Washington Journal of Law, Technology & Arts

Volume 13 | Issue 2 Article 2

1-1-2018

# Bio-Property Contracts in a New Ecosystem: Genetic Resources Access and Benefit Sharing

Mariko Kageyama

WASHINGTON JOURNAL OF LAW, TECHNOLOGY & ARTS
VOLUME 13, ISSUE 2 WINTER 2018

# BIO-PROPERTY CONTRACTS IN A NEW ECOSYSTEM: GENETIC RESOURCES ACCESS AND BENEFIT SHARING

*Mariko Kageyama*[*]


Cite as: 13 Wash. J.L. Tech. & Arts 109 (2018)

http://digital.law.washington.edu/dspace-law/handle/1773.1/1786

## ABSTRACT

*The* 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 *presents a relatively new international legal framework. Although the United States is not currently bound by this legal instrument, its impact may be felt in the life sciences innovation sector and beyond. Transnational implementation mechanisms for the Nagoya Protocol have a combination of property law and contract law as their theoretical underpinning. Stakeholders who are entering into an agreement with their foreign counterparts should honor the Access and Benefit-Sharing scheme as well as domestic laws and policies of Parties to the Protocol to access biological materials located in their jurisdictions. Users' due diligence in obtaining prior informed consent and adhering to mutually agreed terms will contribute greatly to promoting the objectives of the Nagoya Protocol and the Convention on Biological Diversity.*

## TABLE OF CONTENTS



---

[*] Mariko Kageyama, University of Washington School of Law, J.D. Class of 2018. Special thanks go to Dr. Todd A. Wildermuth and Professor T. Andrew Culbert at the University of Washington School of Law for their helpful comments.

## INTRODUCTION

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization ("Nagoya Protocol" or "Protocol")[1] to the Convention on Biological Diversity ("CBD" or "Convention")[2] presents a relatively new international legal framework with respect to cross-border transactions of biological resources. The Nagoya Protocol most likely affects biotechnological, pharmaceutical, cosmetic, agricultural, food, and other industries that obtain non-human genetic materials from other countries for developing useful

[1] The 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, *opened for signature* Feb. 2, 2011, U.N.T.S. A-30619 (entered into force Oct. 12, 2014) [hereinafter Nagoya Protocol], https://www.cbd.int/abs/text/.

[2] Convention on Biological Diversity, *opened for signature* June 5, 1992, 1760 U.N.T.S. 79 (entered into force Dec. 29, 1993) [hereinafter CBD], https://www.cbd.int/convention/text/.

biological products and processes. Although the United States is currently not a Party to the Convention,[3] the treaty's impact may be felt broadly in the life sciences innovation sector and beyond.

This emerging global standard, in combination with the domestic law of the member states, creates complexities with regard to what steps a stakeholder must take to be legally compliant and accountable for their conduct when working with genetic resources and knowledge attributable to a particular geographic region or indigenous community. The implementation mechanisms for this international law in each jurisdiction essentially come down to contracts over the exchange of property between providers and users, reflecting individually negotiated and mutually agreed-upon terms ("MAT"). Regardless of the United States' status as a non-Party to the Nagoya Protocol, contractual obligations may be imposed on whoever wants to use biological resources of foreign origin under the Access and Benefit-Sharing ("ABS") scheme. Such contractual terms will likely incorporate by reference relevant domestic laws of the resource provider. Users should defer to, rather than resist, the extraterritorial application of the provider country's rules and policies.

## I. NAGOYA PROTOCOL BACKGROUND

The 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 is an international agreement governing cross-border transactions of genetic resources. This legal instrument has been in effect since October 12, 2014.[4] It is one of the supplementary agreements to the Convention on Biological Diversity,[5] an umbrella treaty that has been universally adopted by almost the entire world except the United States. Largely

---

[3] As of 2018, the only other jurisdiction in the world that is not a Party to the Convention is Holy See, a church jurisdiction in Rome, Italy. *See* CBD List of Parties, https://www.cbd.int/information/parties.shtml.

[4] Nagoya Protocol, https://www.cbd.int/abs/.

[5] The other supplementary agreement to the Convention is the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *opened for signature* May 15, 2000, 2226 U.N.T.S. 208 (entered into force Sept. 11, 2003), http://bch.cbd.int/protocol/text/.

unbeknownst to Americans, the Nagoya Protocol may have significant positive or negative impact on future global intellectual property strategies, particularly in the life sciences innovation field as discussed below.

### *A. Nagoya Protocol's Objectives*

The Convention on Biological Diversity ("CBD") is an international legally binding treaty with three main goals: the (1) conservation of biodiversity, (2) sustainable use of the components of biodiversity, and (3) equitable sharing of the benefits derived from the use of genetic resources.[6] The Nagoya Protocol, a supplementary agreement to the CBD, is the legal instrument developed specifically to implement the last of these three core goals: providing access to and sharing the benefits arising from the utilization of genetic resources in a fair and equitable manner.[7] The Nagoya Protocol is intended to accomplish this objective by facilitating access to genetic resources, transferring relevant technologies and knowledge, and by allocating appropriate funding. By doing so, the Protocol strives to contribute to the other two primary goals of the CBD: conservation of biological diversity and the sustainable use of its components.[8]

### *B. Treaty Ratification Status*

The CBD is one of the multilateral agreements hosted by the United Nations Environment Programme ("UNEP"). The Convention was opened for signature at the United Nations Conference on Environment and Development—known as the Rio Earth Summit—in 1992 and entered into force in December 1993.[9] As of 2018, 196 countries—indeed, almost the entire world—have ratified the CBD.

The Nagoya Protocol was adopted by the Conference of the

---

[6] CBD art. 1.

[7] Nagoya Protocol preamble; CBD art. 15.

[8] Nagoya Protocol arts. 1, 9.

[9] Nagoya Protocol intro, https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

Parties of the Convention at its tenth meeting in October 2010 in Nagoya, Japan. It was opened for signature in 2011-2012[10] and was entered into force in October 2014 pursuant to Article 33.[11] As of April 2018, 105 countries—just over half of the 196 Parties to the CBD—have domesticated the instrument to become Parties to the Nagoya Protocol.[12] Once joined, member states may not make reservations; they are fully bound by the provisions of the Nagoya Protocol.[13] The Secretariat to both the Convention and the Nagoya Protocol is located in Montreal, Canada,[14] although ironically Canada, a Party to the CBD, has yet to sign the Nagoya Protocol as of this writing.

The United States remains a non-Party to both the Convention and the Nagoya Protocol. The CBD is a non-self-executing treaty under the United States' laws, and thus by itself does not give rise to a domestically enforceable law. Instead, the U.S. government treats the CBD as an Article II treaty, for which the Constitution's Treaty Clause requires that two-thirds of the Senate give its advice and consent, before the President may ratify the agreement.[15] In June 1993, then-President Bill Clinton signed the Convention. However, the treaty has never received an affirmative vote of the Senate, partly due to its low priority status on the Congress's political agenda.[16] Because the United States has yet to become a

---

[10] *Id.* art. 32.

[11] *Id.* art. 33 (providing that the protocol would enter into force on the 90th day after the date of deposit of the 50th instrument of ratification, acceptance, approval or accession by States . . . that are party to the Convention).

[12] CBD, The Access and Benefit-Sharing Clearing-House [hereinafter ABSCH], https://absch.cbd.int/countries/status/party (last visited Mar. 1, 2018) (counting the European Union as among the 105 Parties to the Nagoya Protocol).

[13] Nagoya Protocol art. 34.

