Mutual Recognition Agreements and the Protection of Traditional Knowledge*, COMMONWEALTH TRADE HOT TOPICS, https://www.thecommonwealth-ilibrary.org/in-dex.php/comsec/catalog/download/518/518/4268?inline=1 (". . . the best drafted contract is meaningless if the party who breaches the contract moves out of the state where the contract was entered into and establishes residence in another country.").

176. *See* Paul Kuruk, *Regulating Access to Traditional Knowledge and Genetic Resources: The Disclosure Requirement as a Strategy to Combat Biopiracy*, 17 SAN DIEGO INT'L. L. REV. 1, 26 (2015).

Russia, Canada, and many other smaller states with larger Indigenous populations such as Sri Lanka and New Zealand.[177]

The Protocol advances on the CBD and the Bonn Guidelines by requiring fair access-benefit sharing (ABS), prior informed consent, a global sharing mechanism, a national focal point, and a Clearing-House.[178] The Protocol requires that any benefit arising from utilization of any genetic resources must be shared in a fair way with prior agreed upon terms in accordance with the Convention or with the local Indigenous communities.[179] Benefits, in this context, are widely defined as monetary and non-monetary, which allows, more flexibility for claims to arise.[180] In these transactions, the Acquiring Party (or Parties) are required to obtain prior informed consent from the Provider Party (or Parties).[181] The Acquiring Party is required to adopt formal legislation or contracts that are both transparent and clear for the Provider Party with the improvement and involvement of the Provider, usually the local Indigenous communities.[182] The benefits found and relating to the traditional knowledge are obligated to be shared with the Provider Party and are to be aimed at both supporting biodiversity and promoting the use of the findings globally.[183] Each Party is required to have a designated "focal point" liaison between the CBD and relevant national authorities.[184] Finally, the Protocol established an Access and Benefit-Sharing Clearing-House to share the findings and handle related paperwork between the Parties.[185] The Clearing-House has a wide body of work to support methods and tools used by the Parties in their negotiations and dealings with one another.[186]

1. The Protocol is the most effective means of binding law for the protection of Indigenous traditional knowledge and prevention of biopiracy thus far.

The Nagoya Protocol is the most well-rounded and effective means of protecting traditional knowledge from biopiracy but also facilitating development between countries. The Protocol overcomes some of the shortcomings of the CBD by enhanced specificity and clarity about what is expected

177. *See Parties to the Nagoya Protocol*, SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/abs/na-goya-protocol/signatories/.

178. *See Nagoya Protocol, supra* note 173.

179. *Id.* art. 5(2), (5).

180. *Id*. Annex § 1, 2.

181. *Id.* art. 6(1).

182. *Id.* art. 6(2), (3).

183. *Id.* art. 10.

184. *Id.* art. 13(1).

185. *Id.* art. 14(1).

186. *Id*. art 14(2).

of treaty members. The Protocol also establishes relevant databases, accessible support methods, and promotes Indigenous welfare by involving them in the process before, during, and after development.[187] Instead of the vagueness that seemed to plague the CBD, the Protocol's detailed nature makes it easier for member states to determine when a party has acted contrary to the Protocol. In the United Kingdom, for example, university websites make it clear that any violation of the Nagoya Protocol will be enforced with a variety of civil penalties ranging from fines to injunctions on use of the illegally-obtained resources.[188] Violation of the regulations in the European Union can result in prison time and fines up to €810,000.[189] Thus, the Protocol very clearly advances on any previous instrument, and is a step forward for protections against biopiracy. Most effectively, the international community has actual protections in place that reflect their commitments and will hopefully continue to dissuade and prevent parties of all kinds from taking advantage of Indigenous traditional knowledge.

2. While most effective means of protection, the Protocol has not made advancements and is being bypassed by "digital piracy."[190]

One of the hallmarks of the Nagoya Protocol was its radical shift in ABS requirements for member nations.[191] This was a step forward for Indigenous groups to be a part of the process from start to finish where they had before been routinely left out. The Protocol though, which was signed in 2010, has remained rather stagnant to addressing new threats to traditional knowledge arising from advances in technology, specifically Digital Sequencing Information (DSI).[192] DSI researchers are claiming that advance-

187. *See Nagoya Protocol, supra* note 174, at 32. Art. 10.

188. *See Objectives of the protoco*l, IMPERIAL COLL. OF LONDON, https://www.imperial.ac.uk/research-and-innovation/research-office/what-is-the-nagoya-protocol/objectives-of-the-protocol/ (last visited Sept. 17, 2023).

189. *See The Nagoya Protocol and its impact on your research,* V.O. PATENTS AND COPYRIGHTS, https://www.vo.eu/dossier/nagoya-protocol/ (last visited Sept. 17, 2023).

