VOLUME 63, NUMBER 1, WINTER 2022

"Just" Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good

Margo A. Bagley*

Genome sequence information is being used to develop improvements in diverse product areas from agriculture to therapeutics. In fact, the rapid development of COVID-19 vaccines required access to the genome sequence of the virus. Beyond the COVID-19 context, however, vast amounts of what is being called digital sequence information (DSI) are being used and patented, without permission from the countries that own the genetic resources from which the sequences are derived. This issue is stymieing negotiations in several international fora, including the UN Convention on Biological Diversity ("CBD") and its Nagoya Protocol. These treaties obligate users of genetic resources to share the benefits of resource utilization with the resource providers. But parties disagree profoundly on whether these obligations extend to DSI. And as DSI often obviates the need for access to tangible material, monetary benefits are likely to decline even further.

This Article identifies challenges to and opportunities for achieving "just" sharing outcomes on DSI under the CBD and Nagoya Protocol and argues for the development of a global multilateral benefit-sharing mechanism as a more just and efficient vehicle for compliance with benefit-sharing obligations while retaining open access to sequence information. The prime benefit-sharing beneficiaries are intended to be the indigenous peoples and local communities who conserve and safeguard global biodiversity, yet who often are the most socioeconomically deprived among us. As such, this Article also situates the DSI benefit-sharing controversy within the larger societal moments focused on justice for the vulnerable and climate change mitigation.

> *"When we're not hungry for justice, it's usually because we're too full with privilege."*
>
> Carlos A. Rodríguez

* Asa Griggs Candler Professor of Law, Emory University School of Law. Special thanks to Bob Friedman, Tim Holbrook, Marcel Jaspars, Todd Kuiken, Ruth Okediji, Jake Sherkow, Amber Scholz, Daniel Tarullo, Mark Wu, and participants in the Harvard Law School International Economic Law workshop; the Genetic Engineering and Society Colloquium at North Carolina State University; the 4th Arizona Biosecurity Workshop at Arizona State University; the 23rd International Consortium on Applied Bioeconomy Research Conference in Ravello, Italy; the International Intellectual Property Scholars Conference at Florida State University; symposia/workshops at Emory University School of Law; University of the Pacific, McGeorge School of Law; the University of Queensland, and a side event at the 14th Conference of the Parties to the Convention on Biological Diversity, Sharm El-Sheikh, Egypt, for helpful comments on this project. Thanks also to Dina Awshah, Eric Boyer, Morgan Gobeli, Elizabeth Hemann, Vinh Le, Candace Walther, Demetrius Williams, Cong Zhou, and the Emory McMillan Law Librarians for stellar research support.

Introduction

What do the World Health Organization, the Convention on Biological Diversity, the Convention on the Law of the Sea, and the Food and Agriculture Organization have in common? In addition to being United Nations ("U.N.") bodies or treaties,[1] they are some of the fora where issues of access and benefit-sharing in relation to digital sequence information ("DSI") are under active, sometimes contentious, discussion.[2] What is DSI and why is it engaging the international community? The development of a treatment for Ebola provides one illustration of the nature of concerns regarding DSI.

Zaire ebolavirus is a horrifying virus. In humans, its symptoms include fever, intense vomiting, and diarrhea.[3] Because the virus causes levels of blood-clotting cells to drop, patients often present with uncontrollable internal and external bleeding, including from the nose and eyelids.[4] So news that the U.S. Food and Drug Administration ("FDA") had finally approved a treatment for Ebola in October 2020[5] was cause for great celebration. However, there is a wrinkle in the otherwise positive narrative surrounding the drug's development: the potential inaccessibility of the drug to Africa's neediest patients, despite Regeneron's reliance on West African genetic sequence data in creating the drug.

Ebola is not a new disease; the first reported Ebola outbreak was in Zaire in 1976.[6] But because it appeared sporadically and only in poor African

1. The United Nations Convention on the Law of the Sea, Dec. 10, 1982, 1833 U.N.T.S. 397; *About FAO*, Food and Agric. Org. of the U.N., http://www.fao.org/about/en/ [https://perma.cc/FLE8-YMPN]); *History of the Convention*, Convention on Biological Diversity, https://www.cbd.int/history/ [https://perma.cc/US9Y-XLXW]; *History of WHO*, World Health Org., https://www.who.int/about/who-we-are/history [https://perma.cc/XU5R-SPBQ].

2. *See, e.g.*, G.A. Res. 72/249 (Jan. 19, 2018); Conference of the Parties to the Convention on Biological Diversity, Report of the Conference of the Parties to the Convention on Biological Diversity on its Fourteenth Meeting, U.N. Doc. CBD/COP/14/14 (Mar. 20, 2019); International Treaty on Plant Genetic Resources for Food and Agriculture, *The Benefit-Sharing Fund: Crop Diversity for Food Security*, Food and Agric. Org. of the U.N. 7, 10 (2015); News Release, *WH0 Launches New Global Influenza Strategy*, World Health Org. (Mar. 11, 2019), https://www.who.int/news/item/11-03-2019-who-launches-new-global-influenza-strategy [https://perma.cc/EK6V-X7BC].

3. Laura F. Friedman, *Here's What it Feels Like to Have Ebola*, Bus. Insider (Oct. 2014), https://www.businessinsider.com/what-does-ebola-feel-like-2014-10 [https://perma.cc/QB8F-36AK].

4. *Id. See also* Betsy McKay, *'Ebola Is Now a Disease We Can Treat.' How a Cure Emerged from a War Zone*, Wall St. J. Online (Oct. 30, 2019), https://www.wsj.com/articles/ebola-is-now-a-disease-we-can-treat-how-a-cure-emerged-from-a-war-zone-11572446873 [https://perma.cc/EMF2-GQK6] ("The Ebola virus kills in terrifying ways, shutting down the body's organs and draining victims of the fluids that keep them alive. In outbreaks, it has claimed as many as 9 in 10 patients.").

5. News Release, *FDA Approves First Treatment for Ebola Virus*, U.S. Food & Drug Admin. (Oct. 14, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-ebola-virus [https://perma.cc/KE8E-5ULK].

6. Jolie Kaner & Sarah Schaack, *Understanding Ebola: the 2014 Epidemic*, 12 Globalization & Health 1, 2 (2016). *See What is Ebola Virus Disease?*, U.S. Centers for Disease Control and Prevention, https://www.cdc.gov/vhf/ebola/about.html [https://perma.cc/PJ6B-PLU8]. Zaire is now known as the Democratic Republic of the Congo.

countries,[7] directing enough effort and funding to develop a cure was not a priority for Western drug developers.[8]

That changed in 2014 with the Ebola outbreak in West Africa that resulted in at least 28,000 infections, with a 40% fatality rate.[9] The disease eventually entered the United States, which made finding a treatment a national security matter.[10] Enter Regeneron Pharmaceuticals, developer of the Ebola drug REGN-EB3, now known as Inmazeb™. The drug was developed in part[11] through use of a virus strain sequence obtained by Regeneron from the publicly accessible database GenBank operated by the U.S. National Center for Biotechnology Information ("NCBI").[12] The sequence information for the strain had been uploaded without restriction to the GenBank database by the Bernard Nocht Institute for Tropical Medicine ("BNITM"), a member of the German Leibniz Association, and had been sequenced from a survivor of the 2014 Guinean Ebola outbreak.[13]

BNITM required recipients of *physical* samples of the virus to sign a material transfer agreement ("MTA"), affirming the need to negotiate benefit-sharing arrangements with Guinea for any commercial products[14] developed using those samples in accordance with the United Nations Convention on Biological Diversity ("CBD"). However, BNITM did not require such an agreement for the use of the uploaded *sequence* information.[15]

REGN-EB3 attracted over U.S. $400 million in research and development commitments from the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority

7. *Factors That Contributed to Undetected Spread of the Ebola Virus and Impeded Rapid Containment*, World Health Org. (2015), https://www.who.int/news-room/spotlight/one-year-into-the-ebola-epidemic/factors-that-contributed-to-undetected-spread-of-the-ebola-virus-and-impeded-rapid-containment [https://perma.cc/7F33-PN6F].

8. Kaner & Schaack, *supra* note 6, at 58 (noting that "the current system of drug and vaccine development favors the development of drugs and vaccines for chronic diseases that primarily affect people in the developed world, rather than diseases likely to cause epidemics"). *But see* Fiona Fleck, *Tough Challenges for Testing Ebola Therapeutics*, 93 Bull. World Health Org. 70, 70–71 (2015) (describing challenges with clinical testing for Ebola therapeutics which must be done during an outbreak).

9. *2014-2016 Ebola Outbreak in West Africa*, U.S. Centers for Disease Control and Prevention (Mar. 8, 2019), https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html [https://perma.cc/L3XV-9VGH].

10. *BARDA Procures Regeneron's REGN-EB3 Investigational Ebola Treatment for National Preparedness*, Regeneron (Jul. 29, 2020, 07:00AM), https://investor.regeneron.com/news-releases/news-release-details/barda-procures-regenerons-regn-eb3-investigational-ebola [https://perma.cc/YLU2-TPBF].

11. It is important to note that the Guinean Ebola sequence is valuable in part because of the presence of other sequences in the database that it could be compared with. Such a comparison allowed researchers to ascertain which part of the genome to target in developing a therapeutic treatment. So, both the specific sequence and the "big data" sequences were necessary for the successful development of the drug.

12. Edward Hammond, *Ebola: Company Avoids Benefit-Sharing Obligations by Using Sequences,* Third World Network (May 2019).

13. *Id.* (citing Kristen E. Pascal et al., *Development of Clinical-Stage Human Monoclonal Antibodies That Treat Advanced Ebola Virus Disease in Nonhuman Primates*, 218 J. of Infectious Diseases S612 (2018)); *see also* McKay, *supra* note 4 (describing development and clinical trials of Ebola drugs).

14. Such benefits could have included, for example, free or discounted doses of any drug developed.

15. Hammond, *supra* note 12, at 2. There are no indications that any physical virus samples from BNITM were used by Regeneron in the drug's development, only the sequence information.

("BARDA").[16] It also received "Orphan Drug" designation from both the U.S. Food and Drug Administration and the European Medicines Agency, providing its private sector developer Regeneron with—*inter alia*—tax breaks for R&D expenditures and time-bound market exclusivity for the drug.[17] In addition, more than 100 patent applications have been filed on the drug worldwide, with some already granted in the United States, Nigeria, and South Africa.[18]

Once the drug was shown to work—so effectively that clinical trials were cut short[19]—BARDA contracted to purchase all the drug Regeneron could produce in order to create a domestic stockpile. Moreover, when new outbreaks of Ebola occurred in the Congo in 2020 and 2021, BARDA agreed to provide the drug to the Congolese government for free.[20]

Regeneron stands to profit quite handsomely from its development of Inmazeb™, and it certainly should be well-compensated. However, the Guinean virus strain appears to have been a crucial link in the development of the drug, and while the Guinean government is the sovereign owner of the tangible virus sample from which the sequence was derived, Regeneron is under no obligation to share any monies with that government nor pro-

16. *See* Anthony Markham, *REGN-EB3: First Approval*, Nat'l Ctr. for Biotechnology Info. (Jan. 11, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7799152/ [https://perma.cc/JL6J-CWU2]; Press Release, *Regeneron Announces Agreement with BARDA for the Development of New Antibody Treatment for Ebola*, Regeneron (Sept. 21, 2015, 8:00AM), https://investor.regeneron.com/news-releases/news-release-details/regeneron-announces-agreement-barda-development-new-antibody [https://perma.cc/3P4U-8BH6]; *Annual Report Regeneron Pharmaceuticals, Inc.*, Securities and Exchange Commission (2015); Press Release, *Regeneron Announces New Collaborations with HHS to Develop Antibodies Against Ebola, Influenza and Multiple other Emerging Pathogens*, Regeneron (Oct. 2, 2017, 7:00AM), https://investor.regeneron.com/news-releases/news-release-details/regeneron-announces-new-collaborations-hhs-develop-antibodies [https://perma.cc/L6XK-HA38].

17. *See* Center for Drug Evaluation and Research, Application No. 761169Orig1s000, p. 16 (2019), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761169Orig1s000MultidisciplineR.pdf [https://perma.cc/B76K-YA25]; EU/3/18/2027: Orphan designation for the treatment of Ebola virus disease, https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu-3-18-2027 [https://perma.cc/4WZT-AJQ8]; EMA designation for 'Three human monoclonal antibodies against the EBOV glycoprotein,' https://www.ema.europa.eu/en/documents/orphan-designation/eu/3/18/2027-public-summary-opinion-orphan-designation-three-human-monoclonal-antibodies-against-ebov_en.pdf [https://perma.cc/6DMG-K7P5]; *see also* Kiran N. Meekings et al., *Orphan Drug Development: An Economically Viable Strategy for Biopharma R&D*, 17 Drug Discovery Today 660 (2012); 26 U.S.C. § 45C (allowing up to a 50% tax credit for certain clinical testing expenses related to the use of a drug once it is designated as an orphan drug for a rare disease or condition).

18. *See* Hammond, *supra* note 12, at 4 (citing Regeneron 2019; Indian Patent Office Form 3, filed for application 01717024283, Jan. 10, 2019).

19. Press Release, *Palm Ebola Clinical Trial Stopped Early as Regeneron's REGN-EB3 Therapy Shows Superiority to ZMAPP in Preventing Ebola Deaths*, Regeneron (Aug. 12, 2019, 10:01AM), https://newsroom.regeneron.com/news-releases/news-release-details/palm-ebola-clinical-trial-stopped-early-regeneron-s-regn-eb3 [https://perma.cc/2G2T-93RQ].

20. Jason Beaubien, *Ebola Never Went Away. But Now There's a Drug to Treat It*, Kpbs (Oct. 20, 2020), https://www.kpbs.org/news/2020/oct/20/remember-ebola-well-now-theres-a-drug-for-that/ [https://perma.cc/JAG6-8XR3] ("BARDA bought up all of Regeneron's production — a decision that reflects humanitarian concerns but also is aimed at creating a domestic stockpile — and now is making it available to the Congolese government for free.").

vide special pricing or other benefits related to Inmazeb™.[21] In fact, Guinea and other African countries will be dependent on the goodwill of the United States to make the drug available at an affordable cost even though the drug could not have been developed without sequence information from African genetic resources.[22]

The Ebola drug development scenario is not an isolated instance. Sequence information from untold numbers of organisms is being used to develop improvements in diverse product areas from agriculture to therapeutics.[23] Quite often, such information is being used, and patented, without regard to the origin of the particular organism from which it was derived; in fact, the researcher may not even know or be able to easily trace the original provider country.[24] However, the Nagoya Protocol on Access and Benefit-Sharing ("Nagoya Protocol") to the CBD requires that users of genetic resources share the benefits of such utilization with the providers of the original resources.[25] Although copious monetary benefits are being generated from genetic resource sequence information-based products, there is little evidence to indicate that any meaningful, formal, benefit-sharing is taking place.[26]

The issue of whether or to what extent DSI is subject to such treaty obligations is a point of significant controversy in negotiations in several inter-

21. Hammond, *supra* note 12, at 2.

22. *Id.*; Beaubien, *supra* note 20 (quoting Julien Potet of Doctors Without Borders: "What we would like to see is an international stockpile for needs in Africa, . . . one that may not rely necessarily on the goodwill of the U.S. government to send doses but that rather could be more directly used by countries themselves."). To be clear, Regeneron is under no legal obligation to share benefits with Guinea for a variety of reasons. In particular, the Nagoya Protocol requires countries to ensure their users comply with the domestic ABS legislation of other parties. The United States, though, is not a party to either the CBD or the Nagoya Protocol, and even if it were, Guinea does not yet have domestic implementing legislation in place with which to comply. This need not stop Regeneron from sharing benefits (with Guinea), but it does complicate the narrative.

23. For example, in 2017, a Canadian research team synthesized the horsepox virus using DSI obtained from GenBank. Rourke et al. noted that a physical sample of the virus could have been obtained from the U.S. Centers for Disease Control and Prevention, but the researchers would have had to sign a material transfer agreement with terms affecting the commercialization of future products they might develop. Apparently, the team chose to synthesize the virus to avoid the MTA restrictions. According to Rourke et al., "[t]he synthesis of viruses demonstrates how openly accessible [DSI] creates a major gap in global ABS governance." Michelle Rourke et al., *Policy Opportunities to Enhance Sharing for Pandemic Research*, 368 Science 716, 717 (2020).

24. *See infra*, Section I.A–B.

25. *See* Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, *Tenth Meeting of the Parties to the Convention on Biological Diversity*, U.N. Doc. UNEP/CBD/COP/DEC/X/1 (Oct. 29, 2010) [hereinafter Nagoya Protocol]; The Convention on Biological Diversity arts. 8, 15, June 5, 1992, 1760 U.N.T.S. 143, 152 [hereinafter CBD].

26. *See* Margo Bagley et al., *Fact-Finding Study on How Domestic Measures Address Benefit-Sharing Arising from Commercial and Non-Commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development*, U.N. Doc. CBD/DSI/AHTEG/2020/1/5, annex, 25–30 (Jan. 29, 2020) (noting that no surveyed countries had reported receiving monetary benefits from DSI).

national fora, most particularly the CBD and its Nagoya Protocol.[27] Importantly, an increasing number of countries are amending their legal regimes to either constrain access to DSI, impose benefit-sharing obligations on the fruits of DSI utilization, or both.[28] A recent study of domestic measures on DSI and benefit-sharing commissioned by the CBD Secretariat identified at least five different approaches that countries are taking, creating an alarming web of rules for scientists seeking to use genetic resources and the DSI they contain.[29]

The controversy over DSI is an example of a technological advance that has the potential to impact the interpretation of several international agreements and corresponding legal obligations. The idea that technological advancements can create the need for new domestic laws or international agreements or necessitate changes in the interpretation of existing laws and agreements is not new. On the domestic level, examples include railroads, in vitro fertilization, and DNA testing.[30] On the international level, the ability to create virtually identical digital copies of music and movies—and the concomitant reduction in revenue potential for content creators and providers—led to new forms of protection embodied in the World Intellectual Property Organization's ("WIPO") copyright treaties.[31] The rise of the digital economy precipitated the inclusion of new e-commerce provisions in regional trade agreements to fill gaps in the world trading regime.[32] And climate change effects continue to stymie the effectiveness of negotiated agreements.[33]

---

27. The fora in which issues related to DSI and ABS are being studied and discussed include: the CBD and its Nagoya Protocol; the UN Food and Agriculture Organization ("FAO") International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGRFA"); the FAO Commission on Genetic Resources for Food and Agriculture ("CGRFA"); the World Health Organization ("WHO") Pandemic Influenza Preparedness ("PIP") Framework; the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Folklore; the International Union for Conservation of Nature ("IUCN"); and the Intergovernmental Conference on an international legally binding instrument under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction ("BBNJ"). This Article focuses on the discussions in the CBD and Nagoya Protocol, as the CBD has the widest membership, and decisions on the issue there can be expected to influence, to varying degrees, discussions on this topic in the other fora.

28. *See* Deepa Kharb, *The Legal Conundrum over Regulation of Access and Benefit-Sharing Obligations in Digital Sequence Information over Genetic Resources-Assessing Indian Position,* 24 J. World Intell. Prop., 152, 154–60, (2021).

29. Bagley et al., *supra* note 26.

30. *See* Lyria Bennett Moses, *Recurring Dilemmas: The Law's Race to Keep up with Technological Change*, 2007 U. Ill. J.L. Tech. & Pol'y 239 (2007).

31. *See, e.g.*, Graeme B. Dinwoodie, *The WIPO Copyright Treaty: A Transition to the Future of International Copyright Lawmaking?*, 57 Case W. Rsrv. L. Rev. 751 (2007).

32. *See, e.g.*, Mark Wu, *Digital Trade-Related Provisions in Regional Trade Agreements: Existing Models and Lessons for the Multilateral Trade System*, RTA Exchange, 3–6 (2017).

33. *See, e.g.*, Technology Executive Committee of the U.N. Framework Convention on Climate Change, Technological Innovation for the Paris Agreement, TEC Brief #10 (Sept. 2017) ("To achieve the goals of the Paris Agreement, there is a pressing need to accelerate and strengthen technological innovation so that it can deliver environmentally and socially sound, cost-effective and better-performing climate technologies on a larger and more widespread scale.").

In each of these cases, a scenario that parties did not fully contemplate or address undermines fundamental assumptions in a way that changes the expected bargain of the agreement to the perceived detriment of some participants. Much as the digitization of music and movies facilitated a flood of online peer-to-peer copying that threatened the prime revenue streams of the music and movie industries,[34] the monetary benefits that developing countries were expecting to flow from the Access and Benefit-Sharing ("ABS") regime instituted through the Nagoya Protocol are seemingly being threatened by the declining need for researchers to seek access to tangible genetic resources once sequence information from those resources has been made publicly accessible.[35] Moreover, differing perspectives on the ownership and value of genetic resources and DSI is presenting a clash of fundamental conceptualizations, with many users articulating positions akin to "what's yours is mine and what's mine is mine" while some providers adopt "what's mine is mine and what's yours is mine"[36] stances, neither of which is helpful in reaching consensus on a way forward.

The specter of domestic DSI access constraints is concerning. Indeed, the rapid development of mRNA vaccines against the SARS-CoV-2 virus that causes COVID-19 was facilitated by Chinese researchers' open sharing of the genome sequence of the virus in January 2020.[37] Nevertheless, the concerns of provider countries are legitimate. Notions of justice and fairness permeate the CBD and underlie its objectives.[38] The preamble to the CBD states that "economic and social development and poverty eradication are the first and overriding priorities of developing countries."[39] These priorities are intimately intertwined with the biodiversity conservation goals of the treaty, as the prime benefit-sharing beneficiaries are intended to be the indigenous peoples and local communities ("IPLCs") who conserve and safeguard global

34. *See infra* Section II.D.3, p. 41.

35. *See infra* Section II.B–D; *see also* Stuart Smyth et al., *Implications of Biological Information Digitization: Access and Benefit-Sharing of Plant Genetic Resources*, J. World Intell. Prop. 267, 267 (2020) ("Online digital publicly accessible resources represent a transformative technological shift."). Of course, increasing DSI utilization is not the only impediment to parties receiving meaningful monetary benefits from uses of their genetic resources and associated traditional knowledge. A variety of human, capacity, and financial resource limitations continue to constrain both the implementation and domestic operationalization of the Nagoya Protocol with negative effects for both providers and users of genetic resources and associated traditional knowledge.

