



Convention on Biological Diversity

Distr.
GENERAL

CBD/SBI/3/15/Add.1
13 July 2020

ORIGINAL: ENGLISH

SUBSIDIARY BODY ON IMPLEMENTATION

Third meeting

Quebec City (to be confirmed), Canada, 9-14 November 2020

Item 13 of the provisional agenda*

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

Note by the Executive Secretary

1. The Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-Sharing considered the need for and modalities of a global multilateral benefit-sharing mechanism (Article 10 of the Nagoya Protocol) at its third meeting and adopted decision [NP-3/13](#).
2. In decision NP-3/13, paragraph 5(a), the Executive Secretary was requested to commission a peer-reviewed 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.
3. Accordingly, the Executive Secretary commissioned the study contained herein. The commissioning of the study was made possible by the generous financial support of Belgium, the European Union and South Africa.
4. A draft of the study was made available online for peer review from 9 March to 6 April 2020.¹ The comments received in response have been made available online.² The study was revised in the light of the comments received and the final version is presented below in the form and language in which it was received by the Secretariat.

*CBD/SBI/3/1.

¹ See notification 2020-028 of 10 March 2020 and extension of deadline (see notification 2020-030) of 19 March 2020.

² See <https://www.cbd.int/abs/art10/2019-2020/study.shtml>

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

As requested in decision NP-3/13 (paragraph 5(a)) by the third meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Nagoya Protocol

15 June 2020

Margo Bagley³ and Frederic Perron-Welch⁴

Explanatory note

This study takes an inclusive approach to the possible subject matter of Article 10, with the goal of providing information on a broad range of possible cases in order to facilitate discussions by the Parties. In doing so, the authors do not take a position on the proper resolution of issues of scope, or the appropriateness of or need for a global multilateral benefit-sharing mechanism in any of the cases presented herein. The study does not seek to promote any particular view, nor does it seek to undermine the bilateral approach upon which the Convention on Biological Diversity and the Nagoya Protocol are founded.

The authors recognize that the Parties have differing views on various issues, such as the temporal scope (e.g., does it apply to genetic resources and traditional knowledge associated with genetic resources physically accessed prior to its entry into force but subject to new utilizations), and the subject matter scope (e.g., does it cover ‘digital sequence information’, *ex situ* collections and publicly available traditional knowledge) of the Protocol. The approach used in this study is intended to avoid pre-judging the outcome of discussions between Parties on issues where they do not agree. Parties will need to determine whether any of the categories of cases presented herein establish the need for a global multilateral benefit-sharing mechanism.

The authors also note the relevance of Article 11 of the Nagoya Protocol, recognizing that the report of the 2016 Expert Group Meeting on Article 10 concluded that Article 11 was sufficient to address “genetic resources found *in situ* in more than one Party and traditional knowledge associated with genetic resources when it was shared by one or more indigenous and local communities in several Parties”. However, the Expert Group report also noted that experience with Article 11 by Parties was limited. Therefore, in an attempt to provide the broadest range of possible cases for discussion under Article 10 by the Parties, this study includes some cases that might also be dealt with under Article 11.

In carrying out this study, the authors interpreted the request to identify ‘specific cases’ that might fall within the scope of Article 10 as referring to a request to identify distinct categories of cases, rather than a request to identify individual examples. As such, the cases provided herein are intended to be illustrative, rather than discrete examples of genetic resources or traditional knowledge that fall within the scope of Article 10. Furthermore, in keeping with the inclusive approach aimed for in this study, the authors have opted to use a definition of ‘not possible’ that includes both absolute factual impossibility, and functional impossibility.

Notwithstanding the inclusive approach taken by the authors, the authors recognize that States have the sovereign authority to determine access to genetic resources through legislative, regulatory or administrative measures. Therefore, the authors do not intend this inclusive approach to suggest that a mechanism is needed in cases where 1) it is not possible to grant or obtain prior informed consent as a result of States deciding not to require prior informed consent, or 2) where States are still in the process of developing their access and benefit-sharing measures.

³ Emory University School of Law, Atlanta, Georgia, United States of America.

⁴ Grotius Centre for International Legal Studies, Faculty of Law, Leiden University, Leiden, the Netherlands.

CONTENTS

Executive Summary	5
1. Introduction	10
2. Specific Cases of Genetic Resources That Occur in Transboundary Situations	14
2.1. Shared Ecosystems and Habitats/Species Distributed across National Boundaries.....	15
2.2. Migratory Species	16
2.3. Areas Beyond National Jurisdiction	18
3. Specific Cases of Genetic Resources For Which It Is Not Possible To Grant or Obtain PIC	19
3.1. Genetic Resources of Untraceable Provenance in <i>Ex Situ</i> Collections	19
3.2. Utilization and Screening of Geographically Diverse Samples Sourced from Different Regions and Countries	23
3.3. Digital Sequence Information (DSI)	24
3.3.1. Cases Where no Physical Access is Needed to Utilize Genetic Information	25
3.3.2. Utilization of Genetic Components Found in Multiple Organisms	29
4. Specific Cases of Traditional Knowledge Associated With Genetic Resources that Occur in Transboundary Situations or For Which It Is Not Possible to Grant or Obtain PIC	33
4.1. Traditional Knowledge held by Indigenous Peoples and Local Communities across National Boundaries	33
4.2. Publicly Available Traditional Knowledge Associated with Genetic Resources	35
4.3. Traditional Knowledge Associated with Genetic Resources of Untraceable Origin in <i>Ex Situ</i> Collections	37
5. Conclusions	38
Acknowledgements.....	38
Annex A: List of Interviewees	39

List of Acronyms

ABS	Access and Benefit-Sharing
ABSCH	Access and Benefit-sharing Clearing-House
AHTEG	Ad Hoc Technical Expert Group
BBNJ	Biodiversity beyond national jurisdiction
BLAST	Basic Local Alignment Search Tool
BGCI	Botanic Gardens Conservation International
BNITM	Bernard Nocht Institute for Tropical Medicine
CABI	Centre for Agriculture and Bioscience International
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Facilities
COP	Conference of the Parties
COP-MOP	Conference of the Parties serving as Meeting of the Parties
CMS	Convention on Migratory Species of Wild Animals
DNA	Deoxyribonucleic acid
DSI	“Digital Sequence Information on Genetic Resources”
DSMZ	Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures
EBC	Kew Economic Botany Collection
EBSA	Ecologically or Biologically Significant Area
EEZ	Exclusive economic zone
EU	European Union
GRULAC	Latin American and Caribbean Group
GSD	Genetic Sequence Data
ICC	International Chamber of Commerce
IPEN	International Plant Exchange Network
IPLCs	Indigenous Peoples and Local Communities
INSDC	International Nucleotide Sequence Database Collaboration
IRCC	Internationally recognized certificate of compliance
IUCN	International Union for the Conservation of Nature
Kew	Royal Botanic Gardens, Kew
MAT	Mutually Agreed Terms
MNHN	Muséum National d’Histoire Naturelle
MTA	Material Transfer Agreement
NFP	National Focal Point
PIC	Prior Informed Consent
RBS-ORF	Ribosome binding site – open reading frame
SBI	Subsidiary Body for Implementation
RNA	Ribonucleic acid
UNCLOS	United Nations Convention on the Law of the Sea
WEOG	Western European and Others Group
WIPO	World Intellectual Property Organization
WDCM	World Data Centre for Microorganisms
WFCC	World Federation of Culture Collections

EXECUTIVE SUMMARY

Article 10 of the Nagoya Protocol on Access and Benefit-sharing (“Global Multilateral Benefit-Sharing Mechanism”) calls for Parties to 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 3rd meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Nagoya Protocol adopted decision NP-3/13 on Article 10, which requested the commissioning of a peer reviewed study to identify specific cases meeting the aforementioned criteria.

As summarized in Table 1 below, this study takes a broad approach (see “Explanatory Note”). It analyses specific cases falling into three broad groups: 1) genetic resources occurring in transboundary situations; 2) genetic resources for which it is not possible to grant or obtain prior informed consent; and 3) traditional knowledge associated with genetic resources occurring in transboundary situations or for which it is not possible to grant or obtain prior informed consent.

The first group, **genetic resources occurring in transboundary situations** comprises three specific subgroups: (a) shared ecosystems and habitats/species distributed across national boundaries; (b) migratory species which transit through different jurisdictions; and (c) areas beyond national jurisdiction.

Cases in subgroup (a) include species occurring in neighboring countries (e.g., *Pentas longiflora*), across a range of countries (e.g., *Heliotropium foertherianum*), or even on different continents (e.g., *Catharanthus roseus*)⁵. Situations involving shared ecosystems and habitats/species distributed across national boundaries raise the question of equitable authorization of access and negotiation of the sharing of benefits arising from the utilization of these resources. Such cases could be dealt with under Article 10 and/or Article 11 (“Transboundary Cooperation”).

Regarding subgroup (b) where migratory species transit through and occur in several countries (e.g., the European eel (*Anguilla anguilla*), monarch butterfly (*Danaus plexippus*), and mallard duck (*Anas platyrhynchos*)), a bilateral approach would not reward all those involved in the conservation of a specific resource. In addition, resources found in areas beyond national jurisdiction, such as the high seas, under subgroup (c), could also fall within the scope of Article 10. A specific challenge pertains to ‘straddling’ resources that are present in, or transit between, the High Seas or the deep-seabed (the “Area”) and areas subject to national jurisdiction.

The second broad group involves **genetic resources for which it is not possible to grant or obtain prior informed consent**. This group also comprises three subgroups: (a) genetic resources of untraceable provenance in *ex situ* collections; (b) utilization of samples from large numbers of geographically diverse organisms; and (c) cases involving the use of “digital sequence information” (DSI).⁶

Subgroup (a) involves the holding of genetic resources of untraceable provenance in *ex situ* collections, such as botanical gardens, herbariums, culture collections, gene banks, seed banks, zoos, aquaria, and private collections. Such collections may hold specimens acquired before or after the entry into force of the Convention on Biological Diversity (CBD or Convention), raising questions of temporal scope. Moreover, some specimens may have been deposited without providing country information while presently being accessed for commercial utilization.

Subgroup (b) involves the use of samples from large numbers of geographically diverse organisms. An example presented highlights a patent claiming a method for screening plants and seeds from the genus

⁵ However, in some cases there may be populations of species with sufficient genetic differences to allow identification of source.

⁶ “Digital sequence information” (DSI) is widely acknowledged as a placeholder term for which no consensus on a replacement or precise definition exists to date.

Glycine (soy) for traits relating to maturity and plant growth. The patent discloses that the invention was based on the utilization of over 250 distinct soybean lines, including wild and cultivated species from Australia and Asia, but does not disclose how or where the specimens were obtained (whether *in situ* or from *ex situ* collections) which, while not required for patentability in many countries, could be relevant to ABS for certain Parties.

Regarding subgroup (c), whether access to DSI *per se* is within the scope of the Convention or the Nagoya Protocol (Protocol) remains contested. Even if it is deemed outside the scope of the definition of genetic resources in those instruments, DSI that results from the utilization of a physical genetic resource may still be subject to benefit-sharing obligations. Thus, scenarios in which the bilateral approach would either be factually or functionally impossible to employ are examined in this study. As the Parties have not yet decided on which path to take, this section provides examples of situations where no physical access is needed to utilize genetic information (e.g. via natural product libraries), and where the genetic components utilized were found in multiple organisms (e.g. in the production of steviol glycosides).

The third broad group, **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**, can be further divided into three subgroups: (a) associated traditional knowledge held by IPLCs across national boundaries, (b) publicly available associated traditional knowledge, and (c) associated traditional knowledge of untraceable origin in *ex situ* collections.

Regarding subgroup (a), while possible, bilateral negotiations can be difficult in situations in which traditional knowledge associated with genetic resources is held by indigenous peoples and local communities whose membership spans national boundaries. The study identified three such scenarios: (1) associated traditional knowledge held by a single group across multiple countries; (2) associated traditional knowledge held by more than one group located across multiple countries; and (3) associated traditional knowledge held by a community in one country about a genetic resource originating in another country. Examples include traditional knowledge associated with Judean wormwood (*Artemisia judaica*) and Rosy periwinkle (*Catharanthus roseus*). Key challenges in these situations involve determining who owns the associated traditional knowledge, who thus has a right to grant PIC in accordance with applicable domestic law, and who is entitled to a share in the benefits that may be generated.

Regarding subgroups (b) and (c), many publications and journals exist which catalog traditional plant uses in different regions, such as the *African Pharmacopoeia*. The possibility to grant or obtain prior informed consent for the traditional knowledge involved may not be possible if the knowledge is not traceable to a specific provider. Likewise, many samples of genetic materials contained in *ex situ* collections were collected by ethnobotanists with the help and direction of indigenous peoples and local communities. As a result, traditional uses are sometimes included in the identifying information. While provider country information is generally present, identifying information on the indigenous peoples and local communities from whom the traditional knowledge was derived may not have been included. This may render it impossible to seek prior informed consent for the use of such traditional knowledge.

Based on the research presented within, this study concludes that there may be specific cases that fall within the scope of Article 10, while also not undermining the bilateral approach upon which the Convention and Nagoya Protocol are founded.

Table 1: Summary of Specific Cases for Possible Consideration under Article 10

Broad Groups	Subgroups	Examples	Considerations
Genetic resources occurring in transboundary situations	(a) Shared ecosystems and habitats/species distributed across national boundaries	Species present in neighboring countries (e.g., <i>Pentas longiflora</i>), across a range of countries (e.g., <i>Heliotropium foertherianum</i>), or on different continents (e.g., <i>Cathranthus roseus</i>).	There is not agreement that all of these situations involve a benefit-sharing obligation. As such, some of these types of transboundary cases could be addressed in the context of Article 10, some under Article 11, or some could be completely excluded from consideration in the context of the Protocol.
	(b) Migratory species which transit through different jurisdictions	Migratory species occurring in several countries (e.g., the European eel (<i>Anguilla anguilla</i>), monarch butterfly (<i>Danaus plexippus</i>), and mallard duck (<i>Anas platyrhynchos</i>)).	
	(c) Areas beyond national jurisdiction	i.e. ‘straddling’ resources that occur in, or transit between, the high seas and areas subject to national jurisdiction.	
Genetic resources for which it is not possible to grant or obtain prior informed consent	(a) Genetic resources of untraceable provenance in <i>ex situ</i> collections	Genetic resources from botanical gardens (e.g., The Royal Botanic Gardens, Kew), herbaria (e.g., Muséum National d’Histoire Naturelle botany collections), culture collections (e.g., World Federation for Culture Collections microorganism, plasmid, and cDNA collections), gene banks, seed banks, zoos, aquaria, and private collections.	Parties are not in agreement on whether or to what extent DSI and material in <i>ex situ collections</i> is within the scope of the Protocol. In some of the examples, DSI from multiple, diverse organisms is being utilized, and if it is deemed to be within scope, some users may need to negotiate MAT with multiple governments and many users will not be individually identifiable or traceable.
	(b) Utilization of samples from large numbers of geographically diverse organisms	E.g., a patent claiming a method for screening plants and seeds from the genus <i>Glycine</i> (soy) for traits relating to maturity and plant growth, based on the utilization of over 250 distinct soybean lines. The lines include wild and cultivated species from Australia and Asia, but the patent does not disclose how or where the specimens were obtained.	