[14] CBD art. 24; Nagoya Protocol art. 28; CBD SECRETARIAT, https://www.cbd.int/secretariat/ (last accessed Mar. 1, 2018).

[15] U.S. CONST. art. II, § 2, cl. 2.

[16] *See* Original Resolution Expressing the Sense of the Senate Regarding Conditions for Continued United States Participation Under the Convention on Biological Diversity. S. Res. 239, 103rd Cong., 140 CONG. REC. 15822 (as reported by S. Comm. on Foreign Relations, July 11, 1994); *see also* Robert F. Blomquist, *Ratification Resisted: Understanding America's Response to the Convention on Biological Diversity, 1989-2002*, 32 GOLDEN GATE U. L. REV. 493, 499 (2002) (providing a chronological synopsis of the U.S. government's

Party to the Convention, it is automatically ineligible to become a Party to the Nagoya Protocol pursuant to the CBD provision.[17]

### *C. Nagoya Protocol's Vocabulary*

The Protocol's use-of-terms and scope provisions are found in Articles 2 and 3, respectively. They incorporate and are consistent with the corresponding provisions of its parent treaty.[18] In addition to genetic resources themselves, the Nagoya Protocol applies to traditional knowledge associated with genetic resources and to the benefits arising from the utilization of such traditional knowledge within the scope of the Convention.[19]

However, neither the scope provision nor the use-of-terms provision is definitive enough to create a consensus among Parties over the meaning of key terms, such as "genetic resources" and "traditional knowledge," which would facilitate communication about these important concepts with stakeholders. The term "genetic resources" seems intentionally excluded from the list of definitions in the Protocol. This obvious gap is filled by the Convention, which defines "genetic resources" merely as genetic material of actual or potential value;[20] and "genetic material" as any material of plant, animal, microbial, or other origin *containing functional units of heredity*.[21]

In fact, only five terms are defined under the Protocol Article 2.[22] One such term is "utilization of genetic resources," which Article 2 defines as the act of conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.[23] "Biotechnology" is defined as any technological application that uses biological systems, living organisms, or derivatives thereof, to

---

response to the Convention).

[17] CBD art. 32(1).

[18] Nagoya Protocol arts. 2–3; CBD arts. 2, 4.

[19] Nagoya Protocol arts. 3, 12.

[20] CBD art. 2, para. 11.

[21] *Id.* art. 2, para. 9 (emphasis added).

[22] The remaining two terms listed under Article 2 are "Conference of the Parties" and "Convention." Nagoya Protocol art. 2(a) & 2(b).

[23] *Id.* art. 2(c).

make or modify products or processes for specific use.[24] "Derivative" is further defined as "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, *even if it does not contain functional units of heredity*."[25] Accordingly, the subject matter of the Nagoya Protocol should be construed much more broadly than just DNA itself.

The only explicit threshold to the otherwise highly inclusive concept of "genetic resources" is that human genetic resources are excluded from the framework of the Protocol.[26] Still, traditional knowledge associated with genetic resources of non-human origin is possessed by particular indigenous peoples or individuals, and therefore the Protocol still has legal and ethical implications specifically relating to human subjects research.[27] In the treaty's attempt to grasp the constantly evolving nature of life sciences and biotechnology fields, omitting a definition of "genetic resources" likely reflects the drafters' intention to allow the scope of "genetic resources" to broaden in the future. This would allow the term to cover novel types of materials as they became available with advancements in technology and applications to a wider array of biological resources. For example, over the last several years, the Conferences of the Parties have considered whether to enlarge the scope of the Protocol to encompass such items as digital genetic

---

[24] *Id.* art. 2(d).

[25] *Id.* art. 2(e) (emphasis added).

[26] CBD, Decision Adopted by the Conference of the Parties to the CBD [COP] at its 10th Meeting X/1, Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization, at 3, U.N. Doc. UNEP/CBD/COP/DEC/X/1 (Oct. 29, 2010) (reserving the right to place human genetic resources within the scope of the Protocol by stating "without prejudice to the further consideration of this issue by the [COP]").

[27] *Cf.* In the United States, the Federal Policy for the Protection of Human Subjects or "Common Rule" is federal regulations governing the protection of human subjects in research. 45 C.F.R. pt. 46 (1999); 82 Fed. Reg. 7149 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46); *see also* OFF. FOR HUMAN RESEARCH PROTS., U.S. DEP'T OF HEALTH & HUMAN SERVS., INTERNATIONAL COMPILATION OF HUMAN RESEARCH STANDARDS, 2018 EDITION (2018), https://www.hhs.gov/ohrp/sites/default/files/2018-International-Compilation-of-Human-Research-Standards.pdf (enumerating over 1,000 standards that govern human subjects research in 130 countries).

sequence information or microorganisms manipulated by synthetic biological techniques.[28] Although the underlying context is different, difficulty in delineating the scope and range of biotechnology subject matter is somewhat analogous to patent subject matter eligibility jurisprudence surrounding nucleic acids, proteins, and other biochemical compounds, which has independently developed under the patent laws of the U.S., European Union, and other jurisdictions.[29]

Other legal terms of art that are not separately defined in the treaty provisions but are frequently used throughout the text of the Protocol include prior informed consent ("PIC") and mutually agreed terms ("MAT"), in addition to Access and Benefit-Sharing ("ABS") and its equivalent phrases. The following sections provide more context to these key terms as they are normally understood in the Nagoya Protocol's ABS framework.

### *D. Nagoya Protocol's Conceptual Framework*

The Nagoya Protocol asserts that the first two of the three pillars of the CBD are promoted through fulfilling its third and final goal—fair and equitable sharing of the *economic value of ecosystems and biodiversity*, which encompasses benefits derived from the use of

---

[28] CBD, Decision Adopted by the COP XIII/16, Digital Sequence Information on Genetic Resources, at 1–2, U.N. Doc. CBD/COP/DEC/XIII/16 (Dec. 16, 2016) (establishing an ad hoc technical expert group to examine any potential implications of the use of digital sequence information on genetic resources for the objectives of the Convention and the Protocol); Digital Sequence Information on Genetic Resources Public Meeting, 82 Fed. Reg. 28927 (June 26, 2017) (calling for public comments in consideration for U.S. participation in future CBD and Nagoya Protocol meetings); *see also* Margo A. Bagley, *Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology*, WILSON CENTER: SYNTHETIC BIOLOGY PROJECT (Dec. 2015), http://www.synbioproject.org/publications/digital-dna-nagoya-protocol/.

[29] *See, e.g.*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (ruling that isolated DNA is not within the scope of patent eligible subject matter under the U.S. Patent Act, 35 U.S.C. § 101); *see also* Convention on the Grant of European Patents [European Patent Convention (EPC)] art. 52 & EPC Implementing Regulations r. 27(a) (allowing biological material isolated from its natural environment or produced by means of a technical process as a patentable biotechnological invention).

genetic resources.[30]

Economics play a role here in understanding the Nagoya Protocol's underlying principle. The Protocol introduces an economic perspective to transnational genetic resources management by first recognizing public awareness of the economic value of ecosystems and biodiversity.[31] It further recognizes that the fair and equitable sharing of this economic value with the *custodians* of biodiversity is a key incentive for the conservation of biological diversity and the sustainable use of its components.[32] Under the CBD, custodians of biodiversity include sovereign states as well as indigenous and local communities.

As far as the semantic relationship between the "ecosystem and biodiversity" and "genetic resources" is concerned, the former describes certain variable modes of the natural environment and its elements,[33] while the latter—despite the term not having been explicitly defined in the Protocol itself—ordinarily refers to tangible materials existing as integral components of a certain biological system with intrinsic value recognized at the molecular level.[34] Of course, if digital DNA sequence data falls within the scope of "genetic resources,"[35] then the term would cover not only tangible property, but also intangible information.