36. *See infra* Section II.D.1–2, pp. 29, 34.

37. Institut Pasteur, *Whole Genome of Novel Coronavirus* (Jan. 31, 2020), https://www.sciencedaily.com/releases/2020/01/200131114748.htm [https://perma.cc/E9BX-X7XB].

38. *See infra* Part I, p. 8. *See also* Doris Schroeder & Balakrishna Pisupati, *Ethics, Justice and the Convention on Biological Diversity*, U.N. Environment Programme (Oct. 2010), https://wedocs.unep.org/bitstream/handle/20.500.11822/8046/-Ethics,%20Justice%20and%20the%20Convention%20on%20Biological%20Diversity-20101053.pdf?sequence=3&amp%3BisAllowed= [https://perma.cc/97GA-4XRV].

39. Bagley et al., *supra* note 26.

biodiversity. However, they are often the most socioeconomically deprived and vulnerable members of our global society.[40]

Monetary benefit-sharing, though challenging to operationalize, is just and necessary both to fulfill *all three* objectives of the CBD and perhaps even to basic human flourishing. Without monetary benefit-sharing, necessary investments of financial and human resources to conserve biodiversity (which benefits us all) and aid in socioeconomic development for the most vulnerable among us are unlikely to occur, at least not as soon as they are needed.[41]

Achieving "just" monetary and non-monetary benefit-sharing will require an adjustment of legal obligations and privileges on an international scale. However, the Nagoya Protocol is a relatively new treaty and its strictures in relation to rapid technological advances, such as in synthetic biology, are only just beginning to be understood. It thus is not surprising that there is a dearth of legal scholarship exploring these issues as many scholars may not be aware of the brewing controversy.[42]

This Article seeks to fill this lacuna by identifying challenges to, and opportunities for, achieving "just" sharing outcomes on DSI under the CBD and Nagoya Protocol for the common good. Part I provides background on the CBD and Nagoya Protocol implementation issues that are affecting DSI access and benefit-sharing discussions in treaty negotiations. Part II examines the definitional and scope issues raised by DSI in relation to domestic ABS regimes and the complexity of DSI use scenarios that threaten benefit-sharing goals. Part III considers possible ways forward, by first highlighting the justifications for benefit-sharing and then exploring policy options and principles for creating a global multilateral benefit-sharing mechanism as a more effective vehicle for users to comply with treaty obligations which are not amenable to the current bilateral negotiation model. The Article concludes that "just" benefit-sharing can improve conservation and socioeco-

40. *See, e.g.*, *Indigenous Peoples*, WORLD BANK (Mar. 19, 2021), https://www.worldbank.org/en/topic/indigenouspeoples [https://perma.cc/9T8L-HK92#1] (noting that Indigenous people make up ~ 5% of the global population but account for about 15% of the extreme poor and have a significantly lower life expectancy than non-indigenous people). *See generally* Martha Albertson Fineman, *The Vulnerable Subject: Anchoring Equality in the Human Condition*, 20 YALE J. L. & FEMINISM 1 (2008).

41. Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), *The Global Assessment Report on Biodiversity and Ecosystem Services: Summary for Policymakers*, IPBES, (2019); *see also* Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742, 1744–45 (2007) ("[I]f we want to encourage various activities, it would seem to follow that we should regulate or subsidize those activities.").

42. A search for the phrase "digital sequence information" in the Westlaw journals and law reviews database yielded only four law journal articles, none of which is directed to the DSI benefit-sharing controversy in the CBD and Nagoya Protocol. *See* Mariko Kageyama, *Bio-Property Contracts in a New Ecosystem: Genetic Resources, Access and Benefit-Sharing*, 13 WASH. J. L. TECH. & ARTS 109 (2018); Graham Dutfield & Uma Suthersanen, *Traditional Knowledge and Genetic Resources: Observing Legal Protection Through the Lens of Historical Geography and Human Rights*, 58 WASHBURN L.J. 399 (2019); Michelle Rourke, et al., *The Nagoya Protocol and the Legal Structure of Global Biogenomic Research*, 45 YALE J. INT'L L. 133 (2020); Sam Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research*, 28 ANNALS HEALTH L. & LIFE SCI. 101 (2019).

nomic development while maintaining access and innovation, but getting there will require adjustments in mindset from "mine" to "ours" for both users and providers of physical genetic resources and DSI.

I. Background on the CBD and Nagoya Protocol

Despite a long-established tradition of communal and sovereign ownership,[43] the question of who owns biological resources has been disputed throughout much of modern history. Many view such resources as the common heritage of mankind,[44] notwithstanding communal practices and increasing conceptions of Westphalian sovereignty, including in the UN General Assembly's 1962 Resolution on Permanent Sovereignty of Natural Resources.[45]

The UN Food and Agriculture Organization's ("FAO") 1980 International Undertaking on Plant Genetic Resources briefly introduced a nonbinding common heritage of mankind approach intended to address the status of the extensive *ex situ* collections of germplasm held by gene banks across the globe.[46] However, gene banks were only one of several issues facing biodiversity-rich countries, including rapid biodiversity loss due to deforestation and ethnobotanical research into plants and traditional knowledge leading to lucrative commercial products but no benefit-sharing.[47] Seeking a better approach led to the adoption of the Convention on Biological Diversity.

---

43. *See* Chika B. Onwuekwe, *The Commons Concept and Intellectual Property Rights Regime: Whither Plant Genetic Resources and Traditional Knowledge*, 2 Pierce L. Rev. 65 (2004) (arguing that plant genetic resources are not within the category of commons recognized in international law).

44. *See, e.g.*, Paul Gepts, *Who Owns Biodiversity, and How Should the Owners Be Compensated?,* 134 Plant Physiol. 1295 (2004).

45. G.A. Res. 1803 (XVII) (Dec. 14, 1962).

46. Daniel Robinson, Confronting Biopiracy: Challenges, Cases, and International Debates 24 (2010). *See also* International Treaty on Plant Genetic Resources for Food and Agriculture, Preamble, Mar. 11, 2001, 2400 U.N.T.S. 303.

47. As ethnobotanist Mark Plotkin described the response to his article about the potential for plant-derived drug development:

> I was besieged by venture capitalists who saw ethnobotany as a fail-safe route to quick riches. "We'll raise some capital," one would-be tycoon said, "set up a lab, find some cures, and synthesize the compounds. Then we'll sell it all off to a big drug company and pocket a ton of money." My most serious objection to their schemes stemmed from the take-the-money-and-run approach; they had virtually no interest in the people who were teaching me about the plants or about the fate of the forest in which these plants were found.

Mark Plotkin, Tales of a Shaman's Apprentice: An Ethnobotanist Searches for New Medicines in the Amazon Rain Forest (1993) (quoted in Ranier Bussmann, *Ethnobotany and Biodiversity Conservation*, *in* Modern Trends in Applied Terrestrial Ecology, 521 (R.S. Ambasht & N.K. Ambasht eds., 2001)).

This view was buttressed by the number of important drugs derived from natural products. As described by Professor Bussmann:

> Traditional lore has proven to be an important source of therapeutic drugs. Many antibiotics, tranquilizers, sedatives, anesthetics, pain relievers, and laxatives have come from this source.

A. The CBD: Sovereignty, Conservation, Justice, and Benefit-Sharing

Adopted in 1992 at the Rio Earth Summit, the CBD has three objectives: (1) the conservation of biological diversity, (2) the sustainable use of its components, and (3) the fair and equitable sharing of the benefits generated by the use of genetic resources.[48] The CBD establishes that genetic resources should be viewed not as the common heritage of mankind, freely available to all, but instead as the property of sovereign nations who make access to them available under principles of prior informed consent ("PIC"), mutually agreed terms ("MAT"), and fair and equitable benefit-sharing.[49]

The CBD was a landmark agreement, addressing not only environmental concerns, but also tying them to cultural, socioeconomic, and scientific values.[50] In fact, Schroeder and Pisupati see justice themes as "omnipresent" throughout the treaty.[51] In particular, the CBD goal of biodiversity conservation supports ideals of *intergenerational justice* in preserving resources for future generations, CBD requirements for prior informed consent for traditional knowledge and genetic resources are rooted in *procedural justice*, and CBD provisions requiring the fair and equitable sharing of benefits from the utilization of genetic resources are required by *international justice in exchange* or "just" sharing.[52]

Adoption of the CBD was propelled by both a goal of facilitating access to genetic resources and also a desire to stem the uncontrolled depletion of biodiversity, largely in the global South.[53] But the agreement was also designed to address concerns relating to a particular form of perceived injustice: "biopiracy." Biopiracy has been defined as "the patenting of . . . inventions based on biological resources and/or traditional knowledge that are extracted without adequate authorization and benefit-sharing from other (usually developing) countries, indigenous or local communities."[54] In Arti-

---

Examples are digitoxin and digoxin (for heart failure), egotamine (for migraine), salicin (for pain and inflammation), morphine (for pain), reserpine (for hypertension), quinine from Loja (for malaria), tubocurarine (for surgery), and a host of others.

Ranier Bussmann, *Ethnobotany and Biodiversity Conservation, in* MODERN TRENDS IN APPLIED TERRESTRIAL ECOLOGY 520 (R.S. Ambasht & N.K. Ambasht eds., 2001).

48. CBD, *supra* note 25, art. 1. Issues relating to the protection of traditional knowledge are also important and contentious; however, a discussion of such issues is beyond the scope of this Article.

49. *Id*. arts. 3, 8 & 15. *See also* Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J. L. REFORM 433, 473 (2006).

50. *See* Konstantia Koutouki & Katharina Rogalla von Bieberstein, *The Nagoya Protocol: Sustainable Access and Benefit-Sharing for Indigenous and Local Communities*, 13 VT. J. ENVTL. L. 513, 518 (2011).

51. *See* Schroeder & Pisupati, *supra* note 38; *see also* Ina Lehmann, *The Distributive Justice of the International Biodiversity Regime: An Argument for a Multifaceted Measurement* (July 2012) (unpublished conference paper).

52. *See* Schroeder & Pisupati, *supra* note 38; *see also* CBD, *supra* note 25, arts. 3, 8 & 15. *See generally* William W. Fisher, *Toward Global Protection for Traditional Knowledge* (Centre for International Governance Innovation, Paper No. 198, November 2018).

53. *See* Nagoya Protocol, *supra* note 25, art. 1; Koutouki & Rogalla von Bieberstein, *supra* note 51.

54. Robinson, *supra* note 46, at 21; *see also* Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 COLO. J. INT'L ENVTL. L. & POL'Y 219, 227 (2008); Kaitlin Mara, *Indigenous Groups Express Concerns on*

cle 8(j), the CBD recognizes the "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity."[55] As such, the CBD requires state parties to encourage "the equitable sharing of the benefits arising from the utilization of such knowledge," and genetic resources, in accordance with national law.[56]

The CBD has 196 members and went into effect in 1993.[57] The Conference of the Parties ("COP") is the governing body of the CBD and takes decisions at periodic meetings to advance implementation of the Convention.[58] Its decisions include the promulgation of the Cartagena Protocol on Biosafety,[59] which went into effect in 2003; the non-binding Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization in 2002;[60] the 2010 Aichi Bi-

IP Protection of Their Knowledge, Intel. Prop. Watch (Mar. 3, 2008), http://www.ip-watch.org/weblog/2008/03/03/indigenous-groups-express-concerns-on-ip-protection-of-their-knowledge/ [https://perma.cc/D7QV-H6SM].

55. CBD, *supra* note 25, art. 8(j); *see also* Zafar M. Nomani, *The Access and Benefit-Sharing Regime: An Environmental Justice Perspective*, 49 Env't Pol'y & L. 259, 260 (2019).

56. Robinson, *supra* note 46.

57. Although then-President Bill Clinton signed the CBD in 1993 on behalf of the United States, the treaty was never ratified by the U.S. Senate. Consequently, the United States is not a party to either the CBD or its Nagoya Protocol although it does participate in meetings as an observer. Nevertheless, regulations are apparently in place for U.S. government agencies to comply with CBD and Nagoya Protocol requirements when engaging in commercial and noncommercial scientific research. *See* Geoff Burton, *Implementation of the Nagoya Protocol in JUSCANZ Countries: The Unlikely Lot*, *in* The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges 311 (Elisa Morgera, Matthias Buck & Elsa Tsioumani eds., 2013). While such provisions do not govern private sector and non-U.S.-government public sector research, certain entities, such as the Biotechnology Industry Organization (BIO), have published best practice guidelines for members to follow to comply with the CBD. *See* Biotechnology Industry Organization, *Guidelines for BIO Members Engaging in Bioprospecting*, Biotechnology Industry Org., http://www.bio.org/sites/default/files/Guidelines%20for%20BIO%20Members%20Engaging%20in%20Bioprospecting_0.pdf [https://perma.cc/2LW4-8U3M]. In fact the U.S. National Cancer Institute has a model Letter of Collection which provides for both monetary and non-monetary benefit-sharing. *See* Nat'l Cancer Inst., Div. of Cancer Treatment & Diagnosis, *The NCI Natural Products Repository* (last updated Mar. 10, 2021), https://dtp.cancer.gov/organization/npb/introduction.htm [https://perma.cc/E7J4-EKBX].

58. *See* CBD, *supra* note 25, art. 23.

59. For more on the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which governs the movements of living modified organisms (LMOs), produced by biotechnology, across national boundaries, *See* Secretariat of the Convention on Biological Diversity, *The Cartagena Protocol: Background*, Convention on Biological Diversity, http://bch.cbd.int/protocol/background/ [https://perma.cc/79CY-28E4]. For information on the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety which deals with compensation for damage caused by the trans-boundary movement of LMOs, *See* Secretariat of the Convention on Biological Diversity, *The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety*, Convention on Biological Diversity, http://bch.cbd.int/protocol/supplementary/ [https://perma.cc/NFK3-HPGZ].

60. Conference of the Parties to the Convention on Biological Diversity, *Access and Benefit-Sharing as Related to Genetic Resources: Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization*, Dec. VI/24, U.N. Doc. UNEP/CBD/COP/6 [hereinafter Bonn Guidelines].

odiversity Targets for 2020;[61] and, at its Tenth meeting in 2010 in Nagoya, Japan, the Nagoya Protocol.[62]

B. The Nagoya Protocol on Access and Benefit-Sharing to the CBD

The Nagoya Protocol was necessary because, while the CBD obligated Parties to facilitate access to their genetic resources, and to fairly and equitably share benefits arising from the utilization of genetic resources with provider countries, it offered negligible guidance on how ABS, PIC, and MAT should be accomplished in practice.[63] Consequently, provider countries had wide latitude in developing legislation to implement the CBD, creating a miasma of legal uncertainty for users faced with often burdensome rules for ABS and PIC which varied significantly by country.[64] Over the eighteen years that elapsed between the adoption of the CBD and adoption of the Nagoya Protocol, the CBD Parties studied and debated ways to move forward on this issue.[65] Although the Bonn Guidelines were a helpful step in providing further specificity on ABS and PIC, they were not binding on Parties.[66]

The Nagoya Protocol, as a binding agreement, is a logical step in the evolution of a coherent framework to reduce uncertainty and provide increased uniformity for both users and providers of genetic resources and associated traditional knowledge.[67] It is "*the* instrument for implementation of the access and benefit-sharing provisions" of the CBD.[68] It specifies that benefits arising from genetic resource utilization shall be shared in a fair and equitable way with the provider country on MAT,[69] and requires all Parties to, *inter alia*, ensure that only legally acquired genetic resources and associated traditional knowledge are utilized in their jurisdictions, monitor user compliance via checkpoints, and allow for ABS contract disputes to be resolved in court.[70] It also provides for certain government-issued permits to

61. Conference of the Parties to the Convention on Biological Diversity, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Tenth Meeting: The Strategic Plan for Biodiversity 2011–2020 and the Aichi Biodiversity Targets*, Oct. 29, 2010, U.N. Doc. UNEP/CBD/COP/DEC/X/2.

62. *See* Nagoya Protocol, *supra* note 25.

63. Mattias Ahrén et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*, 83 IUCN Env't Law & Pol'y Paper 14-20 (2012) (describing the challenges with ABS regime implementation under the CBD that led to the Nagoya Protocol).

64. *See id*. at 14 ("Countries that developed domestic ABS frameworks have chosen different ways in which to implement the ABS provisions of the CBD at the national level . . . ABS procedures . . . differ from provider country to provider country, with sometimes long, confusing, cumbersome processes . . .).

65. *See* Secretariat of the Convention on Biological Diversity, *Nagoya Protocol: History*, Convention on Biological Diversity (Nov. 6, 2016), https://www.cbd.int/abs/background/#before-mandate [https://perma.cc/5VCD-4BAX] (describing and listing negotiations and documents leading up to the Nagoya Protocol).

66. *See* Bonn Guidelines, *supra* note 60.

67. *See* Ahrén et al., *supra* note 63.

68. Nagoya Protocol, *supra* note 25, art. 4(4) (emphasis added); *see also* Ahrén et al., *supra* note 64.

69. *See* Nagoya Protocol, *supra* note 25, arts. 5 & 7.

70. *See id.* arts. 17 & 18.

serve as Internationally Recognized Certificates of Compliance ("IRCCs"); evidence that genetic resources and associated traditional knowledge have been accessed in accordance with ABS/PIC/MAT.[71] Furthermore, members must cooperate, as far as possible and as appropriate, in cases where another Party's domestic ABS legislation has been violated.[72]

One important result of the Nagoya Protocol was the creation of an ABS Clearing House where interested parties can, in theory,[73] quickly and easily find information about the ABS laws of each member state, including who to contact (the ABS Focal Point) in a particular country to obtain ABS/PIC/MAT information.[74] The ABS Clearing House is also the repository for the list of IRCCs member states issue to applicants.

The Nagoya Protocol is not an intellectual property ("IP") treaty *per se*; nevertheless, there are links between the goals of the Nagoya Protocol and the purview of domestic patent systems in particular. For example, the misappropriation concerns that influenced the creation of the CBD, and ultimately the Nagoya Protocol, were in large part driven by the fact that patents were being granted on inventions derived from genetic resources and associated traditional knowledge obtained without PIC/ABS/MAT, while the lucrative proceeds from those patents were not being shared with the sovereign owners, providers, and developers of the resources.[75]

1. *Diversity by Design*

The Nagoya Protocol's requirements largely comprise floors—minimum obligations, and not ceilings—upper limits, on the kinds of ABS laws and penalties a country can impose. Thus, while the creation of the ABS Clearing House has improved transparency, considerable uncertainty for researchers remains as they face a panoply of un-harmonized PIC/ABS laws that may vary significantly in scope, obligations, and penalties. Moreover, the compli-

71. *See id.* art. 17.

72. *See id.* art. 15. Denmark's draft legislation provides one approach to complying with this obligation, as it prohibits the utilization of genetic resources (GRs) when the use is based on GRs acquired in violation of GR access regulations in the country where the GRs were accessed. Violations are punishable by fines, or up to two years in prison if willful or grossly negligent, and foreign states and persons appear to have standing to bring relevant actions in Danish courts. *See* Danish Ministry of the Environment, *Implementing the Nagoya Protocol in Denmark*, Convention on Biological Diversity, www.cbd.int/abs/side-events/cop-11/denmark-en.pdf [https://perma.cc/7SRV-NP44].

73. Unfortunately, all countries have not yet uploaded relevant information, nor are new documents always made available in a timely manner, likely due to resource constraints. *See* The Access and Benefit-Sharing Clearinghouse, https://absch.cbd.int/search/nationalRecords [https://perma.cc/GZ4U-2MG9].

74. *See* Nagoya Protocol, *supra* note 25, art. 14.

75. *See, e.g.*, Dutfield & Suthersanen, *supra* note 42; Robinson, *supra* note 46; Sabrina Safrin, *Chain Reaction: How Property Begets Property*, 82 Notre Dame L. Rev. 1917 (2007); *see also* Sheila Jasanoff, Designs on Nature: Science and Democracy in Europe and the United States 203–04 (2011) (noting that "the extension of patents to the life sciences created new classes of property rights in things that were previously outside the realm of what could be owned, or even thought of as subject to ownership claims.").

ance process adopted at the 2014 Conference of the Parties to the CBD serving as the Meeting of the Parties to the Nagoya Protocol ("COP-MOP") in South Korea pursuant to Article 30 of the Nagoya Protocol, is designed to be "non-adversarial, cooperative, simple, expeditious, advisory, facilitative, flexible and cost-effective in nature."[76] It thus lacks the teeth of, for example, the World Trade Organization's dispute settlement mechanism with its trade-based sanctions regime.[77]

In addition, the lack of ceilings in the Nagoya Protocol means that countries can deviate in important ways in the subject matter to which they attach ABS obligations. For example, South Africa's ABS regime goes significantly beyond the CBD and Nagoya Protocol by covering all indigenous biological resources within its scope, not just genetic resources.[78] Indigenous biological resources comprise "any living or dead organism of an indigenous species, any genetic material or derivatives of such organisms, or any chemical compounds and products obtained through use of biotechnology that have been altered with genetic material or chemical compounds found in indigenous species" and are covered by benefit-sharing requirements where their use is based on indigenous traditional knowledge, and there is commercial exploitation.[79] By contrast, the CBD and Nagoya Protocol define genetic resources as limited to "material of actual or potential value containing functional units of heredity."[80]

Consider also the issue of human genetic resources, which CBD Parties have agreed are excluded from the scope of the Treaty but which some countries regulate in relation to ABS requirements.[81] For example, Article 5 of the 2008 Third Revision of China's Patent Act specifies that "[p]atent rights shall not be granted for inventions that are accomplished by relying

76. Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization [hereinafter COP-MOP], *Cooperative Procedures and Institutional Mechanisms to Promote Compliance with the Nagoya Protocol and to Address Cases of Non-Compliance*, Oct. 20, 2014, U.N. Doc. UNEP/CBD/NP/COP-MOP/DEC/1/4. Article 27 of the CBD does contain a dispute settlement procedure; however, it has never been used. Article 30 of the Nagoya Protocol requires Members at the first meeting of the parties to develop and approve cooperative mechanisms to promote compliance and to address cases of non-compliance.

77. Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154. At the time of this writing, the WTO dispute settlement mechanism is not fully functional due to the lack of an Appellate Body to review panel decisions. *See* Aditya Rathore & Ashutosh Bajpai, *The WTO Appellate Body Crisis: How We Got Here and What Lies Ahead?*, JURIST (Apr. 14, 2020, 07:16 PM), https://www.jurist.org/commentary/2020/04/rathore-bajpai-wto-appellate-body-crisis/ [https://perma.cc/YCQ5-WZKS]; William Reinsch, *Ongoing Goings On: A News Update on WTO*, CTR. FOR STRATEGIC & INT'L STUD. (Jan. 31, 2020), https://www.csis.org/analysis/ongoing-goings-news-update-wto-0 [https://perma.cc/TVJ9-XKVG].

78. *See* National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) (S. Afr.) [hereinafter NEMBA]; Bioprospecting, Access and Benefit-Sharing Regulations, 2008 (Act No. R. 138 of 2008) (S. Afr.) [hereinafter BABS Regulations].

79. *Id.* art. 1.

80. CBD, *supra* note 25, art. 2.

81. *See* Conference of the Parties to the Convention on Biological Diversity, U.N. Doc. COP 2 Decision II/11, ¶1(a) (Nov. 17, 1995).

on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations."[82] The PRC Implementing Regulations further state that "[t]he genetic resources referred to in the Patent Law means any material taken from *human*, animal, plant or microorganism, containing genetically functioning units with actual or potential value."[83] Therefore, under the Chinese regime, inventions developed by reliance on human genetic resources cannot be patented if they violate ABS laws. Consequently, while agreement may be reached on certain matters at the international level, considerable variation and diversity in ABS deployment remains across countries.

2. *Implementation Vexation*

Ratification of the Nagoya Protocol has proceeded apace, with 131 current state parties at the time of writing.[84] However, the speed with which the first fifty countries deposited the necessary instruments of ratification for the Nagoya Protocol to come into effect has not been replicated in the national implementation phase. The Nagoya Protocol is complex, and while many countries had some type of ABS measure prior to the Nagoya Protocol going into effect, only six countries and the European Union ("EU") had notified implementing legislation to the CBD prior to the Nagoya Protocol's October 12, 2014, effective date.[85] As of 2018, forty-five countries had submitted ABS legislative or policy instruments to the ABS Clearing House, but many of those documents were still pre-Nagoya Protocol laws.[86]

At the time of the first *Assessment and Review of the Effectiveness of the Protocol* in 2018, many Parties were still in the process of establishing ABS legislative, administrative, and policy measures, and even today, many "still lack the necessary capacity and financial resources to make the Protocol operational."[87] For developing and least developed countries in particular, the implementation process has been time-consuming, resource-intensive, and

82. Patent Law of the People's Republic of China (2008), art. 5., World Intellectual Property Organization, https://www.wipo.int/edocs/lexdocs/laws/en/cn/cn028en.pdf.

83. Implementing Regulations of the Patent Law of the People's Republic of China (2010) [hereinafter PRC Implementing Regulations] art. 26 (emphasis added).

84. *See* Secretariat of the Convention on Biological Diversity, *Parties to the Nagoya Protocol*, Convention on Biological Diversity (2016), https://www.cbd.int/abs/nagoya-protocol/signatories/ [https://perma.cc/378G-H5PU].

85. *See* Jorge Cabrera Medaglia et al., Overview of National and Regional Measures on Access and Benefit-Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol 13 (3d ed. 2014) (noting that as of April 25, 2014, the ABS Measures Database had listed fifty-seven countries and seven regions as having some form of ABS measure).

86. *See* Secretariat of the Convention on Biological Diversity, *Progress Towards Ratification*, Convention on Biological Diversity (2014), https://www.cbd.int/abs/progress/default.shtml [https://perma.cc/MNQ6-VL4W].

87. COP-MOP, *Decision Adopted by the Parties to the Nagoya Protocol on Access and Benefit-Sharing*, Nov. 30, 2018, U.N. Doc. CBD/NP/MOP/DEC/3/1 [hereinafter CBD Decision 3/1]; *see also* Margo Bagley et al., *Fact-Finding Study*, *supra* note 26.

challenging.[88] According to statistics from the assessment, as of 2018, 98% of Parties had designated a national focal point, 71% had ABS measures in some form, but only 44% had measures to implement benefit-sharing on genetic resources.[89] 51% had published information to the ABS Clearing House website, 27% had a checkpoint, and only 18% had issued a permit.[90]

By contrast, the EU was one of the first signatories to enact implementing legislation for the Nagoya Protocol via a regulation on compliance measures for users of genetic resources.[91] The EU Regulation No. 511/2014 ("EU Regulation"), and a complementary implementing Regulation,[92] specify that users of genetic resources and associated traditional knowledge must ensure that benefits are fairly and equitably shared upon mutually agreed terms with providers. The EU Regulation was approved in 2014, and despite being the subject of two legal challenges at the Court of Justice of the EU,[93] it has been fully in effect since October of 2015. As described by the EU Directorate-General for Environment:

> The basic requirement of the regulation is due diligence. Users of genetic resources need to seek, keep and transfer to subsequent users a set of information relevant to genetic resources. If users do not have sufficient information on the legality of access and use, they should obtain a permit, establish mutually agreed terms or stop using the resource.[94]

---

88. *See, e.g.*, Michael Heinrich et al., *Access and Benefit-Sharing Under the Nagoya Protocol—Quo Vadis? Six Latin American Case Studies Assessing Opportunities and Risk*, 11 FRONT. PHARMACOL. 765 (2020) ("The implementation of the Nagoya Protocol varies in the six countries; and while they are all rich in biodiversity, access and benefit-sharing mechanisms differ considerably . . . . Institutional infrastructures to implement national policies are weak, and the level of knowledge about the NP and the CBD within countries remains limited.").

89. CBD Decision 3/1, *supra* note 87, at 10.

90. *Id.*

91. *See* Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, 2014 O.J. (L 150), 59 [hereinafter the Regulation].

92. *See* Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 Laying Down Detailed Rules for the Implementation of Regulation (EU) No. 511/2014 of the European Parliament and of the Council as Regards the Register of Collections, Monitoring User Compliance and Best Practices, 2015 O.J. (L 275), 4 [hereinafter the Implementing Regulation]; *see also* Guidance Document on the Scope of Application and Core Obligations of Regulation (EU) No. 511/2014 of the European Parliament and of the Council on the Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, 2016 O.J. (C 313), 1.

93. Adrian Toutoungi, *EU General Court Rejects Plant Breeders' Challenge to Implementation in EU of Nagoya Protocol Access to Genetic Resources and Benefit-Sharing*, LEXOLOGY (Sept. 2015), https://www.lexology.com/library/detail.aspx?g=1e3e4ac7-7cb0-4fe2-a6dc-2a7a6b43b62b [https://perma.cc/W7DK-ZNRP].

94. *Compliance With Rules on Access and Benefit-Sharing Arising from the Use of Genetic Resources and Associated Traditional Knowledge*, EUR-LEX (June 2018), https://eur-lex.europa.eu/legal-content/en/LSU/?uri=CELEX:32014R0511 [https://perma.cc/LX4J-P8KM].

The EU's desire to ensure, as far as possible, its users' compliance with other Parties' ABS laws is commendable, and certainly intended to enhance the effectiveness of the Nagoya Protocol overall. However, treaty implementation is highly resource-intensive, and a recent study of user experiences with the EU Regulation identifies a variety of challenges experienced by EU users and member states in effectuating the EU Regulation.[95]

If implementation and compliance have been challenging in the well-resourced EU, it is not surprising that many poorer countries without the EU's financial, legal, and administrative resources have struggled mightily with implementing the Nagoya Protocol. Implementation requires the drafting of new laws and regulations, clear, easy to understand and expeditious processes for researchers to gain permission to access genetic resources, and realistic benefit-sharing obligations for access and use, among many other things. Moreover, implementation often requires consultations with sometimes large and diverse groups of IPLCs who may or may not have developed their own community protocols addressing who is authorized to negotiate for the group, who is entitled to share in benefits, what types of restrictions should be placed on usages, and more.[96]

Consider, for example, Guinea, the country from which the Ebola virus strain that Regeneron used to develop Inmazeb™ originated. Guinea is a least developed country, one of the poorest on the planet, with a gross national income per capita of US $930 in 2019.[97] Guinea is a party to the CBD and ratified the Nagoya Protocol in 2015 but has no implementing legislation yet. According to Guinea's *Interim National Report on the Implementation of the Nagoya Protocol*,[98] as of mid-2019, the country had no specific legal framework for ABS, no access conditions, and lacked rules and procedures to formalize the documentation necessary to facilitate access to genetic resources.[99] These deficiencies were identified as being due to a lack of technical, human, and financial capacities to develop and implement a specific legal framework for the Nagoya Protocol.

---

95. *See* Milieu Law & Policy Consulting, *Analysis of Implications of Compliance with the EU ABS Regulation for Research Organisations and Private Sector Companies*, Milieu Law & Pol'y Consulting 16 (May 2020), https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/ABS%20Regulation_Report%20on%20Compliance%20Implications%20for%20public%20and%20private%20sectors.pdf [https://perma.cc/N64J-5DPD].

96. *See* Natural Justice & ABS Capacity Development Initiative, *Experiences and Lessons Learned from the Development and Implementation of Community Protocols and Procedures: Contribution to the First Assessment and Review of the Effectiveness of the Nagoya Protocol*, Nat. Just. 10, www.cbd.int/abs/submissions/assessment/naturaljustice-abs-initiative-en.pdf [https://perma.cc/S8LV-VJZC].

97. *Gross National Income—Guinea*, World Bank, https://data.worldbank.org/indicator/NY.GNP.ATLS.CD?locations=GN [https://perma.cc/64NK-LRMH].

98. Guinea, Interim Nat'l Rep. on the Implementation of the Nagoya Protocol (The Access and Benefit-Sharing Clearing-House 2019).

99. *Id.* However, the report notes that access to biological resources is governed to some extent by livestock, fishing, wildlife, forest codes, "and other documents such as the strategy and the action plan for the conservation of biological diversity (2015-2025)" (translated from the French original using Google Translate).

Thus, when dealing with countries like Guinea, users may lack clarity regarding the process for accessing and using genetic resources, and they may also lack legal certainty if no IRCC can be granted. Where associated traditional knowledge is involved, users may not know who to negotiate with regarding access, benefit-sharing, and consent.[100] As a result, users may be less inclined to access resources from such countries, engage in research collaborations, or share benefits, to the detriment of provider and IPLC development goals.

The EU Regulation only applies to genetic resources and associated traditional knowledge in Nagoya Protocol members with actual ABS measures in place. Because research projects often span years, if not decades, challenges with the Nagoya Protocol are, in some cases, just beginning to be identified. According to one report, some EU genetic resource users have already experienced difficulties in obtaining the necessary proof of ABS compliance from provider countries.[101] This is not surprising, since as of October 2020, only 1934 total IRCCs had been issued by a mere 22 out of 127 countries party to the Nagoya Protocol at that time.[102] Furthermore, almost 80% of those IRCCs were issued by either India (1283) or France (233) leaving the remaining few distributed across 20 countries.[103]

Thus, an unintended consequence of the EU's otherwise commendable and brisk action has been frustration and disenchantment with the ultimate workability of the Nagoya Protocol's bilateral ABS framework, and an understandable resistance to the possible expansion of the Nagoya Protocol's reach to include digital sequence information.[104]

---

100. *See* Natural Justice & ABS Capacity Development Initiative, *supra* note 96 (describing challenges and successes with the development of IPLC bio-community protocols). This is also intertwined with the fact that the contracts may be set up between states and private companies at the expense of indigenous and local communities possibly resulting in a lack of control for IPLCs over the ecosystems they have developed and maintained, which are essential to their heritage and livelihoods. *See* Koutouki & Rogalla von Bieberstein, *supra* note 50, at 518–19, 531.

101. *See* Milieu Law & Policy Consulting, *supra* note 95 ("All the interviewees reported how they all had to write and call several times before obtaining an answer (if any), and how in most of the cases communicating in the local language is a pre-requisite for any further exchange of information. Understanding which authority to contact and which one is the Competent Authority, and what is the specific legal framework in the provider country is reported as a major issue by all the interviewees . . . . They did not report additional costs, but only additional time and delays (up to one year) for obtaining the necessary agreements.").

102. *See Access and Benefit-Sharing Clearinghouse*, Convention on Biological Diversity, https://absch.cbd.int/ [https://perma.cc/6EGG-GWFX].

103. *Id.*

104. *See* Milieu Law & Policy Consulting, *supra* note 95, at 28 ("[A]ll interviewees [state] that competitiveness of European business will significantly weaken if the scope of the EU ABS Regulation was broadened to include digital sequence information (DSI).").

II. Digital Sequence Information, The CBD, And The Nagoya Protocol

October 2020 was intended to be a watershed moment for the CBD. COP15/MOP4 was to be held in Kunming, China, reflecting on ten years since the adoption of the Nagoya Protocol, reckoning with the inability of any Party to meet the Aichi Biodiversity Targets,[105] and adopting a post-2020 biodiversity framework.[106] Of course, the global pandemic has postponed the Parties' consideration of these and other issues in Kunming until 2022, including the hot topic of DSI and its place in the CBD and Nagoya Protocol.

The issue of DSI has taken on considerable importance in the context of these agreements due to advances in technology and legal and policy developments. The mapping of the human genome was a unique accomplishment that, building on earlier legislative, judicial, and technological advances, ushered in the age of biotechnology and its use to address some of the most confounding challenges of our time.[107] More recently, the award of the 2020 Nobel prize in Chemistry to Drs. Jennifer Doudna and Emmanuelle Charpentier was a notable recognition of the disruptive potential of the CRISPR-Cas gene editing discovery to develop therapeutic solutions to debilitating diseases, provide agricultural advances to boost the global food supply, and to change the very nature of humanity with germ-line editing.[108]

Gene editing techniques are one category of tools that facilitate DSI utilization, but many others have been developed over the years as well, including the ability to use viral vectors to insert genes, and to use polymerase chain reaction to rapidly reproduce large amounts of DNA fragments. Also important have been advances in understanding genomic engineering, the creation of open access online databases, and the invention of various analytical tools.[109] Also, the dramatic reduction in the cost to synthesize, sequence, generate, and utilize genomic information has led to a race to digitize most lifeforms on the planet. According to the National Human Genome Re-

105. Secretariat of the Convention on Biological Diversity, Global Biodiversity Outlook 5, 10 (2020) ("At the global level none of the 20 targets have been fully achieved, though six targets have been partially achieved.").

106. *See* Secretariat of the Convention on Biological Diversity, *Processes and Meetings*, Convention on Biological Diversity, https://www.cbd.int/process/ [https://perma.cc/983U-6CC3].

107. *See* Leroy Hood & Lee Rowen, *The Human Genome Project: Big Science Transforms Biology and Medicine*, 5 Genome Med. 79 (2013); *see also What is the Human Genome Project?*, Nat'l Hum. Genome Rsch. Inst. (Oct. 28, 2018), https://www.genome.gov/human-genome-project/What [https://perma.cc/FK9W-DLWS] (quoting Dr. Francis Collins describing the Human Genome Project as "a transformative textbook of medicine, with insights that will give health care providers immense new powers to treat, prevent and cure disease.").

108. Jennifer A. Doudna & Samuel H. Sternberg, A Crack in Creation 13, 20 (2017).

109. *See, e.g.*, Susan Hockfield, The Age of Living Machines: How Biology Will Build the Next Technology Revolution 5, 38, 129 (2019); Geoff Baldwin et al., Synthetic Biology: A Primer (2016); L. J. Kahl & D. Endy, *A Survey of Enabling Technologies in Synthetic Biology*, 7 J. Biol. Eng. 13 (2013).

search Institute, while it cost between $500 million and $1 billion to sequence the reference human genome in 2000, by 2006, the cost had dropped to ~$14 million and by late 2015 to below $1,500.[110]

The low cost of genome sequencing and the high value of aggregated sequences for screening and alignment searching is leading to more sequences being uploaded to publicly accessible databases and thus to less need to access physical genetic material. This conceptual "de-materialization" of genetic material has the potential to enable researchers and corporate entities to bypass CBD and Nagoya Protocol benefit-sharing obligations, much to the consternation of many Parties in biodiversity-rich, but economically poor countries.

A. DSI Technological Developments Affecting Treaty Obligations

The issue of ABS for DSI has thrown a proverbial wrench into the international treaty-based ABS machinery. Stymied expectations are leading to calls for the development of new domestic laws and new or modified international agreements, as well as generating disputes over the proper interpretation of existing laws and treaties.

Although there were some discussions of sequence information issues in the Nagoya Protocol negotiations, they did not gain sufficient traction to warrant an explicit reference in the final agreement. Instead, the CBD and Nagoya Protocol both were drafted primarily with tangible genetic resources in mind, and neither facially addresses the rather different set of "intangible" concerns implicated by DSI. As the civil society organizations ETC Group and Friends of the Earth note in relation to developments in synthetic biology[111]:

> While "traditional" biopiracy involves the physical removal of material from a community to private hands, synthetic biology enables "digital biopiracy" where the DNA of an organism is sequenced in situ, uploaded to the internet as information, and then transferred digitally to a DNA synthesizer to be copied and rebuilt elsewhere. This digital transfer of DNA sequences does not even require a MTA since no physical material is transferred. Yet, the technology allows corporations, governments and individuals

110. *The Cost of Sequencing a Genome*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost [https://perma.cc/WR3N-8JLW].

111. Although there is no agreed definition for the phrase, synthetic biology can be defined as "a field of science that involves redesigning organisms for useful purposes by engineering them to have new abilities. Synthetic biology researchers and companies around the world are harnessing the power of nature to solve problems in medicine, manufacturing and agriculture." *Synthetic Biology*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/policy-issues/Synthetic-Biology [https://perma.cc/J9AF-XAQT].

> to freely take genetic material for private use in new synthetic organisms, which can then be patented as inventions.[112]

Such concerns seem justifiable in light of the wide availability of genome information and tools that can be used to construct modified or fully novel gene sequences that can be emailed or uploaded to commercial enterprises and synthesized to specification.[113] For example, a 2017 study for the United Nations Food and Agriculture Organization's International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGRFA") strikingly highlighted the potential for ABS obligations to be bypassed with the following quote from an interviewed synthetic biology researcher:

> "[B]efore, *we had to ask for the material* . . . if we wanted to repeat or to continue the work . . . that had been done in other labs. But now because of synthetic biology, it's quite easy to standardize some very complex construct and it's easy to do CRISPR. So for instance, if we want to do something and *say nothing to anybody* – let's say someone published something interesting and I want to reproduce or do some specific work on it – *I could just use the data that was published to reproduce {it} myself* . . . and do it very quickly . . . [T]en years ago it was quite complicated. It was easier to ask . . . people [to send the material]. But now . . . if you want to do something very complex, you just do it on your computer and [send it to a foundry] . . . the company will do it for you – it's very cheap."[114]

These developments illustrate what Professor Moses calls "the capacity of new technology to enable new forms of conduct, including alteration of the means by which similar ends are achieved."[115] Being able to extract value from a genetic resource without needing to physically access the genetic resource allows researchers to achieve desired ends without the means of

---

112. *Synthetic Biology 101 Fact Sheets from Friends of the Earth*, SynBioWatch (May 15, 2013), https://www.synbiowatch.org/2013/05/synthetic-biology-101-some-technical-details-from-friends-of-the-earth/ [https://perma.cc/CTY2-4KWV].

113. One such tool is the free "Gene Designer" software available from www.DNA2.0.com. *See First Self-Replicating, Synthetic Bacterial Cell Constructed by J. Craig Venter Institute Researchers*, J. Craig Venter Inst. (May 20, 2010), https://www.jcvi.org/media-center/first-self-replicating-synthetic-bacterial-cell-constructed-j%C2%A0craig-venter-institute [https://perma.cc/GK36-VCZH]. "Genomic science . . . is enabling researchers to "read" the genetic code of organisms from all branches of life . . . Sequencing genomes has now become routine, giving rise to thousands of genomes in the public databases. In essence, scientists are digitizing biology by converting the A, C, T, and G's of the chemical makeup of DNA into 1's and 0's in a computer." *First Self-Replicating Synthetic Bacterial Cell*, J. Craig Venter Inst., https://www.jcvi.org/research/first-self-replicating-synthetic-bacterial-cell [https://perma.cc/T2X5-47CF].

114. Eric Welch et al., Potential Implications of New Synthetic Biology and Genomic Research Trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture 12 (FAO, 2017) (emphasis added). This scoping report was commissioned by the Secretariat of the International Treaty on PGRFA, FAO. *Id*.

115. Moses, *supra* note 30, at 245.

obtaining PIC and negotiating MAT with a country for use of the resource. Consequently, the extracted value is not made the subject of a benefit-sharing agreement as many adopters of the Nagoya Protocol likely envisioned.

Nevertheless, it is important to note that there has been a mismatch between reality and expectations on *both* sides of the ABS divide. Some biodiverse provider states in the global South restrict access to their resources out of fear of exploitation by companies from high income countries. In Indonesia, one of the most species-rich countries on earth, foreign researchers are almost completely barred from accessing genetic resources for study.[116] In fact, in 2007 the Indonesian government refused to share samples of an influenza virus, arguing that it would be used to create vaccines that Indonesian civilians could not afford.[117]

On the other side, the costs of complying with Nagoya Protocol legislative requirements have far exceeded what many users and governments anticipated. In the EU, some users report costs of obtaining PIC/MAT as between EUR 500 to EUR 10,000 per negotiation, requiring up to 500 personnel hours, and taking up to three years to conclude.[118] Such delays to research projects can be costly in the fast-paced environment in which many therapeutics, cosmetics, and even agricultural products are developed. Given these kinds of concerns, user reluctance to engage with the Nagoya Protocol bilateral scheme, let alone expand it to DSI, seems eminently understandable.[119]

"Digital biopiracy" concerns are creating reluctance on the part of some provider countries to enter into even non-commercial research agreements due to the fear that DSI obtained from analyzing genetic material under a PIC/ABS agreement may be uploaded to publicly accessible databases and then used by researchers to develop lucrative, ABS-free, modified organisms and products for commercial applications.[120] As such, it is not surprising to see some provider country governments using the tools that they do have—

116. *See* Max Kozlov, *Science with Borders: Researchers Navigate Red Tape*, THE SCIENTIST (Mar. 1, 2021), https://www.the-scientist.com/careers/science-with-borders-researchers-navigate-red-tape-68443 [https://perma.cc/NZ65-R6N9].

