

**Study for the European Commission on ‘Possible Ways to Address Digital Sequence Information – Legal and Policy Aspects’**

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## List of Acronyms

ABS	access and benefit-sharing
AHTEG	Ad Hoc Technical Expert Group
AN	Accession Number
BBNJ	biological diversity of areas beyond national jurisdiction
BSF	Benefit-Sharing Fund
CBD	Convention on Biological Diversity
COP	Conference of the Parties
COP-MOP	Conference of the Parties serving as the Meetings of the Parties
DNA	deoxyribonucleic acid
DOI	Digital Object Identifiers
DSI	digital sequence information
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAFFSP	Global Agriculture and Food Security Program
Gavi	Global Alliance for Vaccines and Immunisation
GCF	Green Climate Fund
GDPR	General Data Protection Regulation
GEF	The Global Environment Facility
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GFBio	The Global Fund for Biodiversity
GISAID	Global Initiative on Sharing All Influenza Data
GISRS	Global Influenza Surveillance and Response System
GLIS	Global Information System
GUID	Global Unique Identifier
IAF	International Fund for Agricultural Development
IFC	International Finance Corporation
IFFIm	International Finance Facility for Immunisations
INSDC	International Nucleotide Sequence Data Collaboration
IP	intellectual property
IPBES	Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services
IRCC	internationally-recognised certificate of compliance
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	mutually agreed terms
MLS	multilateral system
NDA	National Designated Authorities
NSD	Nucleoside Sequence Data
PGRFA	plant genetic resources for food and agriculture
PIC	prior informed consent
PIP Framework	Pandemic Influenza Preparedness Framework
RNA	ribonucleic acid
SDGs	Sustainable Development Goals

SMTA	Standard material transfer agreement
SOI	Sustainable Ocean Initiative
TK	Traditional knowledge
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
TRP	Technical Review Panel
UK	United Kingdom
UN	United Nations
USA	United States of America
WDCM	World Data Centre for Microorganisms
WFCC	World Federation for Culture Collections
WHO	World Health Organization
WTO	World Trade Organization

## Introduction

In 2016, the Conference of the Parties to the Convention on Biological Diversity ('CBD')<sup>1</sup> recognised for the first time the relevance of, and potential issues surrounding, digital sequence information on genetic resources ('DSI') for the achievement of the CBD's three objectives:<sup>2</sup> namely, the conservation of biological diversity, the sustainable use of its components and, notably, the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.<sup>3</sup> In light of the need for a coordinated and non-duplicative approach, the issue was simultaneously raised by the Conference of the Parties serving as the Meetings of the Parties ('COP-MOP') to the Nagoya Protocol on Access and Benefit-Sharing ('the Nagoya Protocol').<sup>4</sup> An Ad Hoc Technical Expert Group (AHTEG) was established and multiple studies have been undertaken or are currently being conducted to shed light on the highly technical and complex issue of how DSI relates to the scope and workings of the international regime on access and benefit-sharing ('ABS').<sup>5</sup> DSI has been debated during the 2018 COP and COP-MOP,<sup>6</sup> and it is expected that DSI will remain a critical topic at the CBD COP15 as well as in other international fora. Specifically, DSI is also being discussed under the Pandemic Influenza Preparedness Framework (PIP Framework) of the World Health Organisation (WHO)<sup>7</sup>, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)<sup>8</sup> as well as current UN negotiations for a legally binding instrument on marine biodiversity of areas beyond national jurisdiction (BBNJ).<sup>9</sup>

Difficulties in achieving progress on DSI under international regimes on biodiversity and access and benefit-sharing, however, do not only stem from the technical complexity of the subject, but also from the increasingly politicized nature of the debate and the resulting polarised positions among CBD Parties. The current negotiating impasse is expected to have an impact on the negotiations for a post-2020 Global Biodiversity Framework and may start to

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<sup>1</sup> Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993) 1760 UNTS 79 ('CBD').

<sup>2</sup> CBD COP, 'Digital Sequence Information on Genetic Resources' (2016) CBD/COP/DEC/XIII/16, Preamble 1.

<sup>3</sup> Article 1 CBD.

<sup>4</sup> Conference of the Parties to the CBD Serving as the Meetings of the Parties to the Nagoya Protocol ('COP-MOP'), 'Digital Sequence Information on Genetic Resources' (2016) CBD/NP/MOP/DEC/2/14.

<sup>5</sup> See, for example, Convention on Biological Diversity (by S Laird and R Wynberg), 'A Fact Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and Nagoya Protocol' (2018) CBD/DSI/AHTEG/2018/1/3 ('Laird and Wynberg 2018') and '2019-2020 Inter-Sessional Period. Studies on Digital Sequence Information on Genetic Resources' <https://www.cbd.int/abs/dsi-gr/2019-2020/studies.shtml>, accessed December 2019.

<sup>6</sup> CBD COP, 'Digital Sequence Information on Genetic Resources' (2018) CBD/COP/DEC/14/20 and COP-MOP to the Nagoya Protocol, 'Digital Sequence Information on Genetic Resources' (2018) CBD/NP/MOP/DEC/3/12. Please note that CBD COP15 has been postponed due to the continuing impacts of COVID-19; <https://www.cbd.int/doc/notifications/2020/ntf-2020-032-sbstta-sbi-en.pdf>.

<sup>7</sup> World Health Organisation, 'Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits' (2011) A64/VR/10 ('PIP Framework'); see specifically PIP Advisory Group's work on handling Genetic Sequence Data under the PIP Framework, available at [https://www.who.int/influenza/pip/advisory\\_group/gsd/en/](https://www.who.int/influenza/pip/advisory_group/gsd/en/), accessed December 2019.

<sup>8</sup> Summary of the Eighth Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture: 11-16 November 2019, Rome, Italy, *Earth Negotiations Bulletin* (09) 740.

<sup>9</sup> 3rd Session of the Intergovernmental Conference (IGC) on the Conservation and Sustainable Use of Marine Biodiversity of Areas Beyond National Jurisdiction: 19-30 August 2019, UN Headquarters, New York, IISD Reporting Services, available at <https://enb.iisd.org/oceans/bbnj/igc3/>, accessed December 2019.

undermine other international cooperation efforts on biodiversity more broadly, both under the CBD and in other fora. This study examines if and how a sound international law solution can be found to bridge and balance developed and developing countries' demands for equity as well as the need to support scientific research and scientific cooperation in the context of the holistic realization of the three CBD objectives. This study will also seek to discern what non-legal solutions might exist to the DSI issue. This study therefore assesses different legal and non-legal options and identifies creative solutions to the issue of DSI, on the basis of three starting points that are both principled and pragmatic:

- Finding a legal solution that responds to the different needs of CBD Parties and stakeholders around DSI can contribute to the broader effectiveness of the international biodiversity regime;
- Fostering learning across different regimes can also contribute to the effectiveness of the international biodiversity regime: even if other international regimes are not applicable, they can provide tested solutions and lessons learnt that can be adapted to the context of the CBD; and
- Moving beyond the false dichotomy of monetary and non-monetary benefits that often characterises debates on ABS and DSI to ensure a functional approach and indeed, a more expansive view of what constitutes benefits.

The results of this study aim to assist the European Commission in discussions with Member States on possible ways forward.

a) Methodology and scope

This study will analyse and assess seven different options for addressing the issue of DSI: 1) DSI is not covered by the CBD or the Nagoya Protocol; 2) DSI is covered by the CBD and the Nagoya Protocol and no additional measures need be taken; 3) existing CBD/Nagoya Protocol provisions are complemented by the implementation of a new track-and-trace system; 4) a copyright-inspired *sui generis* system is put in place; 5) a multilateral DSI fund is put in place; 6) a broader, principled approach to benefit-sharing is taken, or; 7) a hybrid approach is taken. Options 1 to 5 were partially pre-identified by the European Commission under the terms of reference. Options 6 to 7 were identified on the basis of subsequent research. The analysis of various options is based on a desk-based review of academic and grey literature pertaining to DSI across different disciplines (such as law, natural sciences and political sciences).

The analyses take into account the wider possible effects of each option upon other policy areas as well as whether any changes would lead to substantive sharing of benefits over time. In terms of the scope of this study, while as noted above DSI is also a topic of debate under other treaties, e.g. the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Pandemic Influenza Preparedness Framework (PIP Framework), these areas are only considered for their mutual-learning value. The impacts of the different options to address DSI on these international instruments are not the subject of this study. In the conclusions this study will, however, consider the potential utility of the recommended options to address DSI for the current UN negotiations on a legally binding instrument on marine biodiversity of areas beyond national jurisdiction (BBNJ). It is finally to be noted that this study

will not address the ongoing question of how to effectively regulate the biosecurity concerns surrounding synthetic biology.<sup>10</sup>

The research builds upon earlier work by Professor Elisa Morgera on fair and equitable benefit-sharing conducted within the five-year BENELEX project (2013-2019).<sup>11</sup> The study also integrates insights on bio-prospecting and international scientific cooperation arising from the development and implementation of the One Ocean Hub: an inter-disciplinary collaboration on integrated ocean research and governance between UK and Global South research institutions.<sup>12</sup> In addition to desk-based research, the analyses have been informed by confidential discussions with leading experts on DSI, notably with regard to the international legal and political landscape relevant to DSI, including intellectual property law (Dr Shakeel Bhatti in his personal/academic capacity), and the views of the scientific community on DSI (Dr Rachel Wynberg, University of Cape Town, and Sarah Laird). These three experts have indicated that this study has come to novel and helpful conclusions that could help bridge the current divide in international negotiations and lead to a more constructive engagement with different various stakeholders involved in bio-based innovation. We are extremely grateful for the insights and assistance provided by these experts in helping to develop our thinking in relation to this study.

#### b) Core assumptions and summary of findings

Our core assumption within this study is that in line with the international law principles of good faith and effectiveness, DSI *is* within the scope of the CBD and the Nagoya Protocol but cannot be adequately addressed through a bilateral approach, which is largely considered to characterize ABS under the CBD and Nagoya Protocol. This approach has, in effect, led to a series of legal and practical difficulties in implementation (that make addressing DSI quite complicated under the CBD). It has also focused attention on a transactional approach/ logic of exchange in the context of negotiating mutually agreed terms (MATs) that has been to the detriment of the identification of opportunities for increased cooperation for the realization of all the objectives of the CBD and their global benefits for human well-being as well as the realization of the Sustainable Development Goals.

The problem underlying the bilateral approach inherent in the Nagoya Protocol in the DSI context is the conceptualisation of DSI as ‘*natural information*.’ The fact that genetic resources,

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<sup>10</sup> For discussion, see, for example, A Rai and J Boyle, 'Synthetic Biology: Caught between Property Rights, the Public Domain and the Commons' (2007) 5(3) PLoS Biology 0389; M Redford, 'Genetic frontiers for conservation : an assessment of synthetic biology and biodiversity conservation : technical assessment', (IUCN, 2019) available at <https://portals.iucn.org/library/node/48408>, accessed December 2019; Secretariat of the Convention on Biological Diversity (2019) *Synthetic Biology*, Montreal Technical Series No. 82; P Oldham, S Hall and G Burton, 'Synthetic Biology: Mapping the Scientific Landscape' (2012) 7(4) PLoS ONE 1.

<sup>11</sup> For more information, visit 'The Benelex Project. Benefit-Sharing for an Equitable Transition to the Green Economy' at <https://www.strath.ac.uk/research/strathclydecentreenvironmentallawgovernance/benelex/>, accessed October 2019.

<sup>12</sup> For more information, visit 'the One Ocean Hub' <https://www.strath.ac.uk/research/strathclydecentreenvironmentallawgovernance/oneoceanhub/>, accessed December 2019.



understood as *natural information*,<sup>13</sup> are oftentimes not unique to a particular country, alongside the range of publicly accessible databases (see discussion *option 3 below*) and *ex situ* specimens, means that bilateral ABS arrangements, at least in respect of DSI, may become increasingly difficult to operationalise.<sup>14</sup> Conserved sequences, which “are similar or identical sequences in DNA, RNA and proteins or polysaccharides occurring across species, or within different molecules produced by the same organism”<sup>15</sup> are also extremely common.<sup>16</sup> This has also led some commentators to argue that “the notions of sovereignty and countries of origin ... require reconsideration.”<sup>17</sup>

In addition, DSI poses significant challenges to the bilateral approach to ABS because of the valuation of monetary benefits in respect of the contribution of DSI to commercial products, and the resulting nature and extent of such monetary benefits. It has been underscored that “the value of an individual sequence from a species may be very difficult to quantify”,<sup>18</sup> because its value lies in its potential to be screened with other sequences to find connections between traits and functions.<sup>19</sup> Similarly, one author remarked: “The modalities of genomic data (DSI) use make traceability irrelevant: the value lies in the amounts of data analysed, rarely in a single accession.”<sup>20</sup> The long “cognitive and material distance” between a resource and a final product is a challenge for valuation,<sup>21</sup> if only a very small percentage of a particular sequence is used or when the product of biotechnology has seen many transformations.<sup>22</sup> Questions have therefore arisen as to when benefit-sharing obligations cease to exist,<sup>23</sup> and where such obligations arise along a complex chain of providers and users. Further, and as set out above, conserved or homologous sequences, as well as the spread of particular genes across jurisdictions, present difficulties for valuation of monetary benefits from DSI.<sup>24</sup>

As set out above, genetic resources are often shared by countries with the spectre of ‘jurisdiction shopping’ therefore arising, resulting in oftentimes very low monetary benefits.<sup>25</sup> This raises important issues of equity and has led to the question being asked as to whether the current bilateral ABS approach embodied by the Nagoya Protocol does in fact support fairness

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<sup>13</sup> J H Vogel et al, 'Bounded Openness as the Modality for the Global Multilateral Benefit-Sharing Mechanism of the Nagoya Protocol' in Charles R. McManis and Burton Ong (eds), *Routledge Handbook of Biodiversity and the Law* (Routledge, 2017) 11. See also Laird and Wynberg 2018 (*supra*, n 5), 50 to 51.

<sup>14</sup> *Ibid.*

<sup>15</sup> Laird and Wynberg 2018 (*supra*, n 5), 50.

<sup>16</sup> *Ibid.*, 50 to 51.

<sup>17</sup> M Ruiz Muller, 'Thinking Outside the Box Innovative Options for an Operational Regime on Access and Benefit Sharing' (2010) ICTSD Issue Paper No. 1, 11

<sup>18</sup> E W Welch et al, *Potential Implications of New Synthetic Biology and Genomic Research Trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture* (Secretariat of the International Treaty on PGRFA, 2017), 37.

<sup>19</sup> *Ibid.*

<sup>20</sup> S Aubry, 'The Future of Digital Sequence Information for Plant Genetic Resources for Food and Agriculture' (2019) 10 *Front Plant Sci* 1, 4.

<sup>21</sup> Dutfield in D Scott and D Berry, *Genetic Resources in the Age of the Nagoya Protocol and Gene/Genome Synthesis* (University of Edinburgh, 2016), 23.

<sup>22</sup> Laird and Wynberg 2018 (*supra*, n 5), 51.

<sup>23</sup> L N Slobodian et al, *The Traceability of MGRs and Genomic Tech/Synthetic Biology* (PharmaSea Milestones, 2017).

<sup>24</sup> Laird and Wynberg 2018 (*supra*, n 5), 51.

<sup>25</sup> Ruiz Muller 2010 (*supra*, n 17), 11. See also M Ruiz Muller, 'Access to Genetic Resources and Benefit Sharing 25 Years on' (2018) ICTSD Issue Paper No. 44, 11.

and equity in benefit sharing and support overall conservation and sustainable use.<sup>26</sup> To the extent that better tracking of DSI is possible to provide for monetary benefit-sharing - and this in itself is perhaps questionable (see *options 3 below and 4 below*) – the ability to track would not address issues of fairness and moreover equity associated with the current bilateral ABS system under the Nagoya Protocol.<sup>27</sup>

Accordingly, while in our view DSI is within the scope of the Nagoya Protocol and CBD (*option 1 below*), we contend that the prevailing bilateral approach under the Protocol is neither desirable nor practicable to deal with the issue of DSI. Accordingly, we reject the notion that benefits from the use of DSI need only be dealt with by via MAT and no additional measures need be taken to deal with the peculiarities of DSI, because this approach appears out of sync with current scientific practices (*option 2 below*). We further explore whether additional measures, particularly via the introduction of new mechanisms to track and trace DSI would facilitate the operation of the bilateral ABS system under the Nagoya Protocol but as noted above, do not find this option to be particularly feasible. This is due to difficulties arising under the bilateral system regarding the monitoring of use and the intractability of determining the value and nature of benefit-sharing obligations (*option 3 below*). We further explore whether a *sui generis* system of copyright-like protection (*option 4 below*) for DSI may offer a solution but find that the complexity and likely cost of such a system may very well outweigh its potential benefits.

Based upon our analysis in *options 1 to 4*, we argue that the need for legal certainty, and the difficulties of achieving such certainty on a bilateral basis, weighs in favour of a multilateral solution. We therefore explore in *option 5* potential options for a multilateral approach to monetary benefit-sharing in respect of DSI. We discuss a menu of potential options for the accrual of monetary benefits under such a fund as well as potential sites for its governance. In particular, we identify three potential sites for the operation of such a fund: (1) a multilateral approach based on Article 10 of the Nagoya Protocol, (2) a global fund for biodiversity under the CBD (and therefore centred under the UN system) and, (3) a global fund for biodiversity outside of the existing ABS system. Our favoured approach is for a fund under the CBD, since it is its Treaty objectives which would underpin such a fund. We note, however, that a fund in itself would not necessarily adequately address the equity issues and foster the needed cooperation to harness DSI for the realization of the three objectives of the CBD. We thus explore in *option 6 below* whether more principled approaches are needed to ensure that available resources are targeted to ensure fairness and equity. In essence, while a multilateral fund for the sharing of benefits is very much needed to make a system to address DSI viable, this should be functional to supporting a multilateral platform for dialogue, learning, oversight and priority setting, on the best ways to achieve fairness and equity in benefit-sharing from DSI. Such an approach would ensure that the system would respond to the needs of expected beneficiaries and allow the international community to understand and respond to the different communities involved, including by addressing the needs of scientific researchers.

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<sup>26</sup> See generally Ruiz Muller 2018, *ibid*,

<sup>27</sup> See generally *ibid*, but see particularly 11.

In *option 7* (a *hybrid approach*), we combine the multilateral platform for dialogue, learning, oversight and priority-setting for DSI envisaged in *option 6 below* with the multilateral fund for distribution of benefits set out in *option 5 below*. We propose various mechanisms to support the financial viability of such a fund, including formulation of a *digital domaine public payant* which would be based on a copyright-like approach and see DSI regulated as a semi-commons under which a fee could either be paid for access to or use of DSI, to support the objectives of the CBD. Databases could form a natural point of entry for the operation of the *digital domaine public payant*. More significantly, the multilateral platform for dialogue, learning, oversight and priority setting would seek to work collaboratively with all relevant stakeholders – both in the Global North and the Global South – to create opportunities for consensus building on DSI. It could also provide a clear response to the latest alarming data on the implications of the global biodiversity crisis for the realization of the SDGs and the protection of fundamental human rights. We return in this section to the opportunities to take a multilateral approach under the CBD and the Nagoya Protocol, underscoring the advantages of placing the hybrid approach under the Convention. **The hybrid approach outlined in *option 7* is very much our preferred approach to resolving the DSI issue.**

## Option 1: DSI is not covered by the CBD or the Nagoya Protocol

In this option, we explore the **contention that DSI does not come within the scope of the CBD or the Nagoya Protocol**. After setting out the background to such arguments, we contend that the application of the general principles of international law of effectiveness and good faith, combined with a desire for legal certainty, indicates that this **is not a recommended option**. We contend that considering DSI *within the scope* of the CBD and the Nagoya Protocol is likely to produce positive externalities for law and policy and allow for a more structured approach to the issue across different sectors and regimes.

### a) The conceptual underpinnings of the debate over whether DSI comes within the scope of the CBD and Nagoya Protocol

The topic of DSI poses conceptual questions for the international ABS regime, with the status of DSI under the CBD and the Nagoya Protocol having been discussed extensively but without Parties being able to find agreement. Firstly, the terminology ‘DSI’, which was introduced by the CBD,<sup>28</sup> is not uncontentious as the scientific community and other international processes use related terms, such as ‘resources in silico’ and ‘(genetic) sequence information/data’ which have been held to more accurately and comprehensively represent the subject at hand.<sup>29</sup> Secondly, Parties’ views and those from organisations who have provided submissions to inform the process diverge with regard to the subject-matter scope of the CBD and the Nagoya Protocol in relation to DSI, notably in light of the interpretation of the terms ‘utilization of genetic resources’.<sup>30</sup> Arguments against inclusion focus on the dematerialised state of DSI and presume that the definitions under the CBD only apply to physical resources.<sup>31</sup> Contrarily, arguments in favour of inclusion put forward that the terms under the CBD should include both tangible and intangible components, “i.e. the physical material as well as the actual or potential value it contains in the form of information”.<sup>32</sup> The invitation for submission of views for the 2019-2020 called for further terminological clarification,<sup>33</sup> although some Parties have remarked that such further technical discussions are unlikely to break the current impasse.<sup>34</sup> In the meantime, the CBD AHTEG group met in March 2020 to consider a number of

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<sup>28</sup> CBD Decision Xiii/16.

<sup>29</sup> For a thorough analysis of the challenges surrounding the ‘DSI’ terminology, see Laird and Wynberg 2018 (*supra*, n 5), Chapter 2. On terminology and the scope, see also M Bagley and A K Rai, *The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts* (Wilson Centre, 2013), 20-21.

<sup>30</sup> See, for example, Art. 1 CBD and Art. 1 Nagoya Protocol. See also, Preamble 17 and Article 3(4) an (5) Regulation (Eu) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization in the Union [2014] OJ L 150/59.

<sup>31</sup> See notably Ad Hoc Technical Expert Group (‘AHTEG’) on Digital Sequence Information on Genetic Resources, ‘Synthesis of Views and Information on the Potential Implications of the Use of Digital Sequence Information on Genetic Resources for the Three Objectives of the Convention and the Objective of the Nagoya Protocol’ (2018) CBD/SBSTTA/22/INF/2, 36.

<sup>32</sup> *Ibid*, 35.