	<p>(c) Cases involving the use of “digital sequence information” (DSI)</p>	<p>Situations where no physical access is needed to utilize genetic information (e.g., the International Nucleotide Sequence Database Collaboration, the Earth Biogenome Project, BLAST searches, the Ebola drug RGEN-EB3 case, Protein Data Bank, and Natural Product Libraries). Situations where the genetic components utilized were found in multiple organisms (e.g., production of steviol glycosides, D-glucaric acid, and bioethanol).</p>	
<p>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</p>	<p>(a) Associated traditional knowledge held by IPLCs across national boundaries</p>	<p>Associated traditional knowledge held by more than one group located across multiple countries (e.g., the indigenous Guna people of Panama and Colombia). Associated traditional knowledge held by more than one group located across multiple countries. Associated traditional knowledge held by a community in one country about a genetic resource originating in another country (e.g., traditional knowledge associated with Rosy periwinkle (<i>Catharanthus roseus</i>) and Judean wormwood (<i>Artemisia judaica</i>)).</p>	<p>Key challenges include determining who owns the associated traditional knowledge, who has a right to grant PIC, and who is entitled to a share in the benefits that may be generated. Article 10 or Article 11 may be applicable to some cases. Parties are not in agreement that PIC/MAT obligations apply to all of these cases. Moreover, identifying information on IPLCs from whom traditional knowledge was derived may not be available, rendering the negotiation of PIC/MAT impossible in some cases.</p>
	<p>(b) Publicly available associated traditional knowledge</p>	<p>Publications and journals which catalog traditional plant uses in different regions (e.g., the <i>African Pharmacopoeia</i>).</p>	
	<p>(c) Associated traditional knowledge of untraceable origin in <i>ex situ</i> collections.</p>	<p>Samples of genetic materials contained in <i>ex situ</i> collections collected by ethnobotanists with the help and direction of indigenous peoples and local communities, where identifying information on the indigenous peoples</p>	

		<p>and local communities from whom the traditional knowledge was derived is omitted (e.g., many different individuals from in and outside of a community have provided medicinal use leads, or the use information was taken from a secondary source, such as a pharmacopeia or other extant work which does not list the original providers of the associated traditional knowledge).</p>	
--	--	--	--

1. INTRODUCTION

In November 2018 during the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP), the Parties to the Protocol adopted decision NP-3/13 on a global multilateral benefit-sharing mechanism (Article 10). In paragraph 5(a) of the decision, the Parties requested the commissioning of a peer-reviewed 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 (PIC). This study is the response to that request. It is expected to be submitted for consideration by the third meeting of the Subsidiary Body for Implementation (SBI) scheduled for autumn 2020.

Methodology

In carrying out this study, the authors began by analyzing the Parties' request to "identify specific cases" that might fall within the scope of Article 10. After careful consideration, the authors interpreted the request to "identify specific cases" as referring to a request to identify *distinct categories of cases*, rather than a request to identify *individual examples*.

This interpretation was based on two grounds. First, the authors considered the most pertinent definitions of "specific"⁷ and "case"⁸ in the Oxford English Dictionary. Second, the authors determined that individual examples would not logically justify a global, multilateral approach, as they could theoretically be addressed on a case-by-case basis. As such, the examples provided in this study are intended to be illustrative, rather than each example comprising simply a discrete instance of a genetic resource, or traditional knowledge associated with a genetic resource, that could fall within the scope of Article 10.

Secondly, the authors analyzed the potential meaning of "not possible" in Article 10. The general rule of treaty interpretation contained in the Vienna Convention on the Law of Treaties relies upon a three-fold, good faith assessment of: (1) the ordinary meaning of the term; (2) in its context; (3) in light of the treaty's object and purpose.⁹

The context of Article 10 in light of the treaty's object and purpose suggests that it is meant to address cases that cannot be addressed through the bilateral approach, but this does not fully illuminate the meaning of "not possible". In consequence, the authors relied on the dictionary definitions of "possible"¹⁰ and "impossible"¹¹ and selected a common definition that was in keeping with the inclusive approach aimed for by this study. This definition includes both factual impossibility and functional impossibility (i.e. so improbable, impractical or infeasible that it is not possible). This is consistent with the explanation

⁷ 'specific, adj. and n.' *OED Online*, Oxford University Press, March 2020, <<http://www.oed.com/view/Entry/185999>> accessed 2 May 2020: "2.a. Of qualities, properties, effects, etc.: Specially or peculiarly pertaining to a certain thing or class of things and constituting one of the characteristic features of this."

⁸ 'case, n.1.' *OED Online*, Oxford University Press, March 2020 <<http://www.oed.com/view/Entry/28393>> accessed 2 May 2020: "6.a. An instance of a particular situation; an example of something occurring; a particular circumstance or state of affairs."

⁹ Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331, art 31(1). Additional interpretative materials can be used, however, information relevant to the interpretation of "not possible" in Article 10 is not available (e.g. agreements/instruments made alongside the adoption of the treaty [Decision X/1]; subsequent agreement between the Parties regarding treaty interpretation or application; subsequent practice which establishes the agreement of Parties on interpretation; relevant rules of international law; special meanings intended by the Parties [Article 2]; *travaux préparatoires* and the circumstances of its conclusion).

¹⁰ 'Possible, Adj., Adv., and n.', *OED Online* (Oxford University Press 2020) 'A. adj. 1. That is capable of being; that may or can exist, be done, or happen (in general, or in given or assumed conditions or circumstances); that is in a person's power, that a person can do, exert, use, etc.'; The Cambridge Dictionary defines it as 'able to be done or achieved, or able to exist'; Meriam-Webster Dictionary defines it as 'being within the limits of ability, capacity, or realization'

¹¹ 'Impossible, Adj. and n.', *OED Online* (Oxford University Press 2020) 'A. adj. 1.a. Not possible; that cannot be done or effected; that cannot exist or come into being; that cannot be, in existing or specified circumstances.' The Cambridge Dictionary defines it as 'unable to exist, happen, or be achieved; not possible', also 'extremely difficult to deal with or solve'; Meriam-Webster Dictionary defines it as 'incapable of being or of occurring; felt to be incapable of being done, attained, or fulfilled: insuperably difficult.'

of Article 10 provided in the IUCN Explanatory Guide to the Nagoya Protocol and the understanding of some Parties.¹²

The authors have also considered the matter of equity in deciding whether to address some circumstances. In determining the meaning of ‘fair and equitable’ in the objective of the Nagoya Protocol, and the preambular recognition¹³ that “an innovative solution is required 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 authors have chosen not to interpret ‘fair and equitable’ as a tautological statement. As the Convention and the Nagoya Protocol are legal documents, the authors presume that the Parties used ‘equitable’ in its sense as a legal term of art.¹⁴ Taking into account equitable considerations may be “particularly suitable for discussions in contexts where there are competing interests which have not hardened into specific rights and duties.”¹⁵ This is consistent with the inclusive approach used in this study.

Notwithstanding the inclusive approach taken by the authors, the authors recognize that States have the sovereign authority to determine access to genetic resources through legislative, regulatory or administrative measures. Therefore, the authors do not intend this inclusive approach to suggest that a mechanism is needed in cases where 1) it is not possible to grant or obtain prior informed consent as a result of States deciding not to require prior informed consent (PIC), or 2) where States are still in the process of developing their access and benefit-sharing measures.

Information on 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 was gathered on an expedited basis by the authors from late December 2019 through late February 2020. This included participation by both of the authors in the second meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework to carry out in-person interviews.

The authors conducted interviews with 33 experts from over 25 countries who have specific knowledge of the subjects covered by Article 10 in order to enhance identification of relevant specific cases.¹⁶ The interviewees included national focal points (NFP), and other government personnel in selected countries, as well as academic researchers, staff of *ex situ* collections of genetic resources, industry representatives, members of intergovernmental and non-governmental organizations, representatives of indigenous peoples and local communities (IPLCs) and legal and policy experts. As many interviewees would only speak on condition of anonymity, an anonymized list of interviewees is provided in Annex A.

¹² Although it is not a definitive interpretation, Thomas Greiber and others, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing* (IUCN Environmental Policy and Law Paper 83, IUCN 2012) 129 notes that ‘Article 10 discussions could also take into consideration the lack of practicality of obtaining PIC. See also African Group submission 2019 (“In most of these situations it is impossible – because it is impractical – to obtain PIC from and negotiate MAT with all the actual and potential providers.”).

¹³ Article 31(2) of the Vienna Convention on the Law of Treaties gives the preamble the same status as the remainder of the treaty text in providing context for the interpretation of its terms. As such, it can provide context for further negotiations. See also *ibid* 47.

¹⁴ Brian A Garner, ‘Equitable’, *Black’s Law Dictionary* (8th edn, Thomson West 2004) ‘Just; consistent with principles of justice and right’. See also *Diversion of Water from Meuse (Neth. v. Belg.)* 1937 PCIJ Series A/B No 70, 76: “What are widely known as principles of equity have long been considered to constitute a part of international law.” Equity does not constitute a legal rule, but it may be regarded as a material source of law. See Clive Parry and others, ‘Equity’, *Parry and Grant Encyclopaedic Dictionary of International Law* (3rd edn, Oxford University Press).

¹⁵ Vaughan Lowe, ‘The Role of Equity in International Law’ (1989) 12 *Australian Yearbook of International Law* 54, 73.

¹⁶ “Interview” includes both semi-structured and unstructured communications by phone, email and other forms of electronic communication, and in person. Information from interviews are identified in this study as [interviewer], [interviewee], [Descriptor, if anonymous], date of interview. The study authors selected for interviews, within the time constraints of the study, experts believed to have information about specific cases relevant to the mandate.

Further information on specific cases was obtained through a review of documents relating to Article 10 of the Nagoya Protocol presented on the Secretariat's website.¹⁷ These included the synthesis of online discussions made in response to decision XI/1,¹⁸ the report of the 2013 expert meeting on Article 10,¹⁹ submissions made in response to decision NP-1/10,²⁰ the report of the 2016 Expert Group Meeting on Article 10,²¹ the study prepared for the Expert Group meeting,²² submissions made in response to decision NP-2/10,²³ the note by the Executive Secretary prepared for SBI 2,²⁴ and submissions made in response to decision NP-3/13.²⁵ Additionally, the authors explored articles, treatises and other publications, conducted searches of *ex situ* collection websites, domestic ABS websites, the World Intellectual Property Organization (WIPO) Lex database, and other internet sources, and drew data and findings from several of their earlier research projects.

Scope

As noted above, the Parties have differing views on issues of the substantive, temporal and geographic scope of the Nagoya Protocol.²⁶ A brief description of each of these issues is provided below to contextualize some of the examples provided in the study.

Temporal scope

A question not clearly addressed by the Protocol, and on which the Parties to the Protocol and CBD hold different views, is whether benefit-sharing obligations are triggered only at the time of initial resource access, or when the resource is utilized. This issue, referred to as "temporal scope", relates to the scope and application of the Protocol.²⁷ Significant quantities of genetic resources were accessed in countries

¹⁷ Secretariat of the Convention on Biological Diversity, 'What Has Been Done on the Need for and Modalities of a Global Multilateral Benefit-Sharing Mechanism? Developments since the Entry into Force of the Protocol' (15 April 2019) <<http://www.cbd.int/abs/art10-whatdone.shtml>> accessed 28 February 2020.

¹⁸ Secretariat of the Convention on Biological Diversity, 'Synthesis of the Online Discussions on Article 10 of the Nagoya Protocol on Access and Benefit-Sharing' (8 January 2014).

¹⁹ Secretariat of the Convention on Biological Diversity, 'Report of the Expert Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-Sharing' (19 September 2013).

²⁰ Secretariat of the Convention on Biological Diversity, 'Synthesis of Views Pursuant to Decision NP-1/10' (14 December 2015).

²¹ Secretariat of the Convention on Biological Diversity, 'Report of the Expert Group Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-Sharing' (3 February 2016).

²² Elisa Morgera, 'Study on Experiences Gained with the Development and Implementation of the Nagoya Protocol and Other Multilateral Mechanisms and the Potential Relevance of Ongoing Work Undertaken by Other Processes, Including Case Studies' (22 December 2015).

²³ Secretariat of the Convention on Biological Diversity, 'Submissions on Article 10 of the Nagoya Protocol Pursuant to Decision NP-2/10' (24 April 2018) <<https://www.cbd.int/abs/submissions-np-2-10>> accessed 28 February 2020.

²⁴ Secretariat of the Convention on Biological Diversity, 'Global Multilateral Benefit-Sharing Mechanism (Article 10 of the Nagoya Protocol)' (1 July 2018).

²⁵ Secretariat of the Convention on Biological Diversity, 'Submissions on Article 10 of the Nagoya Protocol Pursuant to Decision NP-3/13' (5 February 2020) <www.cbd.int/abs/art10/2019-2020/submissions.shtml> accessed 28 February 2020.

²⁶ Greiber and others (n 10) 25.

²⁷ Possible triggers, as identified in the 2015 IUCN Submission, are:

- "Adoption of the CBD;
- Entry into force of the CBD;
- Adoption of the Nagoya Protocol;
- Entry into force of the Nagoya Protocol;
- Ratification or other accession to the CBD by the country of origin or country providing the genetic resources;
- Ratification or other accession to the Nagoya Protocol by the country of origin or country providing the genetic resources; or
- Adoption of ABS legislation by the country of origin or country providing the genetic resources."

IUCN Joint SSC-WCEL Global Specialist Group on ABS, Genetic Resources and Related Issues, 'Submission of Views in Preparation for the Expert Meeting on the Need for and Modalities of a Global Multilateral Benefit-Sharing Mechanism of the Nagoya Protocol' (22 September 2015) 4.

across the globe prior to the entry into force of both the CBD and the Protocol, and new utilizations of these resources, currently held in *ex situ* repositories outside the provider country, are taking place after the entry into force of the Protocol.

The Parties to the CBD were unable to agree on temporal scope during the multiyear negotiations, thus the Nagoya Protocol is silent on the topic. This silence does not, however, settle the question, as the Parties disagree on what constitutes retroactivity. Some countries view a utilization trigger as not prohibited retroactivity but, rather, as way of giving effect to the terms and spirit of the Protocol, consistent with Article 28 of the Vienna Convention on the Law of Treaties, while others view it as negatively impacting legal certainty.²⁸

Moreover, because the Protocol is silent on the definition of “access”,²⁹ some Parties are implementing it in a manner that imposes obligations solely on genetic resources that are accessed after the Protocol’s effective date,³⁰ while others are requiring benefit-sharing, and possibly PIC as well, for genetic resources utilized after its entry into force, regardless of when the resources were obtained from the providing country.³¹

Subject matter scope

Parties also have differing views on the breadth of subject matter covered by the CBD and the Nagoya Protocol. Some Parties assert that the use of the phrase “genetic material” in the CBD and Protocol excludes intangible subject matter. Other Parties argue that a ‘broad and dynamic’ understanding of the concept of genetic resources would encompass DSI. As described in Section 3.3 below, while the majority of Parties are not regulating DSI in their ABS regimes, several countries are including intangible sequence information within the definition of genetic resources and some of those are regulating its access. Others, while not considering DSI to be a genetic resource, do accept that it may be a product of utilization and therefore subject to benefit-sharing under MAT.³²

Geographic/spatial scope

The geographic scope of the Nagoya Protocol is also a contested subject among the Parties. This disagreement derives from the scope of the Convention, which includes processes and activities under Parties’ jurisdiction or control in areas beyond national jurisdiction.³³ Some Parties argue that the link between Article 3 of the Protocol and Article 15 limits the geographic scope of the Protocol to genetic

²⁸ See Greiber and others (n 10) 72–73. Vienna Convention on the Law of Treaties (n 7) art 28: “Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.” Markus Kotzur, ‘The Temporal Dimension: Non-Retroactivity and Its Discontents’ in Christian J Tams, and others (eds), *Research Handbook on the Law of Treaties* (Edward Elgar 2014) 155–56 notes that ‘Facts or acts can occur more than once, they can be repeated, and situations might continue to exist – they “live on”, not allowing for a strict bar against retroactive application.’