117. *Id.*

118. *See* Milieu Law & Policy Consulting, *supra* note 95, at 16. It should be noted, however, that somewhat similar delays can attend the negotiation of licensing agreements between companies and universities to transfer technology. *See* Kate Sheridan, *Licensing Biotech Breakthroughs Is a Contentious, Painful Slog. Can the Process Be Fixed?*, STAT+ (Oct. 26, 2021) ("At their worst . . . , negotiations can be hellishly contentious. Venture capitalists may come away believing tech transfer officers have an inflated sense of the value of their university's work and are stymieing them without reason, while tech transfer officers may feel that venture capitalists are plotting to rip off their students and faculty or their institution.").

119. *See, e.g.*, Sarah Laird et al., *Rethink the Expansion of Access and Benefit-Sharing*, 367 SCIENCE 1200, 1200 (2020) ("Many in the scientific community with ABS experience are concerned that DSI might be captured by the same complex ABS policies that they currently must navigate to access physical samples").

120. *See* Alain Pottage, *Too Much Ownership: Bio-Prospecting in the Age of Synthetic Biology*, 1 BIOSOCIETIES 137, 154–155 (2006). This is particularly ironic and problematic as Article 8 of the Nagoya Protocol explicitly encourages countries to ease access requirements for non-commercial research projects.

categorizing DSI as a genetic resource under the CBD and imposing access restrictions—to generate leverage for benefit-sharing negotiations.[121]

B. DSI at the CBD

The term "digital sequence information" occupies an odd place in the CBD and Nagoya Protocol discussions. It was first placed on the agenda at the 2016 COP13/MOP2[122] in Cancun, Mexico during which the Parties authorized the commissioning of a study on the concept and scope of the phrase and the convening of an Ad Hoc Technical Expert Group ("AHTEG") to consider the study. The AHTEG was also charged with making recommendations to the Subsidiary Body on Science, Technical and Technological Advice ("SBSTTA") which would report to COP14/MOP3 on any potential implications of the use of digital sequence information on genetic resources for the three objectives of the CBD.[123] Considering the controversial nature of the topic and the lack of consensus on basic concepts, it is perhaps not surprising that the AHTEG was unable to agree on much of anything except the fact that DSI was a placeholder phrase and likely not the best term for the concept, but to continue to use it until Parties reach an agreement on a different phrase.[124]

It seems clear that at least some Parties to the COP14/MOP3 negotiations viewed the DSI issue through a justice lens. The parties recognized that the use of and access to digital sequence information contributes to furthering scientific research relating to biological diversity, food security and human, animal, and plant health.[125] They also recognized the inability of many to participate in developing those contributions due to technological capacity limitations, and DSI's potential to bypass benefit-sharing through lack of traceability. As shared by South Africa in a submission to the CBD Secretariat, the country lacked a concrete case study for DSI because "DSI might be accessed under academic research terms, uploaded onto databases, and end up being used commercially, potentially by multiple dif-

121. Although addressing a different issue, Paul Stephan's observations apply here as well: "A successful world economy based on as well as promoting technological progress can still fall victim to those who lose out in the process." Paul Stephan, Sovereignty and the World Economy 36 (Va. Pub. L. & Legal Theory Rsch. Paper No. 2020-57, Va. L. & Econ. Rsch. Paper No. 2020-12, 2020).

122. Since the Nagoya Protocol came into effect at the 2014 COP, the COP now also serves as the MOP, the meeting of the parties to the Nagoya Protocol.

123. *See* Sarah Laird & Rachel Wynberg, *Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol*, U.N. Doc. CBD/DSI/AHTEG/2018/1/3, p. 1 (Jan. 2018).

124. *See* Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, *Report of The Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources*, U.N. Doc. CBD/DSI/AHTEG/2018/1/4 (Feb. 2018). In the interest of full disclosure, I served as a member of the 2018 AHTEG.

125. Conference of the Parties to the Convention on Biological Diversity, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity: 14/20. Digital Sequence Information on Genetic Resources,* U.N. Doc. CBD/COP/DEC/14/20, 1 (Nov. 2020) [hereinafter Decision 14/20].

ferent users, without the original providers [being] aware of or involved in this process."[126]

DSI was thus a key issue in November 2018 at COP14/MOP3 in Sharm El-Sheikh, Egypt. There, in adopting COP Decision 14/20, the Parties recognized 1) the importance of DSI for the three objectives of the CBD, 2) the need for conceptual clarity on DSI, and 3) the benefits of access to and use of DSI in scientific research, biological diversity, food security and more.[127] They also recognized that many countries need a greater capacity to access and utilize DSI, that there is a divergence of views among Parties regarding DSI and benefit-sharing, and that there is a lack of information regarding many aspects of DSI utilization and regulation.

Decision 14/20 established a science and policy-based process entailing: 1) the submission of views and information by interested parties, 2) the commissioning and peer review of four DSI studies, and 3) work by a new AHTEG which would review the submissions and studies and provide outcomes to an Open-Ended Working Group ("OEWG") to ultimately be deliberated at COP15/MOP4 in Kunming, China in relation to the post-2020 biodiversity framework.[128]

C. The Decision 14/20 DSI Studies[129]

Articulation of a science and policy-based process necessitated the commissioning of peer-reviewed studies to inform that process and provide answers to questions raised during the COP14 discussions. In particular, Parties sought studies regarding: the scope and concept of DSI and how it is currently being used, the nature and scope of DSI in public and private databases and whether it can be traced for benefit-sharing purposes, and the extent to which Parties have already begun regulating DSI in their domestic regimes. To effectuate the Decision, the CBD Secretariat commissioned the following four studies:

---

126. Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, *Compilation of Views and Information on Digital Sequence Information on Genetic Resources Submitted Pursuant to Paragraphs 9 and 10 of Decision 14/20*, U.N. Doc. CBD/DSI/AHTEG/2020/1/INF/1, at 40 (Feb. 4, 2020); *see also* THE BERNE DECLARATION ET AL., THE BITTERSWEET TASTE OF STEVIA (Ronnie Hall ed., 2015) (arguing that commercialization of Stevia substitute sweeteners using synthetic biology (via DSI) is violating the ABS rights of the Guaraní people in Paraguay and Brazil who first discovered and communicated the sweetening properties of Stevia leaves).

127. Conference of the Parties to the Convention on Biological Diversity, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity: 14/20. Digital Sequence Information on Genetic Resources,* U.N. Doc. CBD/COP/DEC/14/20 (Nov. 2020). Decision NP-3/12 under the Nagoya Protocol supported Decision 14/20 and requested the OEWG to report to it the COP/MOP as well. *See also* Secretariat of the Convention on Biological Diversity, *What Has Been Done on Digital Sequence Information on Genetic Resources?*, CONVENTION ON BIOLOGICAL DIVERSITY (2020), https://www.cbd.int/dsi-gr/whatdone.shtml [https://perma.cc/8PQU-Z38S].

128. See Decision 14/20, *supra* note 126, at 2–3.

129. The studies are available at https://www.cbd.int/meetings/DSI-AHTEG-2020-01 [https://perma.cc/QE5A-KYQH].

Study #1: Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use[130]

This study provides a helpful technical background and context for DSI discussions. It also identified four (narrow to broad) possible groupings of information that could be considered to be within the scope of DSI, evaluated the appropriateness of DSI and other terms such as genomic sequence data, that might be a better subject matter fit, and also explained some of the ways DSI is currently utilized in life sciences research.[131]

Studies #2 and 3: Combined Study on Digital Sequence Information (DSI) in Public and Private Databases and Traceability[132]

The authors' combined study #2 on traceability of digital information, including how traceability is addressed by databases, and study #3 on public and, where possible, private, databases, their terms, access conditions, biological scope and the size, numbers of accessions and their origin, governing policies, and providers and users, into a single study. They also limited their research to one particular type of DSI, nucleotide sequence data ("NSD").

The study identified more than 1,600 databases which contain "trillions" of nucleotide bases, the vast majority of which link directly or indirectly to the International Nucleotide Sequence Database Collaboration ("INSDC").[133] This collaboration is a consortium of three of the largest and most commonly used databases: GenBank at NCBI in the United States, the European Molecular Biology Laboratory-European Bioinformatics Institute in the United Kingdom, and the Data Bank of Japan at the National Institute of Genetics, all of which share their contents and provide tools to advance research which relies on biological information.

Together, these databases contain a large and rapidly growing amount of sequence data and other possible forms of DSI. As of August 2021, GenBank contained over 940 billion bases, with the number of bases doubling approximately every 18 months.[134] Moreover, the amount of publicly

130. Wael Houssen et al., *Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use*, U.N. Doc. CBD/DSI/AHTEG/2020/1/3, annex (Jan. 29, 2020).

131. *Id.* at 4, 46.

132. Fabian Rohden et al., *Combined Study on Digital Sequence Information in Public and Private Databases and Traceability*, U.N. Doc. CBD/DSI/AHTEG/2020/1/4, annex (Jan. 29, 2020).

133. *Id.* at 16.

134. *Genbank and WGS Statistics*, Nat'l Ctr. For Biotechnology Info. https://www.ncbi.nlm.nih.gov/genbank/statistics/ [https://perma.cc/N8V9-Q35X]. DSI in other repositories such as the Protein Data Band and various natural product databases also can be used to develop valuable therapeutic products. *See* Margo A. Bagley & Frederic Perron-Welch, *Study to Identify Specific Cases of Genetic Resources and Traditional Knowledge Associated with Genetic Resources That Occur in Transboundary Situations or for Which It Is Not Possible to Grant or Obtain Prior Informed Consent, Subsidiary Body on Implementation*, U.N. Doc. CBD/SBI/3/15/Add.1 (13 Jul., 2020); Helen M. Berman et al., *The Future of the Protein Data Bank,* 99 Biopolymers 218 (2013); Maria Sorokina & Christoph Steinbeck, *Review on Natural Products Databases: Where to Find Data in 2020,* 12 J. Cheminformatics 20 (2020).

accessible sequence data is only bound to increase considering other initiatives already underway. For example, the Earth Biogenome Project aims to sequence, characterize, and catalogue the genomes of all eukaryotic species on Earth within ten years.[135] The massive amount of data expected to be produced from this project has the potential to be useful for both commercial and non-commercial research, and ultimately may significantly reduce the need for access to physical samples of genetic resources.

The study noted that the INSDC enables scientists to submit their NSD and receive an accession number, which is required by most life science journals for scientists whose publications report NSD-based results.[136] Regarding traceability, country of origin information can be, but is not required to be, submitted with NSD, and is available for 56% of relevant (non-human) NSD.[137] However, INSDC databases are openly accessible, do not require login or registration, and allow users to download the contents of the databases without restriction, something that happens hundreds of thousands of times a day.[138] Moreover, INSDC will not attach statements to database records that restrict access to or limit the use of the data. Thus, tracing what happens to downloaded NSD or even sequences that are being manipulated in the database through, for example, an alignment search, is likely to be impossible in most cases.[139]

Study #4: Fact-finding Study on How Domestic Measures Address Benefit-Sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development[140]

The authors of this study sought information regarding measures for all 196 CBD Parties. They found that while most Parties have not employed administrative, legislative, or other domestic measures to regulate access or benefit-sharing for DSI and many have no intention of doing so in the future, at least sixteen countries and one subnational jurisdiction have domestic ABS measures to address the use of DSI and at least eighteen more are in the process of developing such measures.[141] The study identified several

135. *See* Earth Biogenome Project, https://www.earthbiogenome.org/ [https://perma.cc/3JA2-6QWF].

136. The authors note that the requirement to publish NSD "is intended to enable scientific reproducibility and perpetuate scientific integrity. This practice was codified in 1996, during the Human Genome Project, by the Bermuda Principles, in 2003 by the Fort Lauderdale agreement, and in 2009 by the Toronto Agreement." Rohden et al., *supra* note 132, at 16.

137. *Id.* at 79.

138. *Id.* at 25.

139. *See also* Fabian Rohden & Amber H. Scholz, *The International Political Process Around Digital Sequence Information Under the Convention on Biological Diversity and the 2018-2020 Intersessional Period*, 3 Plants, People, Planet 1, 7 (2021) (noting that "the open publication of a sequence also means that commercial stakeholders can access it freely and profit from it *without being monitored*") (emphasis added).

140. Bagley et al., *supra* note 26. I served as the lead author of this study.

141. *Id.* at 2.

terms used by Parties to refer to DSI in domestic measures, and by researchers in publications, including genomic sequence data, genetic information, genetic heritage, natural information, and sequence information.[142] None of the countries with DSI measures reported monetary benefit-sharing from those measures, though a few reported non-monetary benefits.[143]

The study grouped approaches to DSI into five different categories: (1) DSI is only addressed in conjunction with the utilization of "physical" genetic resources; (2) PIC and MAT are required for DSI independent of access to a "physical" genetic resource; (3) benefit-sharing obligations arise from the use of DSI (but no DSI access requirements are imposed); (4) DSI is only addressed, if at all, in MAT; and (5) some countries without measures regulating DSI employ "non-measures;" policy positions to affirmatively promote public access to DSI in open access databases without benefit-sharing.[144] This panoply of different approaches presents a fractured, complicated landscape for interested researchers to navigate. The study noted broad agreement across CBD Parties that even if DSI is deemed to fall outside of the CBD definition of "genetic resources," DSI produced from the utilization of a genetic resource could still be subject to benefit-sharing.[145]

After considering the findings of these studies, the 2020 Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources agreed, among other things, that DSI could be considered to include DNA and RNA, proteins and epigenetic modifications, and metabolites and other macromolecules.[146] However, a final decision on terminology will be made, if at all, during COP15.[147] In the meantime, DSI continues to be widely used, with the understanding that it is simply a placeholder phrase.

D. DSI and Scope

On one level, the DSI terminology controversy can be viewed as a battle over efforts to cabin the scope of CBD and Nagoya Protocol coverage. If it is

142. *Id.* at 12.

143. *Id.* at 3, 11, 25–27.

144. *Id.* at 10.

145. *Id.* at 11. *See also* Decision 14/20, *supra* note 126, at 2, ¶ 7 (articulating the Conference of the Parties understanding that "when genetic resources are accessed for their utilization, mutually agreed terms can cover benefits arising from the commercial and/or non-commercial use of digital sequence information on these genetic resources, in accordance with applicable domestic measures").

146. Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, *Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources*, U.N. Doc. CBD/DSI/AHTEG/2020/1/7, at 9, tbl. 1 (Mar. 20, 2020). The Table provides several examples of granular subject matter within each group.

147. *See* Decision 14/20, *supra* note 126, at 1 (noting that "the term 'digital sequence information' may not be the most appropriate term and that it is used as a placeholder until an alternative term is agreed"). The Decision also noted "the relevant discussions on digital sequence information on genetic resources and related issues in other United Nations bodies and instruments, such as the Food and Agriculture Organization of the United Nations, the International Treaty on Plant Genetic Resources for Food and Agriculture, the World Health Organization, the World Intellectual Property Organization and the United Nations General Assembly." *Id.*

agreed that DSI is within the scope of the Nagoya Protocol, and DSI is defined broadly, benefit-sharing obligations, and possibly even access requirements, would apply to more types of utilizations than if it is defined narrowly.

An underlying problem in this debate is that commentators and negotiators sometimes assert that DSI is not within the scope of the Nagoya Protocol, without clearly indicating if they mean simply outside of the definition of "genetic resources," or actually not resulting from "utilization of genetic resources" either.[148] Clarity on this point is important, because if the Parties can agree that DSI is within the scope of the Nagoya Protocol as a result of the utilization of genetic resources, that could be a meaningful step toward recognizing that it is possible to compromise, even without agreement on the definition of genetic resources.

Analyzing the context of statements asserting that DSI is out of the scope of the CBD and/or Nagoya Protocol suggests that in most cases, what is meant is merely that DSI is not within the definition of genetic resources. This conclusion flows from the fact that State parties and commentators taking this position still generally mention that DSI can be addressed in MAT (which is within the scope of the CBD and/or Nagoya Protocol) and/or that open access to DSI is a form of non-monetary benefit-sharing, which one would not need to provide if indeed DSI were outside the scope of the CBD and/or Nagoya Protocol.[149]

To contextualize the above, the CBD and Nagoya Protocol define "genetic resources" as "genetic material of actual or potential value" and define "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity."[150] The Nagoya Protocol also defines "utilization of genetic resources" to mean "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention," whereas "[b]iotechnology," as defined in Article 2 of the CBD, means "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."[151]

Three primary views of DSI and CBD/Nagoya Protocol scope are ascertainable from the negotiations and literature: (1) DSI is *not* within the definition of "genetic resources" but may result from utilization of genetic resources and can be addressed in MAT; (2) the CBD/Nagoya Protocol definition of "genetic resources" *should* be interpreted to include DSI; and (3)

148. *See, e.g.*, *Compilation of Views and Information on Digital Sequence Information supra* note 126, at 42 (stating that "DSI does not fulfil the criteria of the definitions of either "genetic material" or "genetic resources" under the Convention and the Nagoya Protocol, and therefore is not covered by those instruments" but later asserting that MAT for a tangible genetic resource can address DSI).

149. *Id.*

150. CBD, *supra* note 25, art. 2.

151. Nagoya Protocol, *supra* note 25, art. 2(c)–(d).

DSI is *not* within the definition of "genetic resources," but *does* result from utilization of genetic resources and monetary benefits should be shared from commercial uses. Unpacking and understanding these views is critical to making progress toward a viable DSI ABS solution.

1. *View 1: DSI is not within the definition of "genetic resources" but may result from utilization of genetic resources and can be addressed in MAT. Beyond MAT, DSI itself is a global non-monetary benefit and no further benefit-sharing for its use need be provided.*

Holders of this view tend to be developed countries, industry or academic commentators sounding the alarm that any limitations on access to DSI caused by ABS laws would be damaging to genetic resource-based innovation and conservation efforts involving DNA barcoding in rich and poor countries.[152] While lauding the many benefits of open access for all countries, these voices decry access limitations and seek to characterize any benefit-sharing obligations (outside the MAT context) as being met by the non-monetary benefits DSI (or Genome/Genetic Sequence Data ("GSD"), a term some holders of this view prefer to DSI)[153] intrinsically provides to all. They also assert that the use of the phrase "genetic *material*" in the CBD and Nagoya Protocol excludes intangible subject matter.[154]

Proponents of this view include Canada, the EU and its Member States, and Japan. In particular, the following assertions are taken from official submissions to the CBD Secretariat:

Canada: "As GSD is effectively obtained via the utilization . . . . on genetic resources, it should be regarded as a result of such utilization. The sharing of these results (the GSD) via access to databases and technology should thus be regarded as a valuable form of non-monetary benefit-sharing, shared openly and globally via benefit-sharing arrangements as set out in mutually-agreed terns to cover the tangible genetic resources."[155]

152. *See, e.g.,* Jim Gaffney et al., *Open Access to Genetic Sequence Data Maximizes Value to Scientists, Farmers, and Society*, 26 Glob. Food Sec. 1, at 6 (2020); *infra* note 163; Int'l Chamber of Com. et al., *Promoting Sustainable Use and Conservation of Biodiversity Through Open Exchange of Digital Sequence Information*, Int'l Chamber of Com. 1–2 (May 24, 2019). Convention on Biological Diversity, *Subsidiary Body on Scientific, Technical and Technological Advice*, https://www.cbd.int/sbstta/ [https://perma.cc/99P6-ZYF9].

153. *See* Subsidiary Body on Scientific, Technical and Technological Advice, *Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources*, U.N. Doc. CBD/SBSTTA/22/INF/4 CBD/DSI/AHTEG/2018/1/4 (2018) ("Some experts noted that "genetic sequence data" is widely used and is a clear term in the scientific community."); *see also* Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources,' *Synthesis of Views and Information on the Potential Implications of the Use of Digital Sequence Information on Genetic Resources for the Three Objectives of the Convention and the Objective of the Nagoya Protocol*, U.N. Doc CBD/DSI/AHTEG/2018/1/2, at 34 (Jan. 9, 2018) (noting that Canada and the United States were "Two Governments [that] preferred the term 'genetic sequence data'").

154. *Id.* at 35.

155. *See* Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, *supra* note 126, at 20.

The EU and its Member States: "DSI is not equivalent to a genetic resource. . . . [t]hat said, we note that conditions for generating and using DSI (in case of non-commercial as well as commercial use), which come from utilization of genetic resources within the scope of the Protocol, can be specified in mutually agreed terms (MAT) when a genetic resource is accessed in accordance with domestic measures on access and benefit-sharing . . . . [unrestricted access to DSI] can be considered to be a form of non-monetary benefit-sharing."[156]

Japan: "'Genetic resources' . . . . refer to tangible materials, and thus do not include DSI/GSD . . . . Mutually agreed terms (MATs), concluded at the time of access to a genetic resource for its utilization, may theoretically cover benefit-sharing from the use of DSI/GSD on the genetic resource . . . ."[157]

Consider further the following from a joint statement submitted to the CBD Secretariat by a consortium of public and private stakeholders (including in industry and academia):

> The unencumbered access to and use of DSI now in the *public domain* benefits countries at all levels of development – it supports conservation, fosters research into technological solutions to tackle societal challenges, and benefits the population as a whole . . . . The rate of scientific advancement and technological development is heavily dependent on unencumbered access to and use of publicly available DSI. Barriers to the sharing and use of DSI would discourage innovation and scientific research. Extensive tracking and tracing mechanisms would be needed – if they were even possible . . . . The net effect on conservation and sustainable use of biodiversity could be negative and in contradiction with the objectives of the CBD and the Nagoya Protocol . . . . *{T}he open sharing of DSI represents a form of non-monetary benefit sharing*.[158]

An interesting aspect of this statement is the implication that because DSI is valuable for research that benefits everyone, no monetary benefits need to be shared for its use. There are at least two weaknesses in this argument. First, provider countries and civil society generally agree that everyone benefits from advancements enabled by open DSI sharing; however, "open" sharing does not equal "just" sharing. Not everyone benefits equally from DSI. This is due to a variety of factors, including, for many provider countries, a lack of R&D absorptive capacity (including equipment, trained

156. *Id.* at 29–30.