On one hand, an ecosystem may exhibit inherent economic value

---

[30] CBD art. 1; Nagoya Protocol preamble (emphasis added).

[31] Nagoya Protocol preamble.

[32] *Id.* (emphasis added).

[33] CBD art. 2, paras. 1 & 8 (defining ecosystem as "a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit," whereas defining biological diversity as "the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems").

[34] *See supra* text accompanying notes 20–21; *see also, e.g.*, Morten Walløe Tvedt & Peter Johan Schei, *The Term 'Genetic Resources': Flexible and Dynamic While Providing Legal Certainty?*, GLOBAL GOVERNANCE OF GENETIC RESOURCES: ACCESS AND BENEFIT SHARING AFTER THE NAGOYA PROTOCOL 18 (Sebastian Oberthür & G. Kristin Rosendal eds., 2014) (illustrating rather inconsistent meanings of the term "genetic resources" as adopted by international organizations).

[35] *See* Bagley, *supra* note 28.

in the biosphere and provide measurable benefits to human beings. This concept is recognized today in the ecosystem services and natural capital contexts.[36] On the other hand, scientific inquiries and sophisticated technology can enhance the economic value of genetic resources as property by deciphering genetic codes and their functions in the living system. It is unlikely that genetic resources as they exist in nature become automatically more valuable in economic terms by virtue of being harvested. In this regard, genetic resources are different from other kinds of natural resources, such as oil and gas. But there are similarities, too. For example, both are commonly viewed as non-ubiquitous, finite resources that should not be overexploited. Indeed, one could even argue that the traditional rule of capture or the labor theory of property would apply to genetic resources in determining property ownership, since those concepts apply to other migratory resources like oil and gas.[37]

To attain the primary objective of the Nagoya Protocol and ultimately reach the overarching goals of the umbrella biodiversity treaty, baseline research and development activities utilizing genetic resources must increase. An increase would provide for the creation of new intellectual property and commodities, promote technology transfer and commercialization in industries, and establish cross-border revenue streams in a fair and equitable manner under the Protocol's grand scheme.

But an increase would come with costs, as it requires both money and manpower to actively protect and conserve biodiversity in balance with other competing economic interests. Further, it is prohibitively more expensive to try to restore habitats once destroyed or lost. Therefore, to promote a sound and balanced economy, the Protocol urges prospectors of genetic resources to either pay the cost up front or to return a part of the profits, assets, and knowledge generated to source countries or communities in exchange for benefits arising from such genetic resources. The term Access and Benefit-Sharing ("ABS") captures this concept.

---

[36] *See* Sharachchandra Lele, et al., *Ecosystem Services: Origins, Contributions, Pitfalls, and Alternatives*, 11 CONSERVATION & SOC. 343, 343–45 (2013).

[37] *See* Jessica L. Roberts, Theories of Genetic Ownership, 38, 46 (Sept. 9, 2015) (unpublished manuscript) (on file with the Petrie-Flom Center, Harvard Law School).

However, uncertainty remains as to whether new international rules governing the use of natural resources have sufficient legal force to mandate resource providers—who are mostly developing countries and indigenous communities—to return benefits to society by fully committing to sustainable development and local capacity building. For example, it is unclear whether resource providers are required to allocate a set amount of funding for regional habitat restoration efforts or for biotechnology specialists training.[38]

### *E. Challenges Posed by the Protocol*

As reaffirmed in its preamble, the Nagoya Protocol is grounded in the fundamental idea that each country should exercise its sovereign rights over its natural resources.[39] This is a fundamental departure from the traditional view that biological resources on Earth are in the public domain and in should be freely available as global common goods. Yet in the property paradigm, countries enforcing their sovereign rights too strictly over biotic resources—including forms of living organisms such as human pathogens and microorganisms found within its national territory—generate concerns that the Protocol's scheme will eventually languish under the tragedy of the anticommons. The tragedy of the anticommons describes a legal environment where multiple owners are each endowed with the right to exclude others from a scarce resource, with no one person possessing an effective privilege of use.[40] When there are too many owners holding rights of exclusion, the resource is prone to underuse.[41] On the contrary, lack of international coordination on the use of finite natural resources on the planet may

---

[38] Nagoya Protocol art. 22 (focusing capacity-building efforts on the least developed countries, small island developing states, and indigenous and local communities); *id.* art. 22, para. 5(h) (listing enhanced contribution of ABS activities to the conservation and sustainable use of biodiversity as a capacity development measure); *see also infra* note 53. *But see id.* art. 9 (merely encouraging, but not requiring, directing benefits towards the biodiversity conservation).

[39] Nagoya Protocol preamble.

[40] Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 623 (1998).

[41] *Id.* at 624.

lead to the tragedy of the commons, where the resources are prone to overuse.[42] An example of this is found in marine biodiversity beyond national jurisdictions, where each country attempts to claim rights over resources on the high seas beyond any country's exclusive economic zone.[43]

In addition to concerns over resource underutilization, apparent regulatory complexities set by the Protocol can stifle innovations and sound competition in a manner contrary to the Protocol's purposes of encouraging active use of genetic resources in the global bioeconomy. This means that unless it is properly administered, the treaty may have a chilling effect on bona fide international bioprospecting activities, and may even create a hostile environment for noncommercial biodiversity researchers.[44]

Furthermore, depending on the degree of flexibility in enforcing the treaty provisions to realize fair and equitable transactions of genetic resources, the Protocol may have substantial implications on global health agenda, such as distribution of drugs, vaccines and antibiotics to developing countries. For example, in pre-Nagoya 2007, Indonesia refused to share its clinical specimens of H5N1 avian flu virus to the World Health Organization ("WHO") in retaliation for the inequitable virus sharing practice in the global health sector that existed at the time.[45] The Indonesian avian flu strain was supposed to be used for vaccine production by a private entity in Australia that planned to use this free virus sample to patent

---

[42] *Id.*

[43] *See* Development of 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, G.A. Res. 69/292, U.N. Doc. A/RES/69/292 (June 19, 2015).

[44] *See, e.g.*, Jörg Overmann & Amber Hartman Scholz, *Microbiological Research Under the Nagoya Protocol: Facts and Fiction*, 25 TRENDS IN MICROBIOLOGY 85 (2017) (arguing that non-commercial basic research will be negatively affected by restrictive policies under the Protocol).

[45] Endang R. Sedyaningsih et al., *Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia*, 37 ANNALS ACAD. MED. SINGAPORE 482, 486 (2008); *see also* Marie Wilke, *A Healthy Look at the Nagoya Protocol: Implications for Global Health Governance*, THE 2010 NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING IN PERSPECTIVE: IMPLICATIONS FOR INTERNATIONAL LAW AND IMPLEMENTATION CHALLENGE, at 123–24 (2013).

a vaccine, and sell the product back to Indonesia at an unaffordable price.[46] This illustrates the frequent tension between stakeholders with competing interests over valuable biological property. As here, these are interests in securing access to human pathogens for public health purposes, protecting intellectual property for profits, and preventing valuable resources from being exploited by foreigners. The avian flu vaccine served as a great lesson for WHO, as WHO and CBD now work together closely to strengthen linkages between biodiversity and human health—particularly in the context of sharing pathogens and relevant clinical information during public health emergencies.[47]

A pragmatic solution to overcome these various challenges would be to keep implementation mechanisms for the Nagoya Protocol simple, transparent, and flexible. A balance must be struck under this paradigm so that legitimate rights holders are adequately protected from unfair dealings, while for-profit bio-prospectors are still deterred from unjust enrichment. As analyzed in the later section on the Access and Benefit-Sharing Clearing-House, the high-level monitoring of ABS activities would probably be the best way for the Protocol to strike this balance. At the same time, the Protocol should allow provider-user negotiation at the ground level to maximize the Parties' freedom of contract. Using the instrument's terminology, as long as prior informed consent ("PIC") can be secured,[48] mutually agreed terms ("MAT")[49] between parties in private contracts are best left to negotiation to the extent permitted by the provider's domestic laws. This approach will maximize the

---

[46] Sedyaningsih et al., *supra* note 45, at 486.

