



**WILDSI**

# **TECHNICAL ANNEX**

For the White paper:

## **FINDING COMPROMISE ON ABS & DSI IN THE CBD: REQUIREMENTS & POLICY IDEAS FROM A SCIENTIFIC PERSPECTIVE**

## Disclaimer

Given the political nature of the topic addressed, we remind the reader that the ideas captured here are not reflective of individual positions of those listed here as authors and represent a consensus rather than a unanimous outcome. Furthermore, this technical annex should not be construed to represent the positions of the affiliated institutes or agencies of the authors.

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## Table of Contents

Executive Summary .....	6
1. Introduction.....	8
1.1 Background and Context .....	8
1.2 The WiLDSI project .....	8
2. Technical Outputs.....	11
3. Conclusion .....	17
4. Compilation of 8 White Papers .....	18
White Paper 1: WiLDSI INSDC hypothetical changes in response to theoretical ABS requests.....	18
White Paper 2: How can a (traceable) system make money? .....	25
White Paper 3: What could a (monetary) benefit-sharing system look like that does not require tracking of NSD usage? What value is delivered by such a system? .....	37
White Paper 4: Creating Legal Certainty for NSD in ABS Frameworks: Learnings from NSD Disclosure in the Patent System.....	41
White Paper 5: Systematic Legal and Governance Analysis of Various Exemplary Models .....	48
White Paper 6: Importance of Open Access Gene Banks from the perspective of Crop Plant Research .....	70
White Paper 7: DSI survey on usage and importance of DSI for biological researchers from South Africa, India, Colombia, Brazil.....	74
White Paper 8: Benefit Sharing post-2020: A Proposal for Cooperative Solutions to Effectively Deliver Benefits from Genetic Resources and NSD .....	77
5. WiLDSI Steering Committee Members.....	86

## List of Figures

Figure 1. Simplified Clearinghouse Model.....	56
Figure 2. Simplified Patent Pool Model.....	56
Figure 3. Typology of Clearinghouse Models .....	58
Figure 4. Statistics on the 37 interviewed scientists with respect to; a) scientific discipline, b) focus of research field, c) funding , d) genetic resource used for sequencing, and e) research sector. ....	76
Figure 5. Ten Premises for the Selection of Models.....	79

## List of Tables

Table 1. Overview Key Features Spectrum of Models. ....	84
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## Glossary of acronyms

ABS	Access and Benefit-Sharing
AHTEG	Ad Hoc Technical Expert Group
CBD	Convention on Biological Diversity
COP	Conference of Parties
CH	Clearinghouses
DSI	Digital Sequence Information
EBI	European Bioinformatics Institute
EMBL	European Molecular Biology Laboratory
ENA	European Nucleotide Archive
EOSC	European Open Science Cloud
EVA	European Virus Archive
GAVI	Global Alliance for Vaccines and Immunization
GBF	Global Biodiversity Framework
GBIF	Global Biodiversity Information Facility
GEF	Global Environment Facility
GGBN	Global Genome Biodiversity Network
GISAID	Global Initiative on Sharing All Influenza Data
GR	Genetic Resource
iBOL	International Bar Code of Life
IFI	Innovative Financing Instruments
INSDC	International Nucleotide Sequence Database Collaboration
IPR	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
JGI	Joint Genome Institute
MAT	Mutually Agreed Terms
MLS	Multilateral System of Access and Benefit-sharing
MTA	Material Transfer Agreement
NCBI	National Center for Biotechnology Information
NP	Nagoya Protocol
NSD	Nucleotide Sequence Data
OEWG	Open-ended Working Group on the Post-2020 Global Biodiversity Framework
PP	Patent Pools
PIC	Prior Informed Consent
PIP	Pandemic Influenza Preparedness
PCT	Patent Cooperation Treaty
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WiDSI	<u>W</u> issensbasierte <u>L</u> ösungsansätze für <u>D</u> igitale <u>S</u> equenz <u>i</u> nformation (Scientific Approaches for DSI)

## Executive Summary

Digital Sequence Information on Genetic Resources (DSI) has been on the international agenda of the Convention on Biological Diversity (CBD) and its *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable sharing of Benefits Arising from their Utilization* (Nagoya Protocol) since 2016. At the 15<sup>th</sup> Conference to the Parties (COP) to the Convention on Biological Diversity (CBD), the Parties will negotiate the Post-2020 Global Biodiversity Framework (Post-2020 Framework) and define the international biodiversity targets for the next 10 years. At this time, the CBD will also consider the outputs of the inter-sessional work (2018-2020) on DSI and how this issue should be dealt with by the Post-2020 Framework.

DSI has proven to be a controversial issue, resulting in strongly differing views, especially on whether DSI falls within the definition of “genetic resources” and whether the use of DSI from open access databases gives rise to benefit-sharing obligations. There is significant concern within the research community that any policy solutions for DSI could have significant impacts on research worldwide, especially if DSI were to be regulated according to the bilateral access and benefit-sharing (ABS) model of the Nagoya Protocol (NP).

The German Federal Ministry of Education and Research (BMBF) funded the interdisciplinary project, *Wissenschaftsbasierte Lösungsansätze für Digitale Sequenzinformation* (WiLDSI) (Scientific approaches for digital sequence information in preparation for COP 15) to look into possible DSI policy options and to raise awareness about DSI among scientific stakeholders from the public and private sectors in Germany as well as across Europe. In addition to raising awareness-raising among stakeholders, A key goal of the project was to assess possible approaches for dealing with DSI in which both open access to DSI is possible for non-commercial research purposes and, at the same time, sustainable benefit-sharing is made possible.

The WiLDSI project research was conducted on the basis of three assumptions regarding any possible solution for DSI: it would need to preserve and maintain open access to sequence databases, respect the reasonable/legitimate concerns of the countries of origin, and show whether and how benefit-sharing (including monetary benefit