157. *Id.* at 34. Switzerland's submission also reflects this view. *See id.* at 42 ("In the view of Switzerland, the terms 'genetic resources' and 'genetic material' clearly refer to tangible matter, while DSI does not fulfil the criteria the definitions of either 'genetic material' or 'genetic resources' under the Convention and the Nagoya Protocol, and therefore is not covered by those instruments.").

158. Int'l Chamber of Com. et al., *Promoting Sustainable Use and Conservation of Biodiversity Through Open Exchange of Digital Sequence Information*, Int'l Chamber of Com. at 1–2 (May 24, 2019) (emphasis added).

personnel, and sometimes even stable electricity and refrigeration) to be able to research and innovate with DSI.[159]

Second, there are many, many patented inventions that benefit all of us, such as cell phones and pharmaceuticals. Yet the owners of patents on large and small elements of those products still expect to be compensated for their use during the term of the patents.[160] Is it just or equitable to deny providers of the genetic resources used to produce DSI a monetary share in its utilization as well?

Gaffney et al. appear to go even further, arguing that the imposition of *any* additional ABS obligations will have a significant negative impact on the future of biological research.[161] This assertion is of dubious validity. While it is not difficult to imagine DSI access limitations negatively affecting research, non-monetary benefit-sharing could help advance biological research by, *inter alia*, pairing provider country scientists (with diverse knowledge capabilities) with user country researchers.[162] In addition, mone-

159. Even the lack of a critical mass of geographically proximate, skilled researchers is a disadvantage. As Paul Stephan notes: "[I]nnovation has a geographic dimension. Knowledge transmission seems to benefit from physical proximity among knowledge workers. In spite of the revolution in remote access over the last forty years, knowledge seems to grow best where innovators have intensive personal contacts with each other." Paul Stephan, *supra* note 121, at 12 (citing Paul Krugman, *Increasing Returns and Economic Geography*, 99 J. Pol Econ. 483 (1991)); *see also* Nirav Patel, *Figure of the Week: Electricity Access in Africa*, Brookings (Mar. 29, 2019), https://www.brookings.edu/blog/africa-in-focus/2019/03/29/figure-of-the-week-electricity-access-in-africa/ [perma.cc/6BRS-9NNK] ("The lack of access to electricity primarily constrains modern economic activities, provision of public services, and quality of life. In addition, it severely limits adoption of emerging technologies in sectors such as banking, education, agriculture, and finance that could otherwise alleviate some of the core challenges facing Africans . . . .").

160. Of course, one of several important differences between a patent and a genetic resource is that patents do have a limited term. *See, e.g.*, Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154; The Agreement on Trade-Related Aspects of Intellectual Property Rights, Jan. 1, 1995, Annex 1C, art. 33 ("The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date"). Nevertheless, set periods for users to provide monetary benefits for the use of genetic resources or DSI could be created, similarly to the system of limited term royalties for uses of indigenous knowledge in South Africa. *See* The Indigenous Knowledge Protection Bill (2018), South African Parliament, Proceedings on Bills, 2018 Fifth Session, Fifth Parliament (Oct. 19, 2018), described in Margo A. Bagley, *Toward an Effective Indigenous Knowledge Protection Regime: Case Study of South Africa*, CIGI Papers No. 207, at 21–22 (2018).

161. Jim Gaffney et al., *Open Access to Genetic Sequence Data Maximizes Value to Scientists, Farmers, and Society*, 26 Glob. Food Sec. 1, at 6 (2020) ("Allowing the imposition of additional Access and Benefit-Sharing (ABS) obligations for the use of [DSI]—other than through the existing mechanism of mutually agreed terms—will have a significant negative impact on the future of biological research and the benefits resulting from it . . . .").

162. *See, e.g.*, Bagley et al., *supra* note 26, annex E (Jan. 29, 2020) (containing the study of Hartmut Meyer, *Case Study: Using Clauses in ABS Contracts and NTAs to Regulate Further Uses of DSI from African (Multi-Country) Livestock Genetic Resources*, which describes agreements from livestock research collaborations between African and European researchers); Michael Halewood et al., *Plant Genetic Resources for Food and Agriculture: Opportunities and Challenges Emerging From the Science and Information Technology Revolution*, 217 New Phytologist 1407, 1409–10 (2018) ("A more formal and extensive partnership between farmers, researchers and other actors to facilitate the flow of information stands to substantially enhance benefits to the variety of plant genetic resources stakeholders . . . . [R]aw sequence information, if it is to be correctly interpreted and exploited, needs to be integrated with an intimate knowledge of the biology of the species under consideration, the phenotype or performance of the individuals or population that has been sequenced, and the agro-ecosystem in which they have been grown, including the cultural context and farmers' management practices").

tary benefit-sharing could, in theory, be accomplished with something in the nature of a low-level tax, and research proceeds apace despite taxes all the time.

Such overly broad statements likely arise from the justifiable apprehension that ABS conditions on DSI could, if poorly crafted, result in unreasonable impediments to product research and/or commercialization. Nevertheless, they seem more likely to engender fear and ill-will than real progress towards a win-win solution.[163] The statement also evidences a lack of appreciation of the legitimacy of certain provider country concerns regarding the inherent value and contributions of genetic resources to the development of new inventions.

Also problematic is Gaffney et al.'s highlighting of Ethiopian teff as a crop that could be made more productive through research on its DSI.[164] That may be true, but the results of such research would likely be patented, and the article nowhere mentions the teff flour patent obtained surreptitiously by a Dutch company which resulted in closed markets and significant losses for Ethiopia, which does not share in the license revenue from the patent on valuable downstream processed products.[165] It is not at all clear why, if DSI access is unrestricted, provider countries should be precluded from monetarily benefiting from patents on DSI inventions if a low-cost sharing mechanism can be developed.

Gaffney et al. correctly note the generally low value of any particular sequence, and that it is when DSI is aggregated that meaningful value is normally generated.[166] They also note the considerable effort that goes into transforming raw materials into downstream products. But these descriptions simply do not justify an absence of monetary benefit-sharing. Moreover, all patented inventions do not involve a significant expenditure of effort as neither level of effort nor R&D spending are criteria for patentability.[167] Considerations of value and level of contribution should rather go to a deter-

163. In that sense it is reminiscent of Jack Valenti, then head of the Motion Picture Association of America (MPAA) who testified before Congress in 1982 that "the VCR is to the American film producer and the American public as the Boston Strangler is to the woman home alone." *Hearings on Home Recordings of Copyrighted Works*, H.R. 4783, H.R. 4794 H.R. 4808, H.R. 5250, H.R. 5488, and H.R. 5705 Before the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the Committee of the Judiciary, 97th Cong. (1982) (statement of Jack Valenti, President, Motion Picture Association of America). The VCR went on to become one of the most important (and lucrative for the motion picture industry) inventions of the twentieth century, with movie studios making more from television (due to VCRs) than from theater showings. *See* Stephen Advokat, *New Era for Hollywood: VCR Profits Outstrip the Theaters*, CHICAGO TRIB. (Jan. 3, 1986).

164. Gaffney et al., *supra* note 163, at 4–5.

165. REGINE ANDERSEN & TONE WINGE, THE ACCESS AND BENEFIT-SHARING AGREEMENT ON TEFF GENETIC RESOURCES: FACTS AND LESSONS VI (FRIDTJOF NANSEN INST., 2012) (noting that "[i]n practice, the teff patent excludes all other parties, including Ethiopia itself, from utilizing teff for most forms of relevant production and marketing in the countries where the patent is granted.").

166. Gaffney et al., *supra* note 163, at 2.

167. *See* Onwuekwe, *supra* note 44, at 83 (noting that "huge research and development costs are neither synonymous with innovation nor one of the criteria for patent protection.").

mination of the *amount* of benefits to be shared, not to whether there is a *need for* benefit-sharing at all.

This view can be characterized as *"'What's Yours is Mine and What's Mine is Mine'*: I can use *your* resources (DSI) and not share any monetary benefits *I* generate from them with you." In a sense, it represents a mindset that does not consider the claims of owners of genetic resources as on a par with owners of other types of research inputs, such as patented inventions. This also seems implicit in the earlier reference to DSI being in the "public domain."[168] The fact that information is publicly available does not mean that it is in the public domain and thus owned by no one. The phrase "public domain" is a national construct and is widely understood in the context of intellectual property to mean that some subject matter is no longer (or was never) protected by exclusive rights under a particular regime, such as patent, copyright, or a *sui generis* protection system, in a given territory. [169]

Whereas no one owns the public domain, however defined, much publicly available information is understood to still be subject to exclusive rights, such as the information disclosed in an issued, non-expired patent document within a particular territory. In fact, many sequences in GenBank are patented and the database includes the following disclaimer:

> The GenBank database is designed to provide and encourage access within the scientific community to the most up-to-date and comprehensive DNA sequence information. Therefore, NCBI places no restrictions on the use or distribution of the GenBank data. However, some submitters may claim patent, copyright, or other intellectual property rights in all or a portion of the data they have submitted. NCBI is not in a position to assess the valid-

168. *See supra* note 162.

169. *See* Ruth L. Okediji, *Negotiating the Public Domain in an International Framework for Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions*, *in* PROTECTING TRADITIONAL KNOWLEDGE: THE WIPO INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE 145 (Daniel Robinson et al. eds., 2017). As Professor Okediji explains:

> [T]here is no single public domain. Rather, every form of IP produces a differently constituted public domain. In copyright law, for example, the public domain includes unprotectable subject matter . . . . and expired copyrighted works . . . . The public domain in patent law similarly comprises ineligible subject matter, expired patents, invalidated patents and prematurely expired patents for which maintenance fees were not paid. And . . . . in practice countries have different terms of patent protection, with some allowing term extensions and adjustments while others do not. In trademark law, the public domain consists mainly of subject matter that has lost its source-identifying function.

See also WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Note on the Meanings of the Term "Public Domain" in the Intellectual Property System with Special Reference to the Protection of Traditional Knowledge and Traditional Cultural Expressions/Expressions of Folklore*, WIPO/GRTKF/IC/17/INF/8, 1–2 (Nov. 24, 2010) ("The public domain, in intellectual property (IP) law, is generally said to consist of intangible materials that are not subject to exclusive IP rights and which are, therefore, freely available to be used or exploited by any person. The public domain is, however, an elastic, versatile and relative concept and it is not susceptible to a uniform legal meaning.").

> ity of such claims, and therefore cannot provide comment or unrestricted permission concerning the use, copying, or distribution of the information contained in GenBank.[170]

Nevertheless, as the United States is not a party to the CBD, unpatented DSI in GenBank might be considered in the public domain here, but the exact same DSI in the companion European Nucleotide Archive database might not be, depending on whether DSI is viewed as within the scope of the EU Regulation as a product of utilization of genetic resources.

2. *View 2: The definition of "genetic resources" should be interpreted to include DSI such that DSI is subject to PIC/MAT under the Nagoya Protocol*

This is the approach of countries in DSI study #4 that are including intangible sequence information within the definition of "genetic resources," and, in some cases, regulating access to DSI even apart from access to physical genetic resources. These parties appear to take the view that a "broad and dynamic" understanding of the concept of genetic resources encompasses DSI.[171]

As noted above, the CBD and Nagoya Protocol define "genetic resources" as "genetic material of actual or potential value," and "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity."[172] "Material" sounds inherently tangible, making the inclusion of DSI in the definition of "genetic resources" a difficult fit. Nevertheless, a 2010 study commissioned by the CBD Secretariat concluded that the meaning of the phrase is potentially "dynamic and flexible" to give effect to the spirit of the CBD.[173]

More problematic, however, is what flows from defining "genetic resources" to include DSI. Namely, access and benefit-sharing obligations attach to DSI if it is a genetic resource.[174]

---

170. *GenBank Overview*, Nat'l Ctr. for Biotechnology Info., https://www.ncbi.nlm.nih.gov/genbank/ [https://perma.cc/C6AK-QHW7].

171. Bagley et al., *supra* note 26, at 14–18 (identifying Bhutan, Malaysia, Peru, Bolivia, China, Colombia, Kenya, Mozambique, Oman, Peru, Uganda as countries taking this approach, although not all are actively imposing requirements); *see also* Peter Schei & Morten Walløe Tvedt, 'Genetic Resources' in the CBD: The Wording, the Past, the Present and the Future 22 (Fridjtof Nansen Inst. 2010) (positing a "broad and dynamic" understanding of the concept of scope in the CBD).

172. CBD, *supra* note 25, art. 2; *see* Nagoya Protocol, *supra* note 25, art. 2 ("The terms defined in Article 2 of the Convention shall apply to this Protocol.").

173. Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, *The Concept of "Genetic Resources" in the Convention on Biological Diversity and How it Relates to a Functional International Regime on Access and Benefit-Sharing*, U.N. Doc. UNEP/CBD/WG-ABS/9/INF/1, at 34 (Mar. 19, 2010).

174. *See* Nagoya Protocol, *supra* note 25, art. 6 ("[A]ccess to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.").

Proponents of access limitations on DSI to facilitate benefit-sharing appear unrealistic in their descriptions of the ease with which DSI could be governed under the existing bilateral regime of the Nagoya Protocol. A study by Ambler et al. rightly notes the historical inequality in relationships between high-income country researchers and vulnerable communities and the ineffectiveness of "trust" relationships to ensure benefit-sharing.[175] It describes initiatives on Indigenous Data Sovereignty and efforts to break the exploitation cycle that are laudable and worthy of closer investigation.[176] However, the authors' solutions of improving track and trace mechanisms or employing new technologies for tracing DSI, such as blockchain,[177] seem surprisingly dismissive of the major challenges that the implementation of the Nagoya Protocol poses for many countries and the non-trivial hurdles employing blockchain for DSI would entail.[178]

Blockchain, one of the most "hyped" technologies today,[179] is incredibly energy-intensive, requiring billions of calculations on computers, which currently require coal or fossil-fuel powered electricity.[180] As DSI Study #2/3 explains, a blockchain system could only be applied to newly generated DSI because it would require a separate, standalone system outside of the public databases and funding for that system and its upkeep.[181] A separate system would be required because much DSI in the public databases is not relevant to ABS, either because it is from humans or from the United States (one of the top four sources of sequence data in INSDC) or another country that does not require ABS for their genetic resources or information.[182] Blockchain would be further limited for DSI because DSI is often not

175. Jon Ambler et al., *Including Digital Sequence Data in the Nagoya Protocol Can Promote Data Sharing*, 39 Trends in Biotechnology 116, 117 (2020).

176. *Id*. at 120. ("The Indigenous Data Sovereignty (IDS) movement recognises individual and collective rights of indigenous peoples to control data from and about their communities and lands, and to privacy."); *see also* Maggie Walter & Michele Suina, *Indigenous Data, Indigenous Methodologies and Indigenous Data Sovereignty*, 22 Int'l J. Soc. Rsch. Methodology 233, 237 (2019).

177. Blockchain is a distributed transaction solution comprising a continuously growing ledger shared by many network participants. Blockchain is designed to provide security, anonymity, and data integrity for transactions without a third party in control. Whereas currency transactions between entities are often centralized and controlled by a third-party organization such as a bank, blockchain can eliminate the need for that third party's presence as a trusted intermediary. Blockchain can store conditions of use for information that travel with the information and bind downstream users. *See, e.g.*, Jesse Yli-Huumo et al., *Where Is Current Research on Blockchain Technology?—A Systematic Review*, PLOS ONE 1–2 (2016).

178. *See* Ambler et al. *supra* note 178, at 119 ("A blockchain distributed ledger . . . could be repurposed for DSI governance, especially if future iterations of the technology address its environmental footprint.").

179. Paul Oldham, Digital Sequence Information: Technical Aspects 43 (2020) (providing a detailed discussion of the possibility of using blockchain technology for DSI benefit-sharing).

180. *See, e.g.*, Jon Truby, *Decarbonizing Bitcoin: Law and Policy Choices for Reducing the Energy Consumption of Blockchain Technologies and Digital Currencies*, 44 Energy Rsch. & Soc. Sci. 399, 401 (2018).

181. Rhoden et al., *supra* note 132 at 57–61 (noting the near impossibility of tracing DSI once it leaves a database).

182. *Id.* at 59–60. For example, the authors of DSI Study #2/3 note that the UK's Darwin Tree of Life project, which plans to sequence 66,000 UK species at a cost of ~100 million GBP, will feed into the Earth Biogenome Project. But it will not go into the theoretical EBG project blockchain system; rather,

uniquely attributable to a particular country, the required computational power would be enormous,[183] and aligning such a system with the existing database system difficult to even envision. Ambler et al. fail to grapple with these fundamental challenges.[184]

The authors of DSI study #2/3 explain in detail the numerous problems with attempting to use blockchain to trace DSI utilization for benefit-sharing and its fundamental differences to Bitcoin, where it is used successfully. They note:

> An incentive is needed to get external stakeholders to give their computational power to the [blockchain] system. It is estimated that bitcoin currently consumes 72.57 terawatt hours annually, comparable to the energy consumption of Austria, which costs 3.628 billion USD annually. . . . At the moment, the worth of bitcoins paid to these stakeholders called bitcoin miners, is higher than the energy cost they invest. *For a blockchain outside of a cryptocurrency application, other financial incentives for these computing costs need to be found or created, which is why to-date, very few blockchain applications exist* . . . .
>
> A major problem for blockchain's applicability to NSD traceability is the possibility of circulation of NSD outside the system. NSD can easily be downloaded, shared online, sent via email and manipulated. *Bitcoin, if taken outside of the block chain is worthless and thus strongly motivates users to stay in the blockchain. NSD outside of a blockchain based sequence system is still NSD and has no loss of value.* In other words, users are motivated to stay in the Bitcoin blockchain because otherwise all value is lost. This motivation would not exist for NSD.[185]

It thus is possible that the costs of the blockchain system could exceed the benefit-sharing monies generated, as many, if not most, uses of DSI would not result in commercialized products.

---

the sequences will be deposited into the INSDC because the UK does not impose ABS obligations and will want the DSI available as open access via the INSDC.

183. *Id.* at 58.

184. The virtues of using blockchain for the Earth Biogenome Project and Earth Bank of Codes have also been touted in a recent article. *See* Michelle Rourke et al., *supra* note 42 (these authors assert that the planned use of Blockchain in the Earth Biogenome Project ("EBG") will track and distribute benefits, without explaining how this will be accomplished). *But see* Rohden et al., *supra* note 132, at 60 (discussing the blockchain system envisioned by the promoters of the EBG, and stating "the whole project is in a rather early stage, there is no concrete information obtainable on how exactly, or whether at all, the blockchain system will be used, how it is going to work, what the costs might be, and who will pay for them."); Paul Oldham, *supra* note 179 (noting that details of the project are "surprisingly hazy.").

185. Rhoden et al., *supra* note 132, at 58, 61. Without that motivation, and with the ability to obtain NSD from the public databases and other sources, finding parties willing and able to invest in the creation of a successful blockchain system seems unlikely in the extreme.

The impracticality of such proposals is further underscored by the lack of success in achieving DSI monetary benefit-sharing in countries that have already adopted domestic measures on DSI. According to DSI Study #4, none of the countries with domestic measures regulating access to DSI reported receiving monetary benefits from DSI utilization.[186] This fact is likely attributable in part to the near impossibility of identifying third party uses and users of DSI once it is uploaded to publicly accessible databases such as the INSDC consortium.[187] As a response to the Ambler et al. article explained, "MAT do not solve the DSI issue, especially once data are published, highlighting the limitations of taking a bilateral approach for DSI. Although the INSDC database infrastructure has made the provenance of uploaded sequences a mandatory requirement, databases are neither regulatory authorities nor parties to MAT and cannot check 'MAT-compliant data consumption' as suggested by the authors."[188]

This view also does not truly engage with the myriad ways in which DSI is used in research and commercialization efforts. For example, as described in a submission by the International Chamber of Commerce ("ICC") arguing against the inclusion of DSI within the scope of the Nagoya Protocol, "in state-of-the-art bioinformatics projects, hundreds to thousands of . . . . sequences may be used to develop a particular commercial product. The final product has a sequence that represents an "average" of all input sequences; [thus] it is virtually impossible to determine the relative value of each individual input sequence."[189] While a single sequence can be valuable, such as in the Ebola drug scenario, the vast majority of uses of DSI involve aggregating sequence information for screening purposes where the individual value of any given sequence is negligible. And even with the Ebola sequence, its value was contingent on having a wealth of other existing sequences/genomes to compare it to so that the section of therapeutic interest could be identified.[190]

While perhaps understandable, View #2 is also unfortunate, as inclusion of DSI within the ambit of "genetic resources" is likely to lead to even poorer outcomes for both research and benefit-sharing on DSI as compared

186. *See* Bagley et al., *supra* note 26, at 11, 25.

187. Rhoden et al., *supra* note 132 at 35 ("Unfortunately, it is not possible to know what happens with ftp- or web-page-downloaded NSD after it is removed from an INSDC member or any other database. This is a point at which traceability of NSD can break down if downstream users . . . do not maintain the AN system of traceability . . . It is therefore not possible to get information on subsequent usage and sharing of data.").

188. Elizabeth J. Karger and Amber Hartman Scholz, *DSI, the Nagoya Protocol and Stakeholders' Concerns*, 36 TRENDS BIOTECH. 110, 111 (2021). In other words, public databases have neither the remit, capability, desire, nor authority to check for MAT compliance for the millions of sequences deposited and accessed each day.

189. ICC TASK FORCE ON ACCESS AND BENEFIT-SHARING, DIGITAL SEQUENCE INFORMATION AND THE NAGOYA PROTOCOL 3 (Int'l Chamber of Com., 2017).