<sup>33</sup> ‘Digital Sequence Information on Genetic Resources: Submission of Views and Information and Call for Expression of Interest to Undertake Studies’ (*Secretariat to the CBD*, 2019) <https://www.cbd.int/doc/notifications/2019/ntf-2019-012-abs-en.pdf>, accessed October 2019

<sup>34</sup> See, for example, ‘Submission by the African Group of Negotiators on Biodiversity-Ad Hoc Group on Digital Sequence Information’ (*Secretariat to the CBD*, 2019).

commissioned peer reviewed studies<sup>35</sup>, including on the concept and scope of DSI<sup>36</sup>, and agreed that while RNA, DNA, proteins, epigenetic modifications, metabolites and other macromolecules could be considered DSI, other ‘associated information’ such as traditional knowledge would not be considered DSI.<sup>37</sup> It remains to be seen how this will be responded to by the Parties at CBD COP15.

b) A legal and policy basis analysis of the inclusion of DSI with the CBD and Nagoya Protocol

While views may diverge on the most persuasive legal interpretation of the scope of the ABS regime, a solution capable of fostering increased cooperation and multilateral learning should be favoured under general principles of international law, notably effectiveness and good faith.<sup>38</sup> These principles support interpretations that contribute to ensure full effect of a treaty, in light of its object and purpose, rather than depriving provisions of impact on the ground.<sup>39</sup> In this regard, it seems to be self-evident that the benefits associated with a genetic resource is often linked to the *information* held within a genetic resource in addition to the physical traits of the specific specimen (see *core assumptions* above). The exclusion of DSI from the scope of the CBD and the Nagoya Protocol is therefore considered to be contrary to the principles of effectiveness and good faith.

A question of relevance to DSI and ABS is, moreover, to what degree data and information can be used to generate benefits without access to the physical resource, which would mean that requirements that follow from international law could be avoided altogether when DSI is excluded from its scope. Whereas current scientific practices mostly use sequences to complement rather than substitute work on physical organisms,<sup>40</sup> rapid technological developments could allow for further detachment in the future.<sup>41</sup> Advances in gene synthesis, for example, are likely to reduce the need for reliance upon physical samples. Any policy choice should anticipate this potential.

Exclusion of DSI from the scope of the CBD and the Nagoya Protocol is also likely to “maintain an uncertain position or the perpetuation of disagreements”,<sup>42</sup> and enables the

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<sup>35</sup> See generally <https://www.cbd.int/dsi-gr/2019-2020/studies/>

<sup>36</sup> W Houssen and others, *Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use* (2020) Convention in Biological Diversity.

<sup>37</sup> Secretariat to the Convention on Biological Diversity, ‘Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources’ (20 March 2020) CBD/DSI/AHTEG/2020/1/7

<sup>38</sup> Secretariat to the Convention on Biological Diversity (prepared by E Morgera, S Switzer and E Tsioumani), ‘Study into the Criteria to Identify a Specialised Access and Benefit-Sharing Instrument, and a Possible Process for Its Recognition’ (2018) UN Doc CBD/SBI/2/INF/17, 14.

<sup>39</sup> M Fitzmaurice, ‘The Law of Treaties’ in Malcolm Nathan Shaw (ed), *International Law* (Oxford University Press 2008), 832-838.

<sup>40</sup> Laird and Wynberg 2018, (*supra*, n 5), 32.

<sup>41</sup> C Lawson and M Rourke, ‘Open Access DNA, Rna and Amino Acid Sequences: The Consequences and Solutions for the International Regulation of Access and Benefit Sharing’ (2016) 24 *Journal of Law and Medicine* 96, 116 refers to one example under the PIP Framework where a vaccine was produced without access to a physical sample.

<sup>42</sup> E Morgera, ‘Fair and Equitable Benefit-Sharing in a New International Instrument on Marine Biodiversity: A Principled Approach Towards Partnership Building?’ (2018) 5 *Maritime Safety and Security Law Journal* 48, p

continuation of an international legal vacuum on DSI. Contrarily, the principles of effectiveness and good faith privilege, “better protection or implementation of universal values, and in addition [ensure] international institutions are involved to monitor or steer the process.”<sup>43</sup> Whereas some members of the scientific community may primarily anticipate positive impacts from exclusion due to the likelihood of ongoing unrestricted access to DSI,<sup>44</sup> it may be that provider-countries will impose stricter restrictions on the generation and publication of DSI in legislation on access.<sup>45</sup> That said, it is to be noted that bulk of Nucleoside Sequence Data (NSD) deposits to the International Nucleotide Sequence Data Collaboration (INSDC) are from 4 countries – USA, China, Canada, and Japan, which together account for more than 50% of country-tagged NSD.<sup>46</sup>

Exclusion from the scope of the CBD and the Nagoya Protocol can overall be considered a lost opportunity to maximise the contribution of DSI to the CBD obligations on scientific research and cooperation that contribute to realizing the CBD’s objectives of conservation and sustainable use, although these are to be balanced against other public goods. Moreover, it may lead to inequitable outcomes for biodiversity-rich countries by circumventing the third objective of the CBD on fair and equitable benefit-sharing, as a consequence of changing scientific practices. **Exclusion of DSI from the scope of the CBD and the Protocol is therefore not a recommended option.**

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68 and A Orakhelasvili, *The Interpretation of Acts and Rules in Public International Law* (Oxford University Press, 2008), 395.

<sup>43</sup> S Zappalà, ‘Can Legality Trump Effectiveness in Today’s International Law?’ in Antonio Cassese (ed), *Realizing Utopia* (Oxford University Press 2012), 105.

<sup>44</sup> See, for example, ‘Submission by the League of European Research Universities (Leru). Digital Sequence Information = Nucleotide Sequence Data! But More Clarity Is Needed on Its Scope.’ (*Secretariat to the CBD*, 2019) <https://www.cbd.int/abs/DSI-views/2019/LERU-DSI.pdf>, accessed October 2019.

<sup>45</sup> S J Hiemstra et al, *Digital Sequence Information (DSI). Options and Impact of Regulating Access and Benefit Sharing - Stakeholder Perspectives* (University of Wageningen, 2019), 13. See also, M A Bagley, *Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology* (Wilson Centre, 2015), 7-8.

<sup>46</sup> F Rohden et al, *Combined Study on Dsi in Public and Private Databases and Dsi Traceability* (Convention on Biological Diversity, 2019).

## **Option 2: DSI is covered by the CBD and the Nagoya Protocol: benefits from use of DSI are to be included in MAT and no additional measures are taken**

The question as to whether DSI is included in the scope of the CBD and the Nagoya Protocol is separate to, and logically precedes, the question of how the provisions of either treaty can apply to DSI. Agreement on the inclusion of DSI within the scope of the CBD and the Nagoya Protocol would therefore have the advantage of allowing international discussions to move forward, onto the question: to what extent can these two treaties apply to DSI? In this option, we explore the contention that no additional measures need be taken to deal with the specific situation of DSI, assessing whether current arrangements under the Nagoya Protocol can bring about benefit-sharing from the use of DSI.

The Nagoya Protocol stipulates that access to genetic resources for their utilisation is subject to prior informed consent from the country of origin,<sup>47</sup> and that benefits arising from the utilisation of genetic resources as well as subsequent applications and commercialisation shall be shared in a fair and equitable way with the country of origin, upon mutually agreed terms ('MAT').<sup>48</sup> These provisions of the Nagoya Protocol thus rely on the idea that a single resource generates benefits for a user that should be shared with the provider MATs. The draft fact-finding study conducted for the CBD on domestic measures that address the use of DSI show that some countries include conditions on the use of DSI as part of prior informed consent (PIC) and MAT.<sup>49</sup> Malawi, for example, includes in its MAT that publication of DSI must be accompanied by a statement that the government of Malawi, "has commercial rights or other further use rights in products or processes developed based on the research results of this DSI [and that] Malawi requires what may be called a certificate of acknowledgement of source and rights, to be included in digital publications".<sup>50</sup>

It is, however, questionable whether this obligation suits the current open-access infrastructure and, for example, the submission formats used by INSDC. More importantly, the bilateral nature of MAT fails to take into consideration that DSI is not used as the sole source for bio-innovation, but it is rather screened with other sequences to find connections between traits and functions. In other words, the premises upon which MATs are based are out of sync with current research practices, resulting in difficulties in the valuation of monetary benefits in respect of the contribution of DSI to commercial products, and in determining if and when benefit-sharing obligations cease to exist. Finally, transparency issues in the biotech sector may result in difficulties in obtaining information regarding both profits and monetary benefits relating to the use of DSI. **In conclusion, the inclusion in MATS of DSI is likely to be plagued by a mismatch with current scientific practices, and the intractability of determining the value and nature of benefit-sharing obligations.** Therefore, this is **not a recommended option.**

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<sup>47</sup> Article 7 Nagoya Protocol.

<sup>48</sup> Article 5(1) Nagoya Protocol.

<sup>49</sup> E K Margo Bagley, Manuel Ruiz Muller, Frederic Perron-Welch, Siva Thambisetty, *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* (Convention on Biological Diversity, 2019).

<sup>50</sup> *Ibid*, 23. See also Submission on DSI by the African Group to the CBD 2019, 4.

### **Option 3: The current system is complemented by a new track-and-trace system**

In this option, we assume DSI *is* considered to fall within the scope of the CBD and the Protocol, and additional measures *are* necessary to ensure benefit-sharing from the use of DSI. Specifically, we explore the contention that the current bilateral approach to ABS could be made operational with regard to DSI through a new track-and-trace system.

In this regard, we explore a number of potential options such as the use of a new monitoring system for the retracing of the source of DSI or the application of blockchain technology to DSI. Due to difficulties in the implementation and operation of these systems, **we do not see blockchain as a recommended option**. Where the focus is put on **track-and-trace only, the improvement of existing structures is needed**. However, we contend that improved tracking does not resolve significant issues related to valuation in the bilateral ABS system. Indeed, within the proposed solution of a multilateral platform (Option 6 below), improving options for tracking should not be the primary focus, but such improvements – where they target existing infrastructures – could contribute to enhancing the interoperability of systems.

#### a) Background

In addition to the difficulty of valuing netary benefits discussed under *option 2 above*, there are other factors that complicate the application of the current ABS regime to DSI, relating to the (in)ability to track information and to monitor use. With regard to NSD, as a specific form of DSI, there is already something of a tracking system in place under the INSDC database structure, which could be further built upon, but even improved implementation is still likely to pose challenges for monitoring and the valuation of monetary benefits. The draft study on traceability conducted for the CBD emphasised that moving beyond existing infrastructures for NSD is likely to be costly, will lead to separation and fragmentation of processes, with negative impacts on research, and may come with its own practical and technical challenges.<sup>51</sup> Keeping this in mind, this section will consider two options for a new track-and/or-trace system in light of the potential to overcome persistent issues of monitoring: a system to trace back the origin upon use and a blockchain-based system.

#### b) Retracing of information

Track-and-trace is not a term with a single unified definition; instead, it may refer both to systems that trace back to the original source upon (commercial) use, or to the continuous tracking processes of information and use along the value chain. Examples of the former include tools developed under the World Federation for Culture Collections (WFCC) and the World Data Centre for Microorganisms (WDCM), to search different databases to identify uses.<sup>52</sup> Yet, it is recognised that the success of such a monitoring system for (commercial) end-uses only is still ultimately dependent on a form of a downstream support system that allows

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<sup>51</sup> Rohden et al 2019 (*supra*, n 46), 50 and 52.

<sup>52</sup> PIP Framework Advisory Group on Monitoring Options 2015, 15; see also P Desmeth, ‘The Nagoya Protocol Applied to Microbial Genetic Resources’ in Ipek KurtböK (ed), *Microbial Resources: From Functional Existence in Nature to Applications* (Academic Press 2017), 214-215 on the TRUST system.



for consistent identification of the source. On the other hand, a ‘regularising procedure’ in cases where such provenance cannot be established, “must remain exceptional”.<sup>53</sup> In case of the WFCC and the WDCM, such a support system consists of the Global Catalogue of Microorganisms,<sup>54</sup> and the Global Unique Identifiers (GUIDs).<sup>55</sup> It must, however, be noted that monitoring of commercial use at the end of a value chain based on retracing of the source is in these instances only applied to specific sub-categories of genetic resources and that it is highly uncertain that the approach could be extended to include uses of all genetic resources and DSI.<sup>56</sup> Indeed, although the recent CBD study on traceability found that 16% of studied DSI submissions to the INSDC had a country tag and for 44% of samples the country of origin could be obtained from the publication, this still leaves a large percentage of submissions for which the country of origin is missing.<sup>57</sup>

With regard to genetic resources, for example, the EU puts a ‘due diligence’ obligation on users, obliging them to: “seek, keep and transfer”<sup>58</sup> important documents such as the internationally-recognised certificate of compliance (IRCC) or equivalent information that includes the date and place of access, a description of the resource, its source, the presence or absence of rights and obligations relating to benefit-sharing, access permits and MAT.<sup>59</sup> Even with regard to physical resources, this chain is often non-linear, with resources, for example, being shared among *ex situ* collections before being passed to other users, posing difficulties for tracking and involving administrative burdens that some (notably non-commercial) users may find hard to comply with.<sup>60</sup> The particular nature of DSI means that some issues related to the tracking of information, notably with regard to identifying provenance through the research process, may be amplified.

As identified by the recent combined study conducted for the CBD on ‘DSI in public and private databases and DSI traceability’,<sup>61</sup> there are, however, some existing infrastructures that could contribute to resolving issues of tracking with regard to certain types of DSI, notably Nucleotide Sequence Data (NSD), without the need for implementation of a new track-and-trace system. NSD “are the direct outcome of nucleotide (DNA or RNA) sequencing of a

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<sup>53</sup> *Mosaicc - Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct* (Belgian Co-ordinated Collections of Micro-Organisms, 2011), p7; also *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* (Secretariat to the Convention on Biological Diversity, 2018), 3.

<sup>54</sup> ‘Global Catalogue of Microorganisms’ <http://gcm.wfcc.info/>, accessed November 2019.

<sup>55</sup> Desmeth 2017 (*supra*, n 52), 216.

<sup>56</sup> Note in this regard also P Oldham and S Hall, *Intellectual Property, Informatics and Plant Genetic Resources* (FAO, 2012), 203-208, which suggests in the context of the ITGPRFA that although patents can still often be traced back to species listed in Annex I of the treaty, that this is likely due to its limited scope and the nature of agricultural biotechnology.

<sup>57</sup> Rohden et al 2019 (*supra*, n 46), 42-43, it is noted, however, that this covers the total amount of INSDC entries but as newly submitted sequences have a much higher percentage of country reporting, so the coverage will increase.

<sup>58</sup> Article 4(3)(b) Regulation (EU) No 511/2014.

<sup>59</sup> Article 4(3)(b)(i-vi) Regulation (EU) No 511/2014.

<sup>60</sup> E Morgera and M Geelhoed, *'Utilisation' in the Nagoya Protocol and the Eu Abs Regulation for the Upstream Actors* (University of Edinburgh, for the European Commission, 2016), 29.

<sup>61</sup> Rohden et al 2019 (*supra*, n 46).

genetic resource”,<sup>62</sup> and also include “information on the sequence assembly, its annotation and genetic mapping.”<sup>63</sup> In particular, where NSD, as a precondition of publication, is submitted to the International Nucleotide Sequence Data Collaboration (INSDC),<sup>64</sup> it is given an individual Accession Number (AN), which is the “cornerstone of NSD traceability”.<sup>65</sup> Since 1998, a metadata field to provide information on the country of origin has been provided in the INSDC database submission form and it has been mandatory to submit this information since 2011.<sup>66</sup> Also, it could be possible within the INSDC to add a field for reference to the unique identifier of the IRCC.<sup>67</sup> Lastly, it could be possible to be given an AN for metadata associated with NSDs, which allows for submission of one form for a project that may cover hundreds or thousands of sequences that are linked to a single collection.<sup>68</sup>

The INSDC is central to the wider network of databases for NSD.<sup>69</sup> Nonetheless, its current potential is limited by the fact that only 16% of analysed NSD did come with a country tag, and none made reference to MAT.<sup>70</sup> Moreover, it has been held that due to the volume of transactions the system may be prone to human error,<sup>71</sup> and can – due to its openness – be misused by users in bad faith.<sup>72</sup> Ensuring user compliance through monitoring and enforcement is likely to be an issue whilst a single sequence can be split into parts, synthesised and modified in a way that it can be made unrecognisable,<sup>73</sup> and can be reused indefinitely.<sup>74</sup> Once linkages between DSI and its original source have been lost, retracing may be very difficult.<sup>75</sup> A further complicating factor is the fact that algorithms can be used to compare sequences to others that exist in other databases, allowing users to identify similar sequences that do not have the same restrictions on use and obligations on benefit-sharing.<sup>76</sup> The resulting unintended consequences could be that some sectors that are more closely linked to specific conditions in certain countries will be more negatively impacted by the obligations that follow from the international

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<sup>62</sup> Ibid, 11.

<sup>63</sup> Ibid, 11.

<sup>64</sup> Journals and literature search engines also use Digital Object Identifiers (DOI) to link the respective publication back to the submitted NSD.

<sup>65</sup> Rohden et al 2019 (*supra*, n 46), 2.

<sup>66</sup> Ibid, 27-28.

<sup>67</sup> Ibid, 36.

<sup>68</sup> Ibid, 33.

<sup>69</sup> Ibid, 15.

<sup>70</sup> Ibid, 39 and 3. It is noted that for 44% of studied NSD entries without a country tag this information could be retrieved from the publication, and the omission was believed to be primarily caused by automated uploads of large amounts of sequences with incomplete metadata; a process that could still be optimised (p 43).

<sup>71</sup> Ibid, 38. See on the volume of transactions also E Karger, *Study on the Use of Digital Sequence Information on Genetic Resources in Germany* (German Competent National Authority for the Nagoya Protocol, 2018), 28.

<sup>72</sup> Rohden et al 2019 (*supra*, n 46), 45-46.

<sup>73</sup> Laird and Wynberg 2018 (*supra*, n 5), 54.

<sup>74</sup> Karger 2018 (*supra*, n 71), 29.

<sup>75</sup> Lawson and Rourke 2016 (*supra*, n 31), 116.

<sup>76</sup> Welch 2017 (*supra*, n 18), 14.

ABS regime,<sup>77</sup> and that other sectors may choose to move away from those countries which have put ABS rules in place, potentially to the detriment of conservation research.<sup>78</sup>

c) Blockchain

Where monitoring end-uses is unlikely to be a successful track-and-trace option for all DSI that would fall within the scope of the CBD and the Nagoya Protocol, the focus has generally been on continuous and consistent tracking of provenance along the value chain. Tracked metadata can further include legal documentation (with PIC/MAT) or it can adopt a more hybrid approach where such information can be retrieved through a separate but interlinked legal database. One option that is frequently mentioned as a new tracking solution is blockchain which is a type of distributed ledger technology. It is most well-known for its application to Bitcoin, but its potential has been recognised much more broadly.<sup>79</sup> It is considered to promote, “the empowerment of citizens”<sup>80</sup> more generally, or of specific users groups in particular, by giving them the opportunity to control their own data, because the technology is autonomous in the sense that it does not rely on a central authority or third party to be implemented.<sup>81</sup> Put simply, blockchain “is an open ledger of information that can be used to record and track transactions, and which is exchanged and verified on a peer-to-peer network”.<sup>82</sup> As the name suggests, blockchain consists of a chain of blocks with information, which are cryptographically time-stamped and linked to record any transaction. The information in the chain is immutable, which means that it is very difficult to change the information in the blocks, thereby providing protection against tampering. A block has a unique hash which identifies the block and its content. Each block also contains the hash of the previous block, thus creating a chain, which makes it suitable for tracking and tracing.

For the purpose of tracking in the context of DSI, blockchain could, in theory, allow for the transfer of sequence data,<sup>83</sup> and of accompanying information on provenance and terms of use, throughout complex value chains. The approach of blockchain likewise aligns well with the fluid, open access, and networked approach of DSI today. There are, however, other advantages associated with the use of blockchain. Firstly, terms of use may not only be included as metadata but can also be attached through so-called smart contracts. Smart contracts are computer programs that can automatically perform some functions,<sup>84</sup> for example the execution of simple, pre-specified terms and conditions, thereby boosting the speed and

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<sup>77</sup> This includes, for example, agriculture which often requires a focus on the region where a specific crop is grown, see Laird and Wynberg 2018 (*supra*, n 5), 51.

<sup>78</sup> See, for example, ‘Joint Submission on Digital Sequence Information on Genetic Resources – Concept and Benefit-Sharing’ (Secretariat to the CBD, 2019) <https://www.cbd.int/abs/DSI-views/2019/DNFS-VBIO-LVB-DSI.pdf>, accessed October 2019, 4. Also, example Scott and Berry (*supra*, n 21), 37.

<sup>79</sup> See, for example, European Parliament, ‘Resolution on Distributed Ledger Technologies and Blockchains: Building Trust with Disintermediation’ P8\_TA(2018)0373.

<sup>80</sup> *Ibid*, Preamble A.

<sup>81</sup> Rohden et al 2019 (*supra*, n 46).

<sup>82</sup> B Clark, ‘Blockchain and IP Law: A Match Made in Crypto Heaven?’ (*WIPO Magazine* 2018) [https://www.wipo.int/wipo\\_magazine/en/2018/01/article\\_0005.html](https://www.wipo.int/wipo_magazine/en/2018/01/article_0005.html), accessed November 2019.

<sup>83</sup> This, however, is complicated by the fact that large sequences will use of massive storage space and computational power, Rohden et al 2019 (*supra*, n 46), 48.

<sup>84</sup> G Hileman and M Rauchs, ‘Global Blockchain Benchmark Study’ (Cambridge Centre for Alternative Finance, 2017) [https://www.ey.com/Publication/vwLUAssets/ey-global-blockchain-benchmarking-study-2017/\\$FILE/ey-global-blockchain-benchmarking-study-2017.pdf](https://www.ey.com/Publication/vwLUAssets/ey-global-blockchain-benchmarking-study-2017/$FILE/ey-global-blockchain-benchmarking-study-2017.pdf), accessed November 2019.

efficiency of transactions.<sup>85</sup> These may function similarly to click-through-agreements which require acceptance of the conditions of use before access to the sequence, with the additional advantage of providing a record that the terms were accepted by the user.<sup>86</sup> Moreover, simple terms could be made easily executable through smart contracts thus solving potential issues of enforcement. Smart contracts “trigger transactions automatically when certain pre-defined conditions are met”.<sup>87</sup> For example, access to DSI could, in theory, be conditioned upon payment of a fee. More profoundly, it has been suggested that smart contracts and blockchain could be used to establish and enforce intellectual property (IP) licenses and transmit payments of licensing fees or royalties to IP owners.<sup>88</sup> Furthermore, encryption for confidential IP data could, for example, be used to provide protection for trade secrets and facilitate compliance with the EU Trade Secrets Directive.<sup>89</sup>

There are, however, also disadvantages associated with the use of blockchain technology. From a holistic environmental perspective, its current energy footprint should not be disregarded. The technology relies on the computational power of each participant in the network (called nodes) but it is estimated that bitcoin’s energy consumption alone, and notably a process called ‘proof-of-work’ which gives the blockchain ledger security against tampering, is comparable to the annual energy consumption in Austria, “which costs 3.628 billion USD annually” and exacerbates resource use and carbon emissions.<sup>90</sup> In addition, it is also predicted to require “high up-front investment for the setup of the system and permanent infrastructure costs for the upkeep”.<sup>91</sup> Accordingly, the benefits generated by such an expensive system are likely to be outweighed quite significantly by its broader costs.