[47] World Health Organization [WHO], *Review of the Pandemic Influenza Preparedness Framework: Collaboration with the Secretariat of the CBD and Other Relevant International Organizations*, at 2, WHO Doc. A70/57 (May 4, 2017) (recommending that the WHO flu preparedness framework be recognized as a specialized international ABS instrument under the Protocol and that CBD share with WHO information regarding the ABS implementation on health emergency cases through a national reporting system under Nagoya Protocol arts. 4(4) & 8(b) & 29); *see also* Daniel Cressey, *Treaty to Stop Biopiracy Threatens to Delay Flu Vaccines*, 542 NATURE 148 (2017) (highlighting WHO's direction to integrate a benefit-sharing mechanism into the global vaccine supply system to expedite seasonal flu vaccine production).

[48] Nagoya Protocol art. 6.

[49] *Id.* art. 5.

positive effects of freedom of contract while promoting access to untapped genetic resources found within the territory of each provider country.

### *F. Nagoya Protocol and Intellectual Property*

Although the subject matter of the Nagoya Protocol is primarily biological, its reach is not limited to environmental and natural resources laws as implied by the parent treaty's title, Convention on Biological Diversity, implies. As demonstrated by the example of the Indonesian avian flu virus, the Protocol frequently implicates law regarding technology and intellectual property. Technology transfer is an important part of the Protocol's objective, as the Protocol purports to contribute to sustainable development by building research and innovation capacities in developing economies, and adding value to genetic resources.[50] Each Party to the Protocol is required to take necessary legislative, administrative or policy measures as appropriate to establish clear rules and procedures for mandating and establishing MAT, including benefit-sharing clauses that address relevant intellectual property rights.[51] This means that under the Nagoya framework, intellectual property rights are presumed to be among a "bundle of rights" to be considered up front in bilateral negotiations between providers and users of genetic resources, and memorialized in a written contract called a material transfer agreement.

Developing MAT over intellectual property rights, or other forms of benefits expected from the use of genetic resources, is similar to drafting a standard technology licensing agreement. This is especially true if benefit-sharing can be unambiguously written in financial terms, such as royalties.[52] However, MAT established under Nagoya are still distinguishable from terms of a technology license in some critical respects. First, although individually negotiated and agreed-upon terms are flexible to a certain extent, they must conform with the domestic laws of the provider country implementing the treaty. The Protocol is designed so that specific measures to implement its ABS scheme are largely left to the

[50] *Id.* preamble.
[51] *Id.* art. 6.3(g)(ii).
[52] *Id.* annex 1(d).

prerogative of each Party. Unless the provider country explicitly disclaims its rights to genetic resources leaving its jurisdiction as a matter of public policy, the provider country's laws may have an extraterritorial reach over all contracting parties, and may even override a contradictory MAT. This could interfere severely with the Parties' freedom of contract.

Another idiosyncratic aspect of an ABS material transfer agreement is that intellectual property may not have been fully developed, or vested, at the time the Parties entered into an executory agreement. Original source organisms or isolated biochemical compounds themselves are merely raw materials of limited commercial value. They are tangible and exhaustible personal property. But intellectual property assets, once successfully developed out of such exhaustible resources of intrinsic value, become significantly more economically valuable. Moreover, intellectual property is inexhaustible and can be shared with others without diminishing its value. Quid pro quo in this context dictates granting relevant intellectual property rights or other forms of economic benefits to the source country in return for gaining access to its original raw ingredients. Regarding benefits, the Protocol assumes a broad range of beneficial arrangements as acceptable forms of benefits that can be exchanged under the ABS scheme. For reference, a non-exhaustive list of different types of benefits, both monetary and non-monetary, is found in the Annex to the Protocol.[53]

Compared to standard technology licensing, parties may have to allow material transfer agreements to contain indefinite language where intellectual property has yet to be developed. This requires parties to initially assume higher risk under the ABS framework, even though they may be able to reassess, and modify original terms after they execute an original agreement. From the industries' perspectives, it may take years for companies to develop patentable products such as pharmaceuticals. In such circumstances, the party requesting access would likely favor a risk-averse approach, such as

---

[53] *Id.* annex (listing plausible types of non-monetary benefits, *inter alia*, sharing of results and collaboration in research programs; participation in product development; admittance to *ex situ* facilities and databases; education and training; transfer of knowledge and technology; capacity-building; food and livelihood security benefits; social recognition; and joint ownership of intellectual property rights).

first conducting preliminary testing, and evaluating target materials before expanding the project to a full industrial scale to lower the risk of breaching any MATs.

In recent decades, traditional knowledge is a type of community-owned intellectual property right recognized not only by the CBD and Nagoya Protocol, but also by the international intellectual property sector.[54] As discussed earlier, the term "traditional knowledge" is not defined within the Protocol or the Convention. However, the World Intellectual Property Organization ("WIPO") defines traditional knowledge as a living body of knowledge passed on from generation to generation within a community that often forms part of a people's cultural and spiritual identity.[55] The CBD Working Group has intensively reviewed the term and concept of traditional knowledge since the 2000s.[56] Referred to as Article 8(j),[57] the current proposed definition of traditional knowledge is: the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.[58] It is generally understood that traditional knowledge has greatly contributed to the discovery, creation, and preservation of valuable community knowledge related to medicinal, therapeutic, and other beneficial use of certain biological resources. However, dealing with traditional knowledge in the context of a material transfer and technology licensing agreement poses novel challenges for most stakeholders.

---

[54] *See generally* U.N. DEP'T OF INT'L ECON. & SOC. AFFAIRS, STATE OF THE WORLD'S INDIGENOUS PEOPLES, at 74, U.N. Doc. ST/ESA/328, U.N. Sales No. 09.VI.13 (2009) (reviewing the history of indigenous peoples in light of intellectual property rights, with emphasis on how the international property rights regime has failed to recognize indigenous customary law).

[55] World Intell. Prop. Org. [hereinafter WIPO], *Traditional Knowledge*, http://www.wipo.int/tk/en/ (last visited Mar. 1, 2018).

[56] CBD Executive Secretary, Glossary of Relevant Key Terms and Concepts Within the Context of Article 8(j) and Related Provisions, U.N. Doc. CBD/WG8J/10/3 (Sept. 10, 2017).

[57] CBD art. 8(j) ("[P]romote . . . wider application [of traditional knowledge] with the approval and involvement of the holders of such knowledge . . . and encourage the equitable sharing of the benefits arising from the utilization of such knowledge.").

[58] CBD Executive Secretary, *supra* note 56, annex.