²⁹ Morten W Tvedt and Ole K Fauchald, ‘Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway’ (2011) 14 *The Journal of World Intellectual Property* 383, 385. See also Greiber and others (n 10) 63–65; Morten W Tvedt and Olivier Rukundo, ‘Functionality of an ABS Protocol’ (Fridjof Nansen Institute 2010); Kabir Bavikatte and Brendan Tobin, ‘Cutting the Gordian Knot: Resolving Conflicts over the Term “Utilization”’ (2010) 4 *Biores* 3.

³⁰ See Article 2 of EU Regulation 511/2014.

³¹ Such as Brazil, Colombia, Costa Rica, and South Africa. See Margo A Bagley and Arti K Rai, ‘The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts’ (Wilson Center 2013) 17–21. See also Elisa Morgera and others, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity* (Brill Nijhoff 2014) 77–80 for further commentary on this matter.

³² Margo A Bagley and others, ‘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’ (Secretariat of the Convention on Biological Diversity 29 January 2020). <<https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf>.

³³ Convention on Biological Diversity, art 4(b).

resources within national jurisdiction, while other Parties assert that the Protocol is silent on this issue.³⁴ As negotiations on an international instrument on biodiversity beyond national jurisdiction – including marine genetic resources – have begun, the authors describe two issues that may still be considered pertinent to Article 10 in Sections 2.2 and 2.3.

Structure

In terms of organization, Section 2 of the study presents specific cases of genetic resources that occur in transboundary situations, including examples of shared ecosystems and habitats, migratory species, and areas beyond national jurisdiction. Section 3 presents specific cases of genetic resources for which it is not possible to grant or obtain PIC. It includes examples of genetic resources of untraceable provenance in *ex situ* collections, utilization of samples from large numbers of geographically diverse organisms, and genomic sequence data/DSI where no physical access is needed to utilize genetic information, and which involve utilization of genetic components found in multiple organisms. Finally, Section 4 presents specific cases of traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain PIC. This includes associated traditional knowledge held by IPLCs across national boundaries, publicly available associated traditional knowledge, and associated traditional knowledge of untraceable origin in *ex situ* collections.

We note that the report of the Expert Group Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-sharing³⁵ identified additional scenarios that could be covered in Section 3, namely, situations in which a Party has not yet developed its procedures and/or it lacks the capacity to grant prior informed consent, including where it was not clear who had the authority to grant PIC and when community protocols included procedures for access but no national PIC requirement had been established; and situations in which a Party has decided not to require PIC. We have chosen not to address these cases, as establishing a global multilateral benefit-sharing mechanism addressing these situations would appear to directly conflict with the exercise of sovereign rights over genetic resources by either preempting or overriding Parties' legal, administrative and/or policy decisions. We wish to emphasize that the mandate for this study is only to identify cases that could fall within the scope of Article 10 to inform discussions in the forthcoming SBI 3 meeting. This study should not be read as making any judgments on the need for a global multilateral benefit-sharing mechanism, the modalities of any such mechanism, or whether to negotiate such a mechanism for any given situation.

2. SPECIFIC CASES OF GENETIC RESOURCES THAT OCCUR IN TRANSBOUNDARY SITUATIONS

Although it is difficult to determine the proportion of genetic resources that span boundaries, it is likely to be high.³⁶ Considering the artificial nature of political boundaries, it is not surprising that many species are distributed across national borders. As described by Morgera and others, transboundary situations can be of at least two types:

‘an *in situ* transboundary situation’ in which genetic resources or traditional knowledge have developed their special characteristics and are still found across borders in natural circumstances; and ‘an *ex situ* transboundary situation’ in which genetic resources or traditional knowledge are now found outside the habitats where they developed their essential characteristics in more than one country.³⁷

³⁴ See Morgera and others (n 29) 81–83 for additional commentary on this matter.

³⁵ Secretariat of the Convention on Biological Diversity, ‘Report of the Expert Group Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-Sharing’ (n 19).

³⁶ Graham Dutfield, ‘Transboundary Resources, Consent and Customary Law’ (2013) 9 *Law, Environment and Development Journal* 259, 260.

³⁷ Morgera and others (n 29) 200.

Examples of these situations are provided below, with the understanding that some may be amenable to resolution under either Article 10 or Article 11, and some may be considered completely beyond the scope of the CBD and Protocol.

2.1. Shared Ecosystems and Habitats/Species Distributed across National Boundaries

Some species are found in neighboring countries, such as *Pentas longiflora*, which is used traditionally to treat fungal infections in Uganda,³⁸ but also is found in Kenya.³⁹ Some are found much farther apart, such as the Rosy periwinkle, or *Catharanthus roseus*, which originated in Madagascar, but appears to have long been cultivated and naturalized in India and other places as well.⁴⁰ A compendium of African medicinal plants published by the African Union catalogs numerous plant species that are native to multiple countries and may be known by different names in various countries.⁴¹

Another example is *Heliotropium foertherianum*, a rosmarinic acid-containing plant used by Pacific islanders to treat cases of ciguatoxin poisoning, is found in New Caledonia, French Polynesia, Vanuatu, Tonga, Micronesia, and even Japan.⁴² A further example is Neem, a tree widely known for its traditional uses in India, but which is native to a number of countries on the Indian subcontinent, including Nepal, Pakistan, Bangladesh, Sri Lanka, and the Maldives, and is also found in parts of Africa.⁴³ The dispersed nature of such transboundary species could conceivably allow users to inaccurately claim acquisition from a country which is not the actual country from which the resource was obtained.⁴⁴ In addition, provider countries imposing benefit-sharing requirements for the utilization of their genetic resources may in some cases be unable to accurately determine that sharing obligations have accrued. In some cases,

³⁸ Kakudidi Esezah and others, 'Antifungal Medicinal Plants Used by Communities Adjacent to Bwindi Impenetrable National Park, South-Western Uganda' (2015) 7 European Journal of Medicinal Plants 184, 188.

³⁹ 'Carnegie Museum of Natural History Herbarium Catalog No CM226483' (*SERNEC Detailed Collection Record Information*, no date) <<http://serneportal.org/portal/collections/individual/index.php?occid=12316926&clid=0%3e>> accessed 29 February 2020.

⁴⁰ 'Arizona State University Vascular Plant Herbarium Catalog No ASU0104660' (*SERNEC Detailed Collection Record Information*, no date) <<http://serneportal.org/portal/collections/individual/index.php?occid=11238099&clid=0>> accessed 28 February 2020 (indicating "Native of Madagascar to India"). There are numerous herbarium records in SERNEC for this plant family collected from a wide diversity of countries, including Cuba, the Bahamas, and the Philippines.

⁴¹ African Union Scientific Technical Research Commission, *African Pharmacopoeia* (2nd edn, African Union 2014) 27. See also The Royal Botanic Gardens, Kew (Kew) has a helpful search tool "Plants of the World" which can be used to identify many of the world's plants which are native to more than one country. See Royal Botanic Gardens, Kew, 'Plants of the World' (no date) <<http://www.plantsoftheworldonline.org>> accessed 28 February 2020.

⁴² See *Use of rosmarinic acid and the derivatives thereof to treat ciguatera* International Patent (PCT) Application No. WO2011012780A1.

⁴³ CABI, 'Azadirachta Indica (Neem Tree)' (*Invasive Species Compendium*, 25 November 2019) <<https://www.cabi.org/isc/datasheet/8112#todistribution>> accessed 28 February 2020. ("There is much confusion in the literature about the natural distribution of *A. indica*. It is considered to be native to dry areas in Afghanistan, Pakistan, India, Sri Lanka, Bangladesh, Myanmar and China").

⁴⁴ Possibly to avoid a benefit-sharing requirement. See Delegation of Switzerland, *The Declaration of the Source of Genetic Resources and Traditional Knowledge in the Swiss Patent Act and Related Swiss Regulations on Genetic Resources – Submission by Switzerland in Response to Document WIPO/GRTKF/IC/30/9*, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO/GRTKF/IC/31/8 (Sept. 2016)[hereinafter, Switzerland, Declaration of Source]. The Swiss government, in explaining a preference in their law for patent applicants to identify the "source" of genetic resources as opposed to the "country of origin" of genetic resources, noted:

If, however, the patent applicant would need to disclose the "the country of origin," as is proposed by some delegations in the IGC negotiations, the patent applicant could disclose any of the countries of origin, namely Austria, France, Germany, Italy, Romania or Switzerland, irrespective of whether the plant was actually sourced in the country of origin that he disclosed. The concept of "country of origin" would thus provide a possibility to avoid disclosing the country that actually provided the genetic resource. This would run counter to the objective of enhancing transparency in access and benefit-sharing.

ibid para 21 (emphasis added). In addition, the Swiss Patent Act provides for post-grant sanctions of up to a 100,000 Swiss Francs fine and publication of a judge's ruling, for the intentional wrongful declaration of a source (Art. 81a PatA). *Ibid* at para. 27.

however, there may be populations of species with sufficient genetic differences to allow identification of source.

2.2. Migratory Species

Many migratory species spend parts of their life cycle in different national jurisdictions or outside national jurisdictional boundaries. Such species thus can be classified as occurring in transboundary situations. The *Convention on the Conservation of Migratory Species of Wild Animals*⁴⁵ (CMS) – a biodiversity-related treaty with 130 Parties focused on the conservation and sustainable use of terrestrial, aquatic and avian migratory species, their habitats and migration routes – defines migratory species as being “the entire population or any geographically separate part of the population of any species or lower taxon of wild animals, a significant proportion of whose members cyclically and predictably cross one or more national jurisdictional boundaries.”⁴⁶

Although the utilization of genetic resources from migratory species is generally subject to the bilateral approach,⁴⁷ this raises questions of equity between States, especially in cases where species migrate across and between continents.⁴⁸ A bilateral approach to benefit-sharing may not equitably channel resources to where they are needed to conserve such species.⁴⁹ The following three examples illustrate some of the challenges arising in the specific case of migratory species. References to patents below are used as a reflection of the utilization of genetic resources, and the possibility that benefits are being generated. The authors do not intend to suggest that benefits are required to be shared in any of the specific examples below.

European eel (Anguilla anguilla)

The European eel (*Anguilla anguilla*) is a species that ranges broadly throughout its lifecycle. In the middle of its life cycle, its habitat extends from the Baltic Sea to North Africa.⁵⁰ Some populations also migrate some distance inland using freshwater systems (unusually, eels live in both salt and fresh water during their lifecycles). However, at the beginning and end of their lifecycle, they traverse the Atlantic Ocean to reach their only known spawning area, the Sargasso Sea (recognized by the CBD COP as an Ecologically or Biologically Significant Area).⁵¹ Although the Sargasso Sea ecosystem is mainly outside of national jurisdiction, it also falls squarely within Bermuda’s exclusive economic zone (EEZ) and parts of other EEZs (e.g. Bahamas, Dominican Republic, United States). Patents have been obtained primarily in the United States and Europe that reference the European eel and biochemicals present in the species such as lectins⁵² and a cytokine.⁵³

⁴⁵ Convention on the Conservation of Migratory Species of Wild Animals (adopted 23 June 1979, entered into force 1 November 1983) 19 ILM 15.

⁴⁶ Ibid art 1(a).

⁴⁷ For example, consider Article 2 of Executive Decree No. 19 of March 26, 2019, on the Regulation of the Access and Control of the Use of Biological and Genetic Resources in the Republic of Panama and on the Establishment of Other Measures (2019), which states in part: “Migratory species that are found due to natural causes are included in the national territory.” (unofficial translation).

⁴⁸ A similar issue could be considered in relation to cosmopolitan species. In the field of biogeography, a species is referred to as “cosmopolitan” if its distribution is exhibited in most or all regions of the world.

⁴⁹ Morgera and others (n 29) 203.

⁵⁰ A James Kettle and others, ‘Where Once the Eel and the Elephant Were Together: Decline of the European Eel Because of Changing Hydrology in Southwest Europe and Northwest Africa?’ (2011) 12 Fish and Fisheries 380.

⁵¹ Secretariat of the Convention on Biological Diversity, ‘The Sargasso Sea’ (*The Clearing House Mechanism of the Convention on Biological Diversity*, 15 June 2015) <<https://chm.cbd.int/database/record?documentID=200098>> accessed 28 February 2020.

⁵² As noted above, the filing and issuance of patents reflects R&D activity and thus indicates that “utilization of genetic resources” is taking place. E.g. *Tumor and infectious disease therapeutic compositions* US Patent No US9035033B2; *Label free biosensors, gram-negative bacteria detection, and real-time and end point determination of antibiotic effects* US Patent No US10287616B2; *Methods and compositions for the inhibition of biofilms on medical devices* US Patent No

Monarch butterfly (Danaus plexippus)

Another well-known migratory species, the monarch butterfly (*Danaus plexippus*), is migratory in the Americas, traversing Mexico, the United States and Canada throughout its life cycle. It has been listed in the CMS Appendix II since 1979. The monarch butterfly has now spread to islands in the Pacific and beyond, where it no longer carries out lengthy migrations.⁵⁴ The monarch butterfly's genome was fully sequenced and released publicly in 2011.⁵⁵

Examples exist of patents or patent filings using cell lines,⁵⁶ and covering sequences,⁵⁷ proteases,⁵⁸ and enzymes⁵⁹ from monarch butterflies. The most geographically concentrated conservation burden for this species falls on Mexico – the only migratory range State that is a Party to the Nagoya Protocol – which is responsible for protecting overwintering sites in the high-elevation Oyamel fir forests of central Mexico. These overwintering sites are under threat from climate change and illegal logging – despite many of the sites being located within a biosphere reserve.⁶⁰ The World Heritage List description recognizes the need to work with local communities on environmental protection and the provision of alternative livelihoods to logging, including promoting benefit-sharing mechanisms for local communities as an incentive to enhance their support for conservation.⁶¹

Mallard duck (Anas platyrhynchos)

A final example is the mallard duck (*Anas platyrhynchos*), a species covered by the *Agreement on the Conservation of African-Eurasian Migratory Waterbirds*⁶² (AEWA), a treaty dedicated to the conservation of migratory waterbirds and their habitats across Africa, Europe, the Middle East, Central Asia, Greenland

US8454566B2; *Bioadhesive microspheres and their use as drug delivery and imaging systems* US Patent No US6365187B2; *Method of using lectins for contraception, prophylaxis against diseases transmittable by sexual contact, and therapy of such diseases, and apparatus for administering lectins* US Patent US6743773B2; *Method of using lectins for prevention and treatment of oral and alimentary tract disorders* US Patent US7790672B2.

⁵³ *Orally administrable immunostimulant product for aquaculture* European Patent (EPO) No EP2349224B1.

⁵⁴ See e.g. Gerald McCormack, 'Cook Islands Biodiversity: Cook Islands' Largest Butterfly - the Monarch' (*Cook Islands Natural Heritage Trust*, 7 December 2005) <<http://cookislands.bishopmuseum.org/showarticle.asp?id=21>> accessed 28 February 2020; Monarch Butterfly New Zealand Trust, 'Monarch Sightings Map' (no date) <<https://www.monarch.org.nz/introduction-to-research/monarch-sightings-map/>> accessed 28 February 2020.

⁵⁵ Shuai Zhan and others, 'The Monarch Butterfly Genome Yields Insights into Long-Distance Migration' (2011) 147 Cell 1171.

⁵⁶ A patent search on WIPO Patentscope returns 221 patents or applications referencing the *Danaus plexippus* (DpN1) cell line described in Laura A Palomares and others, 'Novel Insect Cell Line Capable of Complex N-Glycosylation and Sialylation of Recombinant Proteins' (2003) 19 Biotechnology Progress 185.

