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

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List of Acronyms

ABS	Access and Benefit-Sharing
ABSCH	Access and Benefit-sharing Clearing-House
AHTEG	Ad Hoc Technical Expert Group
BLAST	Basic Local Alignment Search Tool
BGCI	Botanic Gardens Conservation International
CABI	Centre for Agriculture and Bioscience International
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Facilities
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
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
CSIR	Council for Scientific and Industrial Research (South Africa)
DEFF	Department of Environment, Forestry and Fisheries (South Africa)
DNA	Deoxyribonucleic acid
DSI	"Digital Sequence Information on Genetic Resources"
DSMZ	Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures
EBSA	Ecologically or Biologically Significant Area
EEZ	Exclusive economic zone
EU	European Union
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
SBI	Subsidiary Body for Implementation
RNA	Ribonucleic acid
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 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. This study analyses specific cases falling into three broad groups : 1) genetic resources and associated traditional knowledge 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 for which it is not possible to grant or obtain prior informed consent.

The first group, **genetic resources and associated traditional knowledge occurring in transboundary situations** comprises four specific subgroups : (a) shared ecosystems/genetic resources distributed across national boundaries; (b) traditional knowledge held by indigenous peoples and local communities whose membership spans national boundaries; (c) migratory species which transit through different jurisdictions; and, (d) areas beyond national jurisdiction.

Cases in the first subgroup (a) include genetic resources 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*). Situations involving shared ecosystems/genetic resources distributed across national boundaries raise the question of which country has a more legitimate claim to authorize access and negotiate the sharing of benefits arising from the utilization of these species. In such instances, a multilateral model may be more appropriate for this type of dispersed species to which several countries may have a claim of origin.

While possible, bilateral negotiations in the second sub-group (b), where traditional knowledge is held by indigenous peoples and local communities whose membership spans national boundaries, can be complicated. The study identified five scenarios in which traditional knowledge may be held by indigenous peoples and local communities:

- Scenario 1: By a single identifiable group located within a single country;
- Scenario 2: By a single group across multiple countries;
- Scenario 3: By more than one group located in a single country;
- Scenario 4: By more than one group located across multiple countries; and
- Scenario 5: By a community in one country about a genetic resource originating in another country.

Examples include traditional knowledge associated with Rooibos (*Aspalathus linearis*) and Devil's Club (*Oplopanax horridus*). A key challenge in these situations involves determining who owns the associated traditional knowledge and who thus has a right to share in the benefits that may be generated. The examples provided illustrate the possible need for a global multilateral benefit-sharing mechanism for cases, particularly those under scenarios 4 and 5, in which traditional knowledge is held by more than one group across multiple countries.

Regarding subgroupings (c) and (d), where migratory species are shared amongst several countries and a distinction between providers and users of genetic resources is not so clear (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. A multilateral approach might in this case be more efficient and equitable. A multilateral approach also might be more appropriate for resources found in the global commons, or areas where States cannot assert claims to sovereignty, such as the high seas.

The second broad group involves **genetic resources for which it is not possible to grant or obtain prior informed consent**. This group can also be divided into three subgroupings: (a) genetic resources of untraceable origin in ex situ collections; (b) utilization of samples from large numbers of geographically diverse organisms; and (c) genetic resources for which it is not possible to grant or obtain prior informed consent involving the use of genomic sequence data or "digital sequence information".

The first subgroup (a) involves the holding of genetic resources of untraceable origin in *ex situ* collections, such as botanical gardens, herbariums, culture collections, gene banks, seed banks, zoos, aquaria, and private collections. Many such collections hold specimens acquired before the entry into force of the Convention on Biological Diversity, raising questions of temporal scope. Moreover, some specimens may have been deposited without country of origin information while presently being accessed for commercial utilization. Examples are provided to illustrate this challenge, which might be ameliorated by a global multilateral benefit-sharing mechanism.

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

The third subgroup (c) involves genetic resources for which it is not possible to grant or obtain prior informed consent involves the use of genomic sequence data or "digital sequence information". Whether access to "digital sequence information" *per se* is within the scope of the Convention on Biological Diversity or the Nagoya Protocol remains contested. Even if is deemed outside the scope of the definition of genetic resources, "digital sequence information" 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 not be practical or would be effectively infeasible 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 a genetic resource (e.g. the Ebola drug RGEN-EB3), and where the genetic components utilized were found in multiple organisms (e.g. steviol glycosides).

The third broad group, **traditional knowledge associated with genetic resources for which it is not possible to grant or obtain prior informed consent**, can be further divided into two specific subgroups: (a) where traditional knowledge is publicly available, and (b) where traditional knowledge of untraceable origin is held in *ex situ* collections.

Many publications and journals exist which catalog traditional plant uses in different regions, such as the book *Native American Ethnobotany*. 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 country of origin information is often present, identifying information on the indigenous peoples and local communities from whom the traditional knowledge was derived may be omitted. This may render it difficult to seek prior informed consent for the use of such traditional knowledge.

Based on the research presented within, this study concludes that there are specific cases that could justify the need for a global multilateral benefit-sharing mechanism, while also not undermining the bilateral approach upon which the Convention and Nagoya Protocol are founded.

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. 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 May 2020.

Methodology

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 (PIC) was gathered on an expedited basis by the authors from late December 2019 through late February 2020. The authors conducted interviews with 30+ individuals from more than 25 countries in order to enhance identification of relevant specific cases.[3] 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, and legal and policy experts.

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.[4] These included the

[3] "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, persons believed to have information about specific cases relevant to the mandate.

[4] 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.

synthesis of online discussions made in response to decision XI/1,[5] the report of the 2013 expert meeting on Article 10,[6] submissions made in response to decision NP-1/10,[7] the report of the 2016 Expert Group Meeting on Article 10,[8] the study prepared for the Expert Group meeting,[9] submissions made in response to decision NP-2/10,[10] the note by the Executive Secretary prepared for SBI 2,[11] and submissions made in response to decision NP-3/13.[12] 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.

Structure

In terms of organization, Section 2 of the study presents specific cases of genetic resources and associated traditional knowledge that occur in transboundary situations, including examples of shared ecosystems, associated traditional knowledge held by indigenous peoples and local communities (IPLCs) across national boundaries, 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, and includes examples of genetic resources of untraceable origin in *ex situ* collections, utilization of samples from large numbers of geographically diverse organisms, "digital sequence information" where no physical access is needed to utilize genetic information, and utilization of genetic components found in multiple organisms. Finally, Section 4 presents specific cases 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.

We note that the report of the Expert Group Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-sharing[13] identified additional scenarios that could be covered in Section 3,

[5] 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).

[6] 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).

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

[8] 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).

[9] 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).

[10] 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.

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

[12] 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.

[13] 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 8).

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 although no national PIC requirement had been established; and situations in which a Party has decided not to require PIC. We have decided 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 national sovereignty 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 whether to negotiate a global multilateral benefit-sharing mechanism relating to any given case.

2. Specific Cases of Genetic Resources and Traditional Knowledge Associated with Genetic Resources that Occur in Transboundary Situations

Although it is difficult to determine the proportion of genetic resources and associated traditional knowledge that span boundaries, it is likely to be high.[14] Considering the artificial nature of political demarcations, it is not surprising that many species are distributed across national borders. Likewise, patterns of colonization and migration over centuries[15] in conjunction with moving political boundaries have contributed to situations where IPLCs in different countries share traditional knowledge regarding the same genetic resources. As described by Morgera et al., 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.[16]

The first type of situation is discussed in sections 2.1 and 2.2, the second in section 3.1 below.

[14] Graham Dutfield, 'Transboundary Resources, Consent and Customary Law' (2013) 9 Law, Environment and Development Journal 259, 260.

[15] 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.")

[16] 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) 200.

2.1. Shared Ecosystems/Genetic Resources Distributed across National Boundaries

Some genetic resources are endemic in neighboring countries such as *Pentas longiflora*, used traditionally to treat fungal infections in Uganda,[17] but also found in Kenya.[18] Some are found much farther apart, such as the Rosy periwinkle, or *Catharanthus roseus*, which originated in Madagascar, but appears to be endemic to India and other places as well.[19] A compendium of African medicinal plants published by the African Union catalogs numerous plant species that are endemic to multiple countries and may be known by different names in various countries.[20]

Also, many organisms share common genetic components, or can be found in more than one geographic location.[21] For example, *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.[22] Another example is Neem, a tree widely known for its traditional uses in India, but which is endemic 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.[23] The dispersed nature of such species could allow users to inaccurately claim acquisition from a country of origin which is not the actual country from which the resource was obtained to avoid a benefit-sharing requirement. It also raises the question of which country has a more legitimate claim to authorize access and share in benefits from utilization of these species. A multilateral model may be more appropriate for this type of dispersed species to which several countries may have a claim of origin.