Because added value of genetic resources partly comes from its essential attribution to a particular species or variety that originated in a specific locality, geographical indication is presumed to be another type of an intellectual property right to be accounted for in benefit-sharing negotiation, despite absence of the term in the Protocol text. Basically, provider countries would like to protect and control geographical indications over new innovative products that are developed in exchange for genetic resources uniquely sourced from their respective territories. The geographical origin of products has likewise been contemplated in the international trade context. In particular, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") has a whole section dedicated to geographical indications, with special reference to wines and spirits.[59] "Geographical indications" are defined as indications that identify a good as originating in the territory of a member state, or a region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin.[60]

Finally, as far as patent law is concerned, a great deal of unknowns exist in current national policies among the member states as to whether, when a claimed invention is based upon genetic materials sourced from another jurisdiction bound by the Protocol, domestic patent law requires applicants to comply with the Nagoya Protocol as a prerequisite for granting a biotechnology patent. For instance, domestic legislation could create new obligations for a patent applicant to submit an official permit or certificate of compliance to the national patent office.[61] Or the national patent

---

[59] Agreement on Trade-Related Aspects of Intellectual Property Rights § 3, arts. 22–24, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 308 [hereinafter TRIPS Agreement].

[60] TRIPS Agreement, *supra*, art. 22, ¶ 1.

[61] *See* Draft Decision to Enhance Mutual Supportiveness Between the TRIPS Agreement and the Convention on Biological Diversity, *Communication from Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group*, at 2, WTO Doc. TN/C/W/59 (Apr. 19, 2011) (proposing an amendment to the TRIPS Agreement by inserting Article 29*bis*, which requires that patent applicants provide a copy of an Internationally Recognized Certificate of Compliance with the Nagoya Protocol, *infra* text

office could require applicants to disclose the country of origin of foreign genetic materials that led to a claimed invention in a patent publication. [62] Such mandatory disclosure in published patent applications would put countries and communities on notice, and may allow them to challenge patentability in a timely manner.[63] Of course, these public parties must show standing as holders of property rights or traditional knowledge in interest, as well as a valid claim under the applicable law of any given jurisdiction. Relatedly, a domestic law, either by statute or case law, may enable the court to invalidate a patent or render it unenforceable if the alleged infringer can show that the patent-in-suit was derived from genetic resources that were unlawfully acquired in noncompliance with a provider country's laws implementing the Protocol.[64]

---

accompanying notes 87–90) [hereinafter TRIPS Agreement Article 29*bis*].

[62] *See, e.g.*, Zhonghua Renmin Gongheguo Zhuan Li Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, last rev'd Dec. 27, 2008, effective Oct. 1, 2009), art. 5, para. 2 ("Patent rights shall not be granted for inventions that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations."); *id.* art. 26, para. 5 ("With regard to an invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources. If the applicant cannot indicate the original source, he shall state the reasons."), http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html ; *but see, e.g.*, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, recital 27, 1998 O.J. (L 213) 13, 15 (EC) ("[I]f an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents"); *see generally* WIPO, DISCLOSURE REQUIREMENTS TABLE (Oct. 2017), http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf (providing a non-exhaustive list of disclosure requirements related to genetic resources or traditional knowledge in thirty-three jurisdictions).

[63] *See* Wallace Feng, *Appropriation Without Benefit-Sharing: Origin-of-Resource Disclosure Requirements and Enforcement Under TRIPS and the Nagoya Protocol*, 18 CHI. J. INT'L L. 245, 249 (2017).

[64] *See* TRIPS Agreement Article 29*bis*, *supra* note 61, at 3 (providing under Article 29*bis*, paragraph 5, that if relevant national legislation of a provider

## II. ACCESS AND BENEFIT-SHARING CLEARING-HOUSE

The Access and Benefit-Sharing Clearing-House is a public website administered by the CBD Secretariat.[65] It is designed to serve as a one-stop shop for obtaining comprehensive information about the ABS-related activities, such as a list of countries bound by the Nagoya Protocol, each country's point of contact, the status of national legislation, and policy documents.[66] It also provides web links to general administrative information released by the Secretariat, such as minutes and decisions of Conferences of the Parties.[67] Not only government officials, but also innovation business owners, corporate counsel, scientists, technology transfer practitioners at universities, and non-governmental organizations, should be cognizant of what is available on the ABS Clearing-House by visiting the site as often as necessary to obtain the latest information. The site should be particularly useful for keeping those working on projects involving bioscience or biotechnology informed about how this evolving regime may directly affect their activities. The following sections provide important points for these individuals to contemplate before further exploring ABS opportunities, as well as general guidance on where to locate relevant information within the ABS Clearing-House.

### *A. Two Perspectives of a Party*

When reviewing the Nagoya Protocol's Access and Benefit-Sharing framework through the ABS Clearing-House, it is important to consider that being a Party to the Protocol as a sovereign state

---

country is violated, the country may impose sanctions, including revocation of the patent). In the United States, even if misappropriation of genetic resources constitutes a violation of a foreign national law, it is unlikely to give rise to unenforceability of a U.S. patent for inequitable conduct without a finding of but-for materiality of withheld information to patentability; *see* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1291 (Fed. Cir. 2011) (en banc).

[65] Nagoya Protocol art. 14.

[66] ABSCH, *supra* note 12, https://absch.cbd.int/ (last visited Mar. 1, 2018).

[67] ABSCH, CBD Secretariat [hereinafter SCBD] Records, Meetings, https://absch.cbd.int/search/scbdRecords?schema=meeting (last visited Mar. 1, 2018).

means being bound by two sets of reciprocal rules in multilateral transactions of genetic resources: rights and obligations of a provider, and rights and obligations of a user. To illustrate this, Figure 1 exhibits a simplified interrelationship between Parties under the Nagoya Protocol framework. This article discusses the Access and Benefit-Sharing principle primarily with United States users in mind. However, it is important to keep providers' interests in mind to achieve one's intended business objectives without risking encroaching on others' interests.

At the national level, each Party is responsible for implementing its commitment to the treaty through domestic legislation, regulations, and administrative and policy measures.[68] Subject to these domestic laws, a Party exercises state sovereignty over genetic resources as both a provider country and user country with associated rights and obligations. The Party's designated authority, called Competent National Authority, reviews individual access requests containing provisions in the MAT.[69] The authority may encourage benefit-sharing terms so that upon alienation of genetic resources, the Party may retain a right to claim a share in benefits from foreign users.[70] Within the exercise of sovereign rights, the Competent National Authority makes a final determination whether to deny or approve such an access request, and issues a permit or equivalent written evidence certifying that the access requirements have been met.[71] Through these administrative processes, the Party formally grants PIC for taking genetic resources for use overseas. In theory, without such government-issued permits, biological materials are not allowed to be exported from a source country.

On the receiving end, as soon as genetic materials of foreign origin are brought into its jurisdiction by users' request, the Party is obligated to coordinate with the Secretariat to monitor the domestic

---

[68] Nagoya Protocol art. 5 (benefit sharing); art. 6, para. 3 (access); arts. 15–16 (compliance).

[69] *Id.* art. 13.

[70] *See id.* art. 13, para. 2 ("Competent national authorities shall . . . be responsible for advising on applicable . . . requirements for obtaining [PIC] and entering into [MAT].").

[71] *Id.* ("Competent national authorities shall . . . be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met").

activities of the people and entities participating in the system as individual resource users.[72] The monitoring is done by designated in-country Checkpoints to enhance transparency regarding the use of genetic resources after permits are granted.[73] The Party also has a duty to report these ABS-related events through the Clearing-House.[74] Unsurprisingly, any given Party may be involved in the treaty predominantly as a resource user, a resource provider, or both. Presumably, countries and indigenous communities embracing biodiversity hotspots,[75] areas particularly rich in endemic plant and animal species, tend to have greater economic interests at stake as a provider than a user.