⁵⁷ E.g. *Preparation of 3-Hydroxypropionic Acid in Recombinant Yeast Expressing an Insect Aspartate-1 Decarboxylase* International Patent Application (PCT) No WO2015017721A1; *Methods and compositions for synthesizing improved silk fibers* US Patent US10435516B2; *Modulating nudix homology domain (nhd) with nicotinamide mononucleotide analogs and derivatives of same* US Patent Application No US20190350960A1.

⁵⁸ *Uso de proteases intestinais de lagartas de danaus plexippus para a hidrólise das proteínas do leite e produção de fórmulas hipoalergênicas* Brazilian Patent Application No BR102018005066A2.

⁵⁹ *Methods for the enzymatic production of isoprene from isoprenol* International Patent Application (PCT) No WO2014076016A1; *Microorganisms for the production of insect pheromones and related compounds* International Patent Application (PCT) Application No WO2018213554A1.

⁶⁰ UNESCO, 'Monarch Butterfly Biosphere Reserve' (*World Heritage List*, no date) <<https://whc.unesco.org/en/list/1290/>> accessed 28 February 2020.

⁶¹ *Ibid.*

⁶² *Agreement on the Conservation of African-Eurasian Migratory Waterbirds* (adopted 15 August 1996, entered into force 1 November 1999) 2365 UNTS 203.

and the Canadian Archipelago.⁶³ The mallard duck's range includes North and East Africa, Europe and Central Asia, and Iceland and Canada. It is the ancestor of most domestic duck breeds.

Several patents have been obtained, or patent applications made, using genetic resources from mallard ducks, including developing cell lines,⁶⁴ using nucleic acids and cells for producing vaccines,⁶⁵ using immunoglobins for establishing disease resistance in invertebrates,⁶⁶ treatment of hepatitis,⁶⁷ and production of biofuels and bulk chemicals.⁶⁸

As noted earlier, the Parties may conclude that the above examples are amenable to resolution under Article 10, some under Article 11, or that one or more of the examples fall outside of the scope of the Convention and Protocol.

2.3. Areas Beyond National Jurisdiction

International law recognizes certain locations as areas beyond national jurisdiction where States cannot assert claims to sovereignty, such as the high seas and the deep seabed ('the Area'). In late 2017, the United Nations General Assembly adopted Resolution 72/249 to initiate negotiations on a legally binding international instrument on marine biodiversity of areas beyond national jurisdiction (BBNJ) under the aegis of the United Nations Convention on the Law of the Sea (UNCLOS).⁶⁹

Delegates at the third session of the Intergovernmental Conference on the Conservation and Sustainable Use of Marine Biodiversity of Areas Beyond National Jurisdiction engaged, for the first time, in textual negotiations on the basis of a "zero draft". The document's structure addressed general provisions and cross-cutting issues, as well as the four elements identified in the package agreed in 2011. One of these elements is the subject of marine genetic resources, including questions on the sharing of benefits. The fourth session of the Intergovernmental Conference will consider a revised draft text of an agreement which includes a section on marine genetic resources and benefit-sharing.⁷⁰

There are at least two transboundary issues at play in the relationship between the Nagoya Protocol and the prospective instrument on BBNJ. The first pertains to 'straddling' genetic resources, which may traverse, or exist on both sides of, the boundary between a State's EEZ and the High Seas and the deep seabed ("the Area"). The second pertains to marine areas situated over the extended continental shelf of a coastal State. In both of these cases, it could be that the same genetic resource can be found both within national jurisdiction, and in areas beyond national jurisdiction. If the prospective instrument on BBNJ ultimately addresses the genetic resources of high seas waters, these genetic resources would potentially fall under two different regimes.⁷¹ Article 11 would not be applicable, as it only calls for transboundary cooperation in cases where the same genetic resources are found in situ within the territory of more than

⁶³ AEWA, 'AEWA' (no date) <<https://www.unep-aewa.org/en/legalinstrument/aewa>> accessed 28 February 2020 and AEWA, 'Species' (no date) <<https://www.unep-aewa.org/en/species>> accessed 28 February 2020.

⁶⁴ *Immortalized avian cell lines*, International Patent Application (PCT) No WO2009004016A1.

⁶⁵ *Avian telomerase reverse transcriptase*, International Patent Application (PCT) No WO2007077256A1.

⁶⁶ *dsRNA induced specific and non-specific immunity in crustaceans and other invertebrates and biodelivery vehicles for use therein*, International Patent Application (PCT) No WO2009004016A1.

⁶⁷ *Preventives and remedies for chronic hepatitis*, International Patent Application (PCT) No WO2001047545A1.

⁶⁸ *Anoxic biological production of fuels and of bulk chemicals from second generation feedstocks*, International Patent Application (PCT) No WO2014207099A1.

⁶⁹ For further information, see United Nations, "Intergovernmental Conference on Marine Biodiversity of Areas Beyond National Jurisdiction", online: <https://www.un.org/bbnj/>.

⁷⁰ *Revised draft text of an agreement 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*, UN Doc. A/CONF.232/2020/3, Part II: Marine Genetic Resources, Including Questions on the Sharing of Benefits. Decision 74/543 of 11 March 2020 postponed the fourth session of the conference to the earliest possible available date to be decided by the General Assembly.

⁷¹ Tullio Scovazzi, 'The Rights to Genetic Resources beyond National Jurisdiction: Challenges for the Ongoing Negotiations at the United Nations' (Brill | Nijhoff 2020) 236–37.

one Party. Some States have proposed language that would address the questions raised in the above paragraph, but the text is not agreed.⁷²

3. SPECIFIC CASES OF GENETIC RESOURCES FOR WHICH IT IS NOT POSSIBLE TO GRANT OR OBTAIN PIC

Genetic resources of untraceable provenance in *ex situ* collections, the utilization and screening of geographically diverse samples sourced from different regions and countries, and DSI, are all situations that can be considered to involve genetic resources for which it may not be possible to grant or obtain PIC. These cases also implicate other aspects of the Protocol that are not definitively addressed – in particular, the parameters of temporal and subject matter scope, and what it means to access a genetic resource.

3.1. Genetic Resources of Untraceable Provenance in *Ex Situ* Collections

Samples of genetic resources are held in a diversity of *ex situ* repositories across the globe. These collections include botanical gardens, herbaria, culture collections, gene banks, seed banks, zoos, aquaria, and private collections. Many *ex situ* collections hold specimens acquired prior to the entry into force of the CBD, some of which may possibly be accessed for commercial purposes,⁷³ and some contain specimens deposited without provider country information. To add to the complexity, *ex situ* collections across the globe are facing challenges relating to funding and changing research priorities. So-called orphan or endangered collections may be disposed of, including to third parties, rapidly, with possible issues relating to documentation arising for the recipient.⁷⁴

Countries differ on whether Protocol obligations apply to entities making new uses of genetic resources in *ex situ* collections. For example, the EU Regulation implementing the Nagoya Protocol is clear that it does not apply to genetic resources accessed prior to the entry into force of the Protocol.⁷⁵ But legislation in several countries such as Brazil, Colombia, and South Africa, requires benefit-sharing from utilization

⁷² *Textual proposals submitted by delegations by 20 February 2020, for consideration at the fourth session of 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 (the Conference), in response to the invitation by the President of the Conference in her Note of 18 November 2019 (A/CONF.232/2020/3): Article-by-article compilation of textual proposals for consideration at the fourth session dated 15 April 2020, European Union and Indonesian proposals on Article 10(5).*

⁷³ It should be noted that the terms of acquisition for specimens may limit their use to non-commercial utilization only. However, there are also private collections with a commercial focus. One area of use of *ex-situ* collections is in compiling collections or libraries of natural products to be used for screening for desired characteristics. One such library is the TimTec Natural Product Library, which is a commercially available library containing 800 pure natural compounds. The library contains broad diversity of natural materials and the compounds are primarily derived from plants, although samples also come from bacteria, fungus, and animal sources.

Although TimTec notes that “[c]ommon natural sources and reference information is available for the majority of the samples,” it is not clear what reference information is available for the library and whether the scientists who utilize the library access the reference materials, as there are many different sources and geographic locations included. Several patented inventions have used the TimTec Natural product Library. See ‘TimTec Compound Libraries for Screening, Chemical Building Blocks’ (no date) <<https://www.timtec.net/>> accessed 10 June 2020.

⁷⁴ Society for the Preservation of Natural History Collections, ‘Threatened and Orphaned Collections’ (29 March 2017) <https://spnhc.biowikifarm.net/wiki/Threatened_and_Orphaned_Collections> accessed 28 February 2020; Kevin McCluskey, ‘Orphaned and Endangered Collections the Topic at Fort Collins Meeting’ (*ISBER News*, 8 December 2015) <<http://news.isber.org/orphaned-and-endangered-collections-the-topic-at-fort-collins-meeting/>> accessed 28 February 2020; OECD, *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology* (OECD 2001) 23–24.

⁷⁵ See Regulation (EU) No. 511/2014 of the European Parliament and of the Council 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, Art. 2(1) [2014] OJ L150/59.

of genetic resources accessed at a time prior to entry into force of the Protocol.⁷⁶ For countries requiring benefit-sharing from the utilization of genetic resources in *ex situ* collections, a problem arises for specimens deposited without country of origin information, or deposited prior to the CBD or Protocol such that PIC, if now required, was not granted. The following examples are illustrative of the challenge of genetic resources of untraceable provenance in *ex situ* collections and provides information on how some *ex situ* collections deal with access and benefit-sharing requirements for the different resources held in their collections.

Culture collections

The primary *ex situ* repositories of microorganisms are culture collections, many of which are members of the World Federation for Culture Collections (WFCC). The microscopic organisms (or microorganisms) contained in these collections include bacteria, protozoa, fungi and algae. Culture collections may also contain plant and animal cell lines, viruses, and derivatives such as plasmids and complementary DNA (also known as cDNA).⁷⁷

The WFCC has almost 1000 registered collection members or affiliate members from 125 countries.⁷⁸ It also has a code of conduct which “endorses the principles of the Convention on Biological Diversity and requires biological materials to be received and supplied within the spirit of the CBD.”⁷⁹ While most microbial genetic resources in culture collections originate from *in situ* sources, how they are acquired varies.⁸⁰ Public culture collections directly acquire over half of these specimens from ecosystems and natural habitats, with researchers depositing material in the collections often in conjunction with a publication or claim for intellectual property rights, and formal and informal exchanges amongst institutions constituting the balance of the acquisitions⁸¹

In a 2017 submission by the WFCC, in conjunction with two related bodies, two scenarios were provided in which it is not possible to grant or obtain PIC in relation to *ex situ* genetic resources: (1) *in situ* sampling occurred before the entry into force of the Nagoya Protocol but no documentation is available other than the date of the deposit of a specimen, and (2) third parties lacking documentation on date or location of sampling, or PIC, who seek to deposit material in a culture collection. The WFCC explained that:

rather than rejecting material that may have great scientific value, although not having evidence of legality, a culture collection may accept the material but inform the authorities *a posteriori*. When no country of origin is unambiguously identifiable (for

⁷⁶ See Brazil, The Biodiversity Law, Art. 2(VIII), Art. 37), Law No. 13,123/2015); Colombia, Resolution 1348 [2014] and Andean Decision 391, Art. 1, (1996); and South Africa, National Environmental Management: Biodiversity Act, Sec. 80, 2004 (Act No. 10 of 2004) (and 2013 amendments).

⁷⁷ WFCC and others, ‘Submission Of The World Federation For Culture Collection (WFCC), World Data Centre For Microorganisms (WDCM) & Transparent User-Friendly System Of Transfer Programme (TRUST) For Notification SCBD/ABS/VN/KG/Jh/86849’ (2017). See also Kate Davis and others, ‘Ex Situ Collections and the Nagoya Protocol: A Briefing on the Exchange of Specimens between European and Brazilian Ex Situ Collections, and the State of the Art of Relevant ABS Practices’ (International Workshop on The Role to be Played by Biological Collections Under the Nagoya Protocol, Brasilia, Brazil, 2013) 16–17.

⁷⁸ WFCC and others (n 75). See also ‘WFCC Members’ (*World Federation for Culture Collections*, no date) <<http://www.wfcc.info/index.php/membership/>> accessed 28 February 2020. (“768 culture collections from 76 countries have registered with WDCM-CCINFO and 131 of them have registered with WFCC as affiliate members from 49 countries in total 966 registration users”).

⁷⁹ WFCC, *Guidelines for the Establishment and Operation of Collections of Cultures of Microorganisms* (3rd edn, WFCC 2010) para 17.6.

⁸⁰ Jerome H Reichman and others, *Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons* (Cambridge University Press 2016) 169.

⁸¹ Ibid. See also, Gerard Verkley and others, ‘New ECCO model documents for Material Deposit and Transfer Agreements in compliance with the Nagoya Protocol’, *FEMS Microbiology Letters* (2020) 367(5) <https://doi.org/10.1093/femsle/fnaa044>.

instance because the microbial material is ubiquitous) a global multilateral benefit sharing mechanism may be useful as long as it is cost efficient and operationalizable within the scope of the Convention.⁸²

Botanical Gardens

Vast numbers of living specimens of biodiversity reside in the more than 3600 registered “botanical living collections” across the globe.⁸³ These include botanical gardens, zoological gardens, and arboreta. Moreover, some botanical gardens also undertake other forms of *ex situ* conservation, such as tissue collections, fungi, seed, and gene banks, and possess research collections such as herbaria and ethnobotany collections.⁸⁴

The International Plant Exchange Network (IPEN) was established in 2002 by the Verband Botanischer Gärten as a system to facilitate international exchange of living plant material between botanic gardens for non-commercial purposes in compliance with the CBD.⁸⁵ IPEN members use a shared code of conduct, shared exchange documents and trackable identification numbers. The objective of IPEN is to provide a sound basis for cooperation, transparency and communication, taking into account the concerns of both the providers and the users of genetic resources. According to the IPEN Code of Conduct “IPEN member gardens are strongly recommended to treat all [living] plant material 'as if' acquired after the CBD came into effect and therefore being subject to the CBD. This does, however, not imply that responsibility is accepted for retroactive benefit-sharing claims regarding commercial use of plants acquired before the CBD came into effect.”⁸⁶

The Royal Botanic Gardens, Kew (Kew), which is not an IPEN member, curates diverse collections including 50,000 living plants, an arboretum, and several additional collections including a herbarium, and fungi, seed, gene, and other banks totaling 8.5 million items.⁸⁷ Kew’s 2004 ABS policy notes that Kew “makes efforts to share benefits fairly and equitably where they arise from the use of genetic resources which were acquired before the CBD came into force”.⁸⁸ In cases where Kew wishes to commercialise any plant or fungal material collected before the entry into force of the CBD, it will “as far as is possible, share benefits fairly and equitably.”⁸⁹ The Kew Economic Botany Collection (EBC) founded in 1847, is one of the largest specimen collections at Kew, with approximately 90,000 entries comprising “plant raw materials and artefacts representing all aspects of craft and daily life worldwide, including medicines, textiles, basketry, dyes, gums and resins, foods and woods.”⁹⁰ A cursory search of

⁸² WFCC and others (n 75). Indeed, during the process of becoming a Registered Collection under the EU Regulation 511/2014, the Leibniz Institute DSMZ implemented stringent depositor checks before accepting new deposits. As such, a 20% reduction in deposits was observed. Thus, culture collections that rigorously seek to implement the principles of the Nagoya Protocol are faced with the dilemma whether to continue the scientific collection of novel biodiversity or remain legally compliant. See <https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register-of-Collections.pdf>.

⁸³ See Botanic Gardens Conservation International, ‘GardenSearch’ (no date) <https://tools.bgci.org/garden_search.php> accessed 28 February 2020 (cited in Davis and others (n 75) 14).