190. *See* Bond & Scott, *supra* note 9, at 8 ("Digital piracy" is the term used to refer to both DSI DNA reading and CRISPR-Cas9 gene editing).

191. *See The ABS Clearing-House,* CONVENTION ON BIOLOGICAL DIVERSITY (Apr. 5, 2023), https://www.cbd.int/abs/theabsch.shtml ("The ABS Clearing-House is a key tool for facilitating the implementation of the Nagoya Protocol by enhancing legal certainty, clarity and transparency on procedures for access and for monitoring the utilization of genetic resources along the value chain").

192. *See* Bond & Scott, *supra* note 9, at 3*; See also, Digital sequence information,* FOOD AND AG. OF THE UNITED NATIONS, https://www.fao.org/cgrfa/topics/digital-sequence-infor- mation/en/ ("The term "DSI" currently has no agreed definition. Differences in terminology in scientific circles reflect differences in the material referred to, which makes it difficult to harmonize terminology. However, it is clear that "DSI" is a critical tool in the conservation and sustainable use of genetic resources for food and agriculture. Countries rely on access to and exchange of "DSI" to deal with

ments in DNA sequencing and synthesis technology,[193] are disrupting ABS requirements.[194] For a long time, genetic resources have been viewed as a part of the physical materiality of the resource, but with the advancement of DNA sequencing and synthesis and gene editing, the debate has morphed into one about the equivalency of the two.[195] One of the most important "side-steps" or "strategic ambiguities" at the heart of the Protocol regards whether or not genetic resource protection extends only to the physical entity itself alone or also the information that goes along with it.[196]This strategic ambiguity has taken on more importance with the advancements of gene editing — "Reduced costs and increasing technical abilities now allow researchers to sequence DNA, share this digital sequence information (DSI) via online gene-banks or email, and then synthesise [sic] the sequence information back into physical DNA."[197] These new practices are encouraging large companies and government bodies to store up as much DSI as possible for the next big discovery — essentially a new "capital accumulation" or hoarding strategy.[198] Indeed, this changes the entire landscape of bioprospecting and piracy, allowing prospectors to pirate information without ever having to set foot in the field or speaking to the holders of traditional knowledge.[199] Indigenous groups are concerned that this gray area will harm traditional knowledge. Historically, traditional knowledge encompasses the entire physical materiality of the plant, including the information that comes along with it.[200]According to the Brazilian Coordinator of Indigenous Peoples in the Northeast, Indigenous groups view the "genetic heritage" of the plant as a part of traditional knowledge — the plant is not looked at in parts but as one whole.[201] Thus, the definition of DSI should be expanded to

vital issues such as human, animal and plant health, food security and the environment . . . [it also] plays a fundamental role in environmental and biological research, contributing to understanding of the molecular basis of life and evolution and of the ways in which genes can potentially be manipulated to provide new therapies and cures for diseases, new energy sources and other new products").

193. DNA synthesis is "writing" of gene metadata, and DNA synthesis is "reading" of gene metadata.

194. *See* Bond & Scott, *supra* note 9, at 3. Concerns over gene databases being very open are also at the heart of the discussion around ABS and DSI (the largest public database is the International Nucleotide Sequence Database Collaboration).

195. *See* Bond & Scott, *supra* note 9, at 3.

196. *Id.*

197. *Id.*

198. *Id.*

199. *See* Emilio Godoy, *Digital Treatment of Genetic Resources Shakes Up COP15*, EARTH JOURNALISM NETWORK (Dec. 19, 2022), https://earthjournalism.net/stories/digital-treatment-of-ge- netic-resources-shakes-up-cop15.

200. *Id.*

201. *See* Godoy, *supra* note 199.

capture genetic information via DNA sequencing or synthesis.[202] Though putting a mechanism into action will be taking on a growing giant. Currently, there are over 1,750 genebanks worldwide, and attract millions of users every year.[203] Thus, the potential for expansion is great, and the controls are, at this juncture, lacking.

V. SUGGESTIONS FOR FUTURE OF TRADITIONAL KNOWLEDGE PROTECTION IN INTERNATIONAL AND DOMESTIC LAW (FOCUSED ON THE U.S. SYSTEM)

While there have been steps forward internationally and domestically, the relevant protections against biopiracy cannot stop with the Nagoya Protocol. Just as science, technology, and intellectual property systems advance, so must domestic and international policy new biopiracy pioneering. Each domestic policy will clearly vary by state and region in line with the principles of self-determination, and some states may be wary of enacting and entering into treaties, but there may yet be meaningful opportunities for change.