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[17] 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.

[18] 'Carnegie Museum of Natural History Herbarium Catalog No CM226483' (*SERNEC Detailed Collection Record Information*, no date) <http://sernecportal.org/portal/collections/individual/index.php?occid=12316926&clid=0%3e> accessed 29 February 2020. See also Annex C4 describing *Ficus natalensis* is "widespread in tropical Africa."

[19] 'Arizona State University Vascular Plant Herbarium Catalog No ASU0104660' (*SERNEC Detailed Collection Record Information*, no date) <http://sernecportal.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.

[20] African Union Scientific Technical Research Commission, *African Pharmacopoeia* (2nd edn, African Union 2014) 27. See, for example, the entry in Annex C1 which lists the geographic distribution of the plant *Ammi visnaga*, and the six different names for the plant in various African languages.

[21] 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 endemic to more than one country. See Kew, 'Plants of the World' (no date) <http://www.plantsoftheworldonline.org> accessed 28 February 2020.

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

[23] 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").

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

A fundamental premise of the Nagoya Protocol is the need for PIC and mutually agreed terms (MAT) to be obtained from traditional knowledge holders prior to use of associated traditional knowledge, and that benefits from the utilization of traditional knowledge are to be shared with the IPLCs that hold such knowledge. However, for a variety of reasons discussed in this study, this bilateral approach may not always be possible, let alone practical. Traditional knowledge associated with genetic resources may be held by IPLCs in a variety of different ways, including:

- Scenario 1: By a single identifiable group located within a single country;
- Scenario 2: By a single group across multiple countries (whose boundaries may or may not be contiguous);
- Scenario 3: By more than one group located in a single country;
- Scenario 4: By more than one group located across multiple countries (whose boundaries may or may not be contiguous); and
- Scenario 5: By a community in one country about a genetic resource originating in another country.

Bilateral benefit-sharing is generally expected to occur in scenarios 1, 2, and 3 although difficulties may arise in these scenarios as well.[24]

Scenario 2: 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 Columbia, 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.[25] However, it is worth noting that 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.[26]

Scenario 3: Traditional knowledge held by more than one group located in a single country

In an example under this scenario, the multinational corporation Schwabe Pharmaceuticals negotiated a benefit-sharing and product supply agreement with a Xhosa group in one part of South Africa regarding *Pelargonium sidoides*, a plant with a variety of traditional uses that is also widely sold in the U.S. and several countries in Europe as a respiratory treatment by the name of Umcka or Umckaloabo.[27] Later, a group of opponents, including a different Xhosa community, launched a successful challenge to Schwabe's European patent applications relating to *Pelargonium sidoides*, leading, among other things, to the matter of rightful associated traditional knowledge

[24] Although the successive categories introduce additional complexities that may make bilateral negotiations, while possible, impractical. See infra.

[25] MB, Interview with Dario Luque and Jorge Garcia (2020).

[26] Submission, Costa Rica (2015).

[27] Chennells (n 15).

ownership concerning the plant being addressed by what is now the South African Department of Environment, Forestry and Fisheries[28] in conjunction with both communities.[29]

While possible, bilateral negotiations for cases in scenarios 2 and 3 may involve significant complications. A key challenge is often the determination of who owns the associated traditional knowledge and thus has a right to share in the benefits generated. Such ownership disputes may require government intervention to achieve resolution, as multiple communities may share the same knowledge, and the uncertainty over who potential users should approach can significantly delay the conclusion of a benefit-sharing agreement.[30] Moreover, such agreements can be particularly time-consuming and costly to negotiate, as each community may have different (or no) community protocols for dealing with ABS issues.

Scenario 4: Traditional knowledge held by more than one group located across multiple countries

Cases under scenario 4 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, 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.

The Rooibos tea story provides a good example of this scenario. The San and Khoi people are spread across several countries in southern Africa, including South Africa, Botswana, and Namibia. San groups in the different countries each have their own "San Council" decision-making body with whom parties seeking San associated traditional knowledge would need to negotiate.[31] A "decade long" negotiation between rooibos (*Aspalathus linearis*) industry representatives and San and Khoi IPLCs ended in November 2019 with the signing of a historic agreement, in South Africa, specifying that the groups will receive 1.5% of the price paid for unprocessed rooibos,[32] a plant endemic to the Cederberg region of South Africa, near Cape Town.[33] The agreement is

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[28] Previously known as the Department of Environmental Affairs.

[29] Two additional South African cases of scenario 3 are described in Margo A Bagley, 'Toward an Effective Indigenous Knowledge Protection Regime: Case Study of South Africa' (CIGI Papers No 207, Centre for International Governance Innovation 2018) 14–16.

[30] 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.

[31] Chennells (n 15).

[32] Linda Nordling, 'Rooibos Tea Profits Will Be Shared with Indigenous Communities in Landmark Agreement' (2019) 575 Nature 19.

[33] ibid. It is important to note that South Africa's ABS regime goes significantly beyond the CBD and Protocol by covering indigenous biological resources within its scope, not just genetic resources. Indigenous biological resources (any living or dead organism of an indigenous species, any genetic material or derivatives of such organisms, or any chemical compounds and products obtained through use of biotechnology that have been altered with genetic material or chemical compounds found in indigenous species) are covered by benefit-sharing requirements so long as their use is based on indigenous traditional knowledge, and there is commercial exploitation. By contrast, the CBD and Nagoya Protocol define genetic resources as limited to "material of actual or potential value containing functional units of heredity." See also Bagley (n 30) 4; Doris Schroeder and others, 'The Rooibos Benefit Sharing Agreement – Breaking New Ground with Respect, Honesty, Fairness and Care' (2020) 29 Cambridge Quarterly of Healthcare Ethics 1, 4 and Rachel Wynberg and others, 'Formalization of the

significant as it recognizes that Rooibos and its use is part of the San and Khoi people of South Africa's traditional knowledge, and that its exploitation and commercialization by the Rooibos industry should come with adequate compensation.

Delays included a dispute over whether the San and Khoi were indeed entitled to any benefits as the first users of Rooibos as tea, and the commissioning of conflicting studies on that question by the South African Department of Environmental Affairs[34] and industry, respectively.[35] Moreover, when negotiations were nearing a resolution in 2016, the South African Human Rights Commission required new country-wide public consultations to ensure that any agreement had the necessary Khoi-San community PIC.[36] Although an agreement was reached, it was nine years after the San Council first lodged a claim to share benefits from Rooibos. Furthermore, although the agreement *de facto* covers products derived from rooibos as benefits are levied at the farm gate,[37] benefits will not flow directly to the San and Khoi or the South African Government from higher value products resulting from the utilization of the genetic resource and associated biochemicals.[38]

This negotiation was time and resource intensive for the government, IPLCs, and industry. The fact that it took nine years for South Africa, the country with the 2nd strongest economy on the African continent, and with the significant involvement of NGOs assisting associated traditional knowledge holders, to achieve a solution that is still considered to be under-inclusive in terms of beneficiaries,[39] suggests that smaller countries with more fragile economies may not be able to handle such disputes at all. This would be even more likely if governments of countries where other indigenous groups are located take a more active or contentious position, or if the relations between the IPLCs are more fractious than those between the San and Khoi.[40]

Natural Product Trade in Southern Africa: Unintended Consequences and Policy Blurring in Biotrade and Bioprospecting' (2015) 28 Society & Natural Resources 559.

[34] See e.g. Department of Environmental Affairs, *Traditional Knowledge Associated with Rooibos and Honeybush Species in South Africa* (2014) (reporting on the identification of the San and Khoi peoples as originators of traditional knowledge associated with rooibos and honeybush and instructing affected industries to negotiate benefit-sharing agreements with the national Khoisan council).

[35] Boris Gorelik, 'Rooibos: An Ethnographic Perspective' (South African Rooibos Council 2017).

[36] South African Human Rights Commission, *Report of the South African Human Rights Commission: National Hearing Relating to the Human Rights Situation of the Khoi-San in South Africa* (2016). Section 7.5.1 of the report recommended that "relevant departments must immediately initiate broad public consultations, no later than 3 months of the issuing of this report, with Indigenous communities with a view of addressing concerns over the composition and status of the National Khoi-San Council."

[37] Schroeder and others (n __) 4-7).

[38] Rooibos has in excess of 140 patents pending for its biochemical and health properties, see ibid.