⁸⁴ Ibid.

⁸⁵ It should be noted that 98.5% of IPEN’s membership is in the Global North. 97% of these members are located in West, Central or Eastern Europe. See ‘List of (IPEN) registered botanic gardens’ (IPEN, 4 February 2020) <<https://botu07.bio.uu.nl/data/ipenList.php>> accessed 10 June 2020.

⁸⁶ Botanic Gardens Conservation International, ‘International Plant Exchange Network Resources’ (no date) <<https://www.bgci.org/resources/bgci-tools-and-resources/international-plant-exchange-network-resources/>> accessed 28 February 2020.

⁸⁷ Allowing it to bill itself as “the most biodiverse place in the world.” Royal Botanic Gardens, Kew, ‘Welcome to Royal Botanic Gardens, Kew’ (no date) <<https://www.kew.org/>>, accessed 28 February 2020.

⁸⁸ Royal Botanic Gardens, Kew ‘Policy on Access to Genetic Resources and Benefit-Sharing’ <<https://www.kew.org/about-us/reports-and-policies/conservation-and-sustainable-use>> accessed 10 June 2020, s 3.1.

⁸⁹ Ibid. s 4.3.

⁹⁰ Royal Botanic Gardens, Kew, ‘Kew Economic Botany Database’ (no date) <<https://ecbot.science.kew.org/index.php>> accessed 28 February 2020.

the EBC database yielded several examples of historic specimen entries with no provider country information and/or no IPLC information for uses which appeared to comprise associated traditional knowledge.⁹¹

Herbaria

Whereas botanical gardens are known primarily as repositories of living plant specimens, herbaria house dried and preserved plant samples that have been annotated with relevant identifying information on the location from which the sample was taken (which may not be the provider country), the collector, date collected, phenotypic features, and uses, particularly from ethnobotanical collectors. The Index Herbariorum listed 3324 active herbaria in the world as of 15 December 2019, which contained over 390 million specimens.⁹² Many are associated with universities, museums, botanical gardens, or other research institutes.⁹³ They are a rich source of information for research, educational, and even commercial purposes.⁹⁴ Developments in gene sequencing technology now allow for the analysis of herbaria specimens over 100 years old, including long-extinct species.⁹⁵ As with botanical gardens, culture collections, and other *ex situ* repositories, some samples held by herbaria may be missing information on the sample's source or origin.⁹⁶

Evolving approaches to utilization in ex situ collections

The Consortium of European Taxonomic Facilities (CETAF) is a consortium of “publicly funded natural science museums, natural history museums, botanic gardens and biodiversity research centres engaged in taxonomic research and promoting training, research and understanding of systematic biology, palaeobiology and earth sciences. CETAF institutions hold significant zoological, botanical, palaeobiological, palaeontological and geological collections. CETAF developed a Code of Conduct and Best Practice for Access and Benefit Sharing to assist taxonomists and biodiversity researchers in their obligations resulting from the CBD and the Nagoya Protocol. The CETAF Code of Conduct is the first acknowledged best practice under Art. 8 of Regulation (EU) No 511/2014.⁹⁷ CETAF Member institutions

⁹¹ We note that, as emphasized in the 2015 IUCN submission, “there is a real difference between ‘specimens whose provenance is unknown’ and ‘specimens whose provenance is undisclosed’ and that the GMBSM should not become a tool by which particular users or collectors can or would wish to evade national ABS requirements, simply by claiming that they do not know where the resources were collected.” IUCN Joint SSC-WCEL Global Specialist Group on ABS, Genetic Resources and Related Issues (n 25). We are unable to ascertain, without more information, which of these categorizations are correct for the *ex situ* collection examples cited in, or identified during the course of, this study. We also note that in the case of old specimens with incomplete information, it may be possible to track origin information by, *inter alia*, comparing to plants in other digital collections, updating names and consulting experts. See Emma De Haas and others, ‘The Zierikzee herbarium: An analysis of the specimens and origins of an enigmatic herbarium’ (2019), <https://www.researchgate.net/publication/334415495>.

⁹² Barbara M Thiers, ‘The World’s Herbaria 2019: A Summary Report Based on Data from Index Herbariorum’ (New York Botanical Garden 2020) 1.

⁹³ See list of 100 largest herbaria in *ibid* 8–13.

⁹⁴ FPW and MB anonymous interviews with *ex situ* collection personnel (2020). See also Soejarto D. D., Kinghorn A. D., Farnsworth N. R. Potential Sweetening agent of plant origin. III: “Organoleptic evaluation of Stevia leaf herbarium samples for sweetness”. *J. Nat. Prod.* 45, p. 590-598, (1983) cited in U.S. patent No. 9,636,314.

⁹⁵ Freek T Bakker, ‘Herbarium Genomics: Plant Archival DNA Explored’ in Charlotte Lindqvist and Om P Rajora (eds), *Paleogenomics: Genome-Scale Analysis of Ancient DNA* (Springer International Publishing 2019) mentions the successful analysis of a sample 146 years old. See Vanessa C Bieker and Michael D Martin, ‘Implications and Future Prospects for Evolutionary Analyses of DNA in Historical Herbarium Collections’ (2018) 165 *Botany Letters* 409 for the prospects of such utilization.

⁹⁶ MB, interview, anonymous herbaria curator (2020).

⁹⁷ Commission Decision of 10.5.2019 recognising the Code of Conduct and Best Practice for Access and Benefit Sharing of the Consortium of European Taxonomic Facilities as best practice under Regulation (EU) No 511/2014 of the European Parliament and Council, C (2019) 3380 final.

approved the Code of Conduct for application as far as reasonably possible to biological material in their collections.⁹⁸

When acquiring or receiving biological material for purposes other than utilization⁹⁹ from *ex situ* sources, CETAF institutions will evaluate the material's provenance and available documentation, to ensure that it was acquired in accordance with applicable law and that its legal status is clear.¹⁰⁰ In cases where material is obtained for utilization, CETAF institutions will evaluate its provenance and available documentation and, where necessary, take appropriate steps to ensure that it was legally accessed and can thus be legally utilized.¹⁰¹ Member institutions also will strive to share benefits from new utilizations of genetic resources accessed or otherwise acquired prior to the entry into force of the Nagoya Protocol, as far as reasonably possible, in the same manner as for those acquired thereafter – while not accepting responsibility for any retroactive claims.¹⁰²

The Muséum National d'Histoire Naturelle (MNHN), a CETAF member, faces challenges in the matter of access to its collections. MNHN plays a dual role consisting of preserving collections and hosting researchers. As such, it is a provider of *ex situ* genetic resources to which it must ensure access for different groups of researchers: MNHN staff who conduct research on collections, and external and worldwide researchers who are hosted temporarily to study collections. MNHN researchers also often lend specimens to other scientific museums and research centers. It is presently regularizing its practices in line with the requirements set out in the Nagoya Protocol by developing digital tools to ensure traceability by recording all legal documents and ABS obligations linked to collections databases. This will include a designated 'Nagoya database' separate from, but complementary to, collections databases that will allow managers to know of any rights and possible restrictions on use and utilization of the specimens requested for a loan, a sample or a study.

The French law implementing the Nagoya Protocol establishes that a 'new utilization' triggers ABS obligations when there is commercial intent.¹⁰³ This brings – at a minimum – biological material and associated traditional knowledge collected after the entry into force of the CBD within the scope of the law and, possibly, material and associated traditional knowledge collected beforehand. This is leading to a rethinking of access to MNHN's pre-Nagoya botany collections for utilization.¹⁰⁴ This may be a challenge faced by herbaria and other types of *ex situ* collections located in other countries with a utilization trigger for ABS obligations.

3.2. Utilization and Screening of Geographically Diverse Samples Sourced from Different Regions and Countries

In research and development, it is not uncommon for researchers to use large numbers of physical samples in screening and development projects to, *inter alia*, identify promising leads for further

⁹⁸ Consortium of European Taxonomic Facilities (CETAF), 'Code of Conduct and Best Practice for Access and Benefit-Sharing' (CETAF 2018) 4.

⁹⁹ Per EU Regulation 511/2014.

¹⁰⁰ Consortium of European Taxonomic Facilities (CETAF) (n 96) 5.

¹⁰¹ Ibid.

¹⁰² Ibid 6.

¹⁰³ Loi n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages, JORF n°0184 du 9 août 2016, L. 412-6 : « Dans le cas de collections de ressources génétiques ou de connaissances traditionnelles associées constituées avant la publication de la loi n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages, les procédures d'accès et de partage des avantages sur les ressources génétiques relevant de la souveraineté de l'Etat et les connaissances traditionnelles associées à ces ressources génétiques s'appliquent... à toute nouvelle utilisation pour les autres fins. Une nouvelle utilisation est définie comme toute activité de recherche et de développement avec un objectif direct de développement commercial et dont le domaine d'activité se distingue de celui précédemment couvert par le même utilisateur avec la même ressource génétique ou connaissance traditionnelle associée ».

¹⁰⁴ Catherine Aubertin and Anne Nivart, 'Musée et Collections Sous Le Protocole de Nagoya' in François Mairesse (ed), *Définir le musée du XXIe siècle: Matériaux pour une discussion* (ICOFOM 2017).

exploration in many commercially important fields. The following example provides an instance of such screening, without rendering judgment on whether or not agricultural seeds fall within the scope of the Nagoya Protocol.¹⁰⁵

In 2014 the coalition “No Patents on Seeds”¹⁰⁶ opposed a Monsanto patent application¹⁰⁷ in the European Patent Office (EPO) which claimed methods of screening and selecting soybean plants and seeds for plant maturity and growth groupings using single nucleotide polymorphisms (SNPs). The opposition cited the patent application’s assertion that “more than 250 plants from ‘exotic’ species were screened for variations in climate adaption potential and variations in the period of time needed until maturity and harvesting.”¹⁰⁸ The opposers noted that wild and cultivated species from Australia and Asia were identified as the ones screened and that they were chosen to expand the “narrow” genetic base of U.S. soybean lines. The patent application noted that such expansion with “exotic species” can result in germplasm that can better tolerate a variety of environmental stressors and resist diseases, insects, and nematodes.¹⁰⁹

Requiring distinct bilateral agreements to be negotiated for whatever portion of the 258 exotic plant lines¹¹⁰ are subject to provider country benefit sharing obligations is likely functionally impossible from the standpoint of time and cost, even if the provider country of each sample were known, which may not be the case.

3.3. Digital Sequence Information (DSI)

Decision 14/20 of the Conference of the Parties noted 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 2020 Ad Hoc Technical Expert Group (AHTEG) on Digital Sequence Information on Genetic Resources agreed that Groups 1-3 in Table 2¹¹¹ below, could be considered as DSI.

Table 2: 2020 AHTEG - Clarifying the scope of digital sequence information on genetic resources

	Information related to a genetic resource			Associated information
	Genetic and biochemical information			
Group reference	Group 1	Group 2	Group 3	
High-level description of each group	DNA and RNA	Group 1 + proteins + epigenetic modifications	Group 2 + metabolites and other macromolecules	

¹⁰⁵ At least one Party to the Nagoya Protocol, Mexico, does subject agricultural seeds to ABS procedures, see e.g. ABSCH-IRCC-MX-241563-1, ABSCH-IRCC-MX-208823-1 and ABSCH-IRCC-MX-207343-3. In addition, soybeans are not an Annex 1 crop under the Food and Agriculture International Treaty on Plant Genetic Resources for Food and Agriculture.

¹⁰⁶ The coalition included The Berne Declaration, Greenpeace, with support from more than 300 NGOs and farmers. See Emanuela Gambini, ‘No Patents on Seeds Files an Opposition against Monsanto’s Patent EP 2 134 870 B1 Covering the Selection of Soybean Plants and Seeds’ (2015) 6 European Journal of Risk Regulation 134.

¹⁰⁷ European Patent (EPO) EP2134870 B1. The application notes that the invention can be applied to a plant “from the group consisting of members of the genus *Glycine*, more specifically from the group consisting of *Glycine arenaria*, *Glycine argyrea*, *Glycine canescens*, *Glycine clandestine*, *Glycine curvata*, *Glycine cyrtoloba*, *Glycine falcate*, *Glycine latifolia*, *Glycine latrobeana*, *Glycine max*, *Glycine microphylla*, *Glycine pescadrensis*, *Glycine pindanica*, *Glycine rubiginosa*, *Glycine soja*, *Glycine sp.*, *Glycine stenophita*, *Glycine tabacina*, and *Glycine tomentella*.”

¹⁰⁸ Ibid.

¹⁰⁹ European Patent (EPO) EP 2134870 B1, para. 3.

¹¹⁰ Ibid, para. 114. In the patent application the term “line” is defined as referring to “a group of individual plants from the similar parentage with similar traits.” Para. 18.

¹¹¹ Secretariat of the Convention on Biological Diversity, ‘Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources,’ CBD/DSI/AHTEG/2020/1/7 (Mar. 20, 2020).

<p>Examples of granular subject matter</p>	<ul style="list-style-type: none"> • Nucleic acid sequence reads; • Associated data to nucleic acid reads; • Non-coding nucleic acid sequences; • Genetic mapping (for example, genotyping, microsatellite analysis, SNPs, etc.); • Structural annotation. 	<ul style="list-style-type: none"> • Amino acid sequences; • Information on gene expression; • Functional annotation; • Epigenetic modifications (for example, methylation patterns and acetylation); • Molecular structures of proteins; • Molecular interaction networks. 	<ul style="list-style-type: none"> • Information on the biochemical composition of a genetic resource; • Macromolecules (other than DNA, RNA and proteins); • Cellular metabolites (molecular structures). 	<ul style="list-style-type: none"> • Traditional knowledge associated with genetic resources • Information associated with digital sequence information Groups 1, 2 and 3 (for example, biotic and abiotic factors in the environment or associated with the organism) • Other types of information associated with a genetic resource or its utilization.
---	---	---	---	---

There is a divergence of views on whether and/or how DSI falls within the scope of the CBD or the Nagoya Protocol. As such, and as explained in Section 1, the relevance of the material in this section to the Article 10 discussions is contingent on further developments on DSI in the ongoing negotiations under the CBD and Nagoya Protocol. The report of the 2020 AHTEG on DSI notes that “the importance of a concerted and cost-effective international approach to digital sequence information on genetic resources was highlighted, and experts noted possible approaches, including... a possible multilateral approach.”¹¹²

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. Nevertheless, as described in a recent study commissioned by the CBD Secretariat pursuant to COP decision 14/20, at least 15 countries have domestic ABS measures to address the use of DSI and at least 18 more are in the process of developing such measures.¹¹³ It should be noted that even if DSI is deemed to fall outside of the definition of “genetic resources” as understood under the CBD and the Nagoya Protocol, DSI produced from the utilization of a genetic resource could still be subject to benefit-sharing.

The bilateral ABS model can be applied to DSI in certain situations, particularly as part of MAT for the use of tangible genetic material. It also may be feasible where a small number of agreements would be required. However, there are a number of scenarios involving access to and use of DSI for which the bilateral approach would be functionally if not factually impossible. Two such categories of cases are discussed below.

3.3.1. Cases Where no Physical Access is Needed to Utilize Genetic Information

Some third-party commercial and non-commercial uses of information obtained from the utilization of genetic resources held in publicly accessible databases can be considered a situation where it is not functionally possible to obtain consent. A recent study commissioned by the CBD Secretariat identified more than 1,600 databases which contain “trillions” of nucleotide bases.¹¹⁴ The International Nucleotide Sequence Database Collaboration (INSDC) is a consortium of three of the largest and most commonly

¹¹² Ibid, para 30.

¹¹³ Bagley and others (n 30).