190. *See generally* Se-Ran Jun et al., *Ebolavirus Comparative Genomics*, 39 FEMS MICROBIOL REV 764, 764 (2015) (describing the use of more than 100 ebolavirus genomes to "predict regions that could contain epitope-binding sites, which might be good vaccine targets.").

to physical genetic resources, due to the arguably greater challenges in valuing sequence information. Already, some users are reporting unrealistic demands and expectations from certain provider countries seeking large profit percentages that may be difficult to justify in light of both uncertainty about the role the resource/information will actually play in research and its expected contribution.[191] Negotiating value seems particularly challenging for DSI and is likely to lead to providers seeking a disproportionate share of the value of DSI utilization both in terms of the contribution a single sequence may make to a particular invention and the commercial value of the total invention, which could have numerous inputs.

As such, this view could be characterized as "'*What's Mine is Mine and What's Yours Is Mine': We own the DSI, and you need our permission to use it and must share with us significant monetary benefits from whatever you create using it no matter the size of the actual DSI contribution.*"

However, the near impossibility of being able to track or trace the expanding number of uses of DSI does not bode well for holders of this view because of the myriad ways DSI is used in research. In particular, both in exploratory work such as alignment searches, and in the synthesis of finished products, detection of uses may not be possible, as the following examples illustrate.[192]

a. Alignment Searches

Researchers can use a variety of different alignment tools such as the Basic Local Alignment Search Tool ("BLAST"),[193] to search a sequence database for genes similar to those found in a specific organism or used in a particular biosynthesis pathway. In one study, researchers used BLAST and other tools to search for genes similar to those used in the biosynthesis of Gibberellic Acid ("GA"), a compound that regulates plant growth and is useful in, inter alia, developing dwarf coconut trees. The researchers identified seven such genes in other model plant species, which enabled them to predict the likely function of the genes in GA biosynthesis.[194] BLAST searches "use" all of the

191. *Id.*; Milieu Law & Policy Consulting, *supra* note 95, at 16, 22. It is worth noting that this problem is not exclusive to providers in the global South, as the report further explains:

> All interviewed companies and research organizations that reached the stage of obtaining a PIC and MAT experienced difficult negotiations, as some provider countries . . . . have unrealistic expectations concerning the benefit-sharing, for example by requesting large percentages of the profits. This causes delays and, in some cases, has prevented research from occurring altogether. In one notable example, an interviewee . . . . decided to stop negotiations after four years due to unreasonable and excessive demands placed by Maltese authorities.

192. These examples are all taken from Bagley & Perron-Welch, *supra* note 134.

193. *See* National Center for Biotechnology Information, *Basic Local Alignment Search Tool,* U.S. NAT'L LIBR. OF MED., https://blast.ncbi.nlm.nih.gov/Blast.cgi [perma.cc/8KFE-2BEY]. ("BLAST finds regions of similarity between biological sequences. The program compares nucleotide or protein sequences to sequence databases and calculates the statistical significance.").

194. Shafeeq Rahman et al., *Transcriptome-Based Reconstruction of Gibberellic Acid Biosynthetic Pathway in Coconut (Cocos Nucifera L.)* 10 RSCH J. BIOTECH. 56, 63 (2015). There were several intermediate steps and additional databases used in the process. It appears that the authors sequenced the GA enzymes and did

sequences in a database, such as GenBank, in the sense that they are all searched for homology to the reference sequence. An enormous and increasing number of sequences are present in public and private databases and vast numbers of users are conducting searches, some for commercial and others for non-commercial purposes. Thus, assigning a monetary value to any particular sequence based on whether its use is for a commercial or non-commercial purpose, and even tracing its use by entities running BLAST-type[195] searches is currently not feasible.

BLAST alignment searches also may enable a researcher, seeking to use a sequence from a sample to which ABS obligations attach, to locate similar sequences in species from different geographical origins that may lack ABS requirements.[196] Given the difficulties in tracking the use of DSI, such alignment searches may allow a researcher who is so inclined to misstate the true origin of the information utilized in her or his R&D efforts.[197]

b. Synthetic Production of Finished Products

A similar example involves the successful enhancement of the yield of D-glucaric acid, a compound with commercial uses and therapeutic potential, which involves constructing a biosynthetic pathway to produce the acid in *E. coli*. by "combining biological parts from disparate organisms."[198] Development of the biosynthetic pathway required no tangible material from any of the species whose DNA was incorporated into the *E. coli.* Furthermore, the final product is indistinguishable from glucaric acid produced by other means. Therefore, if this biosynthetic system were incorporated into a glu-

---

an alignment using tblastn, which is a function within BLAST that identifies sequences that encode proteins similar to the protein searched. They also used HMMER, which is similar to BLAST, for alignment. They used the alignment to identify thirty-seven genes with homology towards the GA biosynthetic pathway and then used the gene ontology knowledgebase through Blast2GO, which uses BLAST to annotate the functions of the identified genes using existing data. Finally, they compared the annotated genes obtained from gene ontology to the KEGG pathway database, which provides maps of molecular interactions in metabolic pathways, such as biosynthesis. By comparing the thirty-seven genes with homology to the KEGG reference pathway, they were able to identify the seven major genes in the GA pathway. *See* KEGG Pathway Database, https://www.genome.jp/kegg/pathway.html [https://perma.cc/4NSD-L7WK]; Mark Yandell & Daniel Ence, *A Beginner's Guide to Eukaryotic Genome Annotation*, Nature Review Genetics (Apr. 18, 2002), https://www.nature.com/articles/nrg3174 [https://perma.cc/5GRF-46HF]; and Geneontology, http://geneontology.org/ [https://perma.cc/N9EC-9Y82].

195. BLAST is not the only search tool of its kind. There are numerous other tools such as FASTA, BLAST+, BLASTn, and Blast2GO.

196. Margo A. Bagley, *Towering Wave or Tempest in a Teapot? Synthetic Biology, Access and Benefit-Sharing, and Economic Development*, *in* Intellectual Property and The Regulation of The Internet 95 (Susy Frankel and Daniel Gervais eds., 2017).

197. *See* Working Group on Reform of the Patent Cooperation Treaty (PCT), *Further Observations by Switzerland on its Proposals Regarding the Declarations of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO PCT/R/WG/7/9, Annex 4 (Apr. 5, 2005).

198. Namely myo-inositol-1-phosphate synthase (INO) from *Saccharomyces cerevisiae* (yeast), an endogenous *E. coli* phosphatase, myo-inositol oxygenase (Miox) from *Mus musculus* (mice) and uronate dehydrogenase (udh) from *Pseudomonas syringae*. *See* Tae Seok Moon et al., *Production of Glucaric Acid from a Synthetic Pathway in Recombinant Escherichia Coli*, 75 Applied & Env't Microbiology 589 (2009).

caric acid manufacturing pipeline, there would be no way to know from the finished product that DSI from several species had been used in its production.[199]

DSI Study #1 identified another pertinent example involving the production of bioethanol. It notes:

> Related genes from different organisms can be 'shuffled' to produce 'chimeric' enzymes. These can be tested to determine if they have increased productivity, in this case the production of bioethanol. These genes can be reshuffled until enzyme activity is optimized. Shuffled genes that express chimeric enzymes are difficult to trace back to an originating DNA sequence as this is a product of the gene families used and the shuffling process.[200]

To be clear, there currently is no agreement among CBD/Nagoya Protocol parties that benefit-sharing obligations attach to the information described in these examples. Nevertheless, in each case, DSI from multiple diverse organisms is being utilized. If DSI is deemed to be within the definition of genetic resources, users would, in theory, be obligated to track the utilization of untold numbers of sequences and negotiate MAT with multiple governments. Yet, provider country/countries of origin information for sequences may not be available as the database operators may not have required sequence submitters to provide such information.[201] Moreover, even if such information is available, it effectively would be impossible to negotiate benefit-sharing contracts with each provider country with a benefit-sharing claim due to prohibitive transaction costs involved in properly valuing

199. In another oft-cited example, researchers designed and produced a synthetic copy of thebaine, the opiate morphine precursor harvested from poppies for millennia, using yeast embedded with genetic sequence information from several plant species, a bacterium, and a rodent. Robert F. Service, *Modified Yeast Produce Opiates from Sugar*, 349 SCIENCE 677 (2015). But many more such examples exist, including a similar process using yeast or *E.coli* to produce the flavor and fragrance ingredient vanillin, which could include the use of a variety of genes or biosynthetic pathways from various donor organisms, including the vanilla orchid (*Vanilla planifolia*), humans, or bacterial species, among others. *See, e.g.*, Nethanji J. Gallage & Birger Lindberg Møller, *Vanillin—Bioconversion and Bioengineering of the Most Popular Plant Flavor and Its De Novo Biosynthesis in the Vanilla Orchid*, 8 MOLECULAR PLANT 40 (2015) ("[A]n entirely new opportunity for biotechnology-based production of natural vanillin may arise from the recent identification of the vanillin synthase enzyme VpVAN from the vanilla orchid, *Vanilla planifolia and from ground ivy (Glechoma hederacea)*." (emphasis added); *see also* Prashanth Srinivasan & Christina D. Smolke, *Engineering a Microbial Biosynthesis Platform for De Novo Production of Tropane Alkaloids*, 10 NATURE COMMC'N 3634 (2019) (describing "[d]e novo production of tropine, a key intermediate in the biosynthetic pathway of medicinal Tropine alkaloids such as scopolamine, from simple carbon and nitrogen sources in yeast (Saccharomyces cerevisiae)"); Wael Houssen et al., *Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use*, U.N. Doc. CBD/DSI/AHTEG/2020/1/3 (Jan. 29, 2020) (citing Toby H. Richardson et al., *A Novel, High Performance Enzyme for Starch Liquefaction. Discovery and Optimization of a Low PH, Thermostable Alpha-Amylase*, 277 J. BIOL. CHEM. 26501 (2002) (describing method of biofuel production uses genetic components from multiple different species and also utilizes vast amounts of genetic information without the need for physical access to the genetic resources).

200. Houssen et al., *supra* note 199.

201. Rohden et al., *supra* note 132. The country tag in INDSC became a required field for environmental samples in 2011.

the contributions of myriad sequence fragments.[202] Since such uses, however, generally cannot be traced, no bilateral benefit- sharing would take place for numerous untraceable uses of DSI.

The specter of DSI access limitations is a growing concern to users who view open access to DSI as of inestimable value. Already in relation to physical material, difficulties in gaining access to genetic resources have resulted in some users losing significant amounts of time and money in efforts to negotiate PIC and MAT, or choosing to not use resources from countries seen as "difficult."[203] Moreover, in May of 2020, the U.S. State Department held a "Public Teleconference Concerning the Use of Digital Sequence Information on Genetic Resources" with over 150 participants, several of whom shared experiences and expressed concerns with access limitations on DSI and physical genetic resources.[204] As one official noted, "the United States government opposes moves to restrict or control access to and use of DSI. . . . We view efforts to restrict or control access and use, as unacceptable and a threat to R&D, food security and public health."[205]

Fortunately, there is another, arguably superior, way to view DSI as comfortably within the scope of the CBD and Nagoya Protocol: DSI results from the utilization of genetic resources.

3. *View 3: DSI is not within the definition of "genetic resources," but does result from their utilization. Monetary benefits should be shared from commercial uses. DSI's intrinsic non-monetary benefits, while important, are not sufficient to comply with Nagoya Protocol obligations.*

Several biodiversity-rich countries and civil society groups seem amenable to this interpretive approach, agreeing that the term "genetic resources"

202. As noted in one private sector submission, "should DSI be included in the scope of the Protocol, the administrative burden of negotiating a myriad of ABS agreements for sequences with debatable input value will be significant." ICC Task Force on Access and Benefit-Sharing, *supra* note 189, at 3. But as other commentators note, "developments in synthetic biology could make governments reluctant to share [DSI] on openly accessible databases if it means they could miss out on benefits that might otherwise be gained by enforcing their domestic ABS laws." Michelle Rourke et al., *Policy Opportunities to Enhance Sharing for Pandemic Research*, 368 SCIENCE 716, 717 (2020). This comment was made in the context of sharing pathogenic virus sample information but is also applicable to other subject matter regulated by domestic ABS laws.

203. *See* Milieu Law & Policy Consulting, *supra* note 95, at 29–30 (estimating the cost of obtaining PIC/MAT for E.U. users as between €500 to €10,000 per negotiation and requiring up to 500 personnel hours. Some interviewees stated that they no longer work with new genetic resource stocks due to ABS difficulties. Instead, they reuse in-house stocks or identify countries that have more lax ABS requirements. Others reported considering relocating out of the European Union to a country like the United States where ABS compliance requirements are not imposed).

204. *See* U.S. Department of State, *Notice of Public Teleconference Concerning the Use of Digital Sequence Information of Genetic Resources*, 85 FED. REG. 23, 121 (Apr. 24, 2020); *see also* Transcript from the U.S. Department of State Public Teleconference on the Use of Digital Sequence Information of Genetic Resources (May 14, 2020).

205. Transcript of Comments from Christine Dawson, Dir. of the Off. of Conservation and Water in the Bureau of Oceans and Int'l Envi'tl and Sci. Aff. in the Dep't. of State.

refers to tangible material, but also agreeing that DSI is the result of genetic resource utilization. Some may take the view that DSI is within the scope of the CBD and Nagoya Protocol because either the phrase "genetic resources" or the phrase "utilization of genetic resources" should be deemed to encompass DSI.[206] Knowing the exact basis for why DSI is within the scope of the CBD and Nagoya Protocol, however, is critically important. If DSI is interpreted to come within the definition of "genetic resources," then, as noted above, PIC access restrictions can be imposed.[207] This is because the only two items mentioned as being subject to prior informed consent in the Nagoya Protocol are genetic resources in Article 6 and traditional knowledge associated with genetic resources in Article 7. If DSI is not a genetic resource, the Nagoya Protocol does not require PIC.

Even if, however, the definition of "genetic resources" does not include DSI but DSI results from "utilization of genetic resources," then benefit-sharing obligations would attach.[208] This is because Article 3 of the Nagoya Protocol specifies that the Nagoya Protocol applies to genetic resources and to benefits arising from the utilization of such resources, and Article 5 requires benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization to be shared in a fair and equitable way with providers.[209] This third view may be preferable to Views 1 and 2 as it allows for the possibility of a win-win for both users, who would retain open access to DSI, and for providers, who would be entitled to share in benefits from such utilization.

The dissonance between Views 1 and 2 appears to represent a clash in perspectives that can also be seen in the FAIR vs. CARE frameworks relating to digital assets more broadly. The *FAIR Guiding Principles for Scientific Data Management and Stewardship* articulated in 2016, are intended to make data easily *F*indable, *A*ccessible, *I*nteroperable, and *R*eusable.[210] However, as the Global Indigenous Alliance ("GIDA") explains:

> The current movement toward open data and open science does not fully engage with Indigenous Peoples [sic] rights and interests. Existing principles within the open data movement (e.g. FAIR: findable, accessible, interoperable, reusable) primarily focus on characteristics of data that will facilitate increased data sharing

206. Bagley et al., *supra* note 26. Such countries include Brazil, India, and Malawi.

207. *See* Nagoya Protocol, *supra* note 25, art. 6 ("[A]ccess to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.").

208. *See id.* art. 3 ("This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources.").

209. *Id.* arts. 3, 5.

210. *FAIR Principles*, GO FAIR, https://www.go-fair.org/fair-principles/ [https://perma.cc/XUR2-HG9R]. Thanks to Jeremy DeBeer for directing me to this development.

> among entities while ignoring power differentials and historical contexts.[211]

GIDA developed the 2018 *CARE Principles for Indigenous Data Governance* in response to the FAIR principles. CARE stands for *C*ollective benefit, *A*uthority to control data, *R*esponsibility to ensure benefit-sharing and the use of *E*thical processes for maximizing IPLC wellbeing, for justice, and for future uses of the data.[212]

The CARE Principles for Indigenous Data Governance are "people and purpose-oriented, reflecting the crucial role of data in advancing Indigenous innovation and self-determination."[213] Interestingly, instead of advocating for the elimination of the FAIR guidelines, the CARE principles are designed to "complement the existing FAIR principles encouraging open and other data movements to consider both people and purpose in their advocacy and pursuits."[214] The tagline "Be FAIR and CARE" signifies this complementary goal.

The complementary approach of the CARE guidelines is illustrative of this third view of DSI that provides an arguably superior way (vis-a-vis Views 1 and 2) to situate DSI comfortably within the scope of the CBD and Nagoya Protocol. Moreover, benefit-sharing need not necessarily take the form of a bilateral negotiation. The Nagoya Protocol itself provides another possible avenue: a global multilateral benefit-sharing mechanism under Article 10.[215]

III. DSI And Benefit-Sharing: The Need For A New Approach

The changes wrought by digitization in the music, movie, and 3D maker space seem apt for comparison to the issue of DSI, as all three involve technological changes that make intangible information a viable substitute for a tangible product and are the result of the increasing digitization of information.[216] In particular, advances in digital copying and an increase in easily accessible digital information created "piracy" concerns in relation to music and movie file-sharing and 3D printing.

---

211. *Care Principles for Indigenous Data Governance*, Global Indigenous Data All., https://www.gida-global.org/care [https://perma.cc/Z4QU-BQDR].

212. *See id.*

213. *Id.*

214. *Id.*

215. Nagoya Protocol, *supra* note 25, art. 10.

216. *See* Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, *Report of The Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources*, U.N. Doc. CBD/DSI/AHTEG/2018/1/4 p. 8 (Feb. 2018) (noting that "'DSI' could bring transformational change to the use of genetic resources, which may influence the type of benefits and the way benefits are shared. There may be useful lessons in this respect from how digitization of information in other sectors has impacted benefit-sharing, including possible lessons from the music, software, publishing and other industries"); *see also* Erik Brynjolfsson et al., *New World Order: Labor, Capital, and Ideas in the Power Law Economy*, 93 Foreign Affs. 44, 47, 49–50 (2014).

For more than a decade, the Recording Industry Association of America and the Motion Picture Association of America fought the facilitators and perpetrators of unauthorized downloads of copyrighted works from the internet, labeling such actions as "theft" and seeking "justice" in the form of obtaining monetary and, in some cases, criminal penalties against the perpetrators—individuals and organizations alike.[217] Likewise, 3D printing is enabling individuals and companies to cheaply copy patent and copyright-protected articles from internet-accessible digital files.[218]

The comparison, however, largely ends there. The music and movie industries have been quite successful in their efforts. IP-holding music and movie stakeholders are well-organized and have deep pockets to pay for lobbying, lawsuits, and the media and educational outreach efforts of their sustained campaigns. Moreover, they were able to persuade legislators at national and international levels to adopt rules that specifically address and punish certain kinds of copying and uses of digitized works.[219] In addition, the digitized and copied content is protected by the traditional intellectual property rights of copyrights and patents and is seen as creative.[220]

By contrast, the developing country governments and IPLCs most likely to be negatively impacted by DSI misappropriation are neither well-organized nor well-funded on this issue, the genomic sequences generally are not individually protected by the governments with IP rights,[221] and the origins and uses of sequence information may be impossible to ascertain.[222]

As a result, while many if not most provider countries agree that access limitations would be detrimental to research that may enhance the welfare of society at large, countries imposing or considering such limitations appear to believe they have few alternative ways of securing benefits in this

217. Michael Palmedo, *Over 200,000 John Does Sued for File Sharing in the U.S. Since 2010*, INFOJUSTICE.ORG (Aug. 8, 2011), http://infojustice.org/archives/4724 [https://perma.cc/H2WB-VVCL].

218. Ben Depoorter, *Intellectual Property Infringements & 3D Printing: Decentralized Piracy*, 65 HASTINGS L. J., 1483–1504 (2014); Devin R. Desai & Gerald N. Magliocca, *Patents, Meet Napster: 3D Printing and the Digitization of Things*, 102 GEO. L. REV. 1691 (2014); Timothy Holbrook & Lucas Osborn, *Digital Patent Infringement in an Era of 3D Printing*, 48 U.C. DAVIS L. REV. 319 (2015); Lucas Osborn, *Regulating Three-Dimensional Printing: The Converging Worlds of Bits and Atoms*, 15 SAN DIEGO L. REV. 553 (2014).

219. *See* WIPO Copyright Treaty (WCT) art. 14, Dec. 20, 1996, S. Treaty Doc. No. 105-117, 2186 U.N.T.S. 121; Digital Millennium Copyright Act (DMCA), Pub. L. No. 105-304, 112 Stat. 2860 (1998) (codified as created and amended in scattered sections of 17 U.S.C.).

220. Interestingly, IP holders in the United States have been able to leverage domestic law extraterritorially in this context without the need for a new treaty or provision of any sort. *See* Timothy R. Holbrook, *Is There a New Extraterritoriality in Intellectual Property?*, 44 COLUM. J.L. & ARTS 457, 492–94 (2021); Timothy R. Holbrook, *Extraterritoriality and Digital Patent Infringement, in* RSCH. HANDBOOK ON INTELL. PROP. AND DIGIT. TECHNOLOGIES (Tanya Aplin ed. 2018).

221. While isolated genomic DNA sequences may be eligible for patent protection outside of the United States, not surprisingly, there appears to be no major effort underway to patent, at considerable cost, the large quantities of DNA sequence information obtained during non-commercial research expeditions.

222. Due in part to transboundary issues where species are common to more than one territorial jurisdiction. *See* Nagoya Protocol, *supra* note 25, art. 11.

changed environment.[223] This is unfortunate, as benefit-sharing is important for, among other things, conserving and facilitating access to genetic resources that may have therapeutic efficacy to treat a range of diseases, increase food security, and improve human flourishing.