The same study also signals two other important risks of introducing the blockchain technology for track-and-trace of DSI: the first relates to the fact that DSI can easily be distributed outside of the chain and there is no clear incentive for other users to remain within the blockchain.<sup>92</sup> While bitcoin taken outside the blockchain loses all value, which practically ensures that users have all the interest to stay within the system, the same cannot be said for DSI.<sup>93</sup> DSI outside of the blockchain system is still equally valuable as DSI,<sup>94</sup> so there is no incentive to remain within block chain once DSI has been obtained. It is difficult to see how this lack of incentive

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<sup>85</sup> F Perron-Welch, ‘Blockchain Technology and Access and Benefit-Sharing’ (*ABS Canada*, 2018) <<http://www.abs-canada.org/food-for-thought/blockchain-technology-and-access-and-benefit-sharing/>>, accessed November 2019.

<sup>86</sup> *Ibid*, 47.

<sup>87</sup> A Kumar, ‘Smart Contracts on the Blockchain: A Deep Dive into Smart Contracts’ (*Medium* 2017) <https://medium.com/@abhibvp003/smart-contracts-on-the-blockchain-a-deep-dive-in-to-smart-contracts-9616ad26428c>, accessed November 2019.

<sup>88</sup> C Frison et al, ‘Blockchain Technology for IP Management & Governance: Exploring Its Potential to Restore Trust and Resilience in the Plant and Biomedical Sectors’ (Modern Intellectual Property Governance and Openness in Europe: A Long and Winding Road?), 2018, Abstract. See also Clark 2018 (*supra* n 82).

<sup>89</sup> Directive 2016/943 on the Protection of Undisclosed Know-How and Business Information (Trade Secrets) against Their Unlawful Acquisition, Use and Disclosure [2016] OJ L OJ L 157/1; ‘How Can Blockchain and Trade Secrets Support Each Other?’ (*Mathias Avocats* 2017) <https://www.avocats-mathias.com/droit-des-affaires/blockchain-trade-secrets>, accessed November 2019.

<sup>90</sup> Rohden et al 2019 (*supra*, n 46), 47.

<sup>91</sup> *Ibid*, 50.

<sup>92</sup> *Ibid*, 50.

<sup>93</sup> *Ibid*, 50

<sup>94</sup> *Ibid*.

for users to stay within the blockchain could be overcome. The second risk is that introduction of a new system that is not necessarily compatible with existing infrastructures (notably INSDC) may lead to (further) fragmentation of efforts, and increase user costs, with a knock-on effect for innovation and scientific collaboration. Furthermore, many users of DSI are in the Global South, and so this would need to be borne in mind when considering any proposals that add to the cost of use. As has already been noted in the context of a monitoring and tracking study conducted ten years ago, it is not the theoretical and technical feasibility of a system that often determines its success, but such a system must also be socially tested to ensure that the needs of users are met, in order to effectively promote widespread application.<sup>95</sup>

Lastly, it must be noted that legal complexities may also be associated with the use of blockchain technology, related to potential issues of compliance with the EU's General Data Protection Regulation (GDPR) for a network that is publicly accessible,<sup>96</sup> and challenges of determining applicable law and jurisdiction as blockchain is detached from any centralised authority.<sup>97</sup>

d) Moving beyond track-and-trace

It follows from the above that as a track-and-trace system, blockchain is unlikely to be the preferred option. Indeed, as discussed above, opportunities have been identified to further develop existing structures like tracking under the INSDC, by creating better linkages with the original genetic resource and improve traceability of the country of origin, as well as create a new metadata field to include information on the internationally-recognised certificate of compliance (IRCC).<sup>98</sup> In light of the cost effectiveness and high user acceptance of reliance on existing, widely used structures, improvement of such structures is likely to be preferable. Nonetheless, such an improved track-and-trace system still does not address the significant problems of valuation of monetary benefits (*option 2 above*) of the current bilateral system that relies on the negotiation of MATs. It is therefore **not a recommended option**.

Within the proposed hybrid approach we set out in *options 6 below* and *7 below*, the practical value of improved tracking-and-tracing for the operation of a multilateral platform is limited, and will therefore not be the focus of the recommendations under this study. Nonetheless, efforts to improve the general interoperability of systems related to DSI should be encouraged, and as we explore in *option 6 below*, inspiration can be taken from the Global Information System (GLIS) under the ITPGRFA.

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<sup>95</sup> G M Garrity et al, *Studies on Monitoring and Tracking Genetic Resources* (Secretariat to the Convention on Biological Diversity, 2009). Similarly, also Desmeth 2017 (*supra*, n 52), 211: "The misperception of the situation by the lawmakers and inappropriate expertise input during and around the negotiations led to inappropriate solutions that are seen as not relevant and thus rejected because not credible by actors in the field."

<sup>96</sup> T Lyons et al, *Blockchain and the GDPR* (The European Union Blockchain Observatory and Forum, 2018);

<sup>97</sup> Frison et al 2018 (*supra*, n 88); J Mckinlay et al, 'Blockchain: Background, Challenges and Legal Issues' (*DLA Piper Publications* 2018) <https://www.dlapiper.com/en/denmark/insights/publications/2017/06/blockchain-background-challenges-legal-issues/>, accessed November 2019.

<sup>98</sup> Rohden et al 2019 (*supra*, n 46), 53.

It is, lastly, important to note that the recommendations in this study focus on DSI in public databases, like the INDSC. Questions related to DSI from private databases, which is a niche, although significant, area, would need to be studied in their own right.

#### **Option 4: A *sui generis* system inspired by copyright**

Following on from the above discussion, it is clear that the search for ways forward in respect of DSI may need to include other domains of law. In this regard, intellectual property has frequently been raised as having possible relevance to the protection of genetic resources as well as traditional knowledge associated with genetic resources. The relevance of IP law can be indirect, however: and we explore here whether IP law has already addressed similar issues that are faced under the CBD and the Nagoya Protocol with reference to DSI and therefore whether certain legal solutions and lessons learnt can be explored as a source of inspiration under the CBD and Nagoya Protocol. In other words, we are not exploring the *applicability* of IP law to DSI, which would raise questions about pre-empting negotiations under the World Intellectual Property Organization. What we are exploring here is what international biodiversity law *can learn from* IP law in dealing with comparable challenges, with a view to devising an *ad hoc* approach under the CBD and/or the Nagoya Protocol. Such an approach would not be grounded in IP law as such, but draw on useful approaches and tested solutions that have been found in that domain. Notably, **copyright law has evolved into a carefully nuanced system that contains specific solutions potentially capable of responding to the need of different users along a complex value chain that could be compared to that for DSI.** On that basis, we discuss how the tested approaches developed for copyright can be adapted to the context of DSI with a view to 1) recognizing and rewarding the contribution of States that conserve biodiversity on the basis of which DSI is generated; and 2) recognizing more equitably the contributions of researchers in the Global South to the conservation of biodiversity in their own countries and responding to their needs to collaborate with other innovators along the DSI value chain.

Accordingly, in this section we explore the application of solutions inspired by copyright to examine whether a *sui generis* system of protection could act as a possible way forward to address the above-noted concerns surrounding DSI. In doing so, we explore a number of possible options for such a *sui generis* system of protection. We conclude that a number of practical issues might preclude the adoption of a *sui generis* regime based on copyright in and of itself. But there is scope to **infuse elements of a *sui generis* system based on copyright as part of a broader hybrid approach to DSI**, explored more fully in **option 7**.

##### a) Copyright in broad terms

It is important to note at the outset that while it is not incorrect to refer to international copyright law, it is nevertheless the case that there is no ‘international’ copyright right.<sup>99</sup> Accordingly, while numerous treaties exist providing recognition of and protection to copyright,<sup>100</sup> such rights are protected under the domestic laws of countries.<sup>101</sup> Accordingly, copyright law has

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<sup>99</sup> See discussion in B Bodo et al, 'Blockchain and smart contracts: the missing link in copyright licensing?' (2018) 26 International Journal of Law and Information Technology 311, 320.

<sup>100</sup> E.g. Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Paris on July 24, 1971 and amended in 1979.

<sup>101</sup> Bodo 2018 (*supra*, n 99). Such protection is bolstered by the requirements of the World Trade Organisation, General Agreement on Trade-Related Aspects of Intellectual Property, 1869 U.N.T.S. 299 33 I.L.M. 1197.

not been fully harmonised, either at the international level, or within the EU,<sup>102</sup> although the Berne Convention, for example, does set down some general principles applicable to copyright law. Copyright protected works must be original. ‘Ideas’ are not protected by copyright;<sup>103</sup> rather, it is the expression of an idea that is the subject of protection. The minimum term of protection accorded by copyright is the author’s life plus 50 years, or 50 years if the author is not a natural person. Many countries, including those of the EU, have periods in excess of this minimum.

b) DSI and copyright – understanding the context

Discussions on the potential application of copyright to genetic sequences have been ongoing for over 30 years.<sup>104</sup> To the extent that proponents of copyright protection for genetic sequences anticipate important benefits to innovation from the application of such protection, copyright is depicted as having many advantages over other forms of intellectual property protection such as patents.<sup>105</sup> As will be explored more fully below, the monopoly right granted to patent holders may prevent follow-on innovation in respect of a genetic resource and thereby inhibit scientific research and development. In addition, recent court decisions have created significant uncertainty as to the legal protection provided by patent law to certain genetic resources.<sup>106</sup> By contrast, and as will be discussed below, copyright offers a range of exceptions and provides greater scope for follow-on innovation than is the case with patent protection. A *sui generis* system inspired by copyright could potentially draw inspiration from such protections, as well as the more nuanced approach offered by copyright so as to better be able to reflect the different societal and policy needs at the heart of the DSI debate.<sup>107</sup>

If concern for DSI reflects the so-called ‘dematerialisation’<sup>108</sup> of genetic information, the potential application of copyright to DSI is a mark of the so-called ‘new’ materialist movement which seeks to highlight the, “the qualities and characteristics originating from non-human actors’ such that, ‘the scope of original expression beyond that which originates with a human contributor, might result in an expanded incidence of authorship.’”<sup>109</sup> In essence, by focusing upon the agency of non-human actors, “the human contributor might be considered more of a

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<sup>102</sup> Though there are elements of harmonisation within the EU i.e. the Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society [2001] OJ L167/10.

<sup>103</sup> Though ideas may attract patent protection.

<sup>104</sup> See, for example, D L Burk, ‘Copyrightability of Recombinant DNA Sequences’ (1988 to 1989) 29 *Jurimetrics Journal* 469 and I Kayton, ‘Copyright in Living Genetically Engineered Works’ (1982) *George Washington Law Review* 191.

<sup>105</sup> See, for example, discussion in N Lucchi ‘Genetic Copyright: An Alternative Method for Protecting and Using Essential Public Knowledge Assets?’ (2018) 40 *European Intellectual Property Review* 766.

<sup>106</sup> *Ibid.*

<sup>107</sup> *Ibid.*

<sup>108</sup> See, for example, M A Bagley, ‘De-materialising genetic resources: synthetic biology, intellectual property and the ABS bypass’ in Charles R. McManis and Burton Ong (eds), *Routledge Handbook of Biodiversity and the Law* (Routledge, 2017), Chapter 15.

<sup>109</sup> Burk, Dan L., ‘Copyright and the new materialism’ in Jessica C. Lai and Antoinette Maget Dominice (eds), *Intellectual Property and Access to Im/material Goods* (Edward Elgar, 2016), Chapter 2, 61.



curator or steward for the assemblage of actors who contributed to the creative result”<sup>110</sup> which copyright could protect. Here, the ‘creative result’ would be the genetic outputs of nature.

c) Reimagining copyright protection?

To date copyright protection has *not* in general been extended to DSI.<sup>111</sup> Numerous commentators have nevertheless posited that copyright is indeed flexible enough to “handle contemporary technologies that produce living organisms or organic components, but contemporary judges, practitioners, and scholars must reframe and, in some instances, reimagine the proper contours of copyrightability in order to bring living works under copyright protection.”<sup>112</sup> Numerous commentators, however, have in general rejected the notion that copyright protection could apply to naturally occurring DNA sequences.<sup>113</sup>

Some commentators have expressed concern that copyright – and arguably by extension, a *sui generis* system based on copyright - is a ‘poor fit for synthetic biology’ as there is little scope for an author’s expressive choices.<sup>114</sup> In essence, if the central premise of copyright is protection of originality, what scope would there be for originality of expression in respect of the generation of DSI from naturally occurring sequences? Holman, for example, argues that copyright protection for DSI will likely depend upon the element of creativity present in a sequence. By extension, in his view, any extension of copyright protection to what he terms ‘genetic code’ would need to be justified on public policy grounds. For Holman, optimal innovation policy, “would likely impose some sort of requirement that, in order to be copyrightable, a synthetic sequence must incorporate some significant degree of variation relative to the closest naturally-occurring counterpart.”<sup>115</sup>

However, Holman’s view of public policy does not include considerations of the objectives of the CBD or the Nagoya Protocol, which could undergird policy arguments *in favour* of the creation of a *sui generis* regime inspired by copyright law to provide protection for naturally occurring genetic sequences. Such a scheme would reflect the objectives of the CBD with a view to rewarding provider countries for their contribution to biodiversity. Broad acceptance of the need to prioritize these public policy objectives can be justified on the basis of the alarming findings on the unprecedented rate of biodiversity loss and its wide-ranging

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<sup>110</sup> Ibid, 61

<sup>111</sup> Though this is not to say that companies have not tried to assert copyright over DSI; our thanks to Paul Oldham for this insight.

<sup>112</sup> M D Murray, 'Post-Myriad Genetics Copyright of Synthetic Biology and Living Media' (2014) 10(1) Oklahoma Journal of Law and Technology 1, 8. It is notable that copyright has been ‘reframed’ over the years to extend protection to software which has been analogised to genetic ‘code’ by certain commentators such as R Neethu. 'Rethinking the debate on genetic copyright in Europe in the era of biobanks and synthetic biology' (2018) 40 (3) European Intellectual Property Review 172. See also A Torrance, 'DNA Copyright' (2011) 46 Valapraiso University Law Review 1; A Torrance and L Kahl, 'Bringing Standards to Life: Synthetic Biology Standards and Intellectual Property' (2013) 30 Santa Clara High Technology Law Journal 199, pp. 226-227 and Rai and Boyle 2007 (*supra*, n 10).

<sup>113</sup> See, for example, Murray, *ibid*.

<sup>114</sup> Bagley 2017 (*supra*, n 108).

<sup>115</sup> C Holman, 'Charting the Contours of a Copyright Regime Optimized for Engineered Genetic Code' (2016) available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2833948](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2833948), accessed December 2019, 21.

implications for human well-being in the 2019 Global Assessment of Biodiversity and Ecosystems Services.

d) A *sui generis* system inspired by copyright: the example of annotation?

In the previous section, concerns were raised regarding the potential need for originality in any *sui generis* system for DSI inspired by copyright. While it is possible this requirement could be abandoned under a *sui generis* system, it is worth considering whether there are already potential mechanisms under the existing copyright systems which could address this requirement, so the link with copyright is more pronounced. For instance, some commentators such as Zhuang have posited that such originality may arise from annotation. In essence, Zhuang opines that, “the major challenge of 21<sup>st</sup> century genetics is annotating and understanding genes’ functions and structures, rather than determining their DNA sequence.”<sup>116</sup> For example, proteomics experiments produce large quantities of data which require to be interpreted so as to ascertain the relevance from a biological standpoint of any identified proteins.<sup>117</sup> Functional annotation of proteins is hence as significant as the identification of the protein itself.<sup>118</sup> Accordingly, it is the ‘informational annotation’ of a sequence which is of value<sup>119</sup> with such annotation reflecting the geneticist’s expressive choices.<sup>120</sup> Hence according to Zhuang, “when describing a gene, a geneticist selects and arranges from (a) vocabulary an expression that forms a genetic copyright.”<sup>121</sup> This arrangement and the expressive choices involved therein would seemingly fulfil the requirements of originality under copyright law. An agreed vocabulary would also help to facilitate the implementation of a genetic copyright regime with such copyrights then requiring registration to assist in enforcement.<sup>122</sup> In line with the usual application of copyright law, independent creation of an identical annotation would not result in infringement. Numerous exceptions also exist under copyright to provide for a balance between protection and use.<sup>123</sup>

The regime envisaged by Zhuang would also allow others to use the underlying gene since what is protected is the expression; that is, the annotations of the gene can be the subject of copyright protection, not the underlying ‘idea’ behind that expression which in essence is the gene itself.<sup>124</sup> This would allow ‘improvements’ to be made to the ‘idea’, in contrast to the patent regime which does not permit follow-on improvements to patented inventions.<sup>125</sup> A regime inspired by copyright could therefore potentially safeguard, recognize and encourage follow-on innovation, thereby ensuring a better balance in terms of societal interests. However, it is also the case that such a regime might favour researchers and companies who do the bulk

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<sup>116</sup> J J Zhuang, ‘Copyright: Better Fitting Genes’ (2015) 97(3) Journal of the Patent and Trademark Office Society 442.

<sup>117</sup> C M Carnielli et al, ‘Functional annotations and biological interpretations of proteomics data’ (2015) 1854 Biochimica et Biophysica Acta 46.

<sup>118</sup> Ibid.

<sup>119</sup> Zhuang 2015 (*supra*, n 116) 449.

<sup>120</sup> Ibid, 450.

<sup>121</sup> Ibid, 450.

<sup>122</sup> Ibid, 452.

<sup>123</sup> Ibid, 456 – 457.

<sup>124</sup> Ibid, 458.

<sup>125</sup> Ibid, 458 – 459.

of annotation. To the extent that it may be said there is a technological divide between the Global South and the developed world, this could lead to inequitable results.

Ultimately, Zhuang's proposed genetic copyright system which would protect highly annotated sequences has a certain merit. But it would not directly address the claims of provider countries in respect of DSI generated from genetic resources in their territory, since the 'idea' – that is, the 'raw'<sup>126</sup> as opposed to 'curated'<sup>127</sup> genetic information itself – would not be protected. In essence, it is the 'creative effort' that would be rewarded, not the rights of provider countries. Nevertheless, this proposal demonstrates the potential merit of relying on existing approaches from copyright to respond to particular issues in the context of DSI.

(e) A *sui generis* system of protection based on the rights of provider countries?

The application of a regime inspired by copyright to DSI could potentially provide further legal recognition of the sovereignty claims of 'provider' countries over such information, allowing a degree of control as well as monetary benefit-sharing in the form of royalties from licensing. The idea here would be that countries of origin of genetic resources would hold rights similar to copyright over DSI for a certain period of time under a *sui generis* system of protection inspired by copyright. *Sui generis* systems of intellectual property rights protection are not unusual and have been implemented in instances under which existing systems of rights protection were not able to address adequately particular sectoral needs.<sup>128</sup> Examples include *sui generis* database protection,<sup>129</sup> as well as a *sui generis* system of plant variety protection specifically envisaged under Article 27.3(b) of the WTO TRIPS Agreement although these systems are designed to protect the rights of individuals, per se, as opposed to the rights of States.

In respect of the application of a *sui generis* system inspired by copyright to provide legal recognition of the claims of 'provider' countries, a major concern arises regarding the need to address the complexity of 'shared' sequences for which there may not be a single 'provider' country. In essence, and as discussed above, where sequences are shared between countries, the idea of a 'provider' country becomes more problematic, particularly in the context of a regime drawing inspiration from intellectual property. In essence, questions of valuation (discussed above) would abound under such a system and it is difficult to see how these would be overcome. In addition, issues of tracking would inevitably arise. While watermarking of sequences could in principle allow for tracing,<sup>130</sup> and likely satisfy the requirement of original

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<sup>126</sup> Laird and Wynberg 2018 (*supra*, n 5).

<sup>127</sup> Laird and Wynberg 2018 (*supra*, n 5).

<sup>128</sup> Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Elements of a Sui Generis System for the Protection of Traditional Knowledge* (WIPO/GRTKF/IC/3/8, 2002)> accessed December 2019. See also discussion in A Chander and M Sunder, 'The Romance of the Public Domain' (2004) 92 (5) California Law Review 1331, 1355.

<sup>129</sup> See e.g. Directive 96/9/EC on the legal protection of databases [1996] OJ L 77/20.

<sup>130</sup> For further analysis, see N Yamamoto et al, 'A watermarking system for labeling genomic DNA' (2014) 31 *Plant Biotechnology* 241, [https://www.jstage.jst.go.jp/article/plantbiotechnology/advpub/0/advpub\\_14.0609b/article/-char/ja/](https://www.jstage.jst.go.jp/article/plantbiotechnology/advpub/0/advpub_14.0609b/article/-char/ja/), accessed October 2019.

expression such as to attract protection (assuming the requirement for originality is retained), in practice it would not be cost-effective to watermark large amounts of DNA.<sup>131</sup> In addition, such watermarks can be subject to degradation through naturally occurring mutation and at this point in time are not considered a viable or realistic option.<sup>132</sup>

A separate concern arises from the fact that a *sui generis* system based on copyright to recognise and reward provider States would also need to respond to the different needs of groups of *users* of DSI, particularly given that many databases containing DSI are in the ‘true’ public domain<sup>133</sup> with any subsequent restrictions such as costs imposed on such information risking a potential impact on biotechnological innovation in areas such as health, agriculture and biodiversity conservation itself.<sup>134</sup> As James Boyle has opined, “enclosure of the information commons clearly has the potential to harm innovation as well as to support it.”<sup>135</sup> Indeed, it is to be noted that the scientific and legal communities have long expressed concern regarding the potential negative impact of IP rights on innovation. Numerous efforts have therefore been made to innovate around ‘patent thickets’ that seemingly privilege large companies and may lock out individual researchers and small companies - including those in the Global South.<sup>136</sup> So a proposed *sui generis* system should take into account the lessons learnt about actual and potential negative impacts on innovation, including unequal impacts on researchers in the Global South, particularly when they are contributing to biodiversity conservation.

f) A broader system encompassing the range of actors along the DSI value chain?

Taking into account the preceding discussion, there may be merit in exploring the creation of a *sui generis* system of copyright-like protection for DSI which is capable of responding to the variety of needs, and recognizing the various contribution, of different actors all along the DSI value chain: recognition of the ‘provider country’ for its contribution to conservation of biodiversity – while noting the complexity of sequences ‘shared’ between countries - the scientist who assembled the sequence, who annotated it, who genotyped, who aggregated the data as well as potentially the database manager,<sup>137</sup> thereby providing a system that can be responsive to the different ‘creators’ of DSI. Such a system could draw on the operation of the bundle of rights applicable to the musical context.

This context is particularly relevant since it gives explicit recognition to the contribution of the different actors involved in music production with the copyright which affixes to the

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<sup>131</sup> M A Bagley, *Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology* (Wilson Centre, 2016), 12.

<sup>132</sup> Ibid.

<sup>133</sup> Laird and Wynberg 2018 (*supra*, n 5), 45. This is to be contrasted with an open source approach whereby conditions may be attached to the use of such information.

<sup>134</sup> See generally Laird and Wynberg 2018 (*supra*, n 5) on the use of DSI.

<sup>135</sup> J Boyle, ‘The Second Enclosure Movement and the Construction of the Public Domain, in James Boyle (ed), *Collected Papers: Duke Conference on the Public Domain* (Center for the Public Domain, 2003) 33, at 44.