¹¹⁴ Fabian Rohden and others, ‘Combined Study On Digital Sequence Information In Public And Private Databases And Traceability’ (Secretariat of the Convention on Biological Diversity 29 January 2020) 16. Available at : <https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf>.

used databases: GenBank at the National Center for Biotechnology Information 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, which share their contents and provide tools to advance research which relies on biological information.¹¹⁵ Together, these databases contain a large and rapidly growing amount of sequence data and other possible forms of DSI. As of April 2020, GenBank contained over 415 billion bases.¹¹⁶

Moreover, the amount of publicly 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 10 years.¹¹⁷ 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 reduce significantly the need for access to physical samples of genetic resources.

As already noted, there is no agreement among Parties that benefit-sharing obligations attach to such information. However, for countries whose domestic laws do require benefit-sharing for DSI being screened in or obtained from databases such as GenBank, provider country/country of origin information may not be available, as the database operators may not have required sequence submitters to provide such information.¹¹⁸ Moreover, even if such information is available, while it might theoretically be possible to negotiate benefit-sharing contracts with each provider country with a benefit-sharing claim, it effectively would be impossible as well as impractical, due to prohibitive transaction costs, both in terms of time and money.

In addition, users of sequences from these databases generally are not tracked, which makes determining the downstream uses of the sequence information accessed or downloaded impossible, such that countries would not even know who to seek contracts with. In sum, this suggests that, given current free access practices and limited passport data and traceability features of sequence information held in public databases such as the INSDC, and in the many private, in-house databases that download sequence information from INSDC, it may be impossible to determine compliance with ABS obligations in many cases.

For example, Gibberellic acid (GA) regulates plant growth and can allow for the development of (preferred) dwarf coconut trees. In one study, researchers used the Basic Local Alignment Search Tool (BLAST),¹¹⁹ in addition to other alignment search tools, to search for genes similar to those used in GA biosynthesis. They found seven in other model plant species, and were able to then predict the likely function of the genes in GA biosynthesis.¹²⁰ BLAST searches “use” all of the sequences in the GenBank

¹¹⁵ See ‘Response from International Nucleotide Sequence Database Collaboration (INSDC) to CBD Call for Views and Information on Digital Sequence Information on Genetic Resources’ (1 June 2019). See also Rohden and others (n 112).

¹¹⁶ <https://www.ncbi.nlm.nih.gov/genbank/statistics/>. Bases are the nucleotides represented by the letters A, C, G, and T for DNA. It should be noted that much of the INSDC’s content is human DNA, or comes from countries that do not require PIC.

¹¹⁷ <https://www.earthbiogenome.org/>. See also Harris A Lewin and others, ‘Earth BioGenome Project: Sequencing Life for the Future of Life’ (2018) 115 Proceedings of the National Academy of Sciences of the United States of America 4325.

¹¹⁸ Rohden and others (n 112). The country tag in INSDC became a required field for environmental samples in 2011.

¹¹⁹ “BLAST finds regions of similarity between biological sequences. The program compares nucleotide or protein sequences to sequence databases and calculates the statistical significance.” <https://blast.ncbi.nlm.nih.gov/Blast.cgi>.

¹²⁰ Shafeeq Rahman and others, ‘Transcriptome-Based Reconstruction of Gibberellic Acid Biosynthetic Pathway in Coconut (*Cocos Nucifera* L.)’ (2015) 10 Research journal of biotechnology 56, 63. There were several intermediate steps and additional databases used in the process. It appears the authors sequenced the GA enzymes and did 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 37 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 37 genes with homology to the KEGG reference pathway, they were able

database in the sense that they are all searched for homology to the reference sequence. As vast numbers of sequences are present in the databases and vast numbers of users are conducting searches, some for commercial and others for non-commercial purposes, assigning a monetary value to any particular sequence, determining whether its use is for a commercial or non-commercial purpose, and tracing its use by entities running BLAST-type¹²¹ searches is currently not possible.¹²²

Development of Ebola drug REGN-EB3

Currently, there is no established mechanism for PIC to apply to DSI made available in public databases such as GenBank.¹²³ Thus, while bilateral benefit-sharing may in theory be possible, the system is not currently set up to facilitate or enable benefit-sharing in the context of the CBD and Nagoya Protocol. Consider the development of the Ebola drug REGN-EB3 by the pharmaceutical company Regeneron using, in part, a virus strain sequence it obtained from GenBank. 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 Leibniz Association, and had been obtained by synthesis from a survivor of the 2014 Guinean Ebola outbreak.¹²⁴ While BNITM required recipients of physical samples of the virus to sign a material transfer agreement (MTA) affirming the need to negotiate benefit-sharing for commercial products with Guinea pursuant to the CBD and the Nagoya Protocol, it did not require this for the use of the uploaded sequence information.¹²⁵

REGN-EB3¹²⁶ has attracted over US\$ 400 million in research and development commitments from the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority.¹²⁷ It has 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 – among others – tax breaks for R&D expenditures and time-bound market exclusivity for the drug.¹²⁸ Moreover, more than 100 patent applications have been filed worldwide, with some already granted in the U.S., Nigeria, and South Africa.¹²⁹

This is not an isolated occurrence. As observed by Rourke and others:

to identify the seven major genes in the GA pathway. See <https://www.genome.jp/kegg/pathway.html>; <https://www.nature.com/articles/nrg3174>; and <http://geneontology.org/>.

¹²¹ BLAST is not the only search tool of its kind, there are numerous other tools such as FASTA, BLAST+, BLASTn, and BLAST2go.

¹²² In its peer review comments on the combined study on DSI in public and private databases and DSI traceability, the International Nucleotide Sequence Database Collaboration (INSDC) noted that “many uses of [nucleotide sequence data] do not relate to the retrieval of entire records, but rather involve the slicing out and dicing together of small elements of many records (such as a gene from 100 genome assemblies from different species within a taxonomic group).”

¹²³ GenBank, ‘GenBank Overview’ <https://www.ncbi.nlm.nih.gov/genbank/> “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.”

¹²⁴ Edward Hammond, ‘Ebola: Company Avoids Benefit Sharing Obligations By Using Sequences’ (Third World Network May 2019) citing Kristen E Pascal and others, ‘Development of Clinical-Stage Human Monoclonal Antibodies That Treat Advanced Ebola Virus Disease in Nonhuman Primates’ (2018) 218(suppl_5) *Journal of Infectious Diseases* S612.

¹²⁵ *Ibid.*

¹²⁶ ‘PALM Ebola Clinical Trial Stopped Early as Regeneron’s REGN-EB3 Therapy Shows Superiority to ZMapp in Preventing Ebola Deaths’ (*Regeneron Pharmaceuticals Inc.*, 12 August 2019) <<https://newsroom.regeneron.com/news-releases/news-release-details/palm-ebola-clinical-trial-stopped-early-regenerons-regn-eb3>> accessed 28 February 2020.

¹²⁷ See USG Contract No. HHSO100201500013C and USG Contract No. HHSO100201700016C.

¹²⁸ FDA Designation for ‘three human IgG1 mAbs (REGN3470, REGN3471, and REGN3479) directed against different epitopes on Ebola virus glycoprotein’; EMA designation for ‘Three human monoclonal antibodies against the EBOV glycoprotein.’ See also Kiran N Meekings and others, ‘Orphan Drug Development: An Economically Viable Strategy for Biopharma R&D’ (2012) 17 *Drug Discovery Today* 660.

¹²⁹ Hammond (n 122).

In 2017, a Canadian research team synthesized the horsepox virus using [DSI] that was openly accessible on GenBank. The team could have accessed a physical sample of horsepox virus from the U.S. Centers for Disease Control and Prevention, but this would have required signing a material transfer agreement, with potential limits on commercializing future products. There is evidence that the Canadian team decided to synthesize the virus to avoid these legal obligations. The synthesis of viruses demonstrates how openly accessible [DSI] creates a major gap in global ABS governance.¹³⁰

Protein Data Bank

Much like DNA sequences can be obtained from GenBank without physically accessing the genetic material, protein databases such as the Protein Data Bank (PDB) can be used to visualize and mutate existing protein structures. The PDB contains more than 155,000 biomolecule entries that are freely available to the public.¹³¹ Most journals now require scientists to deposit their structures into the PDB as a condition of publication.¹³² The replacement value of the current PDB archives is estimated to be more than US\$ 15 billion.¹³³ According to a recent study, “US FDA approval of 88% of 210 new molecular entities (NMEs or new drugs from 2010 to 2016) was facilitated by open access to ~6,000 PDB structures containing the protein targeted by the NME and/or the new drug itself.”¹³⁴ The importance of the PDB in pharmaceuticals is also indicated by the fact that “these structures were cited in a significant fraction of more than 2 million papers reporting publicly funded, precompetitive research on the drug targets that influenced drug company investment decisions.”¹³⁵

For example, one area of drug discovery facilitated by PDB structures is voltage-gated ion channels (VGIC), which are involved in many signaling pathways and therefore are targets for drugs; the PDB contains more than 750 VGIC structures.¹³⁶ US Patent 8043829B2, assigned to Amgen, Inc., claims a method of treating autoimmune disorders, including multiple sclerosis, type 1 diabetes, psoriasis, and inflammatory bowel disease, by targeting a voltage-gated potassium channel. In determining a toxin to inhibit potassium channels, the patent describes visualizing structures from PDB of toxins from sea anemone, scorpion, marine cone snail and tarantula. The patent uses a peptide analog of OSK1, a toxin from scorpion venom, which was discovered using structural information from diverse organisms deposited in PDB. Thus, using PDB allows individuals to access hundreds of thousands of biomolecule structures from around the world. Requiring bilateral agreements for each provider country with benefit-sharing obligations from which structures were deposited or visualized would be functionally impossible.

Natural Product Libraries

Another possible form of DSI is contained in natural product (NP) databases and collections. Over 120 of these databases and collections have been published since 2000; 98 are still accessible, of which only 50 are open access.¹³⁷ Virtual NP collections are helpful for the first step in exploratory molecular analyses - virtual screening of molecular structures – and the development of NP-based drugs or other kinds of

¹³⁰ Michelle Rourke and others, ‘Policy opportunities to enhance sharing for pandemic research’ (2020) 368 *Science* 717.

¹³¹ H. M. Berman and others, ‘The future of the protein data bank’ (2013) 99 *Biopolymers* 218.

¹³² *Ibid.*

¹³³ David S. Goodsell and others, ‘RCSB Protein Data Bank: Enabling biomedical research and drug discovery’ (2020) 29 *Protein Science* 52.

¹³⁴ *Ibid.* 54.

¹³⁵ *Ibid.*

¹³⁶ *Ibid.*

¹³⁷ Maria Sorokina and Christoph Steinbeck, ‘Review on Natural Products Databases: Where to Find Data in 2020’ (2020) 12 *Cheminform* 1.

active components.¹³⁸ Use of modern cheminformatics technologies of this type can accelerate research and save time and money, with better results.¹³⁹

Many companies that isolate biochemical compounds offer product catalogues and, in some cases, these catalogues also contain compound structures and annotations. These catalogues are often cited in the scientific literature as sources of NP structures, but a number are accessible only to clients on-demand or to registered users.¹⁴⁰ There are a number of country level efforts to catalogue NP within their national borders, such as in Brazil (NUBBEDB), Mexico (BIOFAQUIM) and South Africa (SANCDDB). However, a number of these databases are much broader in their scope and are based on literature searches that may include documented traditional knowledge, e.g. the pan-African natural products library (p-ANAPL),¹⁴¹ AfroDB,¹⁴² NANPDB,¹⁴³ and Northeast Asian TM (TM-MC).¹⁴⁴

“Designing around” the claims of patent on an invention based on the utilization of DSI or a tangible genetic resource

It should be noted that another scenario in which DSI could be used without physical access to a genetic resource is when an entity chooses to ‘design-around’ the claims of a patent that covers an invention made through the utilization of DSI or a tangible genetic resource. Designing around a patent claim is a common competitive tool and involves “eliminating a prescribed element or step found in the patent claims” with the goal of replicating the patented technological benefit while avoiding infringement liability.¹⁴⁵

Intentional design-around activity is generally encouraged and seen as beneficial to society because it often will result in further innovation in the form of the new design-around.¹⁴⁶ In the same way that DSI can be gleaned from a database or publication and used in the development of an invention, third parties can glean information from a patented invention in which DSI was utilized to create a further invention. Some Parties may conclude that by analyzing the invention claimed in the patent and intentionally incorporating some of its elements, entities who perform the design-around have used the genetic resources utilized in creating the patented invention, and that benefit-sharing from the new design-around may be required under their ABS laws. However, no bilateral negotiation may be possible as the country providing the genetic resources may not be known or multiple species from diverse locations may be involved.¹⁴⁷

3.3.2. Utilization of Genetic Components Found in Multiple Organisms

Newer approaches to research, such as synthetic biology, may also involve scenarios for which a bilateral benefit-sharing model are not possible/practical. Synthetic biology is based on the idea that any biological

¹³⁸ Ibid 2.

¹³⁹ Ibid.

¹⁴⁰ Ibid 44.

¹⁴¹ Fidele Ntie-Kang and others ‘Virtualizing the p-ANAPL Library: A Step towards Drug Discovery from African Medicinal Plants’ (2014) 9(3) PLoS ONE e9065.

¹⁴² Fidele Ntie-Kang and others, ‘AfroDb: A Select Highly Potent and Diverse Natural Product Library from African Medicinal Plants’ (2013) 8(10) PLoS ONE e78085.

¹⁴³ Fidele Ntie-Kang and others, ‘NANPDB: A Resource for Natural Products from Northern African Sources’ (2017) 80 J. Nat. Prod. 2067–2076.

¹⁴⁴ Sorokina and Steinbeck, 41-43.

¹⁴⁵ Brian Moran and Benjamin Jensen, ‘Designing Around a Patent as an Alternative to a License’ (*IPWatchdog.com | Patents & Patent Law*, 30 July 2019) <<https://www.ipwatchdog.com/2019/07/30/designing-around-patent-alternative-license/id=111683/>> accessed 28 February 2020. See *State Industries, Inc v AO Smith Corp* 751 Federal Reporter, 2nd Series 1226, 1236 (US Fed Cir 1985): ‘One of the benefits of a patent system is the so-called “negative incentive” to “design around” a competitor’s products.’)

¹⁴⁶ Moran and Jensen (n 143).

¹⁴⁷ MB, Interviews, anonymous synthetic biology industry researcher & general counsel (2020).

system can be viewed as a combination of functional elements or parts that can be organized in new ways to modify living organisms or to produce synthetic products or components.¹⁴⁸ The 2015 AHTEG on Synthetic Biology defined it as “a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems.”¹⁴⁹

Several technologies and tools enable the use of synthetic biology, including genomic databases, registries of biological parts, standard methods for physical assembly of DNA sequences, commercial services for DNA synthesis and sequencing, and advanced bioinformatics.¹⁵⁰ These resources allow researchers to use DNA sequences from many different organisms, accessible in public or private databases, in designing new biosynthetic pathways, re-designing biological systems and in other advanced biotechnological applications.

For example, as described in a submission by the International Chamber of Commerce (ICC) arguing against 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.”¹⁵¹

The following examples illustrate the utilization of DSI from multiple organisms.