A. *Benefit-Sharing Matters*[224]

In 2019, the U.N. Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services issued a Global Assessment Report on Biodiversity and Ecosystem Services with an alarming statistic: approximately one million species face extinction, many within decades, unless the drivers of biodiversity loss are addressed expediently.[225] In addition, more than 570 plant species have become extinct in the past 250 years alone, which is a rate 500 times greater than what would naturally be expected.[226] As one commentator notes, "deforestation, conversion of land to agriculture, and over exploitation have taken a toll."[227] We have seen time and time again that if preserving land in its natural state is not sufficiently lucrative, the land will be put to a different use adverse to biodiversity conservation.[228]

Biological resources have been the basis for new drugs and therapeutic treatments for millennia and are still critical to new discoveries today.[229] For

223. The range of products that could be developed using DSI appears limitless. *See*, *e.g.*, Elizabeth Karger et al., Digital Sequence Information on Genetic Resources (DSI): An Introductory Guide for African Policymakers and Stakeholders (2019) (identifying examples of uses of DSI in pharmaceuticals, agriculture and more); Fernando Almerón-Souza et al., *Molecular Identification of Shark Meat from Local Markets in Southern Brazil Based on DNA Barcoding: Evidence for Mislabeling and Trade of Endangered Species*, 9 Front. Genet. 1993 (2018) (discussing the use of DNA barcodes to identify shark species in meat products); Sylvain Aubry, *The Future of Digital Sequence Information for Plant Genetic Resources for Food and Agriculture*, 10 Front. Plant Sci. 1046 (2019) (discussing the use of DNA sequences in the genetic engineering of plants).

224. The implementation challenges described in Part I translate to limited evidence of benefits from ABS under the Nagoya Protocol and also detrimental impacts on research. These negative outcomes have led at least one multi-country group of scholars to suggest scrapping the ABS system and beginning again at first principles to design a system that is fit for purpose in the 21st century. *See* Sarah Laird et al., *supra* note 119. While there is merit in such a suggestion, a wholesale revision of the ABS system is improbable. Provider countries and IPLCs are unlikely to view the elimination of the bilateral approach as in their interests, at least in situations where specific genetic resources can be identified.

225. IPBES, *supra* note 41.

226. Aelys M. Humphreys et al., *Global Dataset Shows Geography and Life Form Predict Modern Plant Extinction and Rediscovery*, 3 Nat. Ecol. & Evol. 1043 (2019).

227. Virginia Gewin, *From Coffee to Cosmetics, Companies are Looking for Ways to Protect the Plants Their Products are Made From*, GreenBiz (Dec. 9, 2019), https://www.greenbiz.com/article/coffee-cosmetics-companies-are-looking-ways-protect-plants-their-products-are-made [https://perma.cc/MM3U-8NZS].

228. *See, e.g.*, IPBES Secretariat, Global Assessment Report on Biodiversity and Ecosystem Services of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (Eduardo Brondizio et al. eds., 2019) [hereinafter Global Assessment Report] (citing a 300% increase in the value of agricultural crop production since 1970, a 45% increase in raw timber harvesting, and the extraction of approximately sixty billion tons of renewable and nonrenewable resources annually across the globe). The report also notes the cattle ranching and palm oil production related loss of 100 million hectares of tropical forest between 1980 and 2000. *Id.*

229. David J. Newman & Gordon M. Cragg, *Natural Products as Sources of New Drugs over the Nearly Four Decades from 01/1981 to 09/2019*, 83 J. Nat. Prod. 770 (2020).

example, in the early 1990s, approximately eighty percent of marketed drugs were natural products or their analogs and in 2009, more than 100 natural product-based drugs were in clinical studies, with thirteen drugs derived from natural products receiving FDA approval between 2005 and 2007.[230] Moreover, an estimated four billion people rely primarily on natural medicines for their health care and some seventy percent of drugs used for cancer are natural or are synthetic products inspired by nature.[231]

Moreover, in 2015, researchers identified the production of multiple copies of p53, a gene known to inhibit cancer growth, in African elephants, a development which may lead to better cancer treatments for humans.[232] Similarly, researchers are studying a mechanism found in fruit flies that controls their production of an oncometabolite found in brain and kidney cancer patients, which causes tumor formation and growth. In turn, these findings could also lead to better cancer treatments for humans.[233] Developments like these underscore the importance of having available the vast amounts of uncharacterized biodiversity that may hold the key to future cures for our most dreaded diseases.

But we are unlikely to retain the opportunity to access such resources without sufficient incentives for IPLCs to continue supporting and conserving. In fact, the tangible virtues of traditional knowledge and genetic resources benefit-sharing are important for all of us in part because they have the potential to help those most responsible for biodiversity conservation, who also happen to be some of the most vulnerable among us: IPLCs.[234] According to the World Bank:

> There are between 370 and 500 million Indigenous Peoples worldwide, in over 90 countries. Although they make up over 5 percent of the global population, they account for about 15 percent of the extreme poor. Indigenous Peoples' life expectancy is up to 20 years lower than the life expectancy of non-indigenous

230. Jesse W. H. Li & John C. Vederas, *Drug Discovery and Natural Products: End of an Era or an Endless Frontier?*, 325 SCIENCE 161, 161 (Jul. 10, 2009).

231. Global Assessment Report, *supra* note 228, at 10.

232. ABC Science, *Secret to why elephants rarely get cancer is in their genes*, ABC SCIENCE NEWS (Oct. 8, 2015), https://www.abc.net.au/news/science/2015-10-09/genes-explain-why-elephants-rarely-get-cancer/6841096 [https://perma.cc/RNG5-GZZJ].

233. Farah Shamout, *Fruit Fly Finding May Lead to New Cancer Therapies*, GENETIC ENGR. & BIOTECH. NEWS (Jan. 25, 2017), https://www.genengnews.com/topics/drug-discovery/fruit-fly-finding-may-lead-to-new-cancer-therapies/ [https://perma.cc/DBB6-VF9N].

234. *See, e.g.*, William W. Fisher, *The Puzzle of Traditional Knowledge*, 67 DUKE L.J. 1511 (2018); *see also How indigenous knowledge can help prevent environmental crises*, U.N. ENVIRONMENT PROGRAMME (Aug. 9, 2021), https://www.unep.org/news-and-stories/story/how-indigenous-knowledge-can-help-prevent-environmental-crises [https://perma.cc/CBY3-Z9ZB] (quoting Nemonte Nenquimo of Ecuador: "If we allow the Amazon to be destroyed . . . that affects us as indigenous peoples, but it will also affect everyone because of climate change . . . . The struggle we do is for all humanity.").

> people worldwide . . . . Indigenous Peoples . . . *safeguard 80 percent of the world's remaining biodiversity*."[235]

The critical importance of IPLCs in stemming biodiversity loss cannot be overstated. Consider an example from Australia, where in the early part of the last century, the Anangu people, an aboriginal group, was driven from the vast Uluru Park area. Their forced removal led to the extinction (and near extinction) of large numbers of species in the area due to massive wildfires in the 1950s and 1970s that burned three-quarters of the park.[236] This is because the Anangu previously, as part of their traditional land stewardship practices, used controlled burns to keep the underbrush in check, facilitating species survival. While there were forty-six known mammalian species in the park before the Anangu left, only twenty-five remained after the big fires, fires which, according to one expert, "would probably not have occurred had traditional techniques of patch burning been in operation."[237] The Uluru area is currently home to many medicinal plant species, so it is likely that other species with therapeutic potential were lost due to the absence of Anangu stewardship.

Even when extracting products from nature for commercial purposes, IPLC sustainable stewardship practices can provide superior outcomes in ameliorating climate change. As a recent study on the impact of IPLCs in maintaining carbon stores in the Amazon basin describes:

> The Chico Mendes Extractive Reserve in the State of Acre is perhaps one of the best-known sustainable use areas. This ~935,000-ha reserve is managed by traditional populations (historically rubber tappers), whose livelihoods are based on extractivism (rubber, Brazil nuts), subsistence agriculture (cassava, rice, beans), and livestock (cattle, poultry, pigs) . . . . While sustainable use resulted in higher losses than strict protection . . . the net loss of

235. The World Bank, *Indigenous Peoples*, The World Bank, https://www.worldbank.org/en/topic/indigenouspeoples [https://perma.cc/DG4M-T3YY#1]; *see also* Secretariat of the Permanent Forum on Indigenous Issues, *Capacity-Building Workshop on Networking and Information Exchange for National Focal Points and Indigenous and Local Communities in the Latin America and the Caribbean Region*, U.N. Doc. UNEP/CBD/WS-CB/LAC/1/INF/5 (Nov. 16, 2006) (noting that local Communities "have a long association with the lands and waters that they have traditionally lived on or used . . . [and] have accumulated knowledge, innovations and practices regarding the sustainable management and development of these territories including useful environmental knowledge . . . . Some local communities may include peoples of indigenous descent").

236. David Curl, *Uluru: Stories in Stone*, Australian Geographic (Oct. 27, 2010), https://www.australiangeographic.com.au/topics/history-culture/2010/10/uluru-stories-in-stone/ [https://perma.cc/9FEQ-X9DF].

237. *Id.* Similar Native American practices helped control California wildfires. *See* Page Buono, *Quiet Fire*, The Nature Conservancy (Nov. 2, 2020), https://www.nature.org/en-us/magazine/magazine-articles/indigenous-controlled-burns-california/ [https://perma.cc/9FEQ-X9DF] (discussing how indigenous tribes used controlled burning to combat the California wildfires); Lauren Sommer, *To Manage Wildfire, California Looks to What Tribes Have Known All Along*, NPR (Aug. 24, 2020), https://www.npr.org/2020/08/24/899422710/to-manage-wildfire-california-looks-to-what-tribes-have-known-all-along [https://perma.cc/3RZ4-MPCU].

> carbon under a sustainable use regime is still more than four times lower than that observed on other land.[238]

This is important, as deforestation increases carbon emissions from the rainforest, contributing to global warming. The authors' conclusion regarding the benefits of IPLC practices to the common good is compelling:

> IPLCs have a clear and present role to play in curbing global climate change; however, the permanence of this undervalued service depends on local, national, and regional recognition of the rights of forest-dwelling peoples to their land, as well as innovative policies that provide support for their traditional ways of life.[239]

It is important to note that the same U.N. Report that predicts continued dramatic biodiversity losses with ramifications for everyone, everywhere, includes IPLC-related proposals for transformative reversal of the expected biodiversity losses.[240] Specifically it encourages "justice and inclusion in conservation," and tackles "incentives and capacity-building" including "ensuring inclusive decision-making and the fair and equitable sharing of benefits arising from the use of and adherence to human rights in conservation decisions . . . [and] promoting education, knowledge generation and the maintenance of different knowledge systems, including the sciences and indigenous and local knowledge regarding nature, conservation and its sustainable use."[241]

Benefit-sharing to provider communities not only comports with the objectives of the CBD and Nagoya Protocol, but also with international human rights obligations of nations towards IPLCs as a group. The United Nations Declaration on the Rights of Indigenous Peoples ("UNDRIP") and the International Labour Organization Convention on the Rights of Indigenous and Tribal Peoples in Independent Countries ("ILO Indigenous and Tribal Peoples Convention") affirm and protect the basic rights of indigenous peoples to their cultural integrity and natural resources.[242]

UNDRIP enshrines in international law the right of indigenous populations to the conservation of their traditional flora and fauna, the land they are found on, and the resources that result from the use and development of their lands.[243] These communities also have the rights to maintain and control their "cultural heritage, traditional knowledge and traditional cultural

238. Wayne S. Walker et al., *The Role of Forest Conversion, Degradation, and Disturbance in the Carbon Dynamics of Amazon Indigenous Territories and Protected Areas*, 11 PROC. OF THE NAT'L ACAD. OF SCI, S. 2015, 3019 (Feb. 11, 2020).

239. *Id.* at 3023.

240. Global Assessment Report, *supra* note 228, at 56.

241. *Id.* at 17, 23.

242. *See generally* G.A. Res. 61/295, United Nations Declaration on the Rights of Indigenous Peoples (Sept. 13, 2007) [hereinafter UNDRIP]; Indigenous and Tribal Peoples Convention, No. 169, June 27, 1989, 1650 U.N.T.S. [hereinafter ILO Indigenous and Tribal Peoples Convention].

243. UNDRIP, *supra* note 242, arts. 24, 26.

expressions."[244] UNDRIP establishes these rights in the United Nations, making them binding on states parties, and thus binding on the corporations and individuals which are incorporated in those states parties. The ILO Indigenous and Tribal Peoples Convention provides similar language on the rights of indigenous peoples to their natural resources, specifically safeguarding them in international law.[245]

The International Covenant on Economic, Social and Cultural Rights ("ICESCR"),[246] one of the treaties that makes up the International Bill of Rights, also upholds the rights of all peoples, including indigenous and local communities, to adequate intellectual property rights[247] and general rights to an adequate standard of living.[248] These rights specifically derive from the inherent right to dignity and worth of all peoples, which culminate in the inalienable right to freedom from discrimination in all endeavors.[249] This right to freedom from discrimination also extends to partnerships between IPLCs and third parties using genetic materials, or other resources, to conduct research and develop new medications and products. The expectation is that no IPLC will be exploited and forgotten based on their minority or indigenous status. States are obligated to adopt measures to ensure the protection of the interests of indigenous peoples relating to their productions, recognizing that these productions are often expressions of their "cultural heritage and traditional knowledge."[250] These particular intellectual property rights in combination with general rights to a living wage,[251] adequate standard of living,[252] and the right to health and food,[253] all comport with the CBD and Nagoya Protocol's goals and interest in benefit-sharing, including for DSI.

Preserving biodiversity goes hand in hand with benefit-sharing. As IPLCs are most often the protectors of much genetic and agricultural diversity, as well as the traditional knowledge of how to actually use this diversity, giving effect to the CBD and Nagoya Protocol as they relate to the preservation and maintenance of traditional knowledge is also important. Non-monetary benefits in the form of capacity-building, knowledge and equipment transfers, etc., are necessary but insufficient to achieve the kinds of biodiversity conservation gains and socioeconomic improvements needed to incentivize

244. *Id.* art. 31.

245. ILO Indigenous and Tribal Peoples Convention, *supra* note 242, art. 15.

246. International Covenant on Economic, Social, and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR].

247. *Id.* art. 15.

248. *Id.* art. 11.

249. *Id.* arts. 2–3.

250. *See* Comm. on Econ., Soc. and Cultural Rts., *General Comment No. 17 (2005). The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author (article 15, paragraph 1 (c), of the Covenant),* ¶ 32, U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006).

251. ICESCR, *supra* note 246, art. 7(a)(i).

252. *Id.* art. 11.

253. *Id.*

and enable IPLCs to maintain their traditional roles while simultaneously improving their circumstances.[254] Climate change is exacerbating and accelerating biodiversity loss, and monetary benefits are needed both to support IPLCs and actively protect and steward endangered flora and fauna. Such benefits could also provide for the kinds of educational and economic improvements that will facilitate IPLC development of sustainable, income-producing genetic resource and traditional knowledge-based industries.[255]

Moreover, it would be erroneous to assume that because DSI is separated from traditional knowledge, that the knowledge and efforts of IPLCs did not contribute to the ultimate availability of that DSI. Many indigenous groups have been modifying and interacting with the natural environment for millennia in ways that protect, conserve, and possibly improve the quality of medicinal and other plants.[256] Such efforts include developing and imposing strict harvesting protocols for medicinal plants, imposing boundaries to protect herb growth areas, and more.[257] Without such activities, many of the plants from which DSI is derived would likely be extinct.

DSI is indeed useful for conserving biodiversity through research and product development, but reducing the issue strictly to economic concerns underplays its significance. Fair and equitable benefit-sharing from DSI is also about upholding commitments to those that create and sustain the diversity that benefits us all, and about adapting agreements that set out collective human, environmental, and social goals to a changing reality.[258] Beyond the moral and ethical obligations to recognize the vital role IPLCs play in biodiversity research, it is important to recognize that, practically, the entire world is reliant on IPLCs as stewards of biodiversity who can also

254. *See* CBD, *supra* note 25, arts. 20–21; Nagoya Protocol, *supra* note 25, art. 25 (obligating developed countries to provide financial assistance to developing countries and the IPLCs residing therein).

255. *See, e.g.*, U.N. Development Programme, ABS is Genetic Resources for Sustainable Development (2018) (detailing twenty-seven country case studies where "traditional knowledge, science, technology, and human ingenuity have been used to develop novel products from genetic resources" that contribute to sustainable development goals); Margo A. Bagley, *Toward an Effective Indigenous Knowledge Protection Regime: Case Study of South Africa*, Ctr. for Int'l Governance Innovation (Dec. 2018) (describing examples of benefit-sharing agreements aiding IPLCs socioeconomic development); *see also* U.N. Development Programme, Community Approaches to Sustainable Land Management and Agroecology Practices (2017) (describing techniques for improved community land management based on traditional knowledge and innovation).

256. *See* Curl, *supra* note 236 (discussing Anangu people in Uluru); *see also* Madhavi Sunder, *The Invention of Traditional Knowledge*, 70 Law & Contemp. Probs. 97, 109 (2007) (discussing the dynamic nature and inventiveness of traditional knowledge and its holders).

257. *See* Mohamed Khalil, *Biodiversity and the Conservation of Medicinal Plants: Issues from the Perspective of the Developing World*, *in* Intell. Prop. Rights and Biodiversity Conservation: An Interdisc. Analysis of the Values of Med. Plants 232, 242–43 (Timothy M. Swanson ed., 1995); Chidi Oguamanam, *Between Reality and Rhetoric: The Epistemic Schism in the Recognition of Traditional Medicine in International Law*, 16 St. Thomas L. Rev. 59, 74–75 (2003).

258. Edward Hammond, *Finding Traditional Knowledge's Place in the Digital Sequence Information Debate*, Third World Network (July 2020), https://twn.my/title2/briefing_papers/twn/TWB_EHamm_Jul2020_D03.pdf [https://perma.cc/8VBR-JAYK].

offer tradition-based insights for ameliorating the devastating effects of climate change.[259]

As described above, the current framework for access and benefit-sharing is not sufficient to address DSI. However, it may be possible to improve the system from within for both tangible genetic resources and DSI.[260] The Nagoya Protocol's bilateral ABS model can be applied to DSI in certain situations, most notably as part of MAT for the use of tangible genetic material. It also may be feasible where a small number of genetic resources are being used. But for DSI utilizations in which the bilateral approach would be effectively impossible because, *inter alia*, no physical access is needed to utilize genetic information, the uses cannot be traced, and/or genetic information from multiple organisms is being used,[261] a global multilateral benefit-sharing mechanism ("GMBSM") may provide a viable way forward.

B. Possible Ways Forward

As the foregoing sections suggest, much remains to be decided regarding the development of a "just" approach to DSI access and benefit-sharing. With the pandemic raging and the CBD COP15/MOP4 meetings postponed, several entities have, nevertheless, pushed forward with providing DSI ABS information and policy options.[262]

1. *CBD Secretariat DSI Option Categories*

In February 2021, the CBD Secretariat held an informational webinar presenting a compilation of DSI benefit-sharing policy options, without ap-

259. *See id.*; *Indigenous Peoples and Local Communities*, CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/topic/indigenous-peoples-and-local-communities [https://perma.cc/7YP4-QBWK]; *see also* Third World Network, *Comments of the Third World Network on Digital Sequence Information*, CONVENTION ON BIOLOGICAL DIVERSITY (June 1, 2019), https://www.cbd.int/abs/DSI-views/2019/TWN-DSI.pdf [https://perma.cc/R5KD-DQW8]; African Group of Negotiators on Biodiversity-Ad Hoc Group on Digital Sequence Information, *Digital Sequence Information on Genetic Resources: Submission of Views and Information on Terminology, Scope, and Domestic Measures on Access and Benefit-Sharing*, CONVENTION ON BIOLOGICAL DIVERSITY (May 31, 2019), https://www.cbd.int/abs/DSI-views/2019/AfricanGroup-DSI.pdf [https://perma.cc/8Y6Z-RNA6].

260. Of course, the system could be improved from the outside as well, as a global multilateral benefit-sharing mechanism for sharing benefits need not be constituted under the Nagoya Protocol simply because the Nagoya Protocol allows for one to be created.

261. Bagley & Perron-Welch, *supra* note 134, at 25–33.

262. These efforts include a variety of webinars and virtual meetings hosted by, among others, the CBD Secretariat and the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) ABS Capacity Development Initiative supported by the governments of Norway and South Africa. *See generally Webinar Series on Digital Sequence Information on Genetic Resources*, CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/article/dsi-webinar-series-2020 [https://perma.cc/6AGU-2756] (listing numerous webinars, videos, and reports on DSI during 2020 and 2021). These and other virtual gatherings have helped stakeholders and negotiators better understand a range of DSI-related issues and develop some shared understandings that are informing official meetings such as the CBD Open-Ended Working Group on the Post 2020 Biodiversity Framework (OEWG) where DSI is now a center-stage issue leading up to COP15. *See* Convention on Biological Diversity Open Ended Working Group on the Post 2020 Global Biodiversity Framework, *Digital Sequence Information on Genetic Resources,* UN Doc. CBD/WG2020/3/CRP.1 (Aug. 31, 2021).

proving any particular approach.[263] The Secretariat identified six categories of options briefly described below:

0: Status quo: Parties have not agreed on how to address ABS for DSI, so national law governs DSI access and benefit-sharing.

1: DSI fully integrated into approach of CBD & Nagoya Protocol[264]: DSI is treated as a genetic resource, so PIC and MAT are required for access and use. This is a nightmare scenario in terms of transaction costs, but due to current traceability limits, this approach also seems unlikely to result in meaningful benefit-sharing.

2: Standard Benefit-Sharing Terms: No access limitations on DSI. Benefit-sharing is triggered by commercialization-type events involving the use of DSI along the value chain. Standard MAT created and implemented at either the domestic or international level help to lower transaction costs.[265] This option sounds promising in theory, but due to the ways DSI is used (vast numbers of sequences at a time) and the traceability issues already discussed, it would only be likely to capture a small fraction of uses at most and would be likely to mirror the inadequate financial collections of the ITPGRFA.

3: Global Multilateral Benefit-Sharing Mechanism:[266] No access limitations on DSI. Payments either for access to DSI (for example, database subscription, etc.) or for other DSI-related services (for example, cloud analytics or levies on synthesizers). Also possible are voluntary contributions or innovative financing tools such as "biodiversity bonds." This approach has the benefit of not constraining access. However, it does not differentiate between commercial and non-commercial users of DSI and would require monetary contribu-

263. Due to the sensitive nature of the topic and in an effort to avoid pre-judging any particular outcome. *See Webinar Series on Digital Sequence Information on Genetic Resources*, CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/article/dsi-webinar-series-2020 [https://perma.cc/6AGU-2756].