In accordance with domestic legislation, negotiation over MAT may happen directly between the individual user, and the provider country represented by the Competent National Authority or National Focal Points in some cases.[76] However, depending on the individual circumstances, the MAT and PIC negotiation process may also involve private rights owners. Rights owners in this context include private property owners that grant direct access to genetic resources as they are requested. In addition, indigenous or local community representatives holding traditional knowledge associated with genetic resources may also be involved. To complicate the whole picture further, another category of parties in interest may be actively involved in this legal ecosystem as well. Examples are *ex situ* biorepositories, such as non-human gene banks and culture collections, where organisms of different geographic origins are stored in centralized facilities abroad. Stockpiled genetic resources like these are generally publicly available to legitimate

---

[72] Nagoya Protocol arts. 17, 29; *see also id.* art. 15, para. 2 & art. 16, para. 2 (requiring that each user country take appropriate, effective, and proportionate measures to address situations of non-compliance with adopted measures).

[73] *Id.* art. 17, para. 1.

[74] *See id.* art. 14, para. 2 & art. 17, para. 1(a)(iii) (providing that sharing information on ABSCH is without prejudice to the protection of confidential information).

[75] *Cf.* Russell A. Mittermeier et al., *Global Biodiversity Conservation: The Critical Role of Hotspots*, BIODIVERSITY HOTSPOTS 3 (2011).

[76] *Id.* art. 13; *id.* preamble ("*[R]ecognizing* the importance of promoting equity and fairness in negotiation of [MAT] between providers and users of genetic resources.").

researchers upon access request, such as the National Museum of Natural History in the Smithsonian Institution.[77] Indeed, noncommercial researchers worldwide have heavily relied on these authentic third-party biological collections, even though existing biorepositories would not completely substitute scientists' need for acquiring specimens of particular groups of organisms from *in situ* sources, such as their native habitats.[78] These additional players are not represented in Figure 1, but the situation would likely create a legal relationship similar to a trusteeship, guardianship, custodianship, or stewardship.[79]

### *B. Information Available at the Clearing-House*

The Access and Benefit-Sharing Clearing-House's web interface has gone through extensive overhaul and redesigning to improve user-friendliness.[80] Publicly available data stored in the database has grown rapidly in recent years.[81] Most of the records

---

[77] *See* OFF. OF DIR., NAT'L MUSEUM OF NAT. HISTORY, SMITHSONIAN INST., ACCESS AND BENEFIT SHARING POLICY ON GENETIC RESOURCES (effective June 23, 2012) (expressing the full institutional commitment to the CBD and related international instruments, including requesting PIC and MAT before the collection or transport of genetic resources.).

[78] *See* Myrna E. Watanabe, *The Nagoya Protocol on Access and Benefit Sharing: International Treaty Poses Challenges for Biological Collections*, 65 BIOSCIENCE 543 (2015) (highlighting perspectives of noncommercial researchers concerning how the Nagoya Protocol may affect their collection-based work.); *see also* D. Neumann et al., *Global Biodiversity Research Tied Up by Juridical Interpretations of Access and Benefit Sharing*, ORGANISMS DIVERSITY & EVOLUTION 1, 4 (Nov. 27, 2017), https://doi.org/10.1007/s13127-017-0347-1 (asserting that simplified measures should be created specifically for noncommercial research as provided under the Protocol's article 8(a).).

[79] Peter H. Sand, *Sovereignty Bounded: Public Trusteeship for Common Pool Resources?*, 4 GLOBAL ENVTL. POL'YS 47, 52 (2004). An alternative interpretation applicable to new acquisitions of genetic resources is that a jurisdiction in which a public biorepository resides becomes a provider country on a parity with the country of origin of such resources, as long as that repository country has acquired the genetic resources in accordance with the Protocol and the CBD. *See* Nagoya Protocol art. 5, para. 1; art. 6, para 1.

[80] ABSCH, *supra* note 12.

[81] As of the ABSCH's official launch date Oct. 12, 2014, the database under ABS Measures was populated with 26 national records from three jurisdictions;

posted are available with direct web links or for free download in .pdf format. The search engine allows site users to run a query based on specific key words, or to narrow data to a specific country. However, navigating through the Clearing-House is still far from intuitive for first-time users, and takes practice to efficiently locate and retrieve required information. Information at the ABS Clearing-House is organized into three main categories: (1) national records, (2) reference records, and (3) records managed by the Secretariat.[82]

1. National Records

National records are published by participating governments and include national information relevant to the implementation of the Nagoya Protocol, as well as information Parties are obliged to provide in accordance with the Protocol. Types of records indexed under this section include: ABS National Focal Points; Competent National Authorities; ABS Measures; National Websites and Databases; Internationally Recognized Certificates of Compliance; Checkpoints; Checkpoint Communiqués; and Interim National Reports.[83]

Because non-Parties are encouraged to contribute appropriate information to the ABS Clearing-House, even the United States has an entry in the database with its minimum country profile.[84] Furthermore, though as many as ninety-four countries are currently listed as non-Parties to the Protocol, that does not necessarily mean that those countries lack relevant domestic legislation. For instance, Brazil is not yet a Party, but it has recently enacted a federal law providing for its own ABS framework that has a similar effect when combined with a user registration system.[85] By filtering and sorting

---

by the end of 2015, 31 records from five jurisdictions; by the end of 2016, 153 records from 45 jurisdictions; and by the end of 2017, 284 records from 63 jurisdictions. ABSCH, ABS Measures, https://absch.cbd.int/search/nationalRecords?schema=measure (last visited Mar. 1, 2018).

[82] ABSCH, *supra* note 12.

[83] ABSCH, National Records, https://absch.cbd.int (last visited Mar. 1, 2018).

[84] Nagoya Protocol art. 24.

[85] Lei No. 13.123, de 20 de Maio de 2015, DIÁRIO OFICIAL DA UNIÃO

the database, the ABS Clearing-House provides an entry point for obscure information pertaining to Brazil and other non-Parties.[86]

It is noteworthy that the Secretariat is the only authority to issue an Internationally Recognized Certificate of Compliance based on a national permit granted and other related information submitted by the Competent National Authority of a provider country concerning an individual access request.[87] Certificates of Compliance serve as evidence of the authority's decision to grant PIC and of the establishment of MAT.[88] Certificates of Compliance are published on the ABS Clearing-House under the National Records section.[89] These Certificates may disclose additional detail about PIC and MAT as well as specific subject matter covered, whether commercial use is allowed by the permit, and conditions for third-party transfer of genetic resources and associated intellectual property rights.[90] Although analysis of individual ABS projects is beyond the scope of this article, information disclosed in Certificates of Compliance should be highly relevant to other stakeholders as existing model cases.

2. Reference Records

Reference records include resources and information

---

[D.O.U.] de 21.5.2015 (Braz.), http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm; Decreto No. 8.772, de 11 de Maio de 2016, D.O.U. de 12.5.2016 (Braz.); SISGEN: SISTEMA NACIONAL DE GESTÃO DO PATRIMÔNIO GENÉTICO E DO CONHECIMENTO TRADICIONAL ASSOCIADO [National System for the Management of Genetic Heritage and Associated Traditional Knowledge], https://sisgen.gov.br (Braz.).

[86] *See, e.g.*, ABSCH, Brazil– Country Profile, https://absch.cbd.int/countries/BR (last visited Mar. 1, 2018).

[87] *Id.* art. 6, para. 3(e).

[88] *Id.* art. 17, para. 3.