[39] Sarah Ives and others, 'Rooibos Settlement: A Crucial Omission' (2020) 577 Nature 318 (noting that the agreement still does not adequately address the sharing of benefits with small-scale Rooibos farmers who having worked the land for generations and shared oral histories providing valuable information on origins and uses of Rooibos, but do not fit neatly into either Khoi or San category, and that "traditional knowledge does not necessarily have a clear-cut ethnic provenance"). See also Linda Nordling (n 32) (noting questions remain as to "how the funds will reach San and Khoi individuals, many of whom are not well-connected with Indigenous leadership structures such as the San Council").

[40] 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) 656. ("recent experiences suggest that transacting may only be workable in case-specific contexts and in *ad*

Devil's Club (*Oplopanax horridus*) provides another example under this scenario. Considered "the most important spiritual and medicinal plant to most indigenous peoples who live within its range," Devil's Club is a shrub with a diversity of uses, and its various parts are used for more than 30 disease categories by more than 38 linguistic people groups in Western North America.[41] Moreover, several of its medicinal effects, namely, its antifungal, antiviral, antibacterial, and anti-mycobacterial properties, have been confirmed by phytochemical research.[42] Much associated traditional knowledge related to Devil's Club and its uses has been documented and is publicly available. As shown in the maps in Annex A, associated traditional knowledge regarding Devil's Club also is widely distributed between indigenous communities in Canada and the U.S.; thus it is not possible to identify a specific community that would be able to grant PIC or negotiate MAT for associated traditional knowledge-based uses of the plant.

If PIC and MAT were being sought in a case under scenario 4 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 country governments, could terminate the project at its inception, irrespective of its potential for life-saving societal benefits.[43]

Scenario 5: A community in one country holding traditional knowledge associated with a genetic resource originating in another country

The case of Rosy periwinkle is an example that falls under scenario 5. Rosy periwinkle, or *Catharanthus roseus*, originated in Madagascar, but may be endemic in India and other places as well.[44] It also is found throughout the Caribbean[45] and samples of its leaves were sent by a doctor

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hoc ways requiring direct and in most cases painstaking negotiations between indigenous peoples, individual healers if appropriate, and businesses. But even then, things can still go wrong.").

[41] See Annex A. See also Trevor C Lantz and others, 'Devil's Club (Oplopanax Horridus): An Ethnobotanical Review' (2004) 62 HerbalGram 33, which identifies its geographic range as "forested ecosystems from coastal Alaska southward to central Oregon and eastward to the southwestern Yukon, the Canadian Rockies, northwestern Alberta, Montana, and Idaho."

[42] See Leslie Main Johnson, 'Gitksan Medicinal Plants-Cultural Choice and Efficacy' (2006) 2 Journal of Ethnobiology and Ethnomedicine 1 (describing 36 other medicinal plants in addition to Devil's Club, 70% of which "were used similarly by [multiple indigenous] cultures where direct diffusion is not known to have occurred; eleven plants, including the eight most frequently mentioned medicinal plants, also show active phytochemicals or bioassays indicating probable physiologically based therapeutic effects.")

[43] 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 Submission, International Plant Exchange Network (IPEN), 'Comments on behalf of Botanical Gardens' (2017). Moreover, in the culture collection context, an inability to obtain PIC in a timely fashion has resulted in a 20% drop in specimen deposits at one collection, which notes the samples either die before a response to a NFP is received or are later deposited in a collection that does not respect the Nagoya Protocol and does not perform scope checks." Submission, Leibniz Institute (DSMZ)-German Collection of Microorganisms and Cell Cultures, (2017).

[44] 'Arizona State University Vascular Plant Herbarium Catalog No ASU0104660' (n 19).

[45] Dutfield (n 41) 660. ("The plant originally comes from Madagascar but now grows throughout the tropics and has grown in the Caribbean long enough to be considered as a native plant there"). It also was used to treat diabetes in the Philippines, a recorded use that led Eli Lilly researchers to develop another cancer treatment from it (Vincristine). Ibid.

from Jamaica, where it was locally used to treat diabetes, to Canada, where researchers identified and patented a compound useful in treating certain cancers (Vinblastine).[46] While the cancer drug was not based directly on associated traditional knowledge (treating diabetes, not cancer, was the traditional use of the plant), without associated traditional knowledge from Jamaica that prompted transfer of the sample to Canada, the researchers seemingly would not have found the cancer use. There are arguments that both Madagascar and Jamaica should receive benefits, but assessing relative value, and negotiating with multiple governments, without a clear group of IPLCs in the case of Jamaica, might not be possible. As such, a global multilateral benefit-sharing mechanism might be a preferable option for situations under scenarios 4 and 5.

These examples illustrate that though a bilateral approach may be possible in situations in which traditional knowledge is held by indigenous peoples and local communities whose membership spans national boundaries, several complications can arise, the key challenge relates to determining who owns the associated traditional knowledge and who thus has a right to share in the benefits that may be generated.

2.3. Migratory Species

Many migratory species spend parts of their life cycle in different national jurisdictions or outside national jurisdictional boundaries. This places them in the category of genetic resources that occur in transboundary situations. The *Convention on the Conservation of Migratory Species of Wild Animals*[47] (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."[48] Although the utilization of genetic resources from migratory species can be subject to the bilateral approach,[49] this raises questions of equity between States, especially in cases where species migrate across and between continents. The following three examples illustrate some of the challenges arising in the specific case of migratory species.

European eel (Anguilla anguilla)

The European eel (*Anguilla anguilla*) is one such case. In the middle of its life cycle, its habitat ranges 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).

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[46] See *Vincaleukoblastine* US Patent No US3097137A. Graham Dutfield reports that the patent was later licensed for lucrative commercial exploitation to Eli Lilly, Dutfield (n 41).

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

[48] Ibid art 1(a).

[49] 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).

[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.

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). Given its status as an endangered species, range states are taking measures to conserve it and regulate its transboundary movement.[52] Patents have been obtained primarily in the United States and Europe that reference the European eel and biochemicals present in the species such as lectins[53] and cytokine.[54]

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.[55] The monarch butterfly's genome was fully sequenced and released publicly in 2011.[56] Examples exist of patents

[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] E.g. Council Regulation (EC) No 1100/2007 of 18 September 2007 establishing measures for the recovery of the stock of European eel, OJ L248/17.

[53] 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 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.

[54] *Orally administrable immunostimulant product for aquaculture* European Patent (EPO) No EP2349224B1.

[55] 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.

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

or patent filings using cell lines,[57] and covering sequences,[58] proteases,[59] and enzymes[60] from monarch butterflies. The most focused conservation burden for this species lies 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.[61] 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.[62]

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*[63] (AEWA), a treaty dedicated to the conservation of migratory waterbirds and their habitats across Africa, Europe, the Middle East, Central Asia, Greenland and the Canadian Archipelago.[64] 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,[65] using nucleic acids and

[57] 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.

[58] 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.

[59] *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.

[60] *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.

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

[62] ibid.

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

[64] 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.

[65] *Immortalized avian cell lines*, International Patent Application (PCT) No WO2009004016A1.

cells for producing vaccines,[66] using immunoglobins for establishing disease resistance in invertebrates,[67] treatment of hepatitis,[68] and production of biofuels and bulk chemicals.[69]

In cases such as these, where resources are shared amongst several countries and a distinction between provider and users of genetic resources is not so clear, a bilateral approach would not reward all those involved in the conservation of a specific resource. A multilateral approach in the case of migratory species may thus be more efficient and equitable than a bilateral one.[70]

2.4. Global Commons/Areas Beyond National Jurisdiction

International law recognizes certain jurisdictions as global commons or areas where States cannot assert claims to sovereignty, such as the high seas. Subsequent to the 2016 Expert Group Meeting on Article 10, negotiations were launched under the auspices of the United Nations on a legally binding international instrument on marine biodiversity of areas beyond national jurisdiction.[71] 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 of the package identified in 2011: 1) marine genetic resources, including questions on the sharing of benefits; 2) measures such as area-based management tools, including marine protected areas; 3) environmental impact assessment; and 4) capacity building and the transfer of marine technology. 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.[72]

3. Specific Cases of Genetic Resources For Which It Is Not Possible To Grant or Obtain PIC

Genetic resources of untraceable origin in ex situ collections, the utilization of samples from large numbers of geographically diverse organisms, and genomic sequence data/digital sequence information, are all specific cases involving 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.

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[66] *Avian telomerase reverse transcriptase*, International Patent Application (PCT) No WO2007077256A1.

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

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

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

[70] Morgera and others (n 16) 203.

[71] United Nations, "Intergovernmental Conference on Marine Biodiversity of Areas Beyond National Jurisdiction", online: https://www.un.org/bbnj/

[72] *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.

Temporal scope and retroactivity for ex situ collections

An important question not clearly addressed by the Protocol and currently the subject of ongoing debate is whether benefit-sharing obligations are triggered only at the time of initial resource access or also when the resource is utilized. This issue, referred to as "temporal scope", relates to the scope and application of the Protocol and has two primary triggers: the CBD's entry into force (1993) and the Nagoya Protocol's entry into force (2014).[73] Significant quantities of genetic resources were accessed in countries across the world prior to the entry into force of both the CBD and the Protocol, and new utilizations of many of these resources, currently held in gene or seed banks, botanical gardens, and the like, outside the provider country, are taking place after the effective date of the Protocol.

Article 28 of the Vienna Convention on the Law of Treaties, an agreement on treaty interpretation, provides that a treaty does not have retroactive effect unless the parties agree otherwise.[74] It states:

> 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.

This article covers not only any 'act', but also any 'fact' or 'situation which ceased to exist'. Thus, Article 28 also implies that, absent a contrary intention, treaty obligations *do* apply to any 'situation' which has not ceased to exist – that is, to any situation that arose in the past, but continues to exist under the new treaty, or occurs after its entry into force.

he 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 may also disagree on what constitutes retroactivity. Some provider countries may view a utilization trigger as not prohibited retroactivity but, rather, as way of giving effect to the

[73] See Evanson Chege Kamau and others, 'The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and What Are the Implications for Provider and User Countries and the Scientific Community?' (2010) 6 Law, Environment and Development Journal 246, 254–55. See also 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. Other 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. [IUCN submission (2015)]

[74] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331.

terms and spirit of the Protocol.[75] This issue is of particular relevance for samples in *ex situ* collections obtained before the entry into force of the CBD or Nagoya Protocol, but which are currently being utilized by researchers for commercial and non-commercial purposes.

Moreover, because the Protocol is silent on the definition of "access",[76] some Parties, such as the EU, are choosing to implement the agreement in a manner that imposes obligations only on genetic resources that are accessed after the Protocol's effective date,[77] while others are requiring benefit-sharing, and possibly PIC as well, for genetic resources utilized after the Nagoya Protocol's entry into force, regardless of when they were obtained from the providing country.[78]

Digital sequence information and subject matter scope

In addition to temporal scope, issues regarding the breadth of subject matter covered by the CBD and Protocol also remain unresolved. The use of the phrase "genetic material" in the CBD and Protocol suggests that intangibles do not fall within the scope of these agreements. On the other hand, some have argued for a "broad and dynamic" understanding of the concept of genetic resources that would encompass digital sequence information and, as described in Section 3.3 below, several countries are either including intangible sequence information within the definition of genetic resources or as a product of utilization and subject to benefit-sharing.[79]

3.1. Genetic Resources of Untraceable Origin 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, herbariums, culture collections, gene banks, seed banks, zoos, aquaria, and private collections. An issue common to such collections is the presence of specimens acquired before the entry into force of the CBD which may be presently accessed for commercial purposes, and the presence of specimens deposited without country of origin 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 rapidly, with possible issues relating to documentation arising for the recipient.[80]

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[75] See 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) 72–73.

[76] 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 76) 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.

[77] See Article 2 of EU Regulation 511/2014.

[78] Such as Brazil, Colombia, Costa Rica, and South Africa. This section incorporates material from Bagley and Rai (n 74) 17–21.

[79] 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). Available at : https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf.

[80] 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

Countries differ on whether Protocol obligations apply to entities making new uses of genetic resources in *ex situ* collections. For example, the EU Regulation is clear that it does not apply to genetic resources accessed prior to the entry into force of the Protocol.[81] But legislation in many countries such as Brazil, Columbia, and South Africa, requires benefit-sharing from utilization of genetic resources, regardless of when the resources were first accessed.[82]For countries requiring benefit-sharing for 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 specific examples are illustrative of the challenge of genetic resources of untraceable origin in *ex situ* collections which might be ameliorated by a global multilateral benefit-sharing mechanism.

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 have expanded their collections to include other forms of *ex situ* conservation, such as tissue, fungi, seed, and gene banks and herbaria.[84]

The International Plant Exchange Network (IPEN) was established in 2002 as a collective answer by botanical gardens to the requirements of the CBD. It is a registration system for botanic gardens worldwide to exchange plant genetic resources in compliance with the CBD. 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 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."[85]

The Royal Botanic Gardens, Kew (Kew) hosts 50,000 living plants, an arboretum, and several diverse collections including a herbarium, and fungi, seed, gene, and other banks totaling 8.5

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.

[81] 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 [2014] OJ L150/59.

[82] See Brazil, The Biodiversity Law, Law No. 13,123/2015; Colombia, Decree 1348 [2014]; and South Africa, National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004)(and 2013 amendments).

[83] See 'GardenSearch' (*Botanic Gardens Conservation International*, no date) <https://tools.bgci.org/garden_search.php> accessed 28 February 2020 (cited in 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) 14.

[84] Ibid.

[85] 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.

million items.[86] 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."[87] A cursory search of the EBC database yielded several examples of specimen entries with no country of origin information and/or no IPLC information for uses which appeared to comprise associated traditional knowledge.[88] For example, an entry for "BURSERACEAE Commiphora molmol" provides donor information, but no country or geographic region.[89] Another example, for "ASCLEPIADACEAE Gomphocarpus sp" lists "Africa" as its geographic origin.[90] Such types of samples, both of which were collected well before the coming into force of the CBD, would appear to be good candidates for a global multilateral benefit-sharing mechanism if they were being utilized for commercial purposes.[91]

Culture collections

It is estimated that 50% of the living biomass on earth is microbial.[92] These microscopic organisms (or microorganisms) include viruses, bacteria, microscopic fungi such as yeasts and algae, plant and animal cell lines, and derived products such as plasmids and complementary DNA (also known as cDNA).[93] The primary *ex situ* repositories of microorganisms are culture collections, many of which are members of the World Federation for Culture Collections (WFCC). The WFCC has almost 1000 registered collection members or affiliate members from 125 countries.[94] It also has a code of conduct which "endorses the principles of the Convention on Biological Diversity and

[86] Allowing it to bill itself as "the most biodiverse place in the world." Kew, 'Welcome to Royal Botanic Gardens, Kew' (no date) <https://www.kew.org/>, accessed 28 February 2020.

[87] 'Kew Economic Botany Database' (*Kew Science*, no date) <https://ecbot.science.kew.org/index.php> accessed 28 February 2020.

[88] See, e.g., Annex C7 and C8. 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 submission (2015). We are unable to ascertain, without more information, which of these categorizations are correct for the *ex situ* collection examples cited in this study.

[89] See Annex C7.

[90] See Annex C8.

[91] We note that some collections tend to discourage the use of samples for which provenance cannot be clearly identified. However, it is our understanding that this is not a firm prohibition. Thus, such samples may be accessed and used by commercial and non-commercial entities.

[92] 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).

[93] ibid. See also Davis and others (n 84) 16–17.

[94] WFCC and others (n 93). 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").

requires biological materials to be received and supplied within the spirit of the CBD."[95] While most microbial genetic resources in culture collections originate from *in situ* sources, how they are acquired varies.[96] Public culture collections directly acquire about half of these specimens *in situ*, with researchers depositing material in conjunction with a publication, and formal and informal exchanges amongst institutions constituting the balance.[97]

In a 2017 submission by the WFCC, in conjunction with two related bodies, two scenarios were provided in which a global multilateral benefit-sharing mechanism could be appropriate: (1) *in situ* sampling occurred before the entry into force of the Nagoya Protocol but no documentation is available beyond the date of the deposit 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 instance because the microbial material is ubiquitous) a global multilateral benefit sharing mechanism may be useful as long as it is cost efficient."[98]

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 country of origin), the collector, date collected, phenotypic features, and uses, particularly from ethnobotanical collectors. There are more than 3000 herbaria in existence, most of which are associated with universities or other research institutes, and they are a rich source of information for research, educational, and even commercial purposes.[99] Developments in gene sequencing technology are allowing for the analysis of herbaria specimens over 100 years old, including long-extinct species.[100]

Evolving approaches to utilization in ex situ *collections*

The Consortium of European Taxonomic Facilities (CETAF) is a consortium of non-commercial scientific institutions in Europe formed to promote training, research and understanding of systematic biology and palaeobiology. CETAF institutions hold significant botanical collections. In response to the EU Regulation implementing user compliance measures for the Nagoya Protocol

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

[96] 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.

[97] ibid.

[98] WFCC and others (n 93).

[99] Mark S Frank, 'What is a Herbarium? – Florida Museum Science' (*Florida Museum*, 22 December 2016) <https://www.floridamuseum.ufl.edu/science/what-is-a-herbarium/> accessed 28 February 2020.

[100] 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.

(EU Regulation 511/2014), CETAF adopted a Code of Conduct and Best Practice for Access and Benefit-Sharing that has gained recognition as a "best practice" by the European Commission.[101] Participating institutions are encouraged to apply the code of conduct, as far as reasonably possible, to biological material in their collections.[102]

When acquiring or receiving biological material for purposes other than utilization from *ex situ* sources, CETAF institutions will evaluate its provenance and available documentation, to ensure that it was acquired in accordance with applicable law and that its legal status is clear.[103] 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 be legally utilized.[104] Member institutions also will strive to share benefits from new utilizations of genetic resources accessed or otherwised 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.[105]

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, unlike the EU Regulation, establishes the concept of a 'new utilization' when commercial intent is involved,[106] which brings – at minimum – biological material and associated traditional knowledge collected after the entry into force of

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[101] 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.

[102] ibid, Annex, 4.

[103] ibid, 4-5.

[104] ibid, 5.

[105] ibid, 6.

[106] 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… a 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 ».

the CBD within its scope and, possibly, material and ATK collected beforehand. This is leading to a rethinking of access to MNHN’s botany collections, but regularization of their entire herbaria collection (over 8 million items) will be very complex as samples date back to the 18th century.[107] This will be a major challenge faced by all herbaria located in countries with a utilization trigger for ABS obligations.

As with botanical gardens, culture collections, and other *ex situ* repositories, some samples held by herbaria may be missing information on origin and, if uses are provided, may not identify the source of that knowledge. See for example the Herbarium Specimens in Annex C5-C7 for which no country of origin information was provided, as well as the specimen in Annex C8 which lists the geographic origin as “Africa”. Such samples, if used for commercial purposes, could also be good candidates for a global multilateral benefit-sharing mechanism.

3.2. Utilization of Samples from Large Numbers of Geographically Diverse Organisms

The paradigmatic bilateral benefit-sharing scenario involves an agreement regarding a single species intended for commercial or non-commercial research purposes. However, 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 exploration in agricultural, pharmaceutical and other commercially important fields.

For example, in 2014 the coalition “No Patents on Seeds”[108] opposed a Monsanto patent application[109] 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.”[110] 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 application notes 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.[111]

[107] 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); Muséum national d’Histoire naturelle, ‘Botany’ (no date) <https://www.mnhn.fr/en/collections/collection-groups/botany> accessed 28 February 2020; Denis Lamy and Aline Pelletier, ‘La conservation et la valorisation de l’Herbier de Tournefort au Muséum national d’Histoire naturelle’ (2010) 130 La Lettre de l’OCIM 19.

[108] 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.

[109] 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.”

[110] Ibid.

[111] European Patent (EPO) EP 2134870 B1, para. 3.

Requiring distinct bilateral agreements to be negotiated for each of the 258 exotic plant lines[112] might be possible, but possible but is likely impractical from the standpoint of time and cost, even if the country of origin of each sample is known, which may not be the case. To the extent such multi-specimen use inventions are deemed beneficial, a global multilateral benefit-sharing mechanism could avoid hindering such research efforts while providing benefits to support biodiversity conservation and economic development.

3.3. Genomic Sequence Data/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 2018 Ad Hoc Technical Expert Group (AHTEG) on Digital Sequence Information on Genetic Resources generated a list of what potentially could fall under the definition:

a) The nucleic acid sequence reads and the associated data;
b) Information on the sequence assembly, its annotation and genetic mapping. This information may describe whole genomes, individual genes or fragments thereof, barcodes, organelle genomes or single nucleotide polymorphisms;
c) Information on gene expression;
d) Data on macromolecules and cellular metabolites;
e) Information on ecological relationships, and abiotic factors of the environment;
f) Function, such as behavioural data;
g) Structure, including morphological data and phenotype;
h) Information related to taxonomy;
i) Modalities of use.

There is a divergence of views on whether DSI falls within the scope of the CBD or the Nagoya Protocol. As such, 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.

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; a situation which a global multilateral benefit-sharing mechanism could facilitate.

The bilateral ABS model can be applied to DSI in certain situations, particularly as part of mutually agreed terms 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 either be impractical or not feasible. Two such examples are discussed below.

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[112] 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.

[113] Bagley and others (n 84). Available at : https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf.

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 analogized to a transboundary situation or a situation where it is not feasible to obtain consent. A recent study commissioned by the CBD Secretariat identified more than 1600 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 used databases: GenBank at the National Center for Biotechnology Information in the United States, the European Molecular Biology Laboratory-European Bioinformatics Institute, 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 forms of DSI. As of April 2019, GenBank contained over 321 billion bases.[116]

Moreover, the amount of publicly accessible sequence data is only bound to increase in light of 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 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.

For sequences being screened in or obtained from databases such as GenBank, country of origin information may not be available as the database operators may not require sequence submitters to provide such information.[118] Currently only 16% of all INSDC entries have a country of origin listed in the metadata.[119] Moreover, even if such information is available, while it might theoretically be possible to negotiate benefit-sharing contracts with each country from which a sequence originated, it would be impractical and most likely generate prohibitive transaction costs, both in terms of time and money. In addition, users of sequences from these databases are not tracked, which makes determining the downstream uses of the sequence information accessed or downloaded impossible. In sum, this suggests that given current open access practices and limited metadata and traceability features of sequence information held in public databases such as the

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[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.

[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 114).

[116] Rohden and others (n 119). Bases are the nucleotides represented by the letters A, C, G, and T for DNA.

[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 114).

[119] ibid. The authors further note that practically speaking, it is impossible to check if the country of origin of the GR is "correct" as geographic ranges of organisms are not static. For example, many microorganisms and some animals and plants are cosmopolitan (i.e. found everywhere) and thus there are many potential locations for them to be.

INSDC, and in the many private, in-house databases that download sequence information from INSDC, it may be difficult possible to determine compliance with ABS obligations in most 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)[120] to search for genes similar to those used in GA biosynthesis, found seven in other model plant species, and were able to then predict the likely function of the genes in GA biosynthesis.[121] BLAST searches "use" all of the sequences in the GenBank 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-type[122] searches is currently not feasible.[123]

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.[124] 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 it obtained from GenBank. The sequence information for the strain had been uploaded without restriction to the GenBank database by the German Nocht Institute, and had been obtained by synthesis from a survivor of the 2014 Guinean Ebola outbreak.[125] Interestingly, while Nocht 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 made no such requirements for the uploaded sequence information.[126]

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[120] "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.

[121] 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.

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

[123] 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)."

[124] 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."

[125] Edward Hammond, 'Ebola: Company Avoids Benefit Sharing Obligations By Using Sequences' (Third World Network May 2019).

[126] ibid.

REGN-EB3[127] 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.[128] 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.[129] Moreover, more than 100 patent applications have been filed worldwide, with some already granted in the U.S., Nigeria, and South Africa.[130]

Access to SARS-CoV-2 sequence

A recent example illustrating how access to a physical sample is not necessary to obtain useful genetic information involves the novel coronavirus SARS-CoV-2 responsible for the COVID-19 outbreak which emerged in Wuhan, China in late 2019. The full genome sequence of the virus was uploaded to GenBank and publicly accessible as of 11 February 2020,[131] and researchers are being encouraged to "download, share, use, and analyze this data".[132] A coronavirus typing tool also has been developed by Genome Detective which uses "BLAST and phylogenetic methods... to identify the Coronavirus types and genotypes of a nucleotide sequence."[133] Other researchers used BLASTn, a variation of the BLAST tool, to compare complete SARS-CoV2 virus genomes sequences from patient samples to identify "the most closely related viruses available on GenBank" and their species origin.[134]

"Designing around" the claim of patent on an invention based on the utilization of DSI or a physical genetic resource

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 physical 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"

[127] '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.

[128] See USG Contract No. HHSO100201500013C and USG Contract No. HHSO100201700016C.

[129] 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.

[130] Hammond (n 124).

[131] 'Severe Acute Respiratory Syndrome Coronavirus 2 Isolate Wuhan-Hu-1, Complete Genome' (*GenBank*, 2 November 2020) <http://www.ncbi.nlm.nih.gov/nuccore/MN908947.3> accessed 28 February 2020.

[132] However, Professor Zhang, whose lab uploaded the sequence information, does request that researchers "communicate with us if you wish to publish results that use these data in a journal", per Edward C Holmes, 'Novel 2019 Coronavirus Genome' (*Virological*, 11 January 2020) <http://virological.org/t/novel-2019-coronavirus-genome/319> accessed 28 February 2020.

[133] 'Coronavirus Typing Tool' (*Genome Detective*, no date) <https://www.genomedetective.com/app/typingtool/cov/> accessed 28 February 2020.

[134] Roujian Lu and others, 'Genomic Characterisation and Epidemiology of 2019 Novel Coronavirus: Implications for Virus Origins and Receptor Binding' (2020) 395 The Lancet 565.

with the goal of replicating the patented technological benefit while avoiding infringement liability.[135]

Intentional design-around activity is generally encouraged and seen as “beneficial” because it often will result in further innovation in the form of the design-around.[136] However, by analyzing the invention claimed in the patent and intentionally incorporating some (but not all) of its elements, entities who perform the design-around have arguably used, in a sense, the genetic resources utilized in creating the patented invention, thus benefit-sharing from the new design-around may be appropriate, but not amenable to a bilateral negotiation as the origin of the genetic resources may not be known or multiple species from diverse locations may be involved.[137] As such, a global multilateral benefit-sharing mechanism may be appropriate for these scenarios.

3.3.2. Utilization of Genetic Components Found in Multiple Organisms

New approaches to research, such as synthetic biology, may also involve scenarios for which a bilateral benefit-sharing model are not ideal. Synthetic biology is based on the idea that any biological system can be viewed as a combination of functional elements or parts that can be organized in new ways to modify living organisms.[138] The 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.”[139]

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.[140] These resources allow researchers to use DNA sequences from many different species, accessible in public or private databases, in designing new biosynthetic pathways, re-designing biological systems and in other advanced biotechnological applications.

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[135] 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.’

[136] Moran and Jensen (n 134).

[137] MB, Interviews, anonymous synthetic biology industry researcher & general counsel (2020).

[138] Víctor 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).

[139] 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.

[140] 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).

For example, as described in a submission by the International Chamber of Commerce (ICC), "in state-of-the-art bioinformatics projects, hundreds to thousands of (amino acid or nucleic acid) sequences may be used to develop a particular commercial product. The final product has a sequence that represents an "average" of all input sequences; as a consequence, it is virtually impossible to determine the relative value of each individual input sequence."[141]

Steviol glycosides

Smaller but still significant numbers of diverse species may also be used that defy efficient use of a bilateral benefit-sharing approach. Consider U.S. patent application publication 2013/0171328 A1, 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* tabacco (*Nicotiana attenuate),* to produce products for use as commercial sweeteners in food products and dietary supplements.[142]

Morphine precursor

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.[143] 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.[144]

D-glucaric acid

A similar example involves the successful enhancement of the yield of D-glucaric acid by Moon, et al., 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 (Ino1) from *Saccharomyces cerevisiae (yeast)*, an endogenous *E. coli* phosphatase, myo-inositol oxygenase (MIOX) from *Mus musculus (mice)* and uronate

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[141] ICC Task Force on Access and Benefit Sharing, 'Digital Sequence Information and the Nagoya Protocol' (International Chamber of Commerce 2017).

[142] U.S. Pat. Appl. Pub. No. 2013/0171328A1 "Production of Steviol Glycosides in Microorganisms" paragraph 125.

[143] Robert F Service, 'Modified Yeast Produce Opiates from Sugar' (2015) 349 Science 677.

[144] 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* <u>and from ground ivy (Glechoma hederacea)</u>" (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 Tropine 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").

dehydrogenase (udh) from *Pseudomonas syringae*.[145] Glucaric acid is used commercially in dishwashing detergents, anddetergents and is sold as a dietary supplement. However, it also has been studied for therapeutic uses in cancer and cholesterol-lowering treatments.[146] Development of the glucaric acid biosynthetic pathway required no physical material from any of the species whose DNA was incorporated into the *E. coli*. [147] 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 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.[148]

BLAST searches

A further relevant way in which DSI can be used relates to gene sequence alignment searches in databases such as GenBank using the BLAST tool described in Section 3.2.1. 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.[149] 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

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[145] Tae Seok Moon and others, 'Production of Glucaric Acid from a Synthetic Pathway in Recombinant Escherichia Coli' (2009) 75 Applied and Environmental Microbiology 589.

[146] ibid.

[147] 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.

[148] Houssen and others (n 139) 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.

[149] 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.

requirements.[150] Given the difficulties in tracking the use of DSI, such alignment searches may allow researchers who are so inclined to misstate the true origin of the information utilized in their R&D efforts.[151]

In all of these examples, DSI from multiple, diverse, organisms is being utilized, potentially subjecting the users to the need to negotiate MAT with multiple governments engendering uncertainty, delay, and expense, as properly valuing the contributions of sequence fragments may not be possible.[152]

4. Specific Cases of Traditional Knowledge Associated With Genetic Resources For Which It Is Not Possible to Grant or Obtain PIC

Large quantities of associated traditional knowledge are codified in books, movies, *ex situ* collections, and other widely accessible media. Only some of this knowledge may be traceable to currently identifiable IPLCs, and even in those cases, PIC may not have been obtained to make the knowledge widely accessible. Third parties would thus be able to access the traditional knowledge from such sources without PIC and use it without arranging bilateral MAT.

4.1. 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.[153]

Nevertheless, it is important to note that the fact that information is publicly available does not mean it is in the public domain. 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 country. Whereas no one owns the public domain however it is defined in a particular country, 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.

Some countries, such as South Africa, do have protection systems for traditional knowledge, and in those countries, the fact that the knowledge may be publicly available does not necessarily mean that benefit-sharing obligations have expired. National law is key: if a user is in a country that is not Party to the Protocol, or is in a Party that has no cooperative arrangements in the sense of

[150] 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.

[151] ibid.

[152] See ICC Task Force on Access and Benefit Sharing (n 140) ("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").

[153] For example, the Rooibos tea settlement described in Section 2.2 above does not involve prior informed consent, because information regarding the use of Rooibos as a medicinal tea was already publicly available, and neither the Khoi nor San could prevent the use of the information.

Article 16(3) of the Protocol,[154] or if the provider country has not implemented an ABS system, then a user may not have a *legal* obligation in that country in relation to publicly accessible associated traditional knowledge, but may still have an *ethical* obligation to engage in benefit-sharing.

However, benefit-sharing negotiations may not be possible because, *inter alia*, the original holders may not be identifiable or may be extinct,[155] such traditional knowledge may be attributed to a country[156] but not a particular people group, or the knowledge may have been originally published and available prior to the entry into force of the CBD or Protocol.

Native American Ethnobotany

Numerous publications and journals exist which catalog plant use in various regions of the world. One of many examples detailing North American plant use is Dan Moerman's, *Native American Ethnobotany*, which describes plants and associated traditional knowledge by plant, use, and tribe. It is described as:

> "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."[157]

Its organization facilitates literature-based bioprospecting without the need to seek PIC from the relevant IPLCs.[158] The same can be said for the African Pharmacopoeia mentioned in Section 2.1 above, which compiles a wealth of valuable information about a diversity of medicinal plants and their traditional uses without necessarily identifying the IPLC sources of the use information.[159]

Rosy Periwinkle

The Rosy Periwinkle example in Section 2.2 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

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[154] Article 15(3) 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…"

[155] 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. Of course, if the group has died out, then one may question whether benefit-sharing is justified.

[156] Or even a continent, as the specimen in Annex C8 from the Kew EBC lists the use of *Commiphora molmol* for digestive disorders and lists the origin as "Africa."

[157] 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.

[158] FPW, Interview with Kelly Bannister (2020).

[159] African Union Scientific Technical Research Commission (n 20) 27.

the plant, one from the Philippines (Vincristine) and the other from Jamaica (Vinblastine).[160] 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.[161]

Each of these examples represent specific cases which may be amenable to a global multilateral benefit-sharing solution.

4.2. 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, herbariums, 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 country of origin information is often present, identifying information on the IPLCs from whom the genetic resource use information was derived may be omitted.

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.[162] An example of such a herbarium listing, where the collector found the sample growing in Florida, included medicinal use information from a historical text, and matched the plant to a listing in a Brazilian pharmacopeia is provided in Annex C2.[163] Other examples from the Kew herbarium are provided in Annex C7 and C8. Such cases could also be explored for inclusion in a global multilateral benefit-sharing mechanism.

5. Conclusions

This study identifies a variety of specific and distinct cases for which a global multilateral benefit-sharing mechanism could enable the sharing of benefits that would otherwise might not occur, or occur incompletely or with prohibitively high transaction costs, under the bilateral approach to ABS embodied in the CBD and Nagoya Protocol. These include specific cases of genetic resources and associated traditional knowledge that occur in transboundary situations, including examples of shared ecosystems, associated traditional knowledge held by indigenous peoples and local communities (IPLCs) across national boundaries, and migratory species.

Other specific cases include genetic resources for which it is not possible to grant or obtain PIC, including genetic resources of untraceable origin in *ex situ* collections, utilization of samples from large numbers of geographically diverse organisms, "digital sequence information" cases where no physical access is needed to utilize genetic information, and utilization of genetic components found in multiple organisms. Finally, the study identifies specific cases of traditional knowledge associated with genetic resources for which it is not possible to grant or obtain PIC, including publicly available associated traditional knowledge, and associated traditional knowledge of

[160] Dutfield (n 14) 262–63.

[161] ibid.

[162] MB, Interview with Cassandra Quave (2020).

[163] ibid.

untraceable origin in *ex situ* collections. The study notes that, while still possible, a bilateral approach may either be impractical or not feasible in certain specific situations which may possibly be addressed under a multilateral benefit-sharing mechanism.

Based on the research undertaken, this study concludes that there are specific cases that could justify the need for a global multilateral benefit-sharing mechanism, while also not undermining the bilateral approach upon which the CBD and Nagoya Protocol are founded.

ANNEX A: GEOGRAPHIC DISTRIBUTION OF DEVIL'S CLUB

Geographic distribution of devil's club (Figure 2) in relation to the area of cultural use and linguistic recognition (Figure 1) in Western North America (from Leslie Main Johnson, 'Gitksan medicinal plants-cultural choice and efficacy', Journal of Ethnobiology and Ethnomedicine 2006, 2:29)

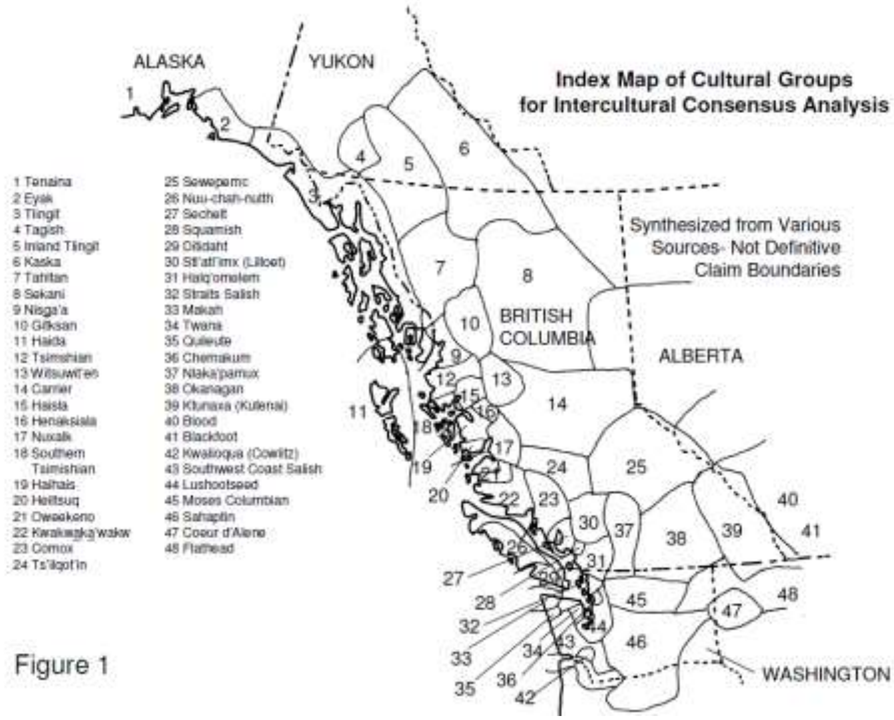


Figure 1

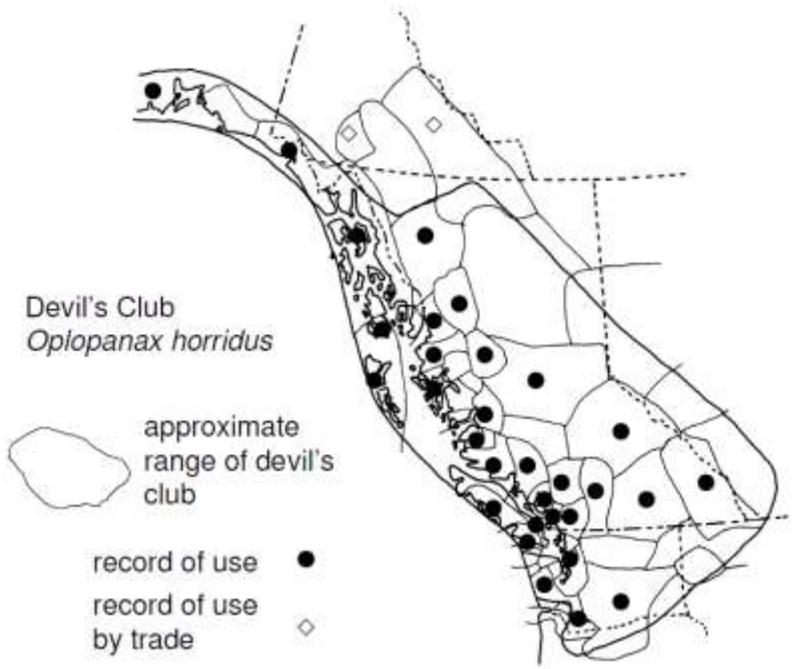
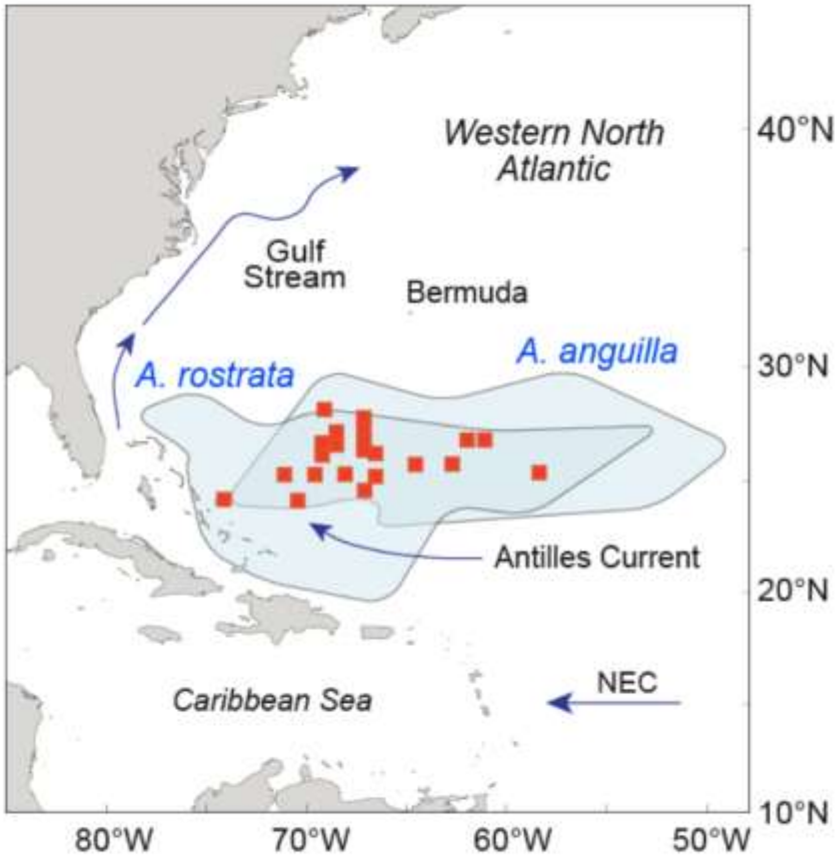


Figure 2

ANNEX B: SPAWNING AREAS OF EUROPEAN AND AMERICAN EELS



Source: MJ Miller & R Hanel, *The Sargasso Sea Subtropical Gyre: The Spawning and Larval Development Area of Both Freshwater and Marine Eels* (Sargasso Sea Alliance, 2011), 5.

ANNEX C: EXAMPLES OF SPECIMENS IN HERBARIA, BOTANICAL GARDENS, AND PUBLICATIONS

C1: Entry for *Ammi visnaga*, African Pharmacopoeia 2014

Ammi visnaga (L.) Lamk.

Family name:

Apiaceae.

Synonym:

(a) Daucus visnaga L.,
(b) Apium visnaga (L.) Crantz
(c) Selinum visnaga E.H.L. Krause,
(d) Sium visnaga Stokes,
(e) Visnaga daucoides Gaertn.

Common name:

(a) Bishop's weed, Toothpick weed, Visnaga Toothpick plant (E).
(b) Plante aux cure-dent, Herbe aux cure-dents (F).

African names:

(a) Arabic: الخلة البلدية
(b) Bambara: N/A
(c) Hausa: N/A
(d) Peuhl: N/A
(e) Swahili: N/A
(f) Yoruba: N/A

Brief description of the plant:

Herbaceous plant of 20 to 80 cm in height, with dentate leaves in strips which are very narrow and whole; stalked umbellate flowers with highly swollen rays at the base; fruits hardly ever as long as wide.

Geographical distribution:

Mediterranean regions of Africa.

Part used:

Fruits.

Names of drug:

Fructus Ammi visnagae. Ammi visnaga fruit. Fruit d'Ammi visnaga.

Definition:

Ammi visnaga fruit is the dried ripe fruits of *Ammi visnaga* (L.) Lamk. (fam. Apiaceae) containing not more than 3 per cent of the bitter principle, Khellin.

C2: Herbarium Specimen: Schinus Terebinthifolia (Florida, text-based medicinal uses)

C3: Herbarium Specimen: Schinus Terebinthifolia (Arizona, disseminated by birds)

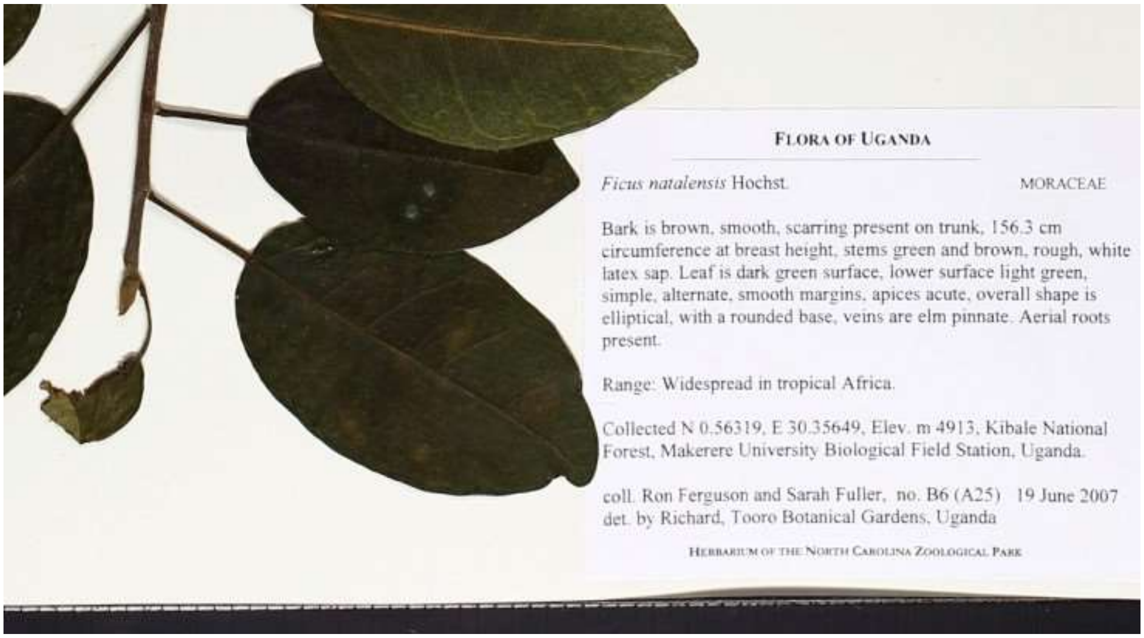
Rancho Santa Ana Botanic Garden Herbarium (RSABG || RSA)

Occurrence ID (GUID): c2d21759-4fc5-4767-8abd-f370eb5be7c9
Secondary Catalog #: 564435
Taxon: *Schinus terebinthifolia* Raddi
Family: Anacardiaceae
Type Status: Not type
Collector: Steve Boyd s.n.
Date: 1994-01-31
Locality: United States, California, Los Angeles County, Claremont: RSABG: Indian Hill Mesa. One of several volunteer plants on the mesa, NNW of the Administration Bldg.
Elevation: 409 meters (1342ft)
Habitat: Sporadically adventive and presumably disseminated by birds.
Preparations: Herbarium sheet - 1

Usage Rights: CC BY-NC (Attribution-Non-Commercial)
Record Id: fcca1454-ffc6-498d-9666-212f9712ca80

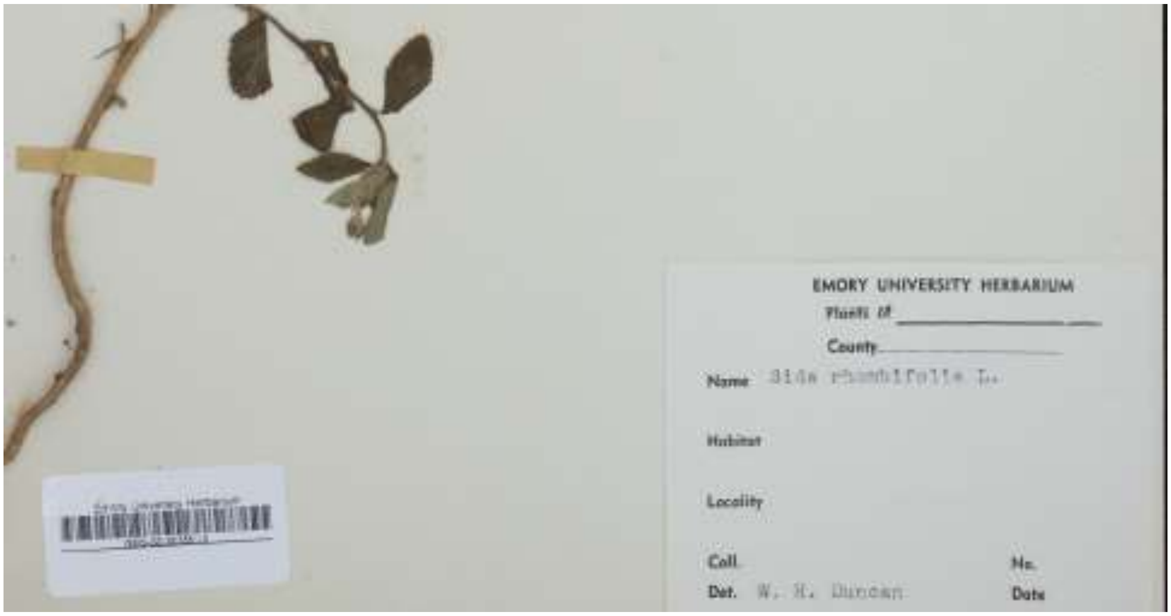
For additional information on this specimen, please contact: Mare Nazaire, Administrative Curator (mnazaire@rsabg.org)

C4: Herbarium Specimen: *Ficus Natalensis* From Uganda (but stated to be "Widespread in tropical Africa")



C5: Herbarium Specimen: Pelargonium Sidiodes (native to South Africa, no country of origin information given)

C6: Herbarium Specimen: No country of origin information provided



C7: Kew EBC Specimen: No country of origin

Catalogue Number: 64327				
No Image	**Plant Name**	42.00 BURSERACEAE Commiphora molmol	**Entry Book Number**	
	Artefact Name	Resin - Genuine Myrrh	**Vernacular Name**	
	Iso Country	Not defined	**TDWG Region**	Not defined
	Parts Held	Resin - Genuine Myrrh	**Geography Description**	
	Uses	Resin - Genuine MyrrhUse: MEDICINES - Digestive System Disorders User: Man	**TDWG use**	MEDICINES - Digestive System Disorders
	Storage	Bottles, boxes etc	**Related Items**	

C8: Kew EBC Specimen: Geographic Region: Africa

Catalogue Number: 49309

Plant Name	107.00 ASCLEPIADACEAE Gomphocarpus sp	**Entry Book Number**	158.1860.29
Artefact Name	Fruit	**Vernacular Name**	
Iso Country	Not defined	**TDWG Region**	Not defined
Parts Held	Fruit	**Geography Description**	Africa
Uses	FruitUse: MEDICINES - Digestive System Disorders User: Man	**TDWG use**	MEDICINES - Digestive System Disorders
Storage	Bottles, boxes etc	**Related Items**	
Donor	Dr Livingstone's Expedition	**Donor No**	74
Donor Date	19/10/1860	**Donor Notes**	
Collector	Kirk Dr	**Collector No**	