<sup>136</sup> See generally Jerome H Reichman and Ruth L Okedji, ‘When Copyright Law and Science Collide: Empowering Digitally Integrated Research Methods on a Global Scale’ (2012) 96 *Minnesota Law Review* 1362.

<sup>137</sup> Albeit that the database may itself enjoy intellectual property protection already; see e.g. Directive 96/9/EC on the legal protection of databases [1996] OJ L 77/20

composition of a piece of music, for example, distinct to the sound recording copyright which typically resides with the production company. Performances of musical works can also attract performance rights protection, with such performance rights existing in addition to any underlying right(s) in the musical piece itself.<sup>138</sup> Accordingly, a range of models could potentially be analogised from, in order to design a *sui generis* system of copyright-like protection for genetic resources capable of taking into account the contribution of different actors along the DSI value chain. This seems particularly promising with a view to **addressing equity issues for researchers in the Global South and recognizing their contributions to biodiversity conservation**. Copyright may in effect be considered more suited than other forms of intellectual property protection such as patents to provide a nuanced approach to protection in that numerous exceptions exist to copyright which would arguably allow for a variety of uses of protected sequences- such as for use in instruction and non-commercial research,<sup>139</sup> which contribute to biodiversity conservation. Furthermore, consideration could be given to disaggregating the copyright inspired bundle to address *different kinds* of DSI, with sectoral approaches also possible.

It must, however, be acknowledged that the large number of actors involved in DSI ‘creation’ would require more in-depth study of how best to operationalise such a scheme without it becoming so complex that the costs of its operationalisation outweigh the benefits. In addition, the impact of any new system, particularly upon innovation globally (and the need to foster cooperation in innovation along the DSI value chain across Global North/South), needs carefully considered. One particular concern that might arise is the very long period of protection normally applicable to copyright although a *sui generis* system of copyright-like protection could arguably deviate from this long period of protection since<sup>140</sup> it could be designed to fall outside the scope of existing copyright treaties.<sup>141</sup> There may also be a benefit to exploring other approaches to managing the relationship between providers/‘creators’ and different types of users such as that encompassed within the open software movement, which is underpinned by the impetus to promote both the “freedom to operate and freedom to cooperate.”<sup>142</sup>

On the whole, there is much potential for the above-described system, which focuses on the potential for a layered, *sui generis* approach to DSI inspired by copyright that recognises the range of ‘creators’ involved in the ‘production’ of DSI. Much more analysis and discussion, however, is needed to make sure that such a system effectively and fairly addresses the concerns of Parties regarding the role of DSI in achieving the objectives of the CBD and possibly also recognising Parties’ and Global South researchers’ contributions to biodiversity conservation. Accordingly, this is **not be an approach that we would recommend on its own,**

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<sup>138</sup> T Iverson, ‘Original compilations of musical works: can DJ sets be protected by copyright?’ in Enrico Bonadio and Nicola Lucchi (eds), *Non-conventional copyright* (Edward Elgar, 2018) 201, 211

<sup>139</sup> Welch 2017 (*supra*, n 18), 22 - citing Torrance 2011 (*supra*, n 109).

<sup>140</sup> Holman 2016 (*supra*, n 115), 30 to 31.

<sup>141</sup> It would also arguably fall outside the scope of the TRIPS Agreement.

<sup>142</sup> Laird and Wynberg 2018 (*supra*, n 5), 37, though see generally 36-38 on open software.

**but could be part of a hybrid system (option 7)** as the proposed dialogue platform (option 6) could provide a forum to assess options in a generative and iterative manner.

g) Operationalisation

Regardless of the scope of a copyright-inspired *sui generis* system for DSI, that is, whether it solely focuses on Parties' contribution to DSI, or takes a more layered approach, in order to function effectively, any such regime would need to be accompanied by some sort of licensing system to ensure a degree of control over the sequence(s) as well as payment of royalties. As described in *option 3 above*, blockchain, together with smart contracts, could be utilised here to ensure a 'quasi-immutable' record of initial ownership<sup>143</sup> together with speedy and efficient licensing arrangements. This would, in effect, allow for a 'private ordering' of copyright.<sup>144</sup> However, as discussed previously, a blockchain based system may in practice prove difficult to operationalise due to the lack of incentives for users not to remove information from the blockchain.<sup>145</sup> However, the advantage of a copyright-like system is that incidences of 'cheating' may be subject to the remedies for infringement available under copyright law such as monetary and equitable relief.

As a way to overcome the above identified problem, suggestions have been made to draw on the so-called *platform economy* and develop a Netflix or Spotify-type bundle for DSI which could be supported by subscription fees.<sup>146</sup> In essence, this model would support highly curated and/or annotated DSI, for which users would pay subscription fees to access. This 'club type' model has been proposed by Correa in respect of access to plant genetic resources for food and agriculture ('PGRFA') in the Multilateral System ('MLS') with those accessing the system paying an annual fee corresponding to, for instance, 0.2% of their annual seed sales of species in the MLS.<sup>147</sup> A subscription system for access to DSI could potentially see the fees redistributed to States as rights holders as a type of monetary benefit-sharing for access to such resources though, as noted above, the bulk of country-tagged NSD deposits to the INSDC are from 4 countries – USA, China, Canada, and Japan which together account for more than 50% of country-tagged NSD.<sup>148</sup> Accordingly, it is not altogether certain that monetary benefit-sharing to 'rights' holders in this context would benefit mega-diverse countries. In addition, such a system, if applied to the broad range of DSI within scope, would be well beyond the realms of financial feasibility as it would require a vast range of bioinformatics tools in order to have any value to users, and would need to be a closed system (otherwise, why pay?), raising costs further.<sup>149</sup> Concerns might also arise as to how to distinguish between different categories of users such as students, researchers from the Global South, as well as non-commercial users

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<sup>143</sup> See discussion in Bodo 2018 (*supra*, n 99).

<sup>144</sup> *Ibid.*

<sup>145</sup> See *option 3 above*.

<sup>146</sup> Rohden et al 2019 (*supra*, n 46), 51.

<sup>147</sup> C M Correa, 'ITPGRFA: Options to Promote the Wider Application of Article 6.11 of the SMTA and to Enhance Benefit-Sharing Legal Opinion' (*Berne Declaration*, 2013) [https://www.utviklingsfondet.no/files/uf/documents/ITPGRFA\\_Legal\\_opinion\\_2013.pdf](https://www.utviklingsfondet.no/files/uf/documents/ITPGRFA_Legal_opinion_2013.pdf), accessed October 2019.

<sup>148</sup> Rohden et al 2019 (*supra*, n 46).

<sup>149</sup> Rohden et al 2019 (*supra*, n 46), 51.

more general – so consideration needs to be given to how this approach would effectively support biodiversity conservation.

Other potential options include requiring users to agree to specific licensing conditions – including, where relevant, payment of remuneration – upon access to certain databases. Sectoral/tailored approaches could be utilised here to ensure fine-tuning of agreements in accordance with the type of DSI/sector. Licenses could, for example, be designed to reflect the class of user with different licenses, for example, applying to commercial and non-commercial use.<sup>150</sup>

In respect of the above, conditions of use notices and click-through agreements requiring users to confirm agreement to certain conditions when accessing DSI via specific databases are not uncommon, but it is unclear to what extent such conditions are adhered to.<sup>151</sup> While there may be ways to ensure greater attention of, and adherence to, the likes of click-through agreements,<sup>152</sup> these would need to be accompanied by traceability mechanisms (see *option 3 above*) to reduce incentives to cheat, as well as ensure payment of royalties. Inserting licenses at the point of access to a database would also require significant interaction between rights holders and databases for such a system to function effectively and there would need to be greater *interoperability* between databases. States as rights holders could, however, be represented collectively so as to reduce associated transaction costs. Inspiration could be drawn here from the private sector with organisations such as Broadcast Music Inc. (BMI) and the American Society of Composers, Authors and Publishers (ASCAP) which currently offer rights management services in the music domain.<sup>153</sup> As outlined above, however, these would not remove the need for enhanced systems of traceability to ensure licensing conditions are adhered to. It is also an open question to what extent publicly available databases such as those under the INSDC would be willing to include licensing conditions for database access with anecdotal evidence suggesting that this idea would not be popular. In addition, the INSDC is publicly financed by the US, EU and Japan and so it is not altogether clear to what extent adding another layer of costly complexity to the system would be supported without defined and demonstrable benefits being established in advance. Without further in-depth study into the costs and benefits of such a system, it is difficult to make a more definitive assessment.

#### h) States' rights under a *domaine public payant* model

Another possibility to protect States' rights in a copyright-like approach is to draw inspiration from the concept of *domaine public payant*, which has already been explored in the context of cultural heritage. In essence, “this principle applies to works that have lost copyright protection and are in the public domain but for some reason are deemed important enough to receive special attention that is expressed in the obligation to pay the state ... a fee for the use of these

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**There are no sources in the current document.**<sup>150</sup> For an insightful commentary on different licensing arrangements, see P Oldham, ‘An Access and Benefit-Sharing Commons? The Role of Commons/Open Source Licenses in the International Regime on Access to Genetic Resources and Benefit Sharing’ (*Secretariat to the CBD*, 2009) UNEP/CBD/WG-ABS/8/INF/3. See also Laird and Wynberg 2018 (*supra*, n 5).

<sup>151</sup> Laird and Wynberg 2018 (*supra*, n 5), 36.

<sup>152</sup> *Ibid.*

<sup>153</sup> Holman 2016 (*supra*, n 115), 32.

works, crafts and arts.”<sup>154</sup> The *domaine public payant*, or the “paying public domain” aims to ameliorate the “harm caused by creating property rights over the common (cultural) pool from which society draws, but at the same time, it imposes certain conditions on the use of works in the public domain ... (such as) the payment of fees.”<sup>155</sup> Applied to the DSI domain, what we term the *digital domaine public payant*, would recognise that DSI should not be treated as a freely exploitable resource,<sup>156</sup> but rather regulated as a semi-commons underpinned by the principle that a fee should be paid in recognition of provider countries’ contribution to biodiversity and in order to support the objectives of the CBD.<sup>157</sup> This logic is based on a combined and integrated reading of the objectives of the CBD and the global recognition of their relevance for the realization of the SDGs, so the criteria for selecting which material is subject to payment is related to the CBD subject matter and global public policy objectives that depended on the effective implementation of the CBD.<sup>158</sup> The *digital domaine public payant* could be *multilateralised* with funds disbursed in accordance with CBD objectives, so as to remove the issues with tracking and tracing as well as valuation identified above as problematic (see *option 7* below). The potential for a multilateral approach is outlined in *option 5* below.

Examples of the *domaine public payant* in the cultural heritage sector can be found at national level, which reveal some operational matters that need to be considered, should the approach be extended to other contexts. Firstly, the *domaine public payant* applies to literary or artistic works which are no longer copyright-protected but available in the public domain, with payment due upon use rather than access, by major users rather than individuals such as publishers, impresarios, record manufacturers, radio and television networks.<sup>159</sup> Secondly, an analysis conducted by WIPO in the 1980s, showed that some countries which apply the *domaine public payant* required authorisation prior to use, or at least a declaration of use, but international experts concluded that this was not a desirable approach in light of the inhibiting effect on access.<sup>160</sup> Furthermore, structural questions arise with regard to the authority that is competent to collect and distribute fees, and the beneficiaries and types of funding provided.<sup>161</sup> In Argentina, for example, payments received under the *domaine public payant* legislation is

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<sup>154</sup> M Ruiz Muller. 'Protecting Shared Traditional Knowledge: Issues, Challenges and Options' (2013) ICTSD Issue Paper No. 39, 14.

<sup>155</sup> L Lixinski, *Intangible Cultural Heritage in International Law* (Oxford University Press, 2013) 199. On the *domaine public payant*, see also D J Gervais, 'The Internationalization of Intellectual Property: New Challenges from the Very Old and the Very New' (2002) 12(3) *Fordham Intellectual Property, Media & Entertainment Law Journal* 931, Giblin, R., 'Reimagining copyright's duration' in Rebecca Giblin and Kimberlee Weatherall (eds), *What if we could reimagine copyright?* (ANU, 2017) chapter 6, D F Robinson, 'Is the Whole Greater than the Sum of its Parts: A critical reflection on the WIPO IGC' in Charles R. McManis and Burton Ong (eds), *Routledge Handbook of Biodiversity and the Law* (Routledge, 2017) chapter 23, C Mouchet, 'Problems of the *Domaine Public Payant*' (1983) 8 *Columbia Journal of Art and Law* 137 and A Dietz, 'A Modern concept for the right of the community of authors (*domaine public payant*)' (1990) XXIV *Copyright Bulletin* 4. A useful overview is provided in WIPO, *Scoping Study on Copyright and Related Rights and the Public Domain* (2010) CDIP/4/3/REV./STUDY/INF/1.

<sup>156</sup> On a broader level, see J L Contreras, 'Data Sharing, Latency Variables and the Science Commons' (2010) 25 *Berkeley Technology Law Journal* 1601.

<sup>157</sup> See generally Lixinski 2013 (*supra* n 155), 203. See also Ruiz Muller 2013 (*supra*, n 154), 15.

<sup>158</sup> Ruiz Muller 2013 (*supra*, n 154) 14.

<sup>159</sup> Mouchet (*supra*, n 155).

<sup>160</sup> WIPO-Berne Union, 'The "Domaine Public Payant"' (*Copyright*, 1982), available at < [https://www.wipo.int/edocs/pubdocs/en/copyright/120/wipo\\_pub\\_120\\_1982\\_06.pdf](https://www.wipo.int/edocs/pubdocs/en/copyright/120/wipo_pub_120_1982_06.pdf)> accessed March 2020.

<sup>161</sup> *Ibid*, p 182.



the only source of income for the Fondo Nacional de las Artes and uses it to provide loans to authors and artists, finance exhibitions and awards or fellowships.<sup>162</sup> Other operational aspects that have been considered at international level and within legal scholarship concern the types of works that are covered, temporal and geographical scope and the method to calculate fees, with discussed options varying from lump-sum payments to proportional revenue levies.<sup>163</sup> Such considerations would also very much apply in the DSI context; most particularly in respect of the questions of how (and arguably when?) should fees be paid and who should disburse funds and to whom and indeed, for which purposes. We return to these issues in our discussion in *option 7 (below)*.

While more in-depth study is needed to understand the opportunities to that arise from adoption of a multilateralised *digital domaine public payant* approach to monetary benefit-sharing for DSI, its value for moving the current debate towards multilateral solutions is that it can take into account both the practical challenge that sequences may be common to a number of countries and the principled issue of ensuring realization of the CBD objectives and contribute to multiple SDGs is significant. As we discuss below, such an approach would be best accompanied by a forum for dialogue and learning – what we term the hybrid approach set out in option 7 - and so we explore further in option 7 possible options for operationalisation of the *digital domaine public payant*.

To sum up, a *sui generis* regime inspired by copyright could potentially have a number of attractive features such as, 1) recognizing and rewarding the contribution of States that conserve biodiversity on the basis of which DSI is generated; and 2) recognizing more equitably the contributions of researchers in the Global South to the conservation of biodiversity in their own countries and responding to their needs to collaborate with other innovators along the DSI value chain. But it would likely encounter practical problems in its operation, including those relating to practicality and cost. Licensing of such a system would require considerable engagement with database managers and greater interoperability between databases. Issues with tracking and tracing would also need to be resolved before such a regime could be entered into and the problems of valuation of monetary benefits outlined in *option 3 above* also remain. Indeed, the problem of valuation seems to militate against any system for DSI based upon a bilateral logic. Concerns also surround the likely costs and benefits of introducing such a complex system. In addition, it would be necessary to assess to what extent a *sui generis* copyright-like regime may create equity issues for innovators in the Global South and how it could be best contribute to biodiversity conservation. For these reasons, **a *sui generis* system of copyright-like protection might be best encompassed within a hybrid system** which moves away from the bilateral logic of exchange and instead takes a multilateral approach whereby payment is via a multilateralised *digital domaine public payant*, accompanied by a platform focused upon dialogue and learning in direct engagement with a wide range of stakeholders such as database operators, researchers, innovators and funders (see **option 7**). However, as noted above, before anything this complex is embarked upon, extensive

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<sup>162</sup> See notably the unpublished work by Maximimiliano Marzetti on this topic (e.g. PhD Dissertation - The Law and Economics of the ‘*Domaine Public Payant*’: A case-study of the Argentinian system).

<sup>163</sup> WIPO Report (*supra* n 160), pp 182-183.

studies of cost/benefit, as well as practicality, must be undertaken. As a preliminary step to this, however, we explore the potential benefits of a multilateral approach in the next option.

## Option 5: A multilateral fund

In our above discussion (*options 1 to 4*), we discussed possible options for accommodating DSI within a bilateral framework. However, we identified a number of practical issues arising from the application of such bilateralism. We also honed in on important issues of equity associated with DSI. In essence, if sequences may be common to a number of countries, would application to DSI of the current bilateral ABS approach support fairness and equity in benefit sharing or even work at all?<sup>164</sup> Accordingly, while blockchain technology, smart contracts and other mechanisms to monitor and track DSI are theoretically possible, and a copyright inspired system for DSI could build upon such mechanisms, they do not address issues of fairness and equity associated with the current bilateral ABS system.<sup>165</sup> We therefore need to scrutinise how a multilateral approach to monetary benefit-sharing could potentially deal with DSI under the CBD and Nagoya Protocol.

In this section we examine certain options for accruing monetary benefits generated from the use of DSI obtained from genetic resources into a multilateral fund for them to be subsequently distributed among Parties.<sup>166</sup> We examine a menu of options to multilateralize the sharing of benefits associated with DSI. It is likely that several of the options discussed here could be combined as part of a broader system or as part of a phased or stepwise approach to DSI.<sup>167</sup> Accordingly, the options discussed below should not be considered as mutually exclusive. They could also be useful as part of a sectoral approach to DSI and in certain instances, we draw on existing sectoral approaches for the purpose of inter-regime learning.

It should further be noted that while our focus here is on monetary benefit-sharing, it is also the case that there is something of a false dichotomy between monetary and non-monetary benefits, because non-monetary benefits have costs and economic value.<sup>168</sup> For instance, sharing raw data on marine genetic resources as an open access resource still requires the development of adequate infrastructure and curation; training has costs related to trainees' travel, precious space/resources on expensive scientific research vessels, trainers' time, and scholarships; and the sharing of best practices requires analysis and effective delivery of information. This is discussed further below (*option 6 below*).

After exploring the functionality of a variety of funding options based on the experience of existing multilateral funds, including those responsible for multilateral monetary benefit-sharing mechanisms (on the side of accruing benefits and that of distributing benefits), we move on to assess issues pertaining to governance and accountability which should be considered in respect of any multilateral benefit-sharing fund, providing an assessment based on the experience of existing multilateral monetary benefit-sharing mechanisms and funds.

Finally, we discuss a possible site of a multilateral fund, exploring the pros and cons of different arrangements. In this regard, we discuss three possible approaches (1) a multilateral approach

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<sup>164</sup> See discussion *above* under 'core assumptions and summary of findings'.

<sup>165</sup> See generally Ruiz Muller 2018 (*supra*, n 25), 11.

<sup>166</sup> Bagley 2016 (*supra*, n 131) 12.

<sup>167</sup> See discussion *below at option 7*.

<sup>168</sup> *Ibid*.

based on Article 10 of the Nagoya Protocol 2) a global fund for biodiversity under the CBD (and therefore centred under the UN system) and (3) a global fund for biodiversity outside of the existing ABS system. We conclude this section with a summary and develop a number of principles which should be considered in the development of such a fund and propose the CBD as the appropriate site of governance for such a fund, while recognising that a more thorough review and research process would be needed to understand the costs and benefits of a multilateral approach, whether under the CBD or elsewhere.

In addition, there are several lessons learnt in multilateral funds in other sectors that can be built upon in the context of DSI. For instance, disbursement of funds should be done in accordance with defined criteria agreed in advance with a range of applicable stakeholders, so that benefit-sharing effectively contributes to the holistic realization of the CBD objectives and relevant SDGs. In addition, careful consideration should be given to the design of governance structures to ensure equity and create opportunities for learning and iterative design to make sure that the fund really responds to beneficiaries' needs and evolving scientific practices.

On the whole, we **favour the establishment of a multilateral fund under the CBD (as part of a hybrid option, as explored in option 7)** because sustainability and predictability of funding is a precondition for well-functioning benefit-sharing mechanisms.

Before we move on to discuss our proposed multilateral approach to monetary benefit-sharing, an important caveat is in order. As set out above (*option 2 above*), the recommendations made in this study extend to DSI in public databases, with private databases likely to be governed by the Nagoya Protocol and mutually agreed terms. Accordingly, whereas public databases could ultimately be governed by the multilateral approach set out below, private databases would need to be governed by the Protocol. As discussed previously, DSI from public databases, would benefit for further study in this regard.

a) Funding – accrual of benefits

In establishing any new multilateral benefit-sharing arrangement, the resources required to operate such a mechanism should be both “sustainable and embedded in the system itself.”<sup>169</sup> While these costs will obviously differ depending upon the nature of the arrangement in question, our examination of potential funding options is underpinned in particular by a concern for financial sustainability. We are also cognisant of the risk that creating an additional multilateral fund for DSI/biodiversity more generally could result in competition with other environmental funds, as well as undermine other – non-monetary – benefits. We therefore take these concerns into account where relevant.

i. *A tax or levy*

We may draw inspiration from the literature on traditional knowledge (TK), in respect of which a number of proposals have been made to deal with shared and widely disseminated TK. An analogy may be made here with DSI. For TK, a small fixed fee imposed on certain products

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<sup>169</sup> Ruiz Muller 2013 (*supra*, n 154) fn 30.

such as biotrade products has been proposed with the idea that this could contribute to an international compensatory fund. This could then be used to fund projects aimed at conservation and sustainable use in certain areas of the world defined in advance.<sup>170</sup>

Based on the above, it is thus worth considering whether a tax or levy might be attractive to deal with DSI. In this regard, Winter has proposed a similar mechanism which he terms a ‘biodiversity charge.’<sup>171</sup> Under his proposed scheme, “any remuneration for the sales of a product, for a patent or breeder’s license or for the rendering of a service would be subject to the payment of a tax if the value-generating object or activity is based on genetic resources (or TK).”<sup>172</sup> This tax would be paid into a worldwide fund for further dissemination according to predefined criteria. Such a tax/fee could also cover material considered to be out of scope of the Nagoya Protocol (i.e. material accessed in all Parties, including those that have not legislated on access, derivatives, and any information generated from natural resources). Clearly, the scope of this proposal is broader than that envisaged above in that it applies to different economic sectors, not only the sale of goods and would apply to all products to which the ‘value-added’ is generated from a genetic resource (or TK). A further option would be to extend the tax/levy to include activities such as mining, logging, industrial agriculture, and oil exploration since these activities cause significant damage to biodiversity.