A. Recommended Domestic Policy Changes: The United States.

The U.S. is well-known for being relatively conservative about entering multilateral treaties (it has still failed to ratify many human rights treaties, including Convention on the Elimination of all Forms of Discrimination Against Women[204] and Convention on the Rights of the Child[205]) so, realistically, encouraging a country like the U.S. to ratify the CBD and then the Nagoya Protocol seems far-fetched. The U.S. has also been unenthusiastic about WIPO progression.[206] The U.S. did not give support to WIPO at all until it was assured that WIPO was not going to be the "norm" for future treaty development.[207] Regardless, there are steps that could be taken to enhance safety measures against biopiracy at a federal level with enhanced patent protections. These protections do not need to turn the patent world on its

202. *See* Godoy, *supra* note 199.

203. *See What is a Genebank*?, CROP TRUST (Sept. 15, 2022), https://www.croptrust.org/news-events/news/what-is-a-genebank/("the [r]ange from national, regional and international. . . [a]nd around the world conserve, between them, about 7.4 million samples of crop diversity.").

204. *See Ratification Status for CEDAW - Convention on the Elimination of All Forms of Discrimination against Women*, UN TREATY BODY DATABASE, https://tbinternet.ohchr.org/layouts/15/TreatyBodyExternal/Treaty.aspx?Treaty=CEDAW (last visited Sept. 17, 2023) [hereinafter, "Ratification Status"].

205. *See Ratification Status for CRC - Convention on the Rights of the Child*, UN TREATY BODY DATABASE, https://tbinternet.ohchr.org/_layouts/15/TreatyBodyExternal/Treaty.aspx?Treaty=CRC.

206. *See* Michael Halewood, *Indigenous and Local Knowledge in International Law: A Preface to Sui Generis Intellectual Property Protection,* 44 MCGILL L.J. 953, 986 (1999).

207. *Id.*

head but could simply involve enhanced scrutiny on the level of review for "prior art" and "novelty" when examining patents that involve traditional knowledge. Some commentators have also suggested that an explicit disclosure requirement should be incorporated into U.S. patent law to compel patent applicants to state if they use traditional knowledge.[208] To aid in this, the USPTO could establish a U.S.-specific patent and/or copyright Clearing-House for researchers and companies to use as a resource before applying. Encouraging an open discourse and ABS between Indigenous groups and corporations wanting to use the information, much like the Nagoya Protocol does, is another simple way that Indigenous groups could become more involved in the process and reap the benefits.

On a more macro-level, the U.S.A will need to examine its domestic relationship(s) with organizations that are promulgating biopiracy in the name of international food-sovereignty. If the three branches of government are as concerned with state-sovereignty as they appear to be (as expressed clearly in the relationship the U.S. has with the international community[209]), then examining these relationships might be a welcome task. At the most basic level, protections should be put in place to defend Indigenous seeds from further loss. Reaching higher, government agencies affiliated with tribal governance and food regulation (such as the USDA) should be focused on re-establishing diverse seed banks and funding projects that will enhance rematriation of seeds and, thus, farming freedom. This will likely increase agrobiodiversity in the U.S. and help establish and support Indigenous traditional knowledge at the same time. These suggestions may also be applied to other domestic IP systems that have not signed any relevant protocols or treaties, especially if their IP frameworks are highly privatized and allow certain nature-related patents.

B. Recommended International Changes.

Internationally, the challenges are both different and the same. Realistically, many large nations may not be interested in ratifying more treaties, though there are still opportunities to make meaningful changes. The international community should focus on expansion and streamlining interna-

208. *See* Aman Gebru, *Patents, Disclosure, and Biopiracy*, 96 DENVER L. REV. 535, 535 (2019) ("[T]he introduction of an explicit requirement in U.S. patent law, compelling patent applicants to disclose their use of TK, can create an efficient patent system and sustainable relationships in the relevant industries.").

209. *See Ratification Status…, supra* note 204 and 205, at 37; *see also*, Paris Nyugen, *A Changing Relationship Between the U.S. and UN*, UNA-NCA, SNAPSHOTS, https://medium.com/una-nca-snapshots/a-changing-relationship-between-the-us-and-un-30db5b9439c2 (stating that ("[T]he U.S. has developed a "cherry-picking" approach to its international engagement/relations, using it as a tool when needed, but not engaging when it is inconvenient or irrelevant"). *See*, UN TREATY BODY DATABASE, *supra* note 204-5, at 37.