[89] *Id.* art. 17, para 2; ABSCH, Internationally Recognized Certificates of Compliance, https://absch.cbd.int/search/nationalRecords?schema=absPermit (listing over 140 Certificates of Compliance that have been issued based on twelve provider countries so far, including Belarus, Bulgaria, Dominican Republic, Guatemala, India, Kenya, Malta, Mexico, Panama, Peru, South Africa, and Spain, among which India has processed the largest number of requests that have led to eighty-six Certificates) (last visited Mar. 1, 2018).

[90] Nagoya Protocol art. 17, para. 4.

immediately relevant to Access and Benefit-Sharing stakeholders. They can be submitted by any registered user of the ABS Clearing-House, including Parties, non-Parties, governments, international organizations, indigenous and local communities, and other key stakeholders. Types of records found under this section are: Virtual Library Records; Capacity-building Initiatives; Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards; and Community protocols and procedures and customary laws.[91] Among these, model clauses, guidelines, best practices and standards seem immediately helpful.[92]

3. Secretariat Managed Records

The CBD Secretariat ("SCBD") regularly publishes official information under this section, including meetings, news stories, notifications, and formal statements. These are classified into: What's New; Notifications; Meetings; and News within this section.[93]

## III. ACCESS AND BENEFIT-SHARING IN ACTION

### *A. Implementation and Enforcement*

The new multilateral legal landscape that has loomed for the last several years under the ABS framework is still in flux. As of 2018, a majority of Parties have been actively working on establishing national programs and building domestic capacity to become fully compliant with the treaty provisions, but there is still considerable

---

[91] ABSCH, Reference Records, https://absch.cbd.int (last visited Mar. 1, 2018).

[92] ABSCH, Reference Records, Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards, https://absch.cbd.int/search/referenceRecords?schema=modelContractualClause (last visited Mar. 1, 2018) (listing twenty-eight publications including those from industries, for example, the Biotechnology Innovation Organization in the U.S. and the International Federation of Pharmaceutical Manufacturers and Associations based in Switzerland.).

[93] ABSCH, SCBD Records, https://absch.cbd.int (last visited Mar. 1, 2018).

work to be done.[94] For example, as of April 2018, Competent National Authorities have been designated and reported to the ABS Clearing-House from fewer than half of the 105 Parties.[95] Likewise, legislative, administrative, and policy measures have been published by only about half of the Parties.[96] Moreover, these country-level implementing measures have not been cross-checked, let alone harmonized.

Legal unpredictability also remains high with respect to the Protocol's cross-jurisdictional enforcement mechanisms. As the Protocol's Article 18 stipulates, each Party is deemed to make efforts to promote mutual recognition and enforcement of foreign judgments and arbitral awards through international dispute resolution mechanisms,[97] which is in line with the comity of nations doctrine.[98] The Protocol at least provides for access to justice by means of an opportunity to seek recourse in cases of disputes arising from MAT.[99] The treaty encourages MAT to include a dispute

---

[94] *See, e.g.,* Iden shigen no shutoku no kikai oyobi sono riyō kara shōzuru rieki no kōsei katsu syōhei na haibun ni kansuru shishin [ABS shishin] [Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization] (May 18, 2017), http://www.env.go.jp/nature/biodic-abs/pdf_04/4-1.pdf (Japan). Japan has been a signatory to the Protocol since May 2011, but it took the country six years to become a Party by establishing ABS Guidelines—domestic implementing measures—which came into force on August 20, 2017. *See* MINISTRY OF THE ENV'T, GOV'T OF JAPAN, ABS GUIDELINES: IMPLEMENTATION OF THE NAGOYA PROTOCOL IN JAPAN (July 2017), http://www.env.go.jp/nature/biodic-abs/pdf/pamphlet_en.pdf.

[95] ABSCH, https://absch.cbd.int/countries/status/party (displaying 45 out of 105 Parties in total as those having at least one Competent National Authority designated, among which Mexico designates as many as six Competent National Authorities) (last visited Mar. 1, 2018).

[96] *Id.* (displaying 45 out of 105 Parties as those having at least one legislative, administrative, or policy measure published, among which India has as many as thirty implementing measures published) (last visited Mar. 1, 2018).

[97] Nagoya Protocol art. 18, para. 3(b). *See also id.* art. 15, para. 3 & art. 16, para. 3 (requiring that parties cooperate in cases of alleged violation of domestic ABS legislation or regulatory requirements as far as possible and as appropriate).

[98] *See* William S. Dodge, *International Comity in American Law*, 115 COLUM. L. REV. 2071 (2015) (classifying recognition of foreign judgments as "adjudicative comity" within the international comity doctrine.).

[99] Nagoya Protocol art. 18, para. 2.

settlement clause that prescribes the jurisdiction to which providers and users will subject any matters of dispute, the applicable law, and options for alternative dispute resolution.[100] On top of that, the dispute settlement provision under the Convention also applies to the Protocol, which provides that if negotiation or third-party mediation does not resolve a dispute, parties must bring a case before an international arbitral tribunal or the International Court of Justice ("ICJ") as a means of dispute settlement.[101] However, an individual or a private entity cannot be a party to ICJ proceedings, nor are ICJ judgments automatically enforceable as domestic law in national courts.[102]

Pursuant to Article 31 of the Protocol, the Conference of the Parties is going to undertake an evaluation of the effectiveness of the Protocol including both its implementation and enforcement mechanisms for the first time on October 12, 2018, four years after entering into force.[103] This assessment must be a critical checkpoint for assuring continued development of the Protocol as an effective legal instrument to further its goal of equitable benefit sharing between users and providers of genetic resources.

Moreover, for a number of years international organizations such as WHO and WIPO, as well as the World Trade Organization ("WTO") and other intergovernmental bodies with overlapping global agendas, have recognized some gaps or incongruence in the CBD and Nagoya Protocol with other legal instruments in several key aspects. Nevertheless, the process of reconciliation has thus far been slow.[104]

---

[100] *Id.* arts. 6, para. 3(g)(i) & art. 18, para 1; *see also* WIPO, WIPO Alternative Dispute Resolution (ADR) for Biodiversity, http://www.wipo.int/amc/en/center/specific-sectors/biodiversity/ (last visited Mar. 1, 2018) ("Biodiversity disputes can concern a wide range of highly specific subject matters relating . . . to patents, genetic resources, traditional knowledge, plant varieties, environment, and food. They . . . can also involve sensitive non-legal components of a commercial, cultural, ethical, or moral nature.").

[101] CBD art. 27, para. 3(b) & 5.

[102] Statute of the International Court of Justice [ICJ] art. 34, ¶ 1, June 26, 1945, 59 Stat. 1055, T.S. No. 993 ("Only states may be parties in cases before the [ICJ]."); Medellín v. Texas, 552 U.S. 491, 511 (2008).

[103] Nagoya Protocol arts. 18, para. 4 & 31.

[104] *See supra* notes 47, 55, 59, 61. *See also, e.g.*, Matrix on Trade-Related

Aside from large-scale initiatives leveraged at the governmental and intergovernmental levels supporting this dynamic legal ecosystem, the question of whether the Nagoya Protocol can continue to operate effectively and sustainably in the future comes down to individual users' due diligence as primary contracting parties of ABS agreements. In other words, the whole legal ecosystem would hardly function without positive participation and cooperation of individual users complying with established procedures and MAT under the rule of law. Contract disputes will inevitably arise from MAT. Because of the significantly contractual basis of how the treaty is going to be implemented, as explained above, appropriate conflict resolution rules must be established to govern conflict of laws in cross-border contract disputes involving genetic resources. International rules for construing bio-property contracts under the Nagoya Protocol are urgently needed to improve predictability of this instrument's enforceability.