What is clear from the discussion of the option to impose a biodiversity tax is that considerable thought would need to go into the appropriate legal vehicle to implement such a charge on a multilateral basis so as to ensure fairness and equity. Regardless of the scope of such a tax, there would likely be a need to differentiate between countries, goods and in this case sectors in the application of such a tax/fee. A binding international treaty would arguably be the first best option to ensure compliance although of course such a tax would need to be established at the national level, which presents difficulties in terms of its operationalisation.

An additional issue which needs to be considered is that a general biodiversity or biotrade product tax, with expansive coverage beyond products derived from DSI, could be framed as marking a fundamental break in the bilateralism of the CBD/Nagoya regime for all genetic resources within scope – including physical samples - not just for DSI. On the one hand, some commentators have noted that this would be potentially beneficial,<sup>173</sup> and in one sense a move beyond the current ABS system is inevitable if one recognises genetic resources as often widely shared between jurisdictions. On the other hand, this would nevertheless require a fundamental shift in paradigm which would need to be very carefully considered. It is also the case that including material outwith the scope of the Nagoya Protocol may somewhat ameliorate this risk. Additionally, and as mentioned above, there is also the potential to include extractive

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<sup>170</sup> Ibid, p. 15.

<sup>171</sup> G Winter, ‘Knowledge commons, intellectual property and the ABS regime’ in Kamau; EC and Winter G (eds), *Common Pools of Genetic Resources Equity and Innovation in International Biodiversity Law* (Taylor & Francis 2013) 285, 298.

<sup>172</sup> Ibid.

<sup>173</sup> E C Kamau and G Winter, ‘An introduction to the international ABS regime and a comment on its transposition by the EU’ (2013) 9 *Law, Environment and Development Journal* 106, 122.

industries within such a tax/levy which would both broaden its scope, as well as expand the potential revenue stream of any such charge.

While the imposition of taxes/levies is expected to be unpopular and face resistance at the international level, the imposition of levies within sectors to promote particular societal goals linked to that sector is a well-established practice. The UK, for example, imposes an ‘apprentice levy’ on employers with pay bills in excess of £3 million to fund apprenticeship training.<sup>174</sup> A biodiversity levy or tax would not just be another tax for revenue-raising purposes but rather would be used to fund projects related to the conservation or sustainable use of biodiversity and thereby contribute to relevant Sustainable Development Goals. Reconceptualising or reframing the above discussed taxes/fees in this way may help such proposals to gain traction though measure design will be key to acceptability as well as likelihood of success.

However, while reframing the issue undoubtedly makes conceptual sense, it is also the case that in administrative terms, a tax/levy scheme would come with considerable challenges which cannot simply be disregarded. It may be difficult to get multilateral buy-in for the proposition of a tax, particularly given the costs of administering such a system, and its operation may impact negatively on research, free exchange and collaboration. Accordingly, while, a tax/levy, if properly designed, should in principle provide for the financial sustainability of such a system, it is also the case that the practical operation of such a scheme, together with its impacts upon particular sectors, needs carefully considered.

*ii. A charge on commercial development*

Numerous proposals have been advanced in the literature whereby an obligation to pay royalties would attach to any IP, such as a patent, based upon based on DSI.<sup>175</sup> Disbursement of such royalties would be through a multilateral fund. Disclosure of the country of origin in respect of patent applications using genetic resources has been implemented in numerous countries and while certain commentators have raised the question of compatibility with the TRIPS Agreement, it is notable that no disputes have been brought to the WTO dispute settlement in respect of this practice.<sup>176</sup> Another possibility is to follow the model of Brazil, whereby a commercialisation charge of 1% is applied to all products “accessed Brazilian genetic heritage, associated traditional knowledge, or that have commercially exploited final products or materials derived (there)from.”<sup>177</sup>

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<sup>174</sup> See, for example, discussion in Dietz 1990 (*supra*, n 155), 21.

<sup>175</sup> ‘Apprenticeship Levy’ (UK Government – Policy Paper, 2016) <https://www.gov.uk/government/publications/apprenticeship-levy/apprenticeship-levy>, accessed December 2019.

<sup>176</sup> M Ruiz Muller, ‘Access to Genetic Resources and Benefit Sharing 25 Years on’ (2018) ICTSD Issue Paper No. 44. Recent developments in WIPO may make this process simpler; see also Rohden et al 2019 (*supra*, n 46), 44 to 45.

<sup>176</sup> Bagley 2016 (*supra*, n 131) 16.

<sup>177</sup> See M Brown, ‘New Brazilian Law on Genetic Heritage gives one year to companies to report on their past activities having used Brazilian genetic heritage’ (*Lexology*, 2017) <https://www.lexology.com/library/detail.aspx?g=3f8fb766-b4f0-437d-80ee-ae2ee742f360>, accessed December 2019.

It should be noted, however, that many genetic resources are shared by more than one country,<sup>178</sup> thereby raising equity concerns although there are ways to address this potential problem, as was discussed above. One further issue that may be more difficult to address is a more practical one; securing sustainable funding may be difficult when there will be a time lag in respect of any commercialisation. Accordingly, payment of royalties based on commercialisation may, at least initially, yield very little by way of funding. By way of illustration of this point, the ITPGRFA is currently reviewing the operation of its standard material transfer agreement (SMTA) with a view to enhancing monetary benefit-sharing. This is due to a lack of commercialisation, which has resulted in a reliance upon donations to fund the Treaty's Benefit-Sharing Fund.<sup>179</sup> Charges based upon commercial development may therefore not be the best option to ensure financial sustainability, though potentially this option could be combined with others from the menu discussed here. A further practical concern may also arise in that there may arise instances in which collections take place in a country and a direct link *is* possible between the sequence and commercialisation. How such scenarios are dealt with under a multilateral fund would need to be carefully considered.

*iii. A subscription fee or one-off payment for access to DSI*

A subscription fee or payment for access to DSI is a further potential way in which funds might be raised for monetary benefit-sharing in respect of DSI. In addition to generating funds, a subscription system can enhance legal certainty and reduce transaction costs due to removal of the need to track and trace.<sup>180</sup> Under this model, a subscription fee or one-off payment would be required to access the numerous databases hosting DSI. However, while a number of specialised databases do require payment,<sup>181</sup> comprehensive public databases such as those within the INSDC are free. Indeed, it is notable the emphasis placed within the INSDC's policy upon, "free, unrestricted access to all of the data records in their database."<sup>182</sup> Sectoral approaches could work here, however, with a subscription system having been proposed in the ITPGRFA inter-sessional process based upon upfront payments, "on the overall revenue generated by crop(s) sales. Benefits are contributed to a global common pool in which accumulated fund support select projects aimed at increasing capacity in member countries, and achieving the Treaty's overall objectives of food security and sustainable agriculture."<sup>183</sup>

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<sup>178</sup> Ruiz Muller 2018 (*supra*, n 25).

<sup>179</sup> Ruiz Muller 2018 (*supra*, n 25), 18.

<sup>180</sup> For an overview, see E Tsioumani 'Consensus Within Reach for Plant Treaty Working Group to Revise ABS System' (ISSC, 2019) <https://sdg.iisd.org/news/consensus-within-reach-for-plant-treaty-working-group-to-revise-abs-system/>, accessed December 2019.

<sup>181</sup> As noted by G Winter, 'Knowledge commons, intellectual property and the ABS regime' in Kamau; EC and Winter G (eds), *Common Pools of Genetic Resources Equity and Innovation in International Biodiversity Law* (Taylor & Francis 2013), 'Traditional Chinese Medicine Database System, which compiles a large number of pre-existing Chinese Medicines databases. Access is possible after registration and against an up-front payment, which is used to cover the maintenance of the system. The user does not have to sign an agreement or disclose the aim of use' p 288, footnote omitted. Winter 2013, also notes that certain commercial databases such as BIOBASEW'S TRANSFAC(r) charge a user fee with further restrictions on third party access and rights, 291.

<sup>182</sup> Laird and Wynberg 2018 (*supra*, n 5), 29.

<sup>183</sup> E 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' (1-3 February 2016) UN Doc UNEP/CBD/ABS/A10/EM/2016/1/2, 20.

The design of any subscription fee applied to different sectors of DSI would need to take into account the different economics underpinning particular sectors and be accompanied by a nuanced/structured approach to respond to different types and uses of DSI with an emphasis on supporting scientific cooperation for conservation and sustainable use of biodiversity. Arguably, subscription fees, if viable at all, would best be discussed within the context of the hybrid *option 7*, given its focus on learning and dialogue with stakeholders, and would additionally require fees to be structured in such a way that students and researchers from the Global South would either not pay for access, or would pay a reduced fee with a view to supporting biodiversity conservation. The combination with a global platform for dialogue and learning outlined in *option 7* would also allow for adapting the fee system in light of growing understanding and multilateral discussion of the different economics underpinning particular sectors.

iv. *Voluntary contributions*

Voluntary contributions could be sought from states, database users and other actors (including the private sector), which could be disbursed multilaterally. The WHO PIP Framework Partnership Contribution is a potentially instructive in this regard. The Partnership Contribution is paid by manufacturers of influenza vaccine, as well as diagnostic and pharmaceutical manufacturers who use the WHO Global Influenza Surveillance and Response System (GISRS). A questionnaire is sent by the WHO every year to potential contributors with the funds then allocated to capacity building, pandemic response and maintenance of the PIP Framework.<sup>184</sup> A similar questionnaire to companies making use of publicly available databases could seek donations to fund capacity building initiatives and biodiversity activities. Governments could also be asked to contribute on a voluntary basis.

There are several counterarguments to the use of voluntary contributions on their own. First, it is doubtful that the financial sustainability of a system can be based solely upon donations. By way of example, the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) is severely underfunded.<sup>185</sup> In that connection, there is also a concern that the establishment of a new funding stream based on donations could result in funding being pulled away from existing institutions. Second, voluntary donations are unpredictable and effectively place the very existence of the system in the hands of donors, thereby inherently raising equity and fairness concerns.

v. *(GREEN)*

Given doubts over the sustainability of certain of the options discussed above, more innovative funding ideas may need to be pursued. A possible option here includes drawing on the Global

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<sup>184</sup> 'Influenza – PIP Partnership Contribution' (WHO, n.d.) [https://www.who.int/influenza/pip/partnership\\_contribution/en/](https://www.who.int/influenza/pip/partnership_contribution/en/), accessed December 2019. See discussion in M F Rourke et al. 'Access and benefit-sharing following the synthesis of horsepox virus' (2020) *Nat Biotechnol* <https://doi.org/10.1038/s41587-020-0518-z>.

<sup>185</sup> G Futhazar, and others, 'The IPES, Biodiversity and the Law: Design, functioning and perspectives of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services' in Charles R McManis and Burton Ong (eds), *Routledge Handbook of Biodiversity and the Law* (Routledge, 2017), Chapter 27.



Fund for AIDS, TB and Malaria's (RED) programme<sup>186</sup> which receives funding for HIV/AIDS specific programmes from goods sold under the (RED) badge.<sup>187</sup> Brands involved in (RED) include Apple, Starbucks, Beats by Dr Dre and Alessi. \$600 million has already been raised from this programme<sup>188</sup> and there may be attractions in pursuing a biodiversity equivalent of (RED). Accordingly, to the extent to which any multilateral benefit-sharing fund linked to DSI converges into a broader fund funding projects linked to objectives such as conservation and sustainable use, there may be merit in pursuing the introduction of a (GREEN) programme for biodiversity to ensure diversity, and hence sustainability, of funding sources. Such a programme would be applied to a subset of products sold on consumer markets and would therefore not attempt to link with DSI-derived products, at least not in an explicit sense. A (GREEN) fund could also have a wider purpose and act more broadly as a biodiversity resource mobilisation tool, rather than seeking solely to address DSI.

vi. *Biodiversity bonds*

Long-term financial sustainability, as well as diversity of funding sources, may also be achieved through the use of financial instruments such as a bond issue. For example, Gavi, the Vaccine Alliance's innovative International Finance Facility for Immunisations (IFFIm) allows 'vaccine bonds' – debt instruments – to be sold to investors.<sup>189</sup> Donors are able to commit to financing over the longer term<sup>190</sup> but funds are able to be raised in the short term.

A biodiversity bond could be issued and based on long-term financial pledges of donor states. Alternatively, a biodiversity bond could provide financing in the short to medium term until fees from commercialisation are realised, if this option is pursued.<sup>191</sup> The risk profile of such a bond issue, based upon long-term commercialisation hopes, is likely to be quite different to that of a bond based upon donor commitments and this may impact upon the appetite of investors for such a product. Furthermore, while the IFFIm works well<sup>192</sup>, other examples of bonds being used to fund global issues such as the World Bank's Pandemic Emergency Financing Facility have been the subject of heavy criticism that it, "serves private sector interests at the cost of global health security"<sup>193</sup> so bond design will be crucial here. It is notable that there is growing appetite to use bonds to secure finance to tackle global issues, with the

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<sup>186</sup> 'Red' (*The Global Fund*, n.d.) <https://www.theglobalfund.org/en/private-ngo-partners/resource-mobilization/red/> accessed December 2019.

<sup>187</sup> See discussion S Sekalala, *Soft Law and Global Health Problems: Lessons from Responses to HIV/AIDS, Malaria and Tuberculosis* (Cambridge University Press, 2017) 199.

<sup>188</sup> Figure as of July 2019; see 'Red' (*The Global Fund*, n.d.) <https://www.theglobalfund.org/en/private-ngo-partners/resource-mobilization/red/> accessed December 2019.

<sup>189</sup> K A Klock, 'International Public-Private Partnerships as Part of the Solution to Infectious Disease Threats: Operational, Legal, and Governance Considerations' in Sam F Halabi (eds), *Global Management of Infectious Disease After Ebola* (OUP, 2016) Chapter 9, 170.

<sup>190</sup> See also discussion in L Gostin, *Global Health Law* (Harvard University Press 2014), Chapter 5.

<sup>191</sup> Indeed, there has been a substantial increase of late in the so-called 'green bond' market: 'Green Bonds' (CBD, n.d.) <https://www.cbd.int/financial/greenbonds.shtml>, accessed December 2019.

<sup>192</sup> See discussion in Gostin 2014 (*supra*, n 190), 156 – 157.

<sup>193</sup> B Brim and C Wenham, 'Pandemic Emergency Financing Facility: struggling to deliver on its innovative promise' (2019) 367 *BMJ* I5719.

Crop Trust currently considering issuing Food Security Bonds<sup>194</sup> to ensure the financial viability of its trust fund.

b) Funding – disbursement of benefits

Disbursement of benefits under a potential multilateral benefit-sharing regime for DSI may fall under at least two potential conceptual arrangements. The first is what can be termed a compensatory liability regime. As we will see, under such a regime, an attempt would be made to correspond the payments of benefits to providers of DSI<sup>195</sup>, although benefit-sharing would not be done bilaterally but through a multilateral fund, thereby reducing transaction costs. The linking of payments to provider countries could take a number of forms and would not necessarily involve tracking DSI along the entire value chain. Such matching of benefits could also take into account the transboundary nature of genetic resources so that benefits could be shared between a number of countries sharing a specific genetic resource.

By contrast, under the second arrangement, the link between provider countries and eligibility for monetary benefits would be replaced by a more general recognition of the ‘value’ of DSI – as well as the contribution of provider countries to conservation – and the need for monetary benefit-sharing. The second arrangement would in some ways involve a simplified architecture and would likely support a project-based approach to benefit-sharing according to pre-defined criteria.

Certain of the funding options explored above could be structured to fit within either of these arrangements though certain more generalised funding suggestions such as donations as well as creation of a (GREEN) brand more clearly fit within the second arrangement. A hybrid of each of these arrangements is also possible. It is therefore to be emphasised that much like the options for accrual of benefits discussed above, these arrangements should not be seen as mutually exclusive.

Finally, we do not wish to present the idea that there should be a ‘one-size-fits-all’ approach for a multilateral fund to address monetary benefit-sharing in relation to DSI. Even if this were possible, there are immense variations in terms of the economics of different sectors and (sub)sectors that need to be considered. More concretely, these variations, and the extent to which they require different responses, mandate in favour of an in-built learning dimension leading to iterative approaches to implementation (to be balanced against realistic approach for users and legal certainty). The idea of an in-built learning approach to support iterative approaches to benefit-sharing is presented in *option 6 below*, and the idea of a multilateral fund and a multilateral platform (*option 6 below*) can be combined in the hybrid option (*option 7*).

i. *Compensatory Liability Regime*

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<sup>194</sup> See Intergovernmental Technical Working Group on PGRFA, ‘Report from the Global Crop Diversity Trust’ (FAO, 2018) <http://www.fao.org/3/CA0107EN/ca0107en.pdf>, accessed December 2019, 13.

<sup>195</sup> As we see *below*, however, in respect of globally disbursed sequences/species, no such ‘matching’ of payments would take place and instead, benefits would flow into a multilateral fund.

As should be clear from the name, a compensatory liability regime is a system based on liability rather than property rights.<sup>196</sup> Whereas a property regime ‘vests exclusive rights in owners’, a liability regime operates according to a ‘use now, pay later’ principle whereby use of the resource is permitted without explicit permission of the rights holder, provided compensation is paid, although limits may be imposed on the use of the resource.<sup>197</sup> Under such a regime, DSI would be recognised as semi-commons (see also hybrid *option 7*).<sup>198</sup>

An example of a compensatory liability regime has been suggested by Ruiz Muller whereby benefits are accrued based on the use of DSI in patents and disbursed to countries hosting the species from which the genetic information was derived.<sup>199</sup> He proposes utilisation of a mechanism to determine geographical distribution of genetic resources such as the International Barcode of Life Initiative could be utilised to assist in determining fund distribution entitlements.<sup>200</sup> For so-called globally disbursed species and sequences which make up the greater percentage of species and sequences accessed for research and development, there would be no payment to individual countries with royalties used instead to fund the system.<sup>201</sup><sup>202</sup> This may in all events end up being a significant proportion of the overall total. MAT/PIC would still be relevant to the sharing of non-monetary benefits<sup>203</sup> in respect of DSI extracted from genetic resources from provider countries.

The scheme outlined above has also been referred to as one centred on ‘*bounded openness*’<sup>204</sup> whereby genetic resources would continue to flow freely but the operation of such a scheme would be bounded in that it would not be free of cost.<sup>205</sup> The proposals outlined above which are based on the payment of royalties into a multilateral fund based on compensation for use of DSI upon, for example, commercialisation would fall broadly under this category.

As should be obvious from the above discussion, the criteria by which funds are distributed under a compensatory liability regime will ultimately be a strong determinant of its success. Clear and transparent criteria will need to be developed in advance and in conversation with relevant actors. Such an arrangement will undoubtedly be complex and may potentially raise equity concerns regarding the capacity of relevant actors to contribute to the conversation. Furthermore, where funding is limited this may cause competition between parties, particularly

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<sup>196</sup> See discussion in G Dutfield, ‘Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation’ (2003) UCTAD-ICTSD Project on TRIPS and Sustainable Development Issue Paper 1, 9.

<sup>197</sup> *Ibid.*, 40.

<sup>198</sup> See generally *ibid.* See also J H Reichman and T Lewis, ‘Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge’, in K E Maskus and J H Reichman (eds), *International Public Goods and Transfer of Technology Under a Globalized* (CUP, 2005), 337, 349.

<sup>199</sup> Ruiz Muller 2018 (*supra*, n 25). In the context of TK, see also Ruiz Muller 2013 (*supra* n 154).

<sup>200</sup> Ruiz Muller 2018 (*supra*, n 25), 14.

<sup>201</sup> Vogel et al 2017 (*supra*, n 13), 378 to 379, building on the work of Oldham et al.

<sup>202</sup> Ruiz Muller 2018 (*supra*, n 25), 14.

<sup>203</sup> Ruiz Muller 2018 (*supra*, n 25), 18.

<sup>204</sup> There is extensive literature on the application of the concept bounded openness, see for example Vogel et al 2017 (*supra*, n 13).

<sup>205</sup> Ruiz Muller 2018 (*supra*, n 25), 2, building on Vogel et al 2017 (*supra*, n 13).

where they have unequal capacities. These points are discussed more fully below where existing international practice in fund disbursement is considered.

ii. *A general (biodiversity) fund*

The second form of disbursement, which is not based on liability regime, would involve payment to and from general fund. This fund would likely be utilised to fund specific projects or programmes based on defined criteria, linked to the CBD objectives and relevant SDGs.

Many international funds provide, at least among others, for *project-based funding*. The Global Environment Facility (GEF) of the World Bank, for example, can cover the incremental costs of projects,<sup>206</sup> whilst the ITPGRFA's Benefit-Sharing Fund primarily provides project-based grants.<sup>207</sup> Project-based funding alone, however, may raise questions of equity when funding is limited and thus causes competition between applicants which may have unequal capacities.<sup>208</sup> Issues can be exacerbated when financing is loan-based, generating debt for those seeking to address problems that may not directly relate to their own doing or which efforts may provide global benefits.<sup>209</sup>

More comprehensive funding strategies may take a more programmatically approach. Funding, in this regard, may be of an enabling nature targeted to the very development of strategic programmes, sometimes mandated under a relevant treaty, such as a national action plan, or for the effectuation of such a strategic programme. The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)<sup>210</sup> provides an example of a fund that seeks to combine both strategic financing, for example, for the implementation of national strategic health plans, and project- or activity-based grants, notably with regard to specific communities, in a single, national application.<sup>211</sup>

Applied to the current context, important questions would need to be asked in advance of establishment of such a fund as to how monies are distributed. An iterative process, drawing on experience of other funds such as those discussed above would ideally be engaged in to develop criteria for the disbursement of funds, whether these are disbursed at a project or programmatic level. Specific selection criteria for funding will depend on the objectives of the fund, and experience at international level suggests that this is often closely linked to the

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<sup>206</sup> 'The Global Environment Facility. Investing in Our Planet' (*The Global Environment Facility*) <https://www.thegef.org/>, accessed November 2019

<sup>207</sup> 'Benefit-Sharing Fund' (FAO) <http://www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/overview/en/>, accessed November 2019.

<sup>208</sup> Morgera 2018 (*supra*, n 42), 65; S Louafi, *Reflections on the Resource Allocation Strategy of the Benefit Sharing Fund* (Swiss Federal Office for Agriculture, 2013).

<sup>209</sup> See in this regard notably criticism of previous climate funds like the World Banks' Climate Investment Funds (CIF) B Wu, 'Where's the Money? The Elephant in the Boardroom' (*Huffpost* 2013) [https://www.huffpost.com/entry/wheres-the-money\\_b\\_3499523](https://www.huffpost.com/entry/wheres-the-money_b_3499523), accessed November 2019.

<sup>210</sup> 'The Global Fund' (*The Global Fund*) <https://www.theglobalfund.org/>, accessed November 2019.

<sup>211</sup> *Modular Framework Handbook* (The Global Fund, 2019). Note that the Handbook contains a very comprehensive list of 'modules' that could be funded by the Global Fund, organised under different 'intervention packages' that also include lists of indicators of success.

overarching treaty and is sometimes further specified through different priorities, focal areas or funding windows. These are very much essential for the overall success of the fund.