Steviol glycosides

Smaller but still significant numbers of diverse organisms may also be used that defy efficient use of a bilateral benefit-sharing approach. Consider U.S. patent 9,284,570 which describes the production of synthetic steviol glycosides as a replacement for stevia and other sweeteners, by engineering yeast, *Escherichia coli*, or plant cells to express novel recombinant genes encoding steviol biosynthetic enzymes to produce steviol or steviol glycosides. The process mentions the possible use of genes or biosynthetic pathways from more than 30 different organisms including a bacterium (*Kitasatospora griseola*), human (*Homo sapiens*), fruit fly (*Drosophila melanogaster*), red jungle fowl (*Gallus gallus*), and tobacco (*Nicotiana attenuate*), to produce products for use as commercial sweeteners in food products and dietary supplements.¹⁵²

Beyond the use of model organisms such as yeast, *E. coli*, or plant cells, the patent also describes production of steviol glycosides in more than 20 different fungal cells including: *Schizosaccharomyces* spp., *Pichia* spp., *Pafia* spp., *Kluyveromyces* spp., *Candida* spp., *Talaromyces* spp., *Brettanomyces* spp., *Pachysolen* spp., *Debaryomyces* spp., and *Yarrowia* spp. It also describes the use of more than 15 different bacterial species including *Zymonas* spp., *Acetobacter* spp., *Citrobacter* spp., *Synechocystis* spp., *Rhizobium* spp., *Clostridium* spp., *Corynebacterium* spp., *Streptococcus* spp., *Xanthomonas* spp.,

¹⁴⁸ Victor de Lorenzo and Antoine Danchin, ‘Synthetic Biology: Discovering New Worlds and New Words. The New and Not so New Aspects of this Emerging Research Field’ (2008) 9 EMBO Rep 822. A strand of synthetic biology research has also focused on de novo organism research. However, in an effort to create a controlled terminology, a 2014 European Commission Scientific Committee report adopted a definition of synthetic biology that begins with a living organism, relegating pre-life de novo research to the field of chemistry. See SCENIHR and others, *Opinion I: Synthetic Biology: Definition* (European Commission Scientific Committees 2014).

¹⁴⁹ CBD, Decision XIII/17: Synthetic biology, CBD/COP/DEC/XIII/17 (16 December 2016). See also Wilfried Weber and Martin Fussenegger, ‘The Impact of Synthetic Biology on Drug Discovery’ (2009) 14 Drug Discovery Today 956 and Presidential Commission for the Study of Bioethical Issues, ‘New Directions: The Ethics of Synthetic Biology and Emerging Technologies’ (Presidential Commission for the Study of Bioethical Issues 2010) 43–46.

¹⁵⁰ See Wael Houssen and others, ‘Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use’ (CBD/DSI/AHTEG/2020/1/3 29 January 2020).

¹⁵¹ ICC Task Force on Access and Benefit Sharing, ‘Digital Sequence Information and the Nagoya Protocol’ (International Chamber of Commerce 2017).

¹⁵² U.S. Pat. Appl. Pub. No. 2013/0171328A1 “Production of Steviol Glycosides in Microorganisms” paragraph 125.

Lactobacillus spp., *Lactococcus* spp. None of these species of fungi and bacteria are traditionally considered as model organisms.¹⁵³

D-glucaric acid

A similar example involves the successful enhancement of the yield of D-glucaric acid by Moon and others, involving constructing a biosynthetic pathway to produce glucaric acid in *E. coli*. The method comprised “combining biological parts from disparate organisms”, 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*.¹⁵⁴ Glucaric acid is used in commercial products and also has been studied for therapeutic uses in cancer and cholesterol-lowering treatments.¹⁵⁵ Development of the glucaric acid biosynthetic pathway required no physical material from any of the species whose DNA was incorporated into the *E. coli*.¹⁵⁶ Furthermore, the final glucaric acid product is indistinguishable from other glucaric acid products. Therefore, if this biosynthetic system were incorporated into a glucaric acid manufacturing pipeline, there would be no way to know from the product that DSI from several species had been used in its production.

Bioethanol production

A recent study commissioned by the CBD Secretariat pursuant to decision 14/20, para 11(b), 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

¹⁵³ 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’ (2015) 349 *Science* 677. 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 and Birger Lindberg Møller, ‘Vanillin—Bioconversion and Bioengineering of the Most Popular Plant Flavor and Its De Novo Biosynthesis in the Vanilla Orchid’ (2015) 8 *Molecular Plant* 40, in which the authors also note at 53 “An 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 and Christina D Smolke, ‘Engineering a Microbial Biosynthesis Platform for de Novo Production of Tropane Alkaloids’ (2019) 10 *Nature Communications* 3634, which describes “de novo production of tropine, a key intermediate in the biosynthetic pathway of medicinal Tropane alkaloids such as scopolamine, from simple carbon and nitrogen sources in yeast (*Saccharomyces cerevisiae*). Our engineered strain incorporates 15 additional genes, including 11 derived from diverse plants and bacteria”).

¹⁵⁴ Tae Seok Moon and others, ‘Production of Glucaric Acid from a Synthetic Pathway in Recombinant Escherichia Coli’ (2009) 75 *Applied and Environmental Microbiology* 589.

¹⁵⁵ *Ibid.*

¹⁵⁶ *Ibid.* The authors explained:

The use of... [Ino1] from *Saccharomyces cerevisiae* to produce high concentrations of myo-inositol through *E. coli* fermentation [had] been previously reported... MIOX is a protein of primarily eukaryotic origin, and the homologues from humans, mice, rats, and pigs are the ones that have been best characterized. The mouse version of [MIOX] had been found to have the most favorable properties upon expression in *E. coli* and was chosen for investigation. A synthetic version of the gene was purchased from DNA 2.0, with codon optimization for *E. coli*... We recently cloned and characterized the gene encoding udh activity from *Pseudomonas syringae* pv. tomato DC3000. The udh gene was found to be very well expressed in *E. coli*, resulting in high enzyme activities.” The original characterization of the enzymes required physical material but after characterization no physical material was required.

(emphasis added). See also Patent SU1753949A3, which describes a method for producing 2-keto-d-glucaric acid and uses the non-model organism *Pseudogluconobacter saccharoketogenes* for production of the d-glucaric acid.

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.¹⁵⁷

Production of alcohol-based energy precursors using synthetic biology can also be accomplished using genes from non-model organisms. For example, one “next generation” biofuel is isobutanol, which can be produced in a variety of organisms.¹⁵⁸ Although the isobutanol pathway has been produced in model organisms such as *E. coli* and *S. cerevisiae*, it has also been used in organisms that are not normally considered model organisms, such as *Klebsiella oxytoca* and *Synecococcus elongatus*.¹⁵⁹ One study, funded in part by the Department of Energy and the Great Lakes Bioenergy Research Center, describes methods for maximizing the productivity of the isobutanol pathway, with applicability to industrial biofuel production.¹⁶⁰ This method includes the use of genes from *B. subtilis*, *E. coli*, and *L. lactis*. It also includes the use of engineered genetic ribosome binding site (RBS) sequences fused to the open reading frames (ORF) of each gene from the aforementioned-bacterial species.

The RBS-ORF fragments were used in an expression library containing 243 unique combinations. The study also analyzed variants of isobutanol enzymes by using PCR mutagenesis to create approximately 10⁶ coding sequence variants. The study thereby screened many combinations of genetic material to identify combinations leading to maximum isobutanol production. Thus, this method of biofuel production, which may be of critical commercial importance in the energy industry, 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.

BLAST searches

A further relevant way in which DSI can be used relates to gene sequence alignment searches in databases such as GenBank using tools such as BLAST described in Section 3.3.1. It is known that many species share genes. Recent research has also demonstrated that the horizontal transfer of genetic material is more common than previously realized.¹⁶¹¹⁶² BLAST alignment searches may allow a user who has identified a sequence of interest, perhaps from a species to which PIC/MAT obligations attach, to locate similar sequences of interest in species different to the one in which the sequence was originally identified. These different species may not be covered by PIC requirements.¹⁶³ 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 his or her R&D efforts.¹⁶⁴

In all of these examples, DSI from multiple, diverse, organisms is being utilized. If it is deemed to be within scope, users may need to negotiate MAT with multiple governments engendering uncertainty, delay, and expense, as properly valuing the contributions of sequence fragments may not be possible.¹⁶⁵

¹⁵⁷ Houssen and others (n 148) citing Toby H Richardson and others, ‘A Novel, High Performance Enzyme for Starch Liquefaction. Discovery and Optimization of a Low PH, Thermostable Alpha-Amylase’ (2002) 277 *The Journal of Biological Chemistry* 26501.

¹⁵⁸ Ghosh IN, Martien J, Hebert AS, et al. OptSSeq explores enzyme expression and function landscapes to maximize isobutanol production rate. *Metab Eng.* 2019;52:324–340. doi:10.1016/j.ymben.2018.12.008.

¹⁵⁹ Ibid.

¹⁶⁰ Ibid.

¹⁶¹ Ibid.

¹⁶² See e.g. Alastair Crisp and others, ‘Expression of Multiple Horizontally Acquired Genes is a Hallmark of Both Vertebrate and Invertebrate Genomes’ (2015) 16 *Genome Biology* 50.

¹⁶³ Margo A Bagley, ‘Towering Wave or Tempest in a Teapot? Synthetic Biology, Access and Benefit Sharing, and Economic Development’ in Susy Frankel and Daniel Gervais (eds), *Intellectual Property and the Regulation of the Internet* (Victoria University Press 2017) 95.

¹⁶⁴ See supra fn 42, Switzerland, Declaration of Source.

¹⁶⁵ 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 (n 149). But as other commentators note, “developments in synthetic biology could make

As noted earlier, Parties are not in agreement on whether or to what extent *ex situ* collections, discussed in Section 3.1, or DSI, discussed in this section, are within the scope of the Protocol. As such, the examples discussed may or may not ultimately be deemed amenable to any solution under Article 10.

4. SPECIFIC CASES OF TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES THAT OCCUR IN TRANSBOUNDARY SITUATIONS OR FOR WHICH IT IS NOT POSSIBLE TO GRANT OR OBTAIN PIC

Patterns of colonization and migration over centuries in conjunction with moving political boundaries have contributed to situations where IPLCs in different countries share traditional knowledge regarding the same genetic resources.¹⁶⁶ A fundamental premise of the Nagoya Protocol is the need for PIC to be obtained and MAT to be negotiated with traditional knowledge holders prior to use of traditional knowledge associated with genetic resources, and that benefits from its utilization are to be shared with the IPLCs that hold such knowledge. However, this bilateral approach may not always be possible where the knowledge is held by transboundary IPLCs or where, for some other reason, it is not possible to grant or obtain PIC.

4.1. Traditional Knowledge held by Indigenous Peoples and Local Communities across National Boundaries

There are at least three transboundary scenarios in which traditional knowledge associated with genetic resources may be held by IPLCs. Namely, by a single group across multiple countries (whose boundaries may or may not be contiguous), by more than one group located across multiple countries (whose boundaries may or may not be contiguous); and by a community in one country about a genetic resource originating in another country. These examples do not preclude the possibility of resolution under Article 11. However, they do illustrate that while a bilateral approach may be possible in some situations in which traditional knowledge is held by IPLCs whose membership spans national boundaries, complications can arise, making it functionally impossible to negotiate PIC and MAT in other situations.

Scenario 1: Traditional knowledge held by a single group across multiple countries

The indigenous Guna people could be considered an example under this scenario. While located in both Panama and Colombia, they are a single group and do not recognize geopolitical boundaries. For ABS agreements involving Guna traditional knowledge and Panamanian genetic resources, the Panamanian government consults with the Guna representatives and, if an agreement is reached, facilitates the distribution of benefits to the group without focusing on the fact that the group is physically located within two countries, and apparently the Colombian government takes the same approach.¹⁶⁷ Therefore this type of scenario could be addressed under Article 11 of the Protocol. However, it should be noted that

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 and others, ‘Policy opportunities to enhance sharing for pandemic research’, (2020) 368 *Science* 717. 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.

¹⁶⁶ Roger Chennells, ‘Traditional Knowledge and Benefit Sharing after the Nagoya Protocol: Three Cases from South Africa’ (2013) 9 *Law, Environment and Development Journal* 169 (noting the “complexity of the origins of communities . . . [in] countries where populations have been disturbed by centuries of migration and colonisation.”)

¹⁶⁷ MB, Interview with Dario Luque and Jorge Garcia (2020). In peer review comments, the government of Colombia noted that it operates in the same way as Panama on these issues.

Costa Rica identified the scenario of the Ngobe Bugle people, who live in both Costa Rica and Panama, as one possibly amenable to a global multilateral benefit-sharing mechanism.¹⁶⁸

Scenario 2: Traditional knowledge held by more than one group located across multiple countries

Cases under Scenario 2 may be some of the most complex ones to address in a bilateral ABS context. Not only are multiple IPLCs involved with varying or non-existent community protocols,¹⁶⁹ multiple sovereign countries are involved and may not be able to easily identify who is entitled to benefits, or reach agreement on how to move forward, leaving researchers unable to obtain necessary permissions or equitably share benefits.

For example, *Artemisia judaica*, also known as Judean wormwood, is a medicinal shrub found widely across desert areas of North Africa and Arabia. Traditional uses of the plant include the treatment of cancer, diabetes, fungal infections, atherosclerosis, and arthritis, and its use as a traditional medicine by a variety of IPLCs in Libya,¹⁷⁰ Jordan,¹⁷¹ Egypt,¹⁷² and beyond, is known. Several patent applications have been filed with claims relating to *A. judaica* and mentioning, directly or through citing other references, traditional uses of the plant. These include European Patent No. EP2170360B1, entitled “Herbal compositions for the treatment of diabetes and/or conditions associated therewith” which claims *A. judaica*-containing compositions for the treatment of diabetes.

For a variety of reasons, benefit sharing obligations may not attach to commercial uses of *A. judaica* to treat the same conditions for which it was used traditionally. If there are situations in which they do, however, it may not be possible to correctly identify which IPLCs, in which countries, are entitled to negotiate PIC and MAT, and the transboundary nature of the genetic resource itself is a further complication.

If PIC and MAT were being sought in a case under Scenario 2 before serious research on a project involving such associated traditional knowledge had begun, the delays in seeking consent from multiple groups in multiple countries, with differing (or non-existent) community protocols, and agreeing to MAT amongst multiple IPLCs (and where legally required, approval from relevant country governments), could halt the project at its inception, irrespective of its potential for life-saving societal benefits.¹⁷³ Alternatively, users may choose to only work with IPLCs in one country, to the possible detriment of IPLCs in the other countries.¹⁷⁴

¹⁶⁸ Submission, Costa Rica (2015). However, peer-review comments by Costa Rica suggest an evolving view that includes the possibility of resolution depending on the consent of the Ngobe Bugle people.

¹⁶⁹ See Natural Justice and 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’ (Natural Justice and ABS Capacity Development Initiative 2017) 20.

¹⁷⁰ U.S. Patent No. 6,350,478 (“*Artemisia judaica* is used in Libyan traditional medicine as an infusion for the treatment of “wasting disease”, almost certain[ly] diabetes mellitus.”). See also Daniel F. Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates* (Earthscan 2010) 60 (citing several publications documenting traditional uses of the plant).

¹⁷¹ M.S. Abu-Darwish, et al., Chemical composition and biological activities of *Artemisia Judaica* essential oil from southern desert of Jordan, *J. Ethnopharmacology* 191 (2016) 161 (“*A. judaica* was described by Jordanian herbalists as traditional agent to treat coronary artery thrombosis and cardiac infarction. . . . it is reported that *A. judaica* has been used in traditional medicine of Bedouins in the Saudi Arabia desert and Sinai.”)

¹⁷² Yasser A. El-Amier, et al., Potential of wild plant *Artemisia judaica* L. as sustainable source of antioxidant and antimicrobial compounds, *J. Experimental Sci.* (2019), 10: 04-08.

¹⁷³ Termination of projects due to an inability to obtain PIC in a timely fashion is not purely hypothetical. A 2017 botanical garden submission notes that because of such a failure, “the first basic research applications and projects had to be cancelled”. See ‘Comments on behalf of Botanical Gardens’ (esp. IPEN – International Plant Exchange Network) (2017).