264. *See* ABS Capacity Development Initiative, *Rep. on the First Global Dialogue on Digital Sequence Information on Genetic Resources* (November 2019) (organized in partnership with the Norwegian Government and the South African Department of Environment, Forest and Fisheries); DEFRA, contract by ICF Consulting Services Limited; Elta Smith, *Digital Sequence Information: An Evidence Review* (Aug. 14, 2020); Elisa Morgera et al., *Study for the European Commission on 'Possible Ways to Address Digital Sequence Information – Legal and Policy Aspects'* (Dec. 2019); *but see* Marcel Jaspars et. al., Tracing Options For Marine Genetic Resources From Within National Jurisdictions 13–20 (2021) (discussiig tracing options for marine genetic resources.).

265. *See*, *e.g.*, Henry E. Smith, *Modularity in Contracts: Boilerplate and Information Flow*, 104 MICH. L. REV. 1175, 1177–78 (2006) (describing the virtues of modularity in reducing transaction costs).

266. *See generally* MANUEL RUIZ MULLER ET AL., "COMMON GROUND, CAUSE AND SENSE FOR USERS, PROVIDERS AND AGENTS: BOUNDED OPENNESS OVER GENETIC RESOURCES" (Jan. 26, 2018); Oldham, *supra* note 179; ELIZABETH KARGER, OPTIONS FOR BENEFIT-SHARING: THE CASE OF DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES (Jun. 2018) (Master's thesis) (on file with author). Another option, borrowing from the copyright context, could be a framework similar to that proposed by Professor Peter Menell in Peter S. Menell, *Adapting Copyright for the Mashup Generation*, 164 U. PA. L. REV. 441 (2016) (proposing a low transaction cost fund for creators of "mashups" involving snippets of many different copyrighted works).

tions from both—a suboptimal outcome for non-commercial, particularly academic, researchers.

4: Non-monetary Benefit-Sharing: There is wide agreement on the need for, and viability of, some forms of technical and scientific cooperation as non-monetary benefit-sharing. However, it is also clear that this option should be an adjunct to monetary benefit-sharing, not a substitute. As such, this option should be complementary to other options.

5: "No PIC, No MAT: No Benefit-Sharing from DSI (DSI is not considered equal to GR)": If DSI is not a genetic resource, then access obligations would not apply.[267]

This palette of options begins (option 0) and ends (option 5) at basically the same place: no international agreement for the sharing of benefits from DSI, beyond individual MAT negotiations or domestic requirements. This is because the option palette begins with the current status quo and ends with an apparent explicit rejection of benefit-sharing for DSI. However, as described in Part III above, the Secretariat's option 5, "No PIC, No MAT: No Benefit-Sharing for DSI (DSI is not considered equal to GR)," reflects an incomplete assessment of the possible sources of benefit-sharing obligations for DSI. Even if DSI is not considered to be a genetic resource, benefit-sharing under the CBD and Nagoya Protocol is still required to the extent DSI results from the utilization of genetic resources, such as through the sequencing of DNA from genetic material, and DSI parameters could be negotiated in MAT for tangible genetic material.[268]

2. *Guiding Principles for DSI Benefit-Sharing Approaches*

As diverse stakeholders explore the above options and generate additional ones, they should do so based on a framework of guiding principles. Some statements of principles/criteria have already been propounded from scientists and other DSI users, including:

a. Open Access

Open availability of DSI and other research data is critical to scientific reproducibility and integrity and is a key contributor to many technological advances in food security, therapeutics, vaccines, and more. Scientists want to know that data will be "publishable, available, linkable, downloadable, and can flow into the downstream databases and software" they use on a daily basis.[269]

267. *See* CBD Secretariat, Policy Options for Access and Benefit-Sharing and Digital Sequence Information, 3 (Apr. 2021).

268. *See* Nagoya Protocol, *supra* note 25, art. 5; CBD, *supra* note 25, art. 15.

269. Amber Hartman Scholz et al., *Finding Compromise on ABS & DSI in the CBD: Requirements & Policy Ideas From a Scientific Perspective*, WiLDSI (Oct. 2020) ("WiLDSI which stands for Wissenschaftliche

b. Simplicity and Legal Certainty

The challenges to implementation of the Nagoya Protocol illustrate well the need for ease of use in any regime developed for DSI ABS. As a group of scientists notes: "Paperwork and stamped documents are incompatible with the scale, technological platforms, and daily realities of scientific inquiry with DSI."[270]

c. Viability

Both technical feasibility and legal enforceability are important for a DSI ABS governance regime. How countries' laws would need to change must be considered, as well as the actual mechanics of operating the system. Long-term viability or "future-proofing" the system is also important to ensure it will be able to handle technological advances in artificial intelligence and big data creation, storage, and processing.[271]

These features are all important and must be considered. However, as the "Be FAIR and CARE" kerfuffle illustrates, the requirements of scientists are likely to be insufficient to address the concerns of all stakeholders and to achieve truly "just" sharing. Incorporation of at least four additional principles will increase the likelihood of CBD/Nagoya Protocol Parties achieving a just and viable outcome:

d. Ensuring flexibility in the uses of funds received from multilateral benefit-sharing

The Nagoya Protocol does not require its Parties to use monetary benefits received towards conservation, which some Parties see as a vice, others as a virtue.[272] While the misuse of funds is to be guarded against, the use of funds for economic development should not categorically be condemned. This is because economic development objectives can directly and indirectly benefit conservation and the Parties should have the flexibility to assess which tools will be most effective in a given situation.[273] Flexibility is also

Lösungsansätze für Digitale Sequenzinformation (Scientific approaches for digital sequence information (DSI)) which, as the name suggests, is a research effort to provide input on DSI from a scientific perspective.").

270. *Id.*

271. *Id.*; *see also* Sylvain Aubry et al., *Bringing Access and Benefit-sharing into the Digital Age*, 6 (October 2020) (calling for the creation of a multi-stakeholder DSI governance committee that could "contribute to the development of a coordinated governance mechanism for the entire ABS framework.") available at https://nph.onlinelibrary.wiley.com/doi/10.1002/ppp3.10186; Smyth et al., *supra* note 35 (describing governance scenarios for DSI ABS).

272. Smith, *supra* note 265.

273. *See*, *e.g.*, Margo A. Bagley, *Toward an Effective Indigenous Knowledge Protection Regime: Case Study of South Africa* (Policy Paper, Centre for International Governance Innovation, Paper No. 207, December 2018) (describing examples of traditional knowledge associated with various genetic resources, namely *lippia javonica*, and *molomo monate*, generating significant economic benefits for IPLC communities). Such considerations also contribute to meeting the first U.N. Sustainable Development Goal: No Poverty. *See The SDGs in Action*, U.N. Dev. Programme, https://www.undp.org/sustainable-development-goals [https://perma.cc/HV98-ZS59].

necessary to enable issues of distributive justice to be incorporated into benefit-sharing approaches.[274]

e. Differential benefit-sharing obligations for non-commercial versus commercial research

The ability to have differential benefit-sharing obligations for non-commercial versus commercial research, such that if commercial products are not produced from DSI utilization, benefit-sharing obligations could be met, if at all, through non-monetary means.

f. Maintaining the bilateral approach for physical genetic resources and associated traditional knowledge

There clearly are significant challenges with the bilateral ABS approach even for tangible genetic resources. Nevertheless, it is not obvious to some CBD/Nagoya Protocol Parties that a GMBSM would be superior, especially given that the primary example in this space, the FAO ITPGRFA, has received and distributed only a tiny fraction of the monetary benefits Parties had originally anticipated would accrue.[275] Moreover, the bilateral approach is currently mandated by the Nagoya Protocol, and is, at a minimum, integral to the ability of IPLCs to give prior informed consent for access to traditional knowledge associated with genetic resources. As such, in order to have any hope of gaining a broad consensus to the adoption of a GMBSM, it must supplement, not replace, the current bilateral approach. However, countries should have the option to voluntarily place some of their genetic resources into the GMBSM. This is because retaining the bilateral approach may unintentionally "penalize" primary DSI generating-scientists (who would otherwise have to deal with both bilateral Nagoya negotiations and the GMBSM) *vis-a-vis* downstream DSI users who will be able to easily use sequences and simiply rely on the GMBSM for compliance.

g. Interest convergence

A truly "just" approach to DSI benefit-sharing will, optimally, provide a win-win scenario for both users and providers. To borrow from Derrick Bell, the interests of both sides will need to converge in a way that provides each with a just outcome.[276]

---

274. *See generally*, JOHN RAWLS, A THEORY OF JUSTICE (rev. ed. 1999).

275. However, the distribution of the monies received to fund competitively awarded projects is generally seen as successful and could provide a model modality for consideration in a GMBSM. *See Benefit-Sharing Fund,* FOOD & AGRIC. ORG. OF THE U.N., http://www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/overview/en/ [https://perma.cc/C85R-DED8]; *see also Divergent Positions on Benefit-Sharing Hold Up Agreement in Talks on Plant Genetic Resources for Food and Agriculture*, SDG KNOWLEDGE HUB (Nov. 5, 2019), https://sdg.iisd.org/news/divergent-positions-on-benefit-sharing-hold-up-agreement-in-talks-on-plant-genetic-resources-for-food-and-agriculture/ [https://perma.cc/38JR-7DRC].

276. *See* Derrick A. Bell, Jr., *Brown v. Board of Education and the Interest-Convergence Dilemma*, 93 HARV. L. REV. 518, 523 (1980) ("The interests of blacks in achieving racial equity will be accommodated only when it converges with the interests of whites.").

All of these considerations and more, including the need for low transaction costs, should be carefully considered when crafting the modalities of an approach to DSI access and benefit-sharing that will be just, equitable, and fit for current and future (technologically changing) purposes. There are already indications that, just as scientists' dependence on physical genetic resources is waning, their need for intangible sequence information from genetic resources may eventually disappear thanks to DNA-free editing and artificial intelligence advances that allow for the prediction and construction of sequences and proteins de novo.[277]

Reaching an international consensus on any of the open-access, multilateral benefit-sharing approaches is not a given, and will likely require the clarification of several important matters such as the scope of DSI to be included, triggers for benefit-sharing, amounts of benefits to be shared, methods of distribution of benefits, beneficiaries, acceptable uses of funds, and modalities of complementary non-monetary benefit-sharing. Moreover, creating a "just" schema also should involve assessing the differential impacts of these proposals on different kinds of users such as academics, small and medium-sized commercial enterprises, and large multinational corporations.

Evaluating DSI access and benefit-sharing proposals with the above principles in mind does not guarantee a just and workable outcome, but hopefully will facilitate that goal. In any event, virtually all of the multilateral open sharing approaches would be preferable to the current status quo with its dearth of DSI benefit-sharing and risk of DSI and genetic resource access limitations.

C. A Global Multilateral Benefit-Sharing Mechanism

Article 10 of the Nagoya Protocol actually anticipates the possible future need for a GMBSM. It states:

> Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be

277. *See* Janina Metje-Sprink et al., *DNA-Free Genome Editing: Past, Present and Future*, 9 FRONTIERS PLANT SCI. 1, 5–6 (2019) (describing evolving techniques that bypass the use of DNA by using protein complexes for transformation); Ewen Callaway, *Deepmind's AI Predicts Structures or a Vast Trove of Proteins*, NATURE 595, 635 (July 22, 2021).

> used to support the conservation of biological diversity and the sustainable use of its components globally.[278]

Article 10 was a last-minute addition to the Protocol. This provision was not meaningfully debated or negotiated, but was viewed as a catch-all that could allow the opportunity to later address unresolved ABS issues by supplementing the bilateral approach with a global multilateral benefit-sharing mechanism that could include monetary and non-monetary benefits.[279] It may be that its time has come.

The idea of a GMBSM as a way to achieve justice in sharing in view of the technological changes that threaten to upset the balance struck in the Nagoya Protocol may be conceptually appealing, but it is frighteningly controversial. A study commissioned by the CBD Secretariat in response to a separate COP14/MOP3 decision, NP-3/13, on the possible need to activate Article 10, identified a variety of scenarios, including DSI, for which the bilateral benefit-sharing model of the Nagoya Protocol might not be possible.[280] Once published for peer-review, the draft study generated more than 100 *pages* of comments from governments, industry, academia, and civil society groups arguing, in many cases, against the need for a GMBSM by contesting the validity of characterizing certain scenarios described in the study as impossible to address in a bilateral negotiation.[281]

The voluminous response to the study was perhaps expected, considering the eliding of the discussion of Article 10 during the Nagoya Protocol negotiations, the challenges that users have faced in relation to ABS for physical genetic resources, and the lack of clarity regarding whether and in what way DSI is in the scope of the Nagoya Protocol. Moreover, some provider countries are concerned that a multilateral approach would impinge on their sovereign genetic resource rights and might ultimately replace the bilateral approach for *all* genetic resources and associated traditional knowledge, not just DSI.[282]

---

278. Nagoya Protocol, *supra* note 25, art. 10.

279. *See* Ahrén et al., *supra* note 63, at 127. The authors call Article 10 a "last-minute addition" to the text of the Nagoya Protocol added "in the context of the final compromise language" of the text. *Id.* They further note that "in this regard . . . its introduction must be understood as part of a strategy geared towards pushing aside some difficult issues during the Protocol's concluding negotiations. *Id.* Article 10 was constructed as a 'catch-all' provision . . . ." *Id. Importantly*, however, they also cite to similar language in Article 15(7) of the CBD that ultimately provided the basis for drafting and adoption of the Cartagena Protocol on Biosafety.

280. Bagley & Perron-Welch, *supra* note 26. This study will also inform discussions at COP15/MOP4, which may begin to consider the possible modalities of a GMBSM if a need for such a mechanism is established.

281. *2019-2020 Intersessional Period: Study Related to Article 10 of the Nagoya Protocol*, Convention on Biological Diversity (Dec. 2, 2020), https://www.cbd.int/abs/art10/2019-2020/study.shtml [https://perma.cc/GK8Y-YV8Y].

282. Countries that are concerned about losing control or losing out may not have grasped that any money received from a GMBSM for uses of DSI is not money they would ever get under the bilateral system, as there is virtually no ability to track uses of DSI. Even if tracking were possible, countries are likely to have few (if any) resources to put towards tracking (at the developing country level).

In June 2021, the CBD Subsidiary Body on Implementation met online to address a variety of CBD topics in advance of COP15/MOP4 in Kunming. During the discussions on Article 10 of the Nagoya Protocol, the African Group inserted into a draft recommendation an innovative proposal for an end-product user fee as part of a GMBSM. The proposal, in Option 2, paragraph 6 alt, states:

> The Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol . . .
>
> *Decides*, in the exercise of their sovereign rights over genetic resources, to establish a multilateral benefit-sharing mechanism, to operate as follows:
>
> (a) Each developed country Party shall . . . take legislative, administrative or policy measures, as appropriate, to ensure that 1 per cent of the retail price of all commercial income resulting from all utilization of genetic resources, traditional knowledge associated with genetic resources or digital sequence information on genetic resources is shared through the multilateral benefit-sharing mechanism to support the conservation and sustainable use of biological diversity, unless such benefits are otherwise being shared on mutually agreed terms established under the bilateral system;
>
> (b) All monetary benefits shared under the multilateral benefit-sharing mechanism shall be deposited in a global biodiversity fund operated by the Global Environment Facility, as the financial mechanism of the Convention, and this global fund shall also be open for voluntary contributions from all sources;
>
> (c) The global biodiversity fund shall be used, in an open, competitive, project-based manner, to support on the ground activities aimed at the conservation of biological diversity and the sustainable use of its components, in line with the ecosystem-based approach, carried out by indigenous peoples, local communities and others, in pursuit of spending priorities identified from time to time by the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services through scientific assessments[.][283]

This proposal would involve the imposition of a one percent user fee on commercial products resulting from tangible genetic resources, DSI, and traditional knowledge. It resonates with many of the various principles and

283. Convention on Biological Diversity Subsidiary Body on Implementation, *Global Multilateral Benefit-Sharing Mechanism (Article 10 of the Nagoya Protocol),* U.N. Doc. CBD/SBI/3/CRP.12 (June 2, 2021); *see also* Jaspars, et. al. *supra* note 264, at 17 (describing the end product approach).

concerns outlined above in having a (hopefully) low transaction cost, ensuring open access to DSI (no tracking nor tracing required), and being future-aware in that technological advances would already be accounted for. It also leaves room for non-monetary features to be part of the mechanism as well.[284] Moreover, it eventually could be deployed for DSI from other genetic resources, not only those under the purview of the CBD, such as from marine resources beyond national jurisdictions, and from tangible genetic resources as well, if Parties so desired.[285]

A sectoral approach is currently being taken to DSI and genetic resources in various fora such as the Intergovernmental Conference on Marine Biodiversity Beyond National Jurisdictions, and the FAO. This is understandable but arguably unfortunate. The biodiversity loss this planet faces crosses sectors and includes marine life, plant life (including for food and agriculture), animal life, and more; they are all under threat. Moreover, DSI from all of these different sectors is generally being used in the same ways for the same overarching scientific and commercial purposes: development of therapeutics, cosmetics, and agricultural improvement. And the DSI is being stored, in many cases, in the same INSDC databases. So creating solutions on a sectoral basis seems inefficient and likely to delay the kind of progress needed to generate the types and levels of benefit-sharing that will really contribute to stemming biodiversity loss and undergirding sustainable development. What is needed is a global solution to a global problem.[286]

Access to DSI and tangible genetic resources is critically important to the development of new and improved food crops and therapeutic products, but "just" benefit-sharing is also important to IPLC stewardship of biodiversity. The African Group proposal in the CBD is clearly a first step in a likely lengthy series of negotiations, but its potential usefulness as a way to address DSI and other biodiversity-related challenges is promising. It may be that an initial pilot program or soft law approach, akin to the non-binding Bonn Guidelines that preceded the Nagoya Protocol, may pave the way for a more permanent, binding regime.

In *The Idea of Justice*, Nobel Prize winner Amartya Sen puts forward a hypothetical in which one must decide which of three children should get a single flute, to which they are all laying claim, in order to illustrate how entities can have competing claims for justice that differ from and rival each other.[287] In this hypothetical, the first child claims entitlement because she is the only one of the three who can actually play the flute. The second child's claim is based on the fact that, unlike the other two children, he is so

284. *Id.* It also recognizes the continuing presence of the bilateral system in the phrase "unless such benefits are otherwise being shared on mutually agreed terms established under the bilateral system."

285. For further information, *see Intergovernmental Conference on Marine Biodiversity of Areas Beyond National Jurisdiction*, United Nations, https://www.un.org/bbnj/ [https://perma.cc/C6Y5-RDGH].

286. *See* Aubry et al., *supra* note 271 (proposing a global governance approach to ABS for DSI).

287. Amartya Sen, The Idea of Justice 12–14 (2009).

poor that he has no toys at all, so the flute should be given to him to play with. The claim of the third child is based on the fact that she put many months of labor into actually making the flute and claims it as her property.

According to Sen, if one only heard one child's story (and neither of the other two), the case for giving the flute to that child would be strong. But having heard all three, the reader is faced with a dilemma, the solution to which would likely be informed by whether the reader subscribed to utilitarian, libertarian, or economic egalitarian philosophies. He explains:

> [I]t is not easy to brush aside as foundationless any of the claims based respectively on the pursuit of human fulfillment, or removal of poverty, or entitlement to enjoy the products of one's own labour. The different resolutions all have serious arguments in support of them, and we may not be able to identify, without some arbitrariness, any of the alternative arguments as being the one that must invariably prevail . . . . There may not indeed exist any identifiable perfectly just social arrangement on which impartial agreement would emerge.[288]

In the DSI context, the CBD/Nagoya Protocol Parties may not have to choose between doing justice for genetic resource providers, IPLCs, and DSI users; they should be able to meet the needs of all three groups. An appropriately designed GMBSM, including non-monetary benefits and a commercial product-based user fee, could ensure open access while providing meaningful benefits for biodiversity conservation, sustainable use, and economic development. Bringing this or any other DSI benefit-sharing solution to fruition, however, will require significant political will, less greed from users and providers, and a recognition of the importance of this moment to the health of our planet.

Conclusion

"It is often stated that the law lags behind technology."[289] The truth of this assertion is evident in the rapid advances in sequence utilization that have rendered aspects of the Nagoya Protocol's bilateral benefit-sharing scheme outdated before much implementing legislation is even in place. These technological advances in the ability to use intangible sequence information as a substitute for physical genetic material raise important questions regarding the interpretation of the scope of the Nagoya Protocol. For textual and practical reasons, reinterpreting the definition of genetic resources to include DSI seems both unhelpful and textually unsupportable. However, recognizing that DSI in databases results from the utilization of

288. *Id.* at 14–15.
289. Moses, *supra* note 30, at 239.

genetic resources at some point is a logical, virtually unassailable proposition. As such, DSI should be considered as within the scope of the Nagoya Protocol but subject only to benefit-sharing obligations, not PIC access limitations.

Open access to DSI along with monetary and non-monetary benefit-sharing, though challenging to operationalize, is just and necessary, both to fulfill the objectives of the CBD and perhaps even to basic human flourishing. Without monetary benefit-sharing, necessary investments of financial and human resources to conserve biodiversity (which benefits us all) and aid in socioeconomic development for the most vulnerable among us, are unlikely to occur—at least not as soon as they are needed. We would do well to recognize that "indigenous land stewardship is a global environmental service that merits both political protection and financial support."[290]

Without a just, equitable, multilateral scheme that allows countries, and the IPLCs within their borders, to share in the monetary benefits associated with commercial uses of DSI, we can expect to see continued domestic implementation of DSI access restrictions, as countries logically use the tools at their disposal, ineffective though they may be, in an effort to address justice, equity, conservation, and economic development concerns. Unfortunately, such access restrictions are unlikely to increase benefitsharing but may be detrimental to scientific advancement and societal welfare.

"*What's Yours is Mine and What's Mine is Mine*" and "*What's Mine is Mine and What's Yours Is Mine*" are two mindsets that require an interest convergence if parties are to successfully develop a workable, resilient, multilateral benefit-sharing scheme for DSI that properly incentivizes conservation without hindering innovation. Only if all sides choose to be more cognizant of the legitimate perspectives and concerns of others, is a just, viable, and sustainable solution likely to be reached.

290. Walker et al., *supra* note 238, at 3023.