Illustrative of the above point is the GEF requirement that financial support for projects should fall within five different focal areas.<sup>212</sup> Support will only be provided for the “incremental costs of projects”: that is, the costs, “associated with transforming a project with national benefits into one with global environmental benefit”.<sup>213</sup> The ‘incremental cost’ criterion is, however, rather ambiguous and its interpretation politicised, with calculations being ‘endlessly contentious’.<sup>214</sup> A clear lesson to be taken from this is that where the inclusion and interpretation of such concepts impact on the disbursement, timing and amount of funding, the potential underlying power asymmetries will have to be given careful consideration when deciding on the aims and specificities of a multilateral fund. Fund design must also ensure smaller groups and communities are able to access funds.

Finally, consideration should be given to support for non-monetary benefit-sharing<sup>215</sup> activities such as technology transfer and staff training. Indeed, the environmental funds listed above also often include opportunities for such technical assistance, sometimes directly linked to Treaty provisions on capacity building and technology transfer, as in the case of the ITPGRFA.<sup>216</sup> Worth mentioning in this regard is the ‘Readiness and Preparatory Support Programme’ under the Green Climate Fund (GCF), which, primarily, aims to strengthen the institutional capacities of National Designated Authorities or direct access entities to effectively and efficiently engage with and access the GCF funding itself.<sup>217</sup> This thus includes assistance for the development of national arrangements for consideration and facilitation of funding proposals, for training of staff for project and programme development and support for stakeholder engagement,<sup>218</sup> important examples of non-monetary benefit-sharing.

In regard to the above, any such fund would likely benefit from better understanding of the interface with non-monetary benefit-sharing such as strengthening research institutions and advancing conservation activities and conservation science in high biodiversity regions. The multilateral identification of gaps in the current landscape of international funds and of actual needs in biodiversity-rich countries could be supported by the global platform for dialogue

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<sup>212</sup> Biodiversity, climate change, land degradation, international waters, chemicals and waste: GEF Secretariat, ‘Gef-7 Replenishment. Programming Directions.’ (2018) GEF/R.7/19.

<sup>213</sup> ‘Incremental Costs’ (*Global Environment Facility* 2007) <https://www.thegef.org/documents/incremental-costs>, accessed November 2019; also J Gupta, ‘The Global Environment Facility in Its North-South Context’ (1995) 4 *Environmental Politics* 19, 25.

<sup>214</sup> Z Young, *A New Green Order? The World Bank and the Politics of the Global Environment Facility* (Pluto Press 2002), 149.

<sup>215</sup> Though see discussion below *option 6 and 7* on the false dichotomy between monetary and non-monetary benefits.

<sup>216</sup> E Tsioumani, ‘Beyond Access and Benefit-Sharing: Lessons from the Emergence and Application of the Principle of Fair and Equitable Benefit-Sharing in Agrobiodiversity Governance’ in Fabien Girard and Christine Frison (eds), *The Commons, Plant Breeding and Agricultural Biotechnologies: Challenges for Food Security and Agrobiodiversity* (Routledge 2018).

<sup>217</sup> ‘Readiness Support’ (*Green Climate Fund*) <https://www.greenclimate.fund/gcf101/empowering-countries/readiness-support>, accessed November 2019. See more broadly on the role of national entities in the GCF system: UNFCCC, ‘Governing Instrument for the Green Climate Fund’ (2011) FCCC/CP/2011/9/Add.1.

<sup>218</sup> *GCF Handbook. Decisions, Policies, and Frameworks* (2019), 408.

discussed in *option 6 below*. Useful features for the platform can also be derived from the discussion of the governance of international funds below.

c) Governance, accountability and decision making

Any multilateral benefit-sharing fund would be required to establish a governance system for decision making in respect of disbursement of funds. Here, existing international practice can be drawn on, in order to distil important lessons for the present context. With regard to decision-making on funding applications, existing multilateral funds rely on a central governing board with representatives. Numbers of members vary between 7 (ITPGRFA's Benefit-Sharing Fund) and 32 (Global Environment Facility) and primarily include government representatives with at least an equal number of representatives from developing and developed countries (see Annex below). Additionally, the Global Agriculture and Food Security Program's (GAFSP) Steering Committee originally also included representatives from the World Bank and supervising entities (e.g. FAO, IFAD, IFC),<sup>219</sup> whilst the Global Fund's Board of 20 (voting) members includes seats for major national donors as well as developing countries. But it also notably includes representation from an NGO from both the developing and developed world, a representative of someone living with the diseases associated with the fund and the private sector.<sup>220</sup> UNAIDS, the WHO, the World Bank and a Swiss member (since that is where the Global Fund is incorporated<sup>221</sup>) have non-voting advisory seats.<sup>222</sup>

As executive bodies have the final say on funding applications, the power balances that follow from its structures and decision-making procedures will have to be given careful consideration. Equal country representation is in this regard not necessarily sufficient, if other factors – including elements of funding discussed above – are geared to tip the scale in one direction. This can be illustrated by GEF, whilst despite 56% of representatives from developing countries or economies in transition and with voting done by consensus, in the past, negotiators and others actors have expressed that they felt that there was frequently “no alternative but to agree” with donor countries.<sup>223</sup>

In contrast to the GEF, the GFATM Board must first try to reach decisions by consensus.<sup>224</sup> Where a vote is taken, a weighted two-thirds majority must be reached comprising the group of donor and private seats, *as well as* the group consisting of the NGO seats, the developing country seats and the representative who is a person living with one of the diseases covered by the Fund.<sup>225</sup> Such a model is clearly designed to both “broaden the deliberative process and to safeguard stakeholder participation.”<sup>226</sup> This **dedication to broad stakeholder participation helps to ensure equity** in the way in which decisions are made by the Global Fund's board.<sup>227</sup>

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<sup>219</sup> *Framework Document for a Global Agriculture and Food Security Program (GAFSP)* (World Bank Group, 2009), 34; although these entities are still part of GAFSP they do not have any voting power.

<sup>220</sup> ‘Board. Members’ (*The Global Fund*) <https://www.theglobalfund.org/en/board/members/>, accessed November 2019.

<sup>221</sup> On the reasons for this, see Klock 2016 (*supra*, n 189), 160.

<sup>222</sup> Sekalala 2017 (*supra*, n 187) 197.

<sup>223</sup> Gupta 1995 (*supra*, n 213) 20.

<sup>224</sup> Sekalala 2017 (*supra*, n 187) 197.

<sup>225</sup> *Ibid.*

<sup>226</sup> *Ibid.*

<sup>227</sup> *Ibid.*

Such multi-sectoral stakeholder participation is **further enhanced by the availability of a partnership forum** as well as a Global Online Forum.<sup>228</sup> Worth mentioning in this regard is Gavi, the Vaccine Alliance, whose board includes an equal balance of donor and recipient countries as well as three intergovernmental organisations – the WHO, UNICEF and the World Bank – together with representatives of vaccine manufacturers from both the developed and developing world.<sup>229</sup> Other board seats are reserved for the Gates Foundation, as well as representatives of civil society. Further seats are allocated based on the needs of the organisation<sup>230</sup> and it is notable that Gavi is recognised as one of the most transparent agencies in the world.<sup>231</sup> While Gavi’s Board focuses on wider strategy, it is nevertheless an interesting institution for its emphasis on representation from a wide array of constituencies as well as transparency.

The governing board will, for its decision-making, also be likely to be supported by an advisory and/or technical body. Of particular inspiration can be in this regard the structure provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), which uses both a Technical Review Panel (TRP) of independent experts to evaluate the technical merit of proposals, and a Grant Approvals Committee to make funding recommendations based on the Panel’s opinion and a proposal’s wider strategic value.<sup>232</sup> The Technical Review Panel in particular has been commended for being able to direct funding in the direction of countries most in need, without *ex ante* allocation, whilst flagging capacity concerns (and language barriers) where relevant and promoting substantial learning, thereby having been held to potentially provide inspiration for other (incl. environmental) multilateral mechanisms.<sup>233</sup> Moreover, the GFATM has also been put forward as an example of **largely successful integration of local, bottom-up knowledge** (through Country Coordination Mechanisms) **and independent, technical expertise** (through the Technical Review Panel) in decision-making.<sup>234</sup>

Questions will need to be raised and answered as to how funds can be accessed, notably who is able to apply for funding and who decides on the application. In this regard, significant differences can be seen when comparing institutional structures within existing multilateral or global funds. With regard to potential applicants, the ITPGRFA’s Benefit-Sharing Fund seems to position itself on one side of the spectrum, by focusing on direct access for State Parties, or any legal or natural person, including gene banks and research institutions, farmers and farmers’ organisations.<sup>235</sup> Despite a helpdesk providing assistance for the preparation of

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<sup>228</sup> Ibid, 208

<sup>229</sup> Klock 2016 (*supra*, n 189), 170.

<sup>230</sup> Ibid.

<sup>231</sup> Ibid, 174.

<sup>232</sup> ‘Technical Review Panel. Overview’ (*The Global Fund*) <https://www.theglobalfund.org/en/technical-review-panel/>, accessed November 2019.

<sup>233</sup> G Schmidt-Traub, ‘The Role of the Technical Review Panel of the Global Fund to Fight Hiv/Aids, Tuberculosis and Malaria: An Analysis of Grant Recommendations’ (2018) 33 Health Policy Plan 335.

<sup>234</sup> L Van Kerkhoff and N A Szlezak, ‘The Role of Innovative Global Institutions in Linking Knowledge and Action’ (2016) 113 PNAS 4603, although the authors also find that some countries have succeeded better than others in maintaining ‘country ownership’ of the process and outcomes than others.

<sup>235</sup> FAO, ‘Report of the Third Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture’ (2009) Resolution 3/2009.

proposals, concerns have been raised of capture of the process by well-established groups and the inability of farmers – the primary target group under the Treaty<sup>236</sup> – to reach the international level through complex procedures.<sup>237</sup> On the other end of the spectrum is the Global Fund to Fight AIDS, Tuberculosis and Malaria, where a separate national committee called a Country Coordination Mechanisms is tasked with the submission of comprehensive proposals.<sup>238</sup> These include representatives from various sectors: multilateral or bilateral agencies, nongovernmental organisations, academic institutions, faith-based organization, the private sector and people living with the diseases,<sup>239</sup> with this inclusive approach being helped by the fact that funding is primarily demand- rather than supply-driven. Nonetheless, issues have occurred when civil society representation did not always reach recommended (40%) quota,<sup>240</sup> or when a heavy presence from donor countries could be felt within the Country Coordination Mechanisms.<sup>241</sup> In response to this, the GFTAM has reviewed its grant architecture to ensure more by way of country ownership as well as enhanced NGO involvement.<sup>242</sup> This shows the **need for an iterative approach to the development of these funds, which allows to respond to what is learnt in implementation and the benefits of reflexive and self-critical approach** has led to strengthened Country Coordination Mechanisms **with greater sectoral and societal engagement.**<sup>243</sup>

An example of a more hybrid approach is GEF’s Small Grants Programme which has been held to work fairly well, and which can be directly accessed by community-based organizations and non-governmental organizations with assistance from a National Coordinator. Although the scheme follows GEF’s focus on global benefits, it aims to do so through community-based initiatives and actions.<sup>244</sup> There have been examples in which the **GEF Small Grants Programme has been more tightly linked to multilateral processes**, such as under the Minamata Convention. **These cases could be studied in more detail, considering that the GEF is already the funding mechanism for the CBD and the Nagoya Protocol, with a view to assessing in what ways they could contribute to integration of local, bottom-up knowledge and independent, technical expertise, as well as greater sectoral and societal engagement with a view to supporting participatory and iterative learning around DSI, the CBD objectives and their contributions to the SDGs.** Whereas other multilateral mechanisms have also opted for more hybrid approaches, it follows from the above that equity

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<sup>236</sup> Article 13.3 ITPGRFA.

<sup>237</sup> Tsioumani 2018 (*supra*, n 216); S Louafi, *Reflections on the Resource Allocation Strategy of the Benefit Sharing Fund* (Swiss Federal Office for Agriculture, 2013).

<sup>238</sup> *The Global Fund to Fight Aids, Tuberculosis and Malaria. The Framework Document* (The Global Fund, 2001), 94.

<sup>239</sup> ‘Country Coordinating Mechanism. Overview’ (*The Global Fund*) <https://www.theglobalfund.org/en/country-coordinating-mechanism/>, accessed November 2019. See more broadly on stakeholder participation in the context of another funding mechanisms (GEF) discussed in this section, for example, GEF Council, ‘Policy on Stakeholder Engagement’ (2017) SD/PL/01.

<sup>240</sup> *Country Coordinating Mechanisms. Governance and Civil Society Participation* (The Global Fund, 2008), 7.

<sup>241</sup> C Clinton, ‘The Global Fund: An Experiment in Global Governance’ (University of Oxford 2014), 319.

<sup>242</sup> Sekalala 2017 (*supra*, n 187) 200 – 201.

<sup>243</sup> *Ibid.*

<sup>244</sup> See also table below and, for example, the GCF Accredited Entities under the GCF and the Operational Focal Points under the GEF.



in access opportunities relies upon the abilities of institutions and individuals and the availability of adequate capacity support.

Overall, it can be concluded that:

- The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATAM) provides a useful starting point for the development of a multilateral/global fund, notably because of its Country Coordination Mechanisms and Technical Review Panel **institutional structures**.
- To make it a better fit for the biodiversity context, efforts could primarily be focused on further **integration of local and indigenous knowledge** in decision-making procedures, learning from the experience of the GEF's Small Grants Programme and the challenges encountered under the ITPGRFA Benefit-sharing Fund. Active involvement of those on the ground is necessary to realize the benefit-sharing rationale 'to share' (implying agency, rather than of the passive enjoyment of benefits).<sup>245</sup>
- Gavi, with its innovative approach to financing in the form of the IFFIm, together with its commitment to **transparency**, may also provide something of exemplar for development of a multilateral or global fund for biodiversity.
- It is also notable that both GFATAM and Gavi are **public-private partnerships**,<sup>246</sup> created because, 'existing international mechanisms plateaued in their impact.'<sup>247</sup> While both organisations are not without criticism,<sup>248</sup> they nevertheless are considered to, "create opportunities for consensus-building and resource mobilisation," through their use of, "(n)ovel forms of shared decision-making and operations"... "which give both private and public actors a shared space to structure and build solutions to problems ... that had previously appeared intractable."<sup>249</sup> By extension, public-private partnerships may perform important 'regime straddling' roles and be able to work within polyglot networks comprised of a "mix of activities, goals and purposes."<sup>250</sup> This is in contrast to traditional intergovernmental organizations, which may often act as hosts to regime shifting by states and other actors.<sup>251</sup> Public-private partnerships may also bring sectors and actors with very different worldviews together, in an effort to transform transnational norms.<sup>252</sup> The potential of public-private partnerships is discussed further below.

#### d) Sites of governance

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<sup>245</sup> Morgera 2018 (*supra*, n 42), 57.

<sup>246</sup> Sekalala 2017 (*supra*, n 187), 196.

<sup>247</sup> Klock 2016 (*supra*, n 189), 175

<sup>248</sup> See, for example discussion in Gostin 2014 (*supra* n 190), Chapter 5.

<sup>249</sup> Klock 2016 (*supra*, n 189), 175

<sup>250</sup> M Chon, 'PPPs in global IP (public private partnerships in global intellectual property)' in Graeme B. Dinwoodie (ed) *Methods and Perspectives in Intellectual Property* (Edward Elgar Publishing, 2013), Chapter 11, 283

<sup>251</sup> L R Helfer, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 Yale Journal of International Law available at <https://digitalcommons.law.yale.edu/yjil/vol29/iss1/2>, accessed December 2019.

<sup>252</sup> Chon 2013 (*supra*, n 250), 283. Please note there is a vast literature on public-private partnerships to achieve sustainable development. See, for example, Philipp Pattberg and others (eds), *Public-Private Partnerships for Sustainable Development: Emergence, Influence and Legitimacy* (Edward Elgar, 2012)

(At least) three potential sites of governance may be identified in respect of the establishment of a multilateral fund.

*iii. Nagoya Protocol*

The first would involve the establishment of a global multilateral benefit-sharing mechanism pursuant to Article 10 of the Nagoya Protocol. Indeed, there has been extensive discussion in the literature on the potentially useful utility of Article 10 to resolve the DSI quandary,<sup>253</sup> which relates to the fact that, “some third party commercial uses of genetic information from publicly accessible databases can be analogised to a transboundary situation or a situation where it is not feasible to get consent.”<sup>254</sup> In essence, a transboundary situation may eventuate when a “gene, a metabolite, a design from biomimicry ... is diffused over species and the species, over jurisdictions.”<sup>255</sup> It could be established as a compensatory liability regime, a broader general fund or a hybrid. There are significant challenges, however, confronting the Nagoya Protocol (including continued divergence of views on Article 10, more limited membership than the CBD), so it may not be preferable to establish such a fund under its auspices.

*iv. CBD*

An alternative approach would be to create a biodiversity fund under the CBD with contributions from different sources, including for the use of various components of biodiversity. While aiming to address the issue of monetary benefit-sharing for DSI under the Nagoya Protocol, its scope would be broader and would be largely structured as a broader general fund, though that is not to say that compensatory approaches could not be included as a hybrid. This would arguably go beyond the scope of Article 10.<sup>256</sup> Several provisions under the CBD could contribute to provide the legal basis of the establishment of such a fund and contribute to a reflection by CBD Parties on more effective and integrated implementation of its three objectives.

Both the creation of a biodiversity fund under the CBD and a DSI global multilateral benefit-sharing mechanism would involve the creation of additional institutional machinery, with associated costs attached. Furthermore, for the proposed CBD biodiversity fund, concern may arise that it would not directly address the DSI issue. Instead, by accommodating different negotiating positions, it could actually result in a lack of legal certainty as well as potentially ‘waste’ institutional resources and risk of competition with other international biodiversity funding sources.

*v. Global Fund for Biodiversity as a public-private partnership*

A final approach would be to build on the model of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) discussed above and construct a funding body *outside* of the existing ABS space. This could be called the Global Fund for Biodiversity – GFBio. The rationale for the creation of such a fund outside of the existing ABS space is similar to that of

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<sup>253</sup> See also E Morgera, ‘What to expect on benefit-sharing from the upcoming 2018 UN Biodiversity Conference (Part II: Nagoya Protocol)’ (*BeneLex Project*, 2018) <https://benelexblog.wordpress.com/tag/nagoya-protocol/>, accessed December 2019.

<sup>254</sup> Bagley 2016 (*supra*, n 131), 12.

<sup>255</sup> Vogel et al. 2017 (*supra*, n 13), 383.

<sup>256</sup> Though this is of course somewhat of a contested point.

the GFATM; that “existing international mechanisms plateaued in their impact.”<sup>257</sup> The proposed fund could be financed by certain of the mechanisms discussed above, but could also ensure more by way of financial certainty by drawing funding from more innovative financial mechanisms such as bonds underwritten by supportive governments. As noted above, inspiration could be drawn from Gavi’s International Finance Facility for Immunisation under which bond holders are paid back over the longer term by donors. It is anticipated that governments hosting industries particularly reliant on DSI would act as donor countries in the first instances. A bond issue such as that proposed above could utilise the World Bank or the FAO<sup>258</sup> as a treasury manager and would fit within the growing discourse promoting ‘ethical investing.’

The proposed GFBio could be structured as a public-private partnership, thereby allowing for flexibility in its construction, as well as speed in its establishment. The GFTAM was, for example, established over a six-month period.<sup>259</sup> Relevant intergovernmental organizations could be invited to participate as board members. Funding would be disbursed in accordance with priorities agreed by a broad range of stakeholders and thereby echo the GFTAM’s emphasis on partnership and bottom-up approaches. The GFBio could also incorporate elements of *option 6 below* in terms of acting as a forum for dialogue, oversight and priority setting for DSI and could give a wide array of constituencies a voice in its operation and governance. This may help to move us away from some of the more ‘silo-ed’ positions which currently surround DSI and potentially promote the underpinning logic of benefit-sharing as an “iterative process, rather than a one-off exercise, of good-faith engagement among different actors that lays the foundation for a partnership among them.”<sup>260</sup> Accordingly, while the GFBio may appear at first site to offer opportunities for monetary benefit-sharing without confronting ‘head on’ the issue of DSI<sup>261</sup> under the CBD or the Nagoya Protocol, it could act as a forum for dialogue and priority setting in this regard. This would potentially help to address a “core challenge for new forms of cooperation” which is their ability to take, “into account of external stakeholder interests. Coalitions of the willing may be created. Yet, these may also affect (directly or indirectly) outsider state or private actors.”<sup>262</sup>

vi. *Fragmentation and the CBD*

While the public-private partnership model clearly has advantages, it must also be recognised that such a model creates significant risks of “fragmentation ... of state-centric legal frameworks and a corresponding shrinkage of public goods” provision.<sup>263</sup> By extension, countries with limited resources may find it difficult to be active across an ever-increasing range of international structures.<sup>264</sup> In this regard, establishment of a GFBio would raise

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<sup>257</sup> Klock 2016 (*supra*, n 189), 175.

<sup>258</sup> ‘Benefit-Sharing Fund’ (FAO) <<http://www.fao.org/plant-treaty/areas-of-work/benefit-sharingfund/overview/en/>>, accessed November 2019.

<sup>259</sup> See discussion in Sekalala 2017 (*supra*, n 187), Chapter 7.

<sup>260</sup> See Morgera 2018 (*supra*, n 42).

<sup>261</sup> See generally *ibid*.

<sup>262</sup> J Pauwelyn, R A Wessel and J Wouters, ‘When Structures Become Shackles: Stagnation and Dynamics in International Lawmaking’ (2014) 25 (3) *European Journal of International Law* 733, 752 and 738.

<sup>263</sup> Chon 2013 (*supra*, n 250), 296.

<sup>264</sup> *Ibid*.

significant concerns with respect to the potential dilution of authority of the CBD on the international sphere. At a time when biodiversity most needs protecting, erosion of the influence of the CBD appears a misstep. Indeed, the CBD offers the treaty objectives under which such a fund should operate.

Accordingly, the establishment of a fund under the CBD offers significant advantages from an international law perspective, though the lessons learned above with respect to the importance of facilitating dialogue, oversight and involvement of a range of constituencies should be borne in mind when creating such a fund such as:

- the development of institutional structures such as the Country Coordination Mechanisms and Technical Review Panel for the operation of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)
- more innovative financing mechanisms such as a bond issue, drawing on the experiences of Gavi, the Vaccine Alliance to ensure short-term financial sustainability that would also nurture trust among various actors;
- governance with relevant ‘constituencies’ such as database managers, developing countries, the scientific community and indigenous communities represented in its decision-making processes, drawing inspiration from the GFATM .

The key idea here would be to give both “**private and public actors a shared space to structure and build solutions to problems ... that had previously appeared intractable.**”<sup>265</sup> Dialogue with a range of affected stakeholders is therefore an important underpinning principle and indeed, we explore this option below (*option 7*) where we propose a so-called hybrid approach whereby a multilateral fund established under the CBD is accompanied by a multilateral platform for dialogue, learning, oversight and priority-setting.

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<sup>265</sup> Klock 2016 (*supra*, n 189), 175.