¹⁷⁴ This appears to be the case regarding self-fertilizing *olotón* maize, which is capable of fixing its own nitrogen, cultivated by indigenous farmers in Mexico and Guatemala for thousands of years. Researchers negotiated a benefit-sharing agreement with a group of IPLCs in one part of Mexico only. Mexico is not a party to the International Treaty on Plant Genetic

Scenario 3: A community in one country holding traditional knowledge associated with a genetic resource originating in another country

The case of the Rosy periwinkle is a Scenario 3 example.¹⁷⁵ Rosy periwinkle, or *Catharanthus roseus*, may have originated in Madagascar, but is now a “resolutely cosmopolitan species now cultivated on six continents and thoroughly integrated into the folk healing traditions of countries as distant from one another as England, Pakistan, Vietnam, and Dominica.”¹⁷⁶ Eli Lilly researchers first investigated the plant after finding, in a literature search for Australasian plants with credible indigenous use patterns, reports of its traditional use in the Philippines as an insulin substitute.¹⁷⁷ Lilly’s first collected samples were from India and ultimately led to the development of the successful cancer drug Vincristine. In a separate development, samples of its leaves were sent by a doctor from Jamaica, where it was locally used to treat diabetes, to Canada, where researchers identified and patented Vinblastine, a different cancer drug.¹⁷⁸

Neither cancer drug was based directly on associated traditional knowledge (treating diabetes, not cancer, was the traditional use of the plant). Nevertheless, without the reported traditional knowledge from the Philippines, and associated traditional knowledge from Jamaica, respectively, neither set of researchers seemingly would have been led to investigate the plant for its potential medical uses. Nevertheless, the example shows a type of scenario where a provider country (India) is different to the country of the IPLCs who contributed traditional knowledge (located in the Philippines), and it is not clear that the specific IPLCs could be identified from the literature source.

4.2. Publicly Available Traditional Knowledge Associated with Genetic Resources

The issue of whether publicly available traditional knowledge associated with genetic resources is within the scope of the Protocol and subject to benefit-sharing remains unresolved. Nevertheless, to the extent that it is considered within the scope of the Protocol, PIC negotiations would not take place, as access is already available without restriction.

Nevertheless, it should be noted that 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.¹⁷⁹ Whereas no one owns the public domain however it is

Resources for Food and Agriculture. See Martha Pskowski, ‘Indigenous Maize: Who Owns the Rights to Mexico’s ‘Wonder’ Plant?’ Yale 360 (2019), <https://e360.yale.edu/features/indigenous-maize-who-owns-the-rights-to-mexicos-wonder-plant>.

¹⁷⁵ See Graham Dutfield, ‘Traditional Knowledge, Intellectual Property and Pharmaceutical Innovation: What’s Left to Discuss?’ in Matthew David and Debora Halbert (eds), *The SAGE Handbook of Intellectual Property* (SAGE 2014). (“[G]enetic resources and traditional knowledge that are in general circulation may no longer have traceable origins or else have known origins that may go back a long time, possibly centuries. The sources of the genetic resources and the knowledge may be completely different. A good example is the rosy periwinkle . . .”)

¹⁷⁶ Michael F. Brown, *Who Owns Native Culture?* (Harvard Univ. Press 2003) 136. See also ‘Arizona State University Vascular Plant Herbarium Catalog No ASU0104660’ (n 38).

¹⁷⁷ *ibid.* See also Sarah Laird, ‘Natural Products and the Commercialization of Traditional Knowledge,’ in Tom Greaves (ed.) *Intellectual Property Rights for Indigenous Peoples: A Sourcebook* (SfAA 1999) 151.

¹⁷⁸ See *Vincalokoblastine* US Patent No US3097137A. Graham Dutfield reports that the patent was later licensed for lucrative commercial exploitation to Eli Lilly, see Dutfield (n 173).

¹⁷⁹ See Ruth L Okediji, ‘Negotiating the Public Domain in an International Framework for Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions’ in Daniel Robinson and others (eds), *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge 2017) 145. 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 copyrightable subject matter . . . and expired copyrighted works. Moreover, copyrights expire at different times in different countries. . . . 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, again, patents have differing terms

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.

Numerous countries in Africa, the Americas, Asia and the Pacific have protection systems for traditional knowledge. In those countries, the fact that the knowledge may be publicly available does not necessarily mean that benefit-sharing obligations are not applicable. National law is key: a user of associated traditional knowledge from a country without legislation protecting such knowledge may not have legal PIC/MAT obligations. However, users of associated traditional knowledge from countries with such legislation, who live either in that country or another country that is a Party to the Protocol, may have PIC/MAT obligations.¹⁸⁰

Benefit-sharing negotiations for publicly available traditional knowledge may not be possible because, *inter alia*, the original holders may not be identifiable or may be extinct,¹⁸¹ such traditional knowledge may be attributed to a country¹⁸² but not a particular people or group, or the knowledge may have been originally published and available prior to the entry into force of the CBD or Protocol. We note that because Art. 8(j) of the CBD and Arts. 5.5 and 7 of the Nagoya Protocol refer to knowledge of IPLCs only, traditional knowledge attributable to countries or extinct groups would not appear to come within the scope of either treaty. As such, Parties are not in agreement on whether there should be benefit-sharing obligations in any of these circumstances.

Plant Compendia

Numerous publications and journals exist which catalog plant use in various regions of the world. One of many examples detailing the uses of African plants is a compendium of African medicinal plants published by the African Union entitled *African Pharmacopoeia*. Developed in response to the “global upsurge in the use of traditional medicines” and the lucrative market for such products, the *Pharmacopoeia* provides “scientifically organized information on useful medicinal plants which have been found efficacious in the management of certain ailments” on the continent of Africa. In doing so, it catalogs more than 160 different plant species that are native to multiple countries and may be known by different names in various countries.¹⁸³ This resource compiles a wealth of valuable information about a diversity of medicinal plants and their traditional uses without necessarily identifying the IPLC sources of the information on their uses.¹⁸⁴

Another example is Dan Moerman’s *Native American Ethnobotany*, which describes plants and associated traditional knowledge by plant, use, and tribe. It is described as:

of protection in different countries, 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 WIPO, ‘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 (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.”).

¹⁸⁰ Article 16(3) of the Nagoya Protocol obligates Parties to “as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements...”

¹⁸¹ For example, the group may have died out. See, e.g. Harmeet Shah Singh, ‘Ancient Tribe Becomes Extinct as Last Member Dies’ (CNN.com, 5 February 2010) <<https://edition.cnn.com/2010/WORLD/asiapcf/02/05/india.extinct.tribe/index.html>> accessed 28 February 2020.

¹⁸² Such as Traditional Chinese Medicine. See generally, Xijun Wang, ed., *Serum Pharmacology of Traditional Chinese Medicine: Technologies, Strategies and Applications* (Academic Press 2017).

¹⁸³ African Union Scientific Technical Research Commission (n 39) 27.

¹⁸⁴ African Union Scientific Technical Research Commission (n 39).

“An extraordinary compilation of the plants used by North American native peoples for medicine, food, fiber, dye, and a host of other things. Anthropologist Daniel E. Moerman has devoted 25 years to the task of gathering together the accumulated ethnobotanical knowledge on more than 4000 plants. More than 44,000 uses for these plants by various tribes are documented here. This is undoubtedly the most massive ethnobotanical survey ever undertaken, preserving an enormous store of information for the future.”¹⁸⁵

Because indigenous peoples are found across Canada, the United States, and Mexico,¹⁸⁶ a mixture of CBD and Nagoya Protocol Parties and non-Parties, PIC/MAT would not be required in all cases of use of associated traditional knowledge from this volume. Nevertheless, this compendium is an example of the kind of publication that facilitates literature-based bioprospecting without the need to seek PIC from relevant IPLCs where otherwise required by national law.¹⁸⁷

Rosy Periwinkle

The Rosy Periwinkle example in Section 4.1 above provides a further illustration of the commercial use of publicly available traditional knowledge associated with genetic resources. Two cancer medications were developed based on initial leads from traditional knowledge regarding the plant, one from the Philippines (Vincristine) and the other from Jamaica (Vinblastine).¹⁸⁸ Both of the traditional knowledge leads were for diabetes, but the Philippines case was based on publicly available knowledge whereas the Jamaican one was not.¹⁸⁹

4.3. Traditional Knowledge Associated with Genetic Resources of Untraceable Origin in *Ex Situ* Collections

Many samples of genetic materials collected by ethnobotanists and deposited in botanical gardens, herbaria, and other repositories were obtained with the assistance and direction of IPLCs who used the materials for medicinal and other purposes. As a result, traditional uses of plants and other materials are sometimes included in the identifying information for the sample, particularly in herbaria deposits. However, while provider country information is often present, identifying information on the IPLCs from whom the genetic resource use information was derived may not be.¹⁹⁰ In some cases, this is because many different individuals from in and outside of a community have provided medicinal use leads, or because the use information was taken from a secondary source, such as a pharmacopeia or other extant work which does not list the original providers of the associated traditional knowledge.¹⁹¹

Again, Parties are not in agreement that PIC/MAT obligations apply to the various cases described in this section. Moreover, identifying information on IPLCs from whom traditional knowledge was derived may not be available, rendering the negotiation of PIC/MAT impossible in some cases.

¹⁸⁵ Daniel E. Moerman, *Native American Ethnobotany* (Timber Press 1998). Description from Amazon.com <<https://www.amazon.com/Native-American-Ethnobotany-Daniel-Moerman/dp/0881924539>> accessed 28 February 2020.

¹⁸⁶ See, e.g., Christina Leza, *For Native Americans, US-Mexico border is an 'imaginary line'* (*The Conversation*, 19 March 2019) <<https://theconversation.com/for-native-americans-us-mexico-border-is-an-imaginary-line-111043>> accessed 23 May 2020, noting that “Today, tens of thousands of people belonging to U.S. Native tribes live in the Mexican states of Baja California, Sonora, Coahuila and Chihuahua. . . . Many Native Americans . . . call the U.S.-Mexico border “the imaginary line” – an invisible boundary created by colonial powers that claim sovereign indigenous territories as their own. . . . Officially, various federal laws and treaties affirm the rights of federally recognized tribes to cross between the U.S., Mexico and Canada.”

¹⁸⁷ FPW, Interview with expert in ethnobotany (2020).

¹⁸⁸ Dutfield (n 34) 262–63.

¹⁸⁹ *Ibid.*

¹⁹⁰ We note that such information often is included as notes on herbarium sheets. For new acquisitions it is possible to seek PIC from IPLCs and this is generally considered good practice (cf. CETAF Code of Conduct, page 6 footnote 10 and Annex 2 Section 1).

¹⁹¹ MB, Interview with expert in ethnobotany (2020).

5. CONCLUSIONS

This study identifies a variety of distinct categories of cases that could, depending on decisions of the Parties, fall within the scope of Article 10. These include specific cases of genetic resources and associated traditional knowledge that occur in transboundary situations, highlighting examples of shared ecosystems and habitats, migratory species, and areas beyond national jurisdiction. Several types of transboundary genetic resource situations have been identified which embody challenges for a bilateral approach to benefit-sharing; though the authors note that there is not agreement that each of these situations involves a benefit-sharing obligation. As such, some of these types of transboundary cases could be addressed in the context of Article 10, some under Article 11, or some could be completely excluded from consideration in the context of the Protocol.

Other categories of cases include genetic resources for which it is not possible to grant or obtain PIC, including genetic resources of untraceable provenance in *ex situ* collections, utilization of samples from large numbers of geographically diverse organisms, DSI cases where no physical access is needed to utilize genetic information, and utilization of genetic components found in multiple organisms. Parties are not in agreement on whether or to what extent *ex situ* collections or DSI are within the scope of the Protocol. In several of the examples presented, DSI from multiple, diverse, organisms, is being utilized, and if it is deemed to be within scope, some users may need to negotiate MAT with multiple governments and many users will not be individually identifiable or traceable.

Finally, the study identifies specific cases of traditional knowledge associated with genetic resources held by indigenous peoples and local communities (IPLCs) across national boundaries, and of associated traditional knowledge for which it is not possible to grant or obtain PIC, including publicly available associated traditional knowledge, and associated traditional knowledge of untraceable origin in *ex situ* collections.

Based on the research undertaken, this study concludes that there could be specific cases that fall within the scope of Article 10. Whether any of these cases establish a need for a global multilateral benefit-sharing mechanism, and what the modalities of such a mechanism would be if a need were established, are to be determined by the Parties to the Nagoya Protocol.

ACKNOWLEDGEMENTS

The authors would like to thank Eric Boyer and Candace Walther for excellent research assistance, and the CBD Secretariat staff (Worku Yifru, Beatriz Gomez, Austein McLoughlin, and Rodrigo Sara) for their helpful involvement throughout the study process.

ANNEX A: LIST OF INTERVIEWEES

	Type of Interviewee	UN Region	Form of communication	Date
1	Academia, TK expert	Western European and Others Group (WEOG)	Video conference	19.01.2020
2	Academia, Ethnobotanist	WEOG	In-person interview	14.01.2020
3	Government, Party to Nagoya Protocol	Latin American and Caribbean Group (GRULAC)	In-person interview	10.01.2020
4	Government, Party to Nagoya Protocol	GRULAC	In-person interview	10.01.2020
5	Industry, Synthetic biology researcher	WEOG	Telephone	06.01.2020
6	Industry, Intellectual property law counsel	WEOG	Telephone	06.01.2020
7	Academia, Ethnobotanist	WEOG	Video conference	16.01.2020
8	Government, Party to Nagoya Protocol	WEOG	In-person interview	25.02.2020
9	Government, Party to Nagoya Protocol	WEOG	In-person interview	25.02.2020
10	Government, Party to Nagoya Protocol	WEOG	In-person interview	24.02.2020
11	Government, Party to Nagoya Protocol	WEOG	In-person interview	25.02.2020
12	Government, Party to Nagoya Protocol	WEOG	Correspondence	27.02.2020
13	Government, Party to Nagoya Protocol	Asia & Pacific Group	In-person interview	25.02.2020
14	Academia, Biologist	GRULAC	In-person interview	24.02.2020
15	Government, Party to Nagoya Protocol	African Group	In-person interview	24.02.2020
16	Government, Party to Nagoya Protocol	Asia & Pacific Group	In-person interview	25.02.2020
17	Regional IGO	Asia & Pacific Group	In-person interview	25.02.2020
18	IPLC	African Group	In-person interview	26.02.2020
19	IPLC	WEOG	In-person interview	22.02.2020
20	Government, Party to Nagoya Protocol	African Group	In-person interview and questionnaire	22.02.2020
21	Government, Party to Nagoya Protocol	African Group	In-person interview	22.02.2020
22	Government, Party to Nagoya Protocol	African Group	In-person interview	26.02.2020
23	Government, Party to Nagoya Protocol	Asia & Pacific Group	In-person interview	24.02.2020
24	Government	Asia & Pacific	In-person interview	24.02.2020

		Group		
25	Academia	GRULAC	In-person interview	24.02.2020
26	Government, Party to Nagoya Protocol	Eastern European Group	In-person interview	25.02.2020
27	Government, Party to Nagoya Protocol	GRULAC	In-person interview	25.02.2020
28	Regional IGO	African Group	In-person interview	25.02.2020
29	IPLC	Asia & Pacific Group	In-person interview	25.02.2020
30	Regional IGO	African Group	In-person interview	22.02.2020
31	Government, Party to Nagoya Protocol	African Group	Correspondence	09.03.2020
32	Regional IGO	Asia & Pacific Group	Correspondence	30.03.2020
33	Academia, synthetic biology researcher	WEOG	Telephone	05.03.2020