### *B. Implications for United States Stakeholders*

The United States' status as a non-Party to the Nagoya Protocol notwithstanding, it is in the best interest of Americans to keep the door open to opportunities for exploring untapped genetic resources located outside the U.S boundaries, as firms and institutions benefit from continued engagement in joint enterprises with global partners from member states. These countries include economically important jurisdictions like the European Union, Mexico, China, India, and South Africa.[105] In these scenarios, it would be unwise to steer clear of international research and development opportunities in fear of stepping into the unknown realm of the Nagoya Protocol. However, once bound by the ABS scheme, it is difficult to imagine that any government authority would grant special exceptions or privileges to American users merely on the ground that the U.S. is a

---

Measures Pursuant to Selected Multilateral Environmental Agreements, *Note by the Secretariat* (Revision), at 77, WTO Doc. WT/CTE/W/160/Rev.8 (Oct. 9, 2017) (providing a comprehensive list of topics previously addressed by the Conference of the Parties to CBD relating to international trade and the work of WTO, including the TRIPS Agreement).

[105] *See* ABSCH, *supra* note 12.

non-Party to the Protocol. As the Protocol Article 24 sets forth, Parties must encourage non-Parties to adhere to the Protocol.[106]

More broadly, any attempt to import biological materials into the United States without proper documentation, including a formal permit issued by a provider country's government, might invoke U.S. domestic laws like the Lacey Act.[107] The Lacey Act can hold a party liable for transporting species taken illegally in violation of a foreign law, although its enforceability in the ABS context is unknown.[108] Therefore, even on a voluntary basis, one should defer to the international regulatory framework and abide by MAT as the best course of action. This recommendation is valid even with the U.S. government's current status as a non-Party to the Convention—an outlier in the United Nations community for unrelated political or diplomatic reasons.

From a more practical standpoint, it would be prudent for U.S. stakeholders, or potential users in any other jurisdictions that are non-Parties, for that matter, to first identify and collaborate with their foreign counterparts and legal counsel licensed in their respective jurisdictions. Realistically, this would be the only way American stakeholders can make an informed decision beyond just obtaining baseline knowledge through the ABS Clearing-House, because unlike the treaty member states, the U.S. federal government currently lacks an office, website, and budget formally dedicated to providing services on ABS-related matters for American general public.[109] In contrast, stakeholders in member states should have more direct access to relevant information resources as well as the country's administrative departments that serve as National Focal Points or Checkpoints for their citizens.

---

[106] Nagoya Protocol art. 24.

[107] Lacey Act Amendments of 1981, 16 U.S.C. §§ 3371–3378 (2012).

[108] *Id.* § 3372 (making it unlawful for any person to import in foreign commerce any fish, wildlife, or plant, whether live or dead, including parts taken, possessed, transported, or sold in violation of foreign laws.).

[109] *But see* CBD, United States of America – Country Profile, https://www.cbd.int/countries/nfp/default.shtml?country=us (listing U.S. Department of State and other federal government agencies' representatives as National Focal Points) (last visited Mar. 1, 2018); *see also* Digital Sequence Information on Genetic Resources Public Meeting, 82 Fed. Reg. 28927 (June 26, 2017) (indicating the U.S. Department of State as the agency point of contact for a CBD-related public hearing in the U.S.).

They should be able to tell the current status of domestic implementing measures and guide you through necessary application procedures. Until the international standard and best practices are sufficiently established, each provider country will continue to be responsible for educating potential users of legal procedures and paperwork required to meet specific ABS requirements. The need for such foresight is obvious, given that provider countries are the ones in the best position to expound their own domestic statutes, rules, court decisions, and policies. Meanwhile, relevant industries that are likely subject to the Nagoya Protocol regulations in their primary activities should seriously address the compliance issue in their risk assessment in relation to international project management, technology transfer, and global intellectual property rights management.

## CONCLUSION

Once the Nagoya Protocol becomes fully operational as a globally recognized system in the next few years, there should be increased transparency, consistency, and accountability for transactions of genetic resources among all players. Although the United States is neither a signatory to the Convention on Biological Diversity nor the Nagoya Protocol, American stakeholders are not free to disregard these international rules. Because the principal mechanism of implementing the Nagoya Protocol has a contractual basis characterized by the Prior Informed Consent and Mutually Agreed Terms, U.S. stakeholders who are going to enter into an agreement under the Access and Benefit-Sharing scheme should defer to this new international regulatory framework. Participants should acknowledge the Mutually Agreed Terms incorporating foreign domestic laws of a Party laid down to effectuate fair dealing in biological materials across jurisdictions.

The long-term success of the Nagoya Protocol depends on individual users' due diligence and compliance with the new global standard of utilizing genetic resources in a fair and equitable manner. However, too much formality in procedures or extraterritorial restrictive control by governments may function as a strong disincentive to timely and efficient access to genetic materials and may have a chilling effect on bona fide biodiversity

research and bioprospecting activities that could lead to discoveries of next-generation cancer therapies or biotechnological breakthroughs. Nevertheless, it is in the interest of everyone involved in bio-property transactions to comply with local rules regardless of whether one's home country is a signatory. While the regulatory landscape is still in flux, an initial comprehensive review of the Nagoya Protocol's implementation status for the last four years—due in late 2018—will be an important stepping stone to envisioning the future development of this new ecosystem.

## PRACTICE POINTERS

- Potential stakeholders planning to access genetic materials are strongly encouraged to familiarize themselves with the developing standards of the Nagoya Protocol through the online Access and Benefit-Sharing Clearing-House.
- As users of genetic resources, stakeholders are additionally expected to work closely with their foreign counterpart representing the country that is a Party to the Nagoya Protocol, and to exercise due diligence in obtaining information on domestic implementing measures of their jurisdiction for full legal compliance.

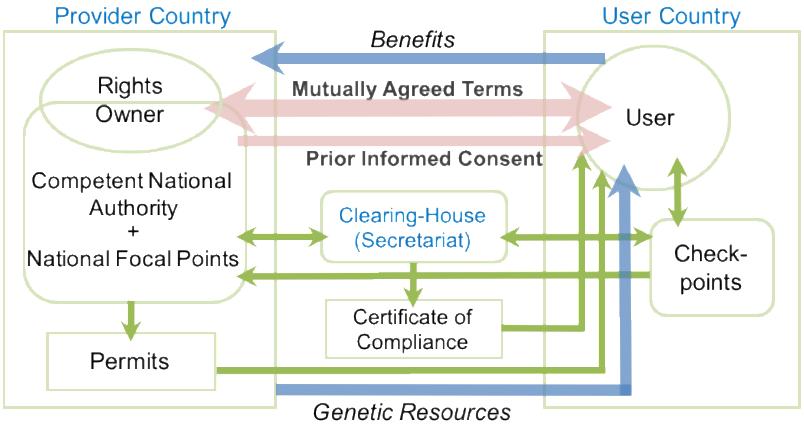


**Figure 1. The Framework of the Nagoya Protocol.**

Under the Nagoya Protocol's Access and Benefit-Sharing ("ABS") scheme, acquiring genetic resources is subject to Prior Informed Consent ("PIC") of the provider country. Benefit-sharing will be executed according to Mutually Agreed Terms ("MAT"). Each country designates National Focal Points, which provide information on ABS to stakeholders and administer domestic regulations. An Internationally Recognized Certificate of Compliance is issued by the Secretariat based on national permits granted by the Competent National Authority of the provider country and is published on the ABS Clearing-House. Designated national Checkpoints collect relevant information, and monitor and report on the utilization of genetic resources to support compliance and increase transparency.