tional committees such as the IGC, so that placeholder agreements can be enacted while negotiations ensue. Treaties pulling support from large promulgators of agro-neocolonialism would also be an effective means to stopping at least some of the unmitigated seed piracy going on. Further, listening to grassroots organizations like Seed Freedom Movement[210] and Southern African Faith Communities [211] would likely amplify concerns of the Indigenous groups who are actually suffering from the effects of biopiracy, prospecting, and pioneering. This amplification would hopefully lead to international policies that are more accurately reflective of the problems and directed towards mitigation. Placing Indigenous persons in roles of leadership at genebanks and other large bodies involved in the dissemination and control of DSI and CRISPR information would also create space for a variety of viewpoints to be heard. This is especially relevant with the growing problem of DSI and CRISPR being viewed by the Global North as "separate" from the physical materiality of the resource.[212]

In the most recent COP, relating to the CBD and the Nagoya Protocol, the topic of DSI was at the heart of the discussions.[213] Goal D of COP15 states that monetary and non-monetary benefits acquired through DSI need to be shared equitably with Indigenous people, and plans are underway for expansion until 2050.[214] Target 13 espouses a similar view.[215] Finally, the newly reached agreement recognized that there are differing views on DSI in the international community and agreed to discuss a multilateral mechanism to manage ABS and DSI.[216] At COP15, new targets were established to be achieved into 2030, though this is where the UN failed to achieve its ten Aichi Targets laid out in 2010.[217] There is cynicism directed at the 2030 goals. Commentators are concerned that if DSI is shared on a project-based approach that the Global North will invade the Global South to set up pro-

210. *See Seed Freedom*, *supra* note 97.

211. *See Open Letter*, *supra* note 105.

212. *See* Godoy, *supra* note 199.

213. *COP15:Nations Adopt Four Goals, 23 Targets for 2030 in Landmark UN Biodiversity Agreement*, THE CONVENTION ON BIOLOGICAL DIVERSITY (Dec. 19, 2022), https://www.cbd.int/article/cop15-cbd-press-release-final-19dec2022 ("Digital sequence information on genetic resources – a dominant topic at COP15 – has many commercial and non-commercial applications, including pharmaceutical product development, improved crop breeding, taxonomy, and the monitoring of invasive species"); *See Digital Sequence Information on Genetic Resources*, THE CONVENTION ON BIOLOGICAL DIVERSITY (Dec. 19, 2022), https://www.cbd.int/doc/c/c181/12cf/d29ef8c3f6bd4ec701699d9d/cop-15-l-30- en.pdf.

214. *Id*.

215. *Id.*

216. *Id*.; *See* Bond & Scott, *supra* note 8, at 3 ("Some governments argued that, if unaddressed, DSI could undermine the Nagoya Protocol on ABS, while others attempted to dismiss the issue as outside the remit of the Protocol and CBD treaty altogether").

217. *See* Dicke *supra* note 157, at 27.

jects and plunder resources as the CBD allowed for in the past.[218] A multilateral mechanism that defines terms and starts to control the gene arms race that is underway would likely be the most effective means of international control of the new frontiers of biopiracy at this juncture.

CONCLUSION

While protections against biopiracy have been put in place recently, and there have been serious advancements in defense of Indigenous traditional knowledge, there is a lack of effective cross-sectoral dialogue, as well as disjointed global frameworks and applications. To claim that international and certain domestic communities are often running in diagonal lines and that protections against advancing technology are not always a first concern seems to be a fair summation. Specifically, many domestic IP policies in developing nations were created to keep pace with the Global North at the expense of effective protective patent principles that allowed for communal knowledge to be protected. International accords are often vague, lacking in true effective force, and leave traditional knowledge open to being taken advantage of in many ways, especially when biotechnology advancements speedily create new avenues of biopiracy that cannot and likely will not be addressed quickly. The IGC's decades-long negotiations, which have not made any remarkable progress, are suggestive of the fact that these, and other similar negotiations, are more ceremonial than they are aimed at coming to a meaningful close.

Hence, goading international or domestic "dinosaurs" into action seems to be an almost impossible task. The area which the most growth comes from, and likely will continue to come from, are grassroots organizations and the Indigenous peoples themselves. Yet these tend to be the organizations and groups that are routinely silenced, ignored, or do not have the requisite bargaining power. So, the most paramount and effective, and yet the most difficult, way to protect traditional knowledge, and what comes with it, may only come when these groups and organizations are truly invited into the process.

218. *See* Manon Lemaire, *Biodiversity COP15: What future for Digital Sequencing Information?*, IDDRI (Feb. 23, 2023), https://www.iddri.org/en/publications-and-events/blog-post/biodiversity-cop15-what-future-digital-sequencing-information ("Although this decision avoided a blockage in the adoption of the global framework, the discussion on the subject is far from being settled and only marks the starting point for new international negations.").

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