## Option 6: A multilateral platform for benefit-sharing

Whereas the analyses of options 5 have focused primarily on a multilateral fund as a monetary benefit-sharing option, this option explores a more principled approach to ensure that available resources, regardless of the way they are generated, are targeted in such a way to ensure fairness and equity in relation to benefit-sharing.<sup>266</sup> Such a principled approach is mainly concerned with establishing a multilateral platform for dialogue, oversight and priority-setting around DSI to support global partnerships on scientific cooperation for conservation and sustainable use.

The platform could allow approaching the DSI issue ‘from the side’, moving beyond the dichotomy inherent in the perception of monetary versus non-monetary benefits, definitions and the subject-matter scope of the CBD, in order to concentrate on dealing with the actual barriers to the realization of equity and fairness in benefit-sharing. In this regard, this option builds upon and implements existing obligations and opportunities, notably on information-sharing, capacity-building, technology transfer and scientific cooperation as forms of benefit-sharing. The creation of a multilateral platform is **a recommended option**, that is both compatible with a multilateral fund (*option 5 above*) and can respond to the shortcomings identified in previous options if it is implemented as part of a hybrid solution, discussed as *option 7 below*.

### a) Beyond monetary and non-monetary benefits

A platform for coordination of efforts and multilateral cooperation would allow us to go beyond narrow debates on the nature and types of benefits that can and should be shared. Such a platform would notably also allow us to move beyond the traditional - and in our view false - distinctions typically made between monetary and non-monetary benefits. In this regard, an argument that is often brought against the formalisation of benefit-sharing arrangements regarding use of DSI, and of monetary benefits in particular, is that publication of sequences in open access databases already represents a significant form of non-monetary benefit-sharing as it allows anyone, including researchers in provider countries and the Global South, to use the information.<sup>267</sup> This argument, however persistent, does not take into account the limited capacity of different countries and different users to access and make use of the information contained in databases.<sup>268</sup> Similarly, power imbalances may also impact on the way actors can control their data once it has been publicly shared, or on the way research collaborations are structured and conducted. Nonetheless, many countries in the Global South, such as Brazil, South Africa and Malaysia, are both user and provider and are likely to benefit from open access.

As the above illustrates, an emphasis on the difference between monetary and non-monetary benefits reveals a false dichotomy, which lies in the fact that non-monetary benefits ultimately bear economic costs,<sup>269</sup> and rely on financial investment in support of capacity building to level

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<sup>266</sup> This analysis primarily draws upon Morgera 2018 (*supra*, n 42).

<sup>267</sup> CBS/SBSTTA/22/Inf/2, 21.

<sup>268</sup> *Ibid.*, 20. Note, however, that the recent CBD study on traceability does find that users of information in the main databases (INSDC databases) are distributed fairly homogeneously over all countries of the world: Rohden et al 2019 (*supra*, n 46), 27.

<sup>269</sup> Morgera 2018 (*supra*, n 42), 54.

the playing field and realise their full potential. In this regard, a multilateral platform could focus on overcoming the actual barriers to the realization of equity and fairness in benefit-sharing and could be based on a dialogue with expected beneficiaries, and on the identification of integrated responses.

Our proposed multilateral platform is underpinned by a concern for cooperation, as well as facilitating and brokering scientific cooperation and capacity building. The proposed platform is an attempt to provide space for dialogue between the multiplicities of actors involved in the use of DSI, with a view to producing a more effective response to their needs. The proposed multilateral platform could also facilitate the co-production of ‘solutions’ to DSI, with such co-produced solutions encompassing the views and needs of the range of communities involved. In this sense, we foresee that such a platform could allow for inter-institutional, inter-sectoral and cross-scalar learning.

b) Taking inspiration from the governance of the GLIS: tackling the issue ‘from the side’

An example of a platform for multilateral cooperation can be found under the ITPGRFA, where the Global Information System (GLIS) has arguably been devised to address specific barriers to fair and equitable benefit-sharing in the form of information-sharing not just through the creation of an online database but the inter-linked development of a multilateral platform for targeted dialogue and iterative learning. The GLIS thus aims to facilitate fair and equitable benefit-sharing, by increasing interoperability of systems, by creating a mechanism at the multilateral level to undertake a series of inter-related tasks that identify and address shortcomings in bilateral relations, namely: assessing progress and monitoring effectiveness of enhanced and coordinated information-sharing opportunities; providing institutional support to broker and oversee scientific cooperation and capacity-building; and identifying any gaps or issues that could proactively be addressed at international level.<sup>270</sup>

A positive aspect of the approach is the fact that it tackles the issue of DSI “from the side, rather than head on”.<sup>271</sup> It does not necessarily require agreement on a definition or on DSI’s inclusion in the scope of the CBD or the Nagoya Protocol. Instead, it provides a combined approach to strategic implementation of existing obligations and opportunities, notably on information-sharing, capacity-building, technology transfer, scientific cooperation as forms of benefit-sharing. It may also explore and systemise opportunities among existing infrastructures and practices, such as open-access databases and their approaches to attach use conditions to DSI.<sup>272</sup>

Another interesting aspect of the GLIS is its reliance on existing information systems<sup>273</sup> with a view to minimising the impact on current infrastructures and procedures, and focusing on

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<sup>270</sup> Ibid, 58. Article 17 ITPGRFA; GLIS terms of reference.

<sup>271</sup> Ibid, 75.

<sup>272</sup> Ibid, 74. These include conditions of use notices, click through agreements, open source MTAs, and user agreements, see also above Option 1 and Laird and Wynberg 2018 (*supra*, n 5) 36-39.

<sup>273</sup> Article 17(1) ITPGRFA.

improving interoperability.<sup>274</sup> One means it employs to do so,<sup>275</sup> is adding a ‘digital object identifier’ (DOI) to identify a resource. DOIs are designed to coexist with other identifiers that often aim to serve particular communities and the achievement of specific objectives. The DOIs are hence intended to be used for “all purposes that are beyond the intended scope of existing identifiers, such as information sharing across different information systems and different communities”.<sup>276</sup>

The GLIS can also provide a helpful example for the creation of a clearing-house mechanism under the BBNJ instrument.<sup>277</sup> As a web-based entry point to information and knowledge, accessible via < <https://ssl.fao.org/glis/>>, it is geared both to the strengthening of capacity for the conservation, management and utilisation of resources and the sharing of benefits, and pays special attention to the needs of developing countries.<sup>278</sup> In doing so, it provides more than an online repository of information, which is the primary function of the clearing-houses under the CBD and the Nagoya Protocol. By contrast, the GLIS Programme of Work foresees a comprehensive, phased approach, covering not only the creation of a web-based platform, but also aiming to facilitate access to sources and associated information. It also aims to promote and facilitate interoperability and transparency on rights and obligations of users, to enhance opportunities for communication and international and multidisciplinary collaboration, to provide for capacity development and technology transfer for the conservation, management and use of resources, and to create a mechanism to assess its own progress and monitor effectiveness.<sup>279</sup>

It is notable, however, that GLIS is still in the very early stages of development, having mainly focused on assigning DOIs across organisations,<sup>280</sup> and it has not been free from controversy.<sup>281</sup> Nonetheless, GLIS provides an important example of conceiving of fair and equitable benefit-sharing as a governance process that needs inter-institutional, inter-sectoral and cross-scalar learning. In particular, where GLIS focuses on opportunities and synergies within and between existing systems, there lies potential for an approach that is developed from direct dialogue with the scientific community, thus minimising risks of negative and unforeseen impacts on scientific cooperation and innovation and maximising opportunities for biodiversity conservation and its contributions to multiple SDGs. Such an approach can contribute to build trust across the current divides in the DSI debate, by demonstrating sustained commitment to understanding the actual causes of inequity in a dialogue with affected communities and to co-

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<sup>274</sup> The Governing Body to the ITPGRFA, 'The Vision and the Programme of Work of the Global Information System' (2015) IT/GB-6/15/Res 3, Annex I, par 3.

<sup>275</sup> See also above *option 3*.

<sup>276</sup> 'FAQS - the GLIS Portal and Digital Object Identifiers' <http://www.fao.org/plant-treaty/areas-of-work/global-information-system/faq/en/>, accessed October 2019.

<sup>277</sup> Morgera 2018 (*supra*, n 42).

<sup>278</sup> Article 13(2) and Article 17 ITPGRFA and ITPGRFA Res 3/2015, Annex 1, par 6; also, Morgera 2018 (*supra*, n 42), 76. See on how these articles relate to GIS and the other workings of the multilateral system also: C Ker et al, 'Building a Global Information System in Support of the International Treaty on Plant Genetic Resources for Food and Agriculture' in Halewood et al (eds), *Crop Genetic Resources as a Global Commons: Challenges in International Governance and Law* (Routledge 2013).

<sup>279</sup> ITPGRFA Res 3/2015, 4-6 with detailed indicators on how these broader objectives can be achieved.

<sup>280</sup> A Alercia et al, *Digital Object Identifiers for Food Crops. Descriptors and Guidelines of the Global Information System* (FAO, 2018).

<sup>281</sup> Morgera 2018 (*supra*, n 42), 75 briefly on issues with regard to the DivSeek initiative.

develop in a transparent and multilateral setting problems that usually arise, and may remain hidden or underestimated in their cumulative/systemic impacts, at the bilateral level.

Moreover, inspiration to further sharpen and develop the approach may be drawn from other international processes, to ascertain how their terms and conditions can support the aims of the multilateral platform.<sup>282</sup> The proposed approach would not be completely novel under the CBD, with the Sustainable Ocean Initiative (SOI) Global Dialogue with Regional Seas Organizations and Regional Fisheries Bodies on Accelerating Progress towards the Aichi Biodiversity Targets able to provide a precedent in this regard. SOI has provided a regular process to share experiences and identify opportunities to enhance collaboration across sectors towards internationally agreed goals. It has further allowed for discussions on the need for specific tools, guidelines or other initiatives with a view to further strengthening opportunities for collaboration.<sup>283</sup>

Facilitating opportunities for interactions to promote learning, including through deliberation by multiple stakeholders,<sup>284</sup> is recognized increasingly within international law processes as a fundamental imperative in situations where a range of actors, and indeed regimes, are stakeholders to a particular issue. Rather than attempt to resolve issues though, for example, an emphasis on strict legal hierarchies, deliberative strategies designed to foster learning and information sharing,<sup>285</sup> should be brought to the fore.<sup>286</sup> Our proposed multilateral platform very much fits within such an approach.

c) Facilitating and brokering scientific cooperation and capacity-building

The multilateral platform can provide an opportunity to learn on an ongoing basis how benefit-sharing approaches to DSI can work or not for scientists, as well as the implications for biodiversity conservation and sustainable use. On that basis, the platform could proactively identify opportunities to facilitate and broker, and possibly also oversee and identify gaps or issues in, an otherwise ad hoc flow of information-sharing, scientific cooperation and capacity-building activities. A more institutionalized approach could respond to the needs of those benefitting from information-sharing, provide oversight of the distribution of benefits across different regions, and contribute to a more systematic encouragement of virtuous circles through capacity building.

A multilateral platform could also support iterative partnership-building around enhancing the implementation of CBD and other relevant international instruments such as the proposed BBNJ instrument. The clearinghouse mechanism already proposed under the current BBNJ negotiations could, for instance, be envisaged as not just an online repository of information,

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<sup>282</sup> Note that under Regulation (EU) No 511/2014 (Article 7) research funding is an entry point for monitoring compliance.

<sup>283</sup> 'Sustainable Ocean Initiative' (CBD) <https://www.cbd.int/soi/>, accessed December 2019.

<sup>284</sup> M A Young., 'Fragmentation or interaction: the WTO, fisheries subsidies, and international law' (2009) 8 (4) *World Trade Review* 477, 479. Though see S Oberthür, 'Interplay Management: Enhancing Environmental Policy Integration Among International Institutions' (2009) 9 *International Environmental Agreements: Politics, Law and Economics* 371, 382.

<sup>285</sup> See generally Young 2009, *ibid*.

<sup>286</sup> See also discussion in Morgera, Switzer and Tsioumani 2018 (*supra*, n 38).



but also a multi-stakeholder process to support a concerted and iterative dialogue to identify and respond to needs and priorities of beneficiaries, and international institutional support for setting priorities, brokering scientific cooperation, capacity-building and technology-transfer opportunities.<sup>287</sup> This could also support the identification of users that could become benefit-sharing trend-setters in their sector (as developers and implementers of best practices in fair and equitable benefit-sharing), and assess the financial viability of both monetary and non-monetary benefit-sharing, the challenges in linking monetary benefits to intellectual property rights as well as the delivery of monetary and non-monetary benefits.<sup>288</sup>

A principled multilateral approach can also address questions of fairness and equity from a human rights perspective,<sup>289</sup> in order to balance competing rights and interests, avoid discrimination, and respond to the needs of the vulnerable, while preventing negative environmental and socio-economic consequences of scientific research. This would be particularly interesting to align with recent international clarifications of the inter-dependence of biodiversity and basic human rights (discussed under the hybrid option 7),<sup>290</sup> and the need to interpret and implement the SDGs in accordance with human rights law.<sup>291</sup>

As discussed in the previous sections, the multilateral platform could also respond to the need for the international community to understand to the different communities of practices involved in the use of DSI, thereby more effectively responding to the needs of researchers and the conservation community through co-development of solutions. The platform would also assess on an ongoing basis the financial viability and functionality of the system, working collaboratively with database operators and researchers – both in the Global North and the Global South, with a view to adapting the system in light of changing scientific practices and the different economics underpinning particular sectors. The platform could also allow discussion of any unintended consequences on fairness and equity, including in the use of various funding and governance options, or the use of copyright-like systems.

d) In conclusion: a multilateral multifunctional platform on DSI

It follows from the above that the adoption of a multilateral approach through a platform for cooperation (including dialogue, learning, oversight and priority-setting) as recommended by this study results from a careful combination of:

- A clearinghouse mechanism, as a web-based entry point to information and knowledge;
- A forum for dialogue to enhance collaboration across sectors and stakeholders to contribute to the achievement of the CBD objectives and the SDGs, thereby
  - promoting further information sharing (feeding back into the clearinghouse), deliberation and mutual learning;

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<sup>287</sup> Morgera 2018 (*supra*, n 42) 76.

<sup>288</sup> E Tsioumani, 'Beyond Access and Benefit-Sharing: Lessons from the Law and Governance of Agricultural Biodiversity' BENELEX Working Paper n 9 (SSRN, 2016), at 28-29.

<sup>289</sup> Morgera 2018 (*supra*, n 42) based on Special Rapporteur in the field of cultural rights (UNHRC), 'The Right to Enjoy the Benefits of Scientific Progress and Its Applications' (2012) A/HRC/20/26, par 65-69.

<sup>290</sup> A/HRC/34/49.

<sup>291</sup> A/HRC/RES/37/24 & A/HRC/RES/37/25.

- providing international institutional support for facilitating and brokering scientific cooperation opportunities;
- identifying information-sharing, technology-transfer and regulatory and institutional capacity-building needs and available assistance; and
- building, and assessing the effects of, partnerships, including public-private partnerships – on the basis of information available on the clearinghouse and multi-stakeholder dialogue;
- A multilateral and multi-stakeholder mechanism to identify and assess obstacles, and to propose enhancements, to the interoperability of existing systems (arising from the dialogue with database managers, researchers, users, and feeding into the clearinghouse); and
- A multilateral and multi-stakeholder mechanism to increase transparency about and assess the distribution of benefits across regions, as well as to discuss good practices and lessons learnt in ensuring fairness and equity in benefit-sharing (arising from the dialogue and feeding into the clearinghouse, and incrementally shaping funding and governance of the platform as a whole).

It is recognised that these and other objectives are unlikely to all be achieved at the same time and that it will be necessary to **set priorities, through a deliberative approach**. In this regard, the multilateral platform could also draw on some of the insights garnered from our analysis of multilateral funds (*option 5 above* and the *Annex below*), notably the emphasis on learning and building consensus among private as well as public actors through “a shared space to structure and build solutions to problems.”<sup>292</sup> A similar, inclusive and potentially transformative approach should be taken to the operationalisation of the platform, the allocation of funds, and continuous reflection on the effectiveness and equity implications of the platform’s workings.

It is noted, however, that more detailed recommendations with regard to the operation, priorities and governance of the multilateral platform would benefit from further study in consultations with experts from different disciplines and stakeholders.

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<sup>292</sup> Klock 2016 (*supra*, n 189), 175.

## Option 7: Hybrid approach

In this option, which we term the hybrid approach, we combine the multilateral platform for dialogue, learning, oversight and priority-setting for DSI envisaged in *option 6 above*, with the multilateral fund for distribution of benefits set out in *option 5*. We also revisit a number of our other options (notably *option 4*) with a view to proposing improved processes for dealing with DSI.

**A hybrid approach is the most strongly recommended option**, because it can combine the advantages of numerous of the previous options and respond to their individual shortcomings. It can provide a carefully calibrated approach that can show how it responds to the various demands expressed by various CBD stakeholders (developed and developing States, the scientific community, the conservation community). It distinguishes itself from the “shopping lists” approach, where the international community, unable to find consensus, would identify a variety of options that are disconnected from each other and risk spreading resources too thin in trying to pursue them all without clear joined-up thinking. Instead, the hybrid approach proposed here is based on a reasoned combination of various proposals, structured into a logical sequence so that the demonstration of how the international community is carefully responding to the various concerns that have been identified from different sides of the DSI can contribute (in itself) to pave the way for building trust and political willingness to engage with this proposal.

### a) An overview

The proposed hybrid option combines:

- The **multilateral platform for dialogue, learning, oversight and priority-setting** (option 6 above). This would focus on:
  - Collaboratively identifying of integrated responses to capacity and operational needs;
  - Identifying and co-developing funding mechanisms for monetary benefit sharing (see *below*), taking into account the range of needs of relevant actors, including safeguarding ‘open science’;
  - Co-developing *criteria* for disbursement of funds by a range of stakeholders, so that benefit-sharing effectively contributes to the holistic realization of the CBD objectives and relevant SDGs;
  - Contributing to governance structures to ensure equity;
  - Creating opportunities for learning and iterative design to make sure that the fund really responds to evolving beneficiaries’ needs and evolving scientific practices;
  - Convening dialogues with stakeholders to stay abreast of the implications of scientific and technological developments for benefit-sharing and the fund.
- A **multilateral fund** (option 5 above) to ensure financial viability. This could have multiple approaches, co-developed in phases thanks to the learning approach supported by the multilateral multifunctional platform (*above*). This in turn could allow to fit with

the different economics of different sectors and (sub)sectors, which could draw both from payments arising from:

- The development of the **copyright-like *sui generis* approach** via the creation of a multilateralised **digital domaine public payant** to ensure sustainable financing
- **A bond system** to ensure financial sustainability in the interim.

The combination of the multilateral multifunctional platform and the multilateral fund could benefit from the governance approaches of the ITPGRFA GLIS and the GFTAM to integrating expertise from the bottom up and support the agency of beneficiaries (rather than their passive enjoyment of benefits) – **beneficiaries’ agency is in effect an essential, often overlooked, element of fairness and equity in benefit-sharing.**<sup>293</sup> The platform would need to make specific efforts to ensure the integration of local and indigenous knowledge in decision-making procedures, as well as scientists from different geographies and capacities, database managers, experts from different sectors. In this regard, the hybrid approach would build upon some of the lessons discussed above in respect of the operation of multilateral funds (*option 5* above), with a view to ensuring transparency and genuine partnership-building. It would thereby include an emphasis on equity in terms of building capacity, as well as the integration of local expertise. It would also be underpinned by concerns for the promotion of substantive and continuous learning (across different disciplines necessary to tackle the DSI issues from different perspectives and a variety of beneficiaries) and take an inclusive and representative approach to developing guiding principles for both the accrual of funds as well as fund disbursement.

To those ends, the platform will start with a participatory exercise of peer-learning and peer-review of the relationship between overall costs and benefits for providers and users, and also consider concerns for conservation, equity, public health, and open science underpinning the current approach, as well as of the benefits and costs that are likely to result from moving to a system of multilateral benefit-sharing. This will be the first step of an iterative process of participatory evaluation and due diligence that will set a paradigm-shift from the current, simplistic and predominantly bilateral approach to ABS under the CBD.

b) *Opearationalizing the digital domaine public payant as part of the platform*

In terms of the establishment of a multilateral fund to accompany the multilateral multifunctional platform described above, the establishment of a mechanism we term the ‘*digital domaine public payant*’ (preliminarily discussed above (*option 4*)), would focus on **generalized benefit-sharing.**<sup>294</sup>

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<sup>293</sup> Notably in connection with the co-production of knowledge and everyone’s international human right to benefit from scientific advancements (Universal Declaration of Human Rights Article 27(1); International Covenant on Economic, Social and Cultural Rights, Article 15): E Morgera, "The Need for an International Legal Concept of Fair and Equitable Benefit-sharing" (2016) 27:2 *European Journal of International Law* 353-383, and E Morgera, "Fair and Equitable Benefit-sharing at the Crossroads of the Human Right to Science and International Biodiversity Law" (2015) 4 *Laws* 803-831.

<sup>294</sup> Such an approach would also sidestep the fact that certain jurisdictions have denied copyright protection to hybrid gene sequences - e.g. Delhi High Court in *Emergent Genetics India Pvt. Ltd. v. Shailendra Shivam and Ors* (as noted in Welch 2017 (*supra*, n 18), 23). See also Ruiz Muller 2013 (*supra* n 154).

The operationalisation of the *digital domaine public payant* would require a determination to be made in respect of three issues: how and when would payment be made: what sort of mechanism would payment be made to; and how would funds be disbursed. We deal with each in turn.

- i) How and when would payment be made?

Payment for the *digital domaine public payant* could be constructed in (at least three) potential ways. The first would involve payment upon access to DSI, the second would involve payment upon use, while the third would be based upon payment for use but operationalised through the blockchain-associated feature of smart contracts.

**Payment upon access** to DSI would involve constructing a regime somewhat contrary to the *domaine public payant* within the cultural sector – whereby payment is generally upon use. In the case of those accessing DSI, instead, paying a fixed but potentially tiered fee upon access to DSI through publicly accessible databases would allow to take into account different categories of users. Payment upon access would ameliorate the need for track and tracing and address some of the issues of valuation of monetary benefits outlined above. Payments would be made into a central, multilateral fund and distributed in accordance with the objectives of the CBD (see also *option 5 above* and *option 2 above*).

In order to operationalise a regime of payment upon access, further study and consultation with all relevant stakeholders including database holders, scientists and conservationists, indigenous people and local communities would be required, to better understand the impacts of specific options in practice. Whilst more detailed recommendations are, therefore, beyond the scope of this study, it is our opinion that potential operationalization of the *digital domaine public payant* through the application of a fee applied to public database access, as suggested above, would only be feasible if encompassed as part of the hybrid approach outlined here. In essence, the creation of a multilateral platform for dialogue, learning, oversight and priority-setting envisaged as part of what we term the hybrid option would be underpinned by the principle of collaboration with, for example, database operators and researchers, with significant representation of those from the Global South. Accordingly, both normatively, and operationally, the *digital domaine public payant*, if instituted through payment upon access to DSI, is to be differentiated from a stand-alone charge for database access that does not come with an institutional set-up that addresses, among other things, the need to safeguard the norm of open science and equity. The distinction here stems from the fact that a stand-alone charge for database access without the type of engaged conversations with all potential stakeholders we foresee under the hybrid approach runs the risk of not taking the norm of open science into account fully in its implementation. Such dialogue would by extension be required in order to overcome some of the practical issues previously discussed (*option 5*) with the operationalisation of a subscription or access fee.

An alternative to payment upon access would be **payment upon use**. While difficulties abound with the operationalisation of a system of payment upon use due to the issues with tracking and tracing discussed previously, inspiration could be drawn from the Pandemic Influenza

Preparedness Framework's Partnership contribution which, as noted above (*option 5*), is paid by manufacturers of influenza vaccine, as well as diagnostic and pharmaceutical manufacturers who use the WHO Global Influenza Surveillance and Response System (GISRS). This is operationalised via a questionnaire sent by the WHO every year to potential contributors, with the funds then allocated to capacity building, pandemic response and maintenance of the PIP Framework.<sup>295</sup> A similar system could be devised for companies making use of, for example, the INSDC, with payment, set at a fixed percentage of turnover or gross profit, made compulsory – as opposed to voluntary - for certain companies using DSI and with a turnover above a certain threshold. There would hence be no need to track and trace benefits to use, since any payment would be a fixed fee tied to use of DSI in a broader sense.

The compulsory nature of the system of payment upon use explored above would overcome the problems with a voluntary scheme discussed above (*option 5*) and targeting payment at companies with a turnover above a certain amount would avoid equity issues associated with payment upon access which could potentially have a detrimental impact upon researchers and companies from the Global South. Payment upon use could potentially require close cooperation with databases to ensure that an accurate list of users is compiled although other mechanisms could potentially be devised here. The operationalisation of a system for payment upon use would also require close cooperation with Parties in which each applicable company is domiciled as the compulsory nature of any such fee means that it would likely require to be imposed at national level before being transferred into a multilateral fund to be disbursed in accordance with the objectives of the CBD. Accordingly, as with payment upon access, operationalisation of a system based upon use would require to be situated as part of a multilateral platform (discussed in *option 6*) for dialogue, learning, oversight and priority-setting underpinned by the principle of collaboration with, for example, all interested and affected stakeholders. Such a platform could potentially also arrive at a process for compulsory payment direct to a multilateral fund, as opposed to being imposed domestically before being disbursed to a multilateral fund. This would have the positive effect of not interfering with already existing domestic schemes such as Brazil's 1% levy upon use (*option 5 above*), though it could result in a double burden of payment for certain companies. This would require careful consideration, as would the fact that any such charge, as noted above, if implemented nationally (depending upon what is agreed), could cause concrete problems for implementation and result in patchy compliance across jurisdictions. Similar issues with the implementation of a biodiversity tax were also raised above (*option 5*).

It should be noted that one significant disadvantage of either system is of course the likely non-cooperation of the United States in any such system, though this is an issue which underpins any attempt to 'resolve' the issue of DSI multilaterally. However, the phased, iterative approach which underpins the hybrid option discussed here with a multilateral fund being tied

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<sup>295</sup> 'Influenza – PIP Partnership Contribution' (WHO, n.d.) [https://www.who.int/influenza/pip/partnership\\_contribution/en/](https://www.who.int/influenza/pip/partnership_contribution/en/), accessed December 2019. See also Rourke et al. (*supra*, n 184).

to a learning platform may be of interest to a range of actors in the US, thereby potentially helping to bring about a transformation in worldviews (*see discussion below at (d)*).

Of course, some might suggest that an alternative to, or a complement to the above, could be operationalisation of the *digital domaine public payant* through the **blockchain-associated feature of smart contracts** (*option 3 above*). Nonetheless, the disadvantages of the use of blockchain need to be reiterated here (energy footprint, requirement for users to have sufficient computer power to participate, the potential incompatibility with existing databases such as INDSC, and the issue that data can often still be accessed outside of the blockchain). Rather than including blockchain in a hybrid approach, we see merit in instead using the multilateral platform discussed above (*option 6*) to identify in a collaborative manner with database operators and researchers in the Global North and the Global South ways to improve the functioning and inter-operability of existing structures. This could, for example, involve greater operationalisation and use of clickwrap or clickthrough agreements that are sparsely used by some databases. Accordingly, regardless of how the *digital domaine public payant* is instituted, the multilateral platform discussed above (*option 6*) is a vital element to its operationalisation going forward.

It is to be noted that there may well be other mechanisms to ensure payment under the *digital domaine public payant* with the multilateral platform discussed above being central to the process of deciding upon how best such payment can be secured. The platform would be based on a process of dialogue to ensure that a scheme designed to promote equity via monetary benefit-sharing does not result in inequity through an adverse impact on, for example, researchers from the Global South. In addition, the choice of the appropriate method would be based on learning across sectors such as those from the cultural heritage arena to really get a sense of the various options available and their implications for the CBD objectives. As discussed previously, the multilateral platform could draw on some of the insights garnered from our analysis of multilateral funds (*option 5 above* and the *Annex below*), including the emphasis on the creation of opportunities for consensus building, as well as offering both private as well as public actors “a shared space to structure and build solutions to problems.”<sup>296</sup>

The relationship between the *digital domaine public payant* and the platform is thus crucial. The platform ensures that all potential impacts of any payment upon open science are considered and dealt with before implementation of such a charge. The platform is therefore vital as a practical and structured mechanism to ensure that any potential negative impacts of the payment on open science are avoided by engaging in direct dialogue with scientists. In essence, the platform will help to calibrate any potential implementation of the *digital domaine public payant* in response to the actual needs of scientists by including them as stakeholders in the conversations around responding to DSI. The platform would also support and document learning about the use and impacts of *digital domaine public payant* so that the latter can be gradually improved in light of experience.

Finally, it should be underscored that the *digital domaine public payant* is only one potential way to secure funding for the hybrid approach. To that end, dialogue under the platform can

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<sup>296</sup> Klock 2016 (*supra*, n 189), 175.

tease out more clearly the risks and benefits of different options for accruing monetary benefits, though, clearly, more studies would be required here. Without it (or a similar mechanism to generate monetary benefits), significant risks exist to equity, legal certainty and innovation if, for example, more restrictive national regimes on DSI are implemented.

It also needs to be noted that the iterative, horizontal approach to mutual learning envisaged under the platform could well reject the feasibility of the *digital domaine public payant* at the current time, in which case the other options (including innovative financing mechanisms discussed at *option 5*) would come into play. But turning to other forms of financing wouldn't ameliorate the need for a multilateral platform for dialogue envisaged here. It is also possible that the *digital domaine public payant* (or whatever scheme is arrived at, in terms of financing the envisaged multilateral fund) could be a temporary measure, if a trust fund mechanism was established which could eventually be self-sustaining if properly funded in the first instance.

ii) What sort of mechanism would payment be made to? How it would be disbursed?

Our clear preference here is for payment to be made to a multilateral fund (*option 5*) and disbursed in accordance with the objectives of the CBD and the contributions to multiple SDGs. There would be no attempt to track and trace with the focus of disbursement upon supporting projects which serve the objectives of the CBD. This would accordingly extend the ABS principles underpinning the CBD in respect of DSI to a collective multilateral fund (*option 5 above*) entrusted with management of monetary benefit sharing.<sup>297</sup> This would not involve countries renouncing sovereignty, but could in some ways reaffirm it,<sup>298</sup> while at the same time moving away from the commercial, bilateral logic of the CBD by recognising the difficulties associated with the operation of the current ABS approach to DSI.<sup>299</sup> In essence, payment to and disbursement from a multilateral fund, taking into account the lessons from our analysis in *option 5* would resolve the issues of valuation previously identified as so problematic (*options 1 to 3*) in the context of DSI and help to ensure achievement of the objectives of the CBD.

c) The centrality of the CBD

Finally, we would recommend that the hybrid approach be developed **under the CBD** (developing further our discussion under *option 5 above*), to rely on the existing structure under the Treaty. Notably, it is the CBD that provides the objectives and international obligations to guide the exercise and also enjoys – almost – universal membership. It is also flexible enough to adapt to the demands of other international regimes. Compared to other international treaties, the CBD is already remarkably open to inputs and engagement with a variety of stakeholders and the hybrid proposal would mark a step-change in that connection to ensure that the treaty remains effective and adapted to the evolution of conservation science. While the Nagoya Protocol could offer an avenue under its Article 10, there are clear disadvantages to this option

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<sup>297</sup> For discussion in the context of the arts, see Dietz 1990 (*supra*, n 155), 20. For discussion within the context of traditional knowledge, see Ruiz Muller 2013 (*supra*, n 154).

<sup>298</sup> In a similar vein, Ruiz Muller 2010 (*supra*, n 17) 12.

<sup>299</sup> See general discussion in *ibid*, 10. See also Ruiz Muller 2013 (*supra*, n 154) for discussion in the context of TK.



due to, among other things, the limited membership of the Protocol. The CBD already contains a series of broad obligations that can underpin international cooperation on DSI, notably **the combined reading of the obligations under:**

- **Article 12(c)** on research and training for “Parties, taking into account the special needs of developing countries [to] in keeping with the provisions of Articles 16, 18 and 20, promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.”; and
- **Article 17** on the exchange of information, whereby Parties “shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries” and “such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies.”

Articles **16** on technology transfer, **18** on technical and scientific cooperation and **20** on financing are also relevant to the implementation of the CBD Article **15** on ABS, notably Article 15(7) whereby each Party “shall take legislative, administrative or policy measures...with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Party providing such resources”, as well as Article 15(6) whereby each Party “shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.”

These provisions can also contribute to the implementation of the Nagoya Protocol, the preamble to which underscores, *that Parties* “*recogniz[e]* the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention.”

Two key questions would, however, remain to be addressed: the relevance of a hybrid approach for databases in the US and the opportunity for the BBNJ process to link a new international legally binding instrument to an external platform. It can be hypothesized that if the hybrid approach creates a useful and fruitful dynamic of cooperation with database operators and scientists, it will be of interest to US database operators and scientists, as well as of BBNJ-related database operators and scientists to participate in its process and remain connected with the rest of the global scientific community. In this regard, and as discussed above (*option 5 and 6*), offering such a shared space to different actors with differing worldviews, may allow

for normative transformation<sup>300</sup> and allow for new responses to be garnered to deal with common issues.

Normative transformation in this domain are not a pipe dream and indeed, we can see an example of such transformational change in the creation of the Global Initiative on Sharing All Influenza Data (GISAID). This Initiative is the result of much by way of international effort to create, “consensus on a novel (flu virus) sharing mechanism enabling public and animal health authorities to continue their surveillance work.”<sup>301</sup> The effort to conclude GISAID involved considerable engagement with a range of actors such as data providers and researchers, as well as requiring mediation of diplomatic tensions arising from the sharing of such data.<sup>302</sup>

More fundamentally, even in the absence of the type of normative transformation, research on regime interactions has underlined the importance of what may be termed, *enabling interplay management*, which focuses upon sharing knowledge, communication and understanding, to promote learning between regimes.<sup>303</sup> In that regard, “a more systematic approach to make information and knowledge about other relevant institutions and the potential for synergy with them available holds the promise”<sup>304</sup> of enhanced and mutually supportive interactions between regimes.<sup>305</sup> Providing an opportunity for the BBNJ process for a new international legally binding instrument to connect to the platform we envisage here therefore has its own advantages in terms of promoting synergies between these already overlapping regimes and thereby promoting more effective interactions and mutual learning. This would also be in line with the emerging general international law principle of mutual supportiveness.<sup>306</sup>

Broad acceptance of the need to prioritize these public policy objectives can be justified on the basis of the alarming findings on the unprecedented rate of biodiversity loss and its wide-ranging implications for human well-being, as evidenced in the 2019 Global Assessment of Biodiversity and Ecosystems Services. The urgency of the global biodiversity crisis also needs to be fully appreciated from an international human rights law perspective: as authoritatively clarified by the UN Special Rapporteur on the Human Rights and the Environment in 2017, the full enjoyment of everyone’s human rights to life, health, food and water depend on healthy ecosystems and their benefits to people, so the protection and realisation of basic human rights depend on successful efforts to prevent biodiversity loss.

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<sup>300</sup> Chon 2013 (*supra*, n 250) 283.

<sup>301</sup> S Elbe and G Buckland-Merrett, ‘Data, disease and diplomacy: GISAID’s innovative contribution to global health’ (2017) 1 *Global Challenges* 33.

<sup>302</sup> *Ibid.*

<sup>303</sup> Oberthür 2009 (*supra* n 284) 387.

<sup>304</sup> *Ibid.*, 383.

<sup>305</sup> Morgera, Switzer and Tsioumani 2018 (*supra*, n 38). See also Switzer, Morgera, Burci and Tsioumani, ‘Biodiversity, pathogen sharing and international law’ In S. Negri (ed.), *Environmental Health in International and EU Law: Current Challenges and Legal Responses* (pp. 253-271). London.

<sup>306</sup> See generally R Pavoni, ‘Mutual Supportiveness as a Principle of Interpretation and Law-Making: A Watershed for the ‘WTO-and-Competing-Regimes’ Debate?’ (2010) 21 *European Journal of International Law* 649.

## Conclusion

The issue of DSI has been a topic of discussion under the CBD since 2016, and it is expected to be a critical topic at the CBD COP in 2020. Progress at international level has, however, been very slow due to technical and political complexities. This study investigated if a sound and practical solution can be found and presented through EU leadership, to bridge and balance the interests of developing and developed countries, and contribute to the achievement of the CBD's three objectives: biodiversity conservation, sustainable use of biological resources, and fair and equitable benefit-sharing.

This study presented 7 options to address the matter of DSI:

1. DSI is not covered by the CBD or the Nagoya Protocol;
2. DSI is covered by the CBD and the Nagoya Protocol and no additional measures are taken;
3. Existing CBD/Nagoya Protocol provisions are complemented by the implementation of a new track-and-trace system;
4. A copyright-inspired *sui generis* system is put in place;
5. A multilateral DSI fund is put in place;
6. A broader, principled approach to benefit-sharing is taken through a multilateral, multifunctional platform, or;
7. A hybrid approach is taken that can clearly respond to the various demands expressed by various CBD stakeholders, which (in itself) can help pave the way for building trust and political willingness.

It was found that exclusion of DSI from the scope of the CBD was not a recommended option, as it was interpreted to be contrary to the principles of international law of effectiveness and good faith and could undermine legal certainty (*option 1*). However, it was recognised that application of existing ABS rules without additional measures is likely to cause adverse effects, due to problems of valuation and mismatch with current scientific practices (*option 2*). It was also found that implementation of a new or improved track-and-trace system would be insufficient to address these issues, as well as tracking and monitoring the use of DSI (*option 3*). An innovative approach has therefore been suggested.

A hybrid approach (*option 7*), combining positive and complementary elements of *options 4 – 6* is held to be the preferred option in this regard. At its heart is a multilateral platform for dialogue, learning, oversight and priority-setting (*option 6*). A more principled approach to benefit-sharing for DSI, which tackles the issue 'from the side' and focuses on beneficiaries' agency as a cornerstone for fairness and equity in benefit-sharing, as well as the need for continuous dialogue and learning across disciplines and sectors, allows for a focus on desirable outcomes rather than technical obstacles to progress. It also seeks to overcome the false dichotomy between monetary and non-monetary benefits, by focusing on the need to break barriers to realization of equity and fairness in benefit-sharing, and by basing itself on dialogue between beneficiaries. This, however, also raises the matter of financial viability (*option 5*), with the preferred option being a multilateral fund. Lessons can be learnt in this regard from the decision-making processes and governance structures that underpin existing global or

multilateral funds, notably those that foresee in effective, participatory processes for the delivery of equity. Moreover, innovative approaches should be explored, notably, a derivative of copyright-like *sui generis* approach which we term the digital domaine public payant would both recognise that DSI should not be treated as a freely exploitable resource, and guarantee a sustainable and equitable source of funding for the achievement of the platform's activities in support of the realization of all the CBD objectives and their contributions to multiple SDGs and the protection of basic human rights that are dependent on biodiversity.

**Annex Table: Overview of Six Existing Multilateral or Global Funding Mechanisms**

<b>Fund</b>	<b>Objectives</b>	<b>Financing</b>	<b>Primary types of funding</b>	<b>Procedures</b>
Global Environment Facility (GEF) ( <i>World Bank</i> )	To meet the agreed incremental cost of activities that generate global environmental benefits (GEBs) under five different focal areas: biodiversity, climate change mitigation, land degradation, international waters, chemicals and waste.	Contributions from (39) donor countries.	Funding for enabling activities to prepare a plan or programme for the purpose of fulfilling commitments under a Convention.  Financing for the incremental costs of projects, associated with transforming a project with national benefits into one with global environmental benefits.	Proposals are submitted through Operational Focal Points (OFPs) or by country governments.  Proposals are submitted to a GEF agency or to the GEF secretariat, which provides provisional approval of individual projects.  Submitted to The Council, which adopts the overall programme of work by consensus. The Council has 32 members (14 from developed countries; 16 from developing countries; 2 from economies in transitions).  The work is supported by the Scientific and Technical Advisory Panel (STAP).
ITPGRFA's Benefit-Sharing Fund (BSF) ( <i>FAO</i> )	Objectives of the ITPGRFA, with priorities following from the Global Plan of Action: information exchange, technology transfer and	Nett. 0.77% contribution of sales of patented product OR	Primarily project-based grants which contribute to the achievement of the objectives of the ITPGRFA.	Contracting Parties or any legal or natural person (e.g. including gene banks, research institutions, farmers and farmers' organisations; regional and

	capacity-building; managing and conserving plant genetic resources on farm; sustainable use of plant genetic resources.	0.5% of gross sales.  And voluntary contributions.	Also funding for the development and implementation of Strategic Action Plans.	international organisations) can submit a proposal.  An independent panel of experts screens the proposals against eligibility criteria.  A decision on the application is made by the Bureau, with 7 members (1 each from Africa, Asia, Europe, GRULAC, Near East, North America, South West Pacific).
Green Climate Fund (GCF) (UNFCCC)	To make a significant and ambitious contribution to the global efforts towards attaining the goals set by the international community to combat climate change, taking into account the urgent and immediate needs of developing countries that are particularly vulnerable.	Contributions from donor countries.	Project- and programme-based funding in accordance with climate change strategies and plans.  Also loans, grants, equity and guarantee under private sector window.  Other support includes the Readiness and Preparatory Support Programme, which seeks to enhance the capacities of NDAs and direct access entities, through grants or technical assistance.	Private sector (41%) and public sector (59%) can submit proposals through GCF Accredited Entities (including sub-national, national or regional organisations, international entities, and private sector entities).  Funding decisions are made by consensus by the Governing Board, made up of 24 members: 3 from Asia-Pacific States; 3 from the African States; 3 from Latin American and the Caribbean; 1 from SIDS; 1 from LDCs; 1 from

			<p>Additionally, GCF has an extensive capacity-building programme, focusing on: institutional capacity-building; enhancement/creation of an enabling environment; capacity-building for the implementation of adaptation measures; development of research and systematic observation, including meteorological, hydrological and climatological services; education, training and awareness raising.</p>	<p>the developing country Parties not included in the above; 1 to rotate between developing countries not included in the above.</p> <p>GCF has also dedicated resources to further development of direct access</p> <p>Activities between developing countries and GEF are streamlined through National Designated Authorities (NDAs) who also nominate entities for accreditation.</p>
<p>Global Agriculture and Food Security Program (GAFSP) <i>(World Bank)</i></p>	<p>Five objectives: raising agricultural productivity; linking farmers to markets; reducing risk and vulnerability; improving non-farm rural livelihoods; technical assistance, institution-building and capacity development.</p>	<p>Contributions from donor countries (6 main donors).</p>	<p>Investment grants for countries and regional organisations to fill financial gaps of comprehensive national agriculture and food security strategies and investment plans.</p> <p>Technical assistance financing for regional organisations in partnership with supervising entities with technical expertise.</p> <p>Loans, credit guarantees, and</p>	<p>Proposals are submitted through a public sector window by countries or regional organisations, or a private sector window by private firms or financial institutions.</p> <p>Proposals are reviewed by the GAFSP Technical Advisory Committee. They are approved by the GAFSP Steering Committee, with members from the 3 original donor countries (Canada, Spain, US) and other donor (including</p>

			equity capital for private sector firms and financial institutions.	private sector), and at least an equal number from recipient countries from Africa and other regions in the world (currently 16 voting members total).  Processes are coordinated by GAFSP Coordination Unit. World Bank holds in trust and administers funds.
The Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund) ( <i>Independent</i> )	To attract, leverage and invest additional resources to end the epidemics of HIV, tuberculosis and malaria and to support attainment of the Sustainable Development Goals.	Donor-based: * 93% from donor countries; * 7% from private sector, foundations and innovative financing initiatives.  (RED) label initiative to generate private funding,	Funding for programme continuation; tailored funding for focused portfolios; tailored funding for national strategic plans; tailored funding for transition; a full review of the previous funding programme.  Funding is organised through a modular framework with different ‘intervention packages’ and indicators of success. These include both programmatic intervention, capacity-building and more specific project-based approaches.	Country Coordination Mechanisms (CCMs) submit funding application on behalf of a country. CMMs include representatives from all sectors: multilateral or bilateral agencies, NGOs, academic institutions, faith-based organisations, private sector and people living with the diseases.  Proposals are first reviewed by a Technical Review Panel (TRP) formed by independent, technical experts, and then by a Grants Approval Committee with representatives from the Fund’s senior management and technical,



				<p>bilateral and multilateral partners.</p> <p>Funding proposals are approved by a Board of 20 members, with equal representation of implementing and donor countries and including representatives from ‘communities’, NGOs and the private sector.</p>
Gavi – the Vaccine Alliance	To save children's lives and protect people's health by increasing equitable use of vaccines in lower income countries, through vaccine and health system strengthening programmes.	<p>* Direct contributions through grants and agreements from donor governments, foundations corporations and organisations (77%)</p> <p>* Innovative finance (23%): The International Finance Facility (market financing),</p>	Funding for health system strengthening programmes (full portfolio planning) and for vaccine and/or CCEOP support (partial portfolio planning).	<p>Proposals are submitted through a national coordination forum (Inter-agency Coordinating Committee, Health Sector Coordinating Committee or equivalent body), which include members from different ministries and other key immunisation stakeholders (recommended: academics, technical advisory group, national regulatory authority, private sector representatives).</p> <p>Proposals are reviewed by an Independent Review Committee, with independent experts in public health, epidemiology, supply chain, developmental finance and</p>

		<p>Gavi Matching Fund, Loan Buydown</p>		<p>economics.</p> <p>Gavi's Chief Executive Officer decides on the final grant application.</p> <p>The Gavi Board, comprised of 28 members, including independent individuals, organisations incl. World Bank, WHO, UNICEF, developing and donor countries, and vaccine industry, is responsible for strategic direction and policymaking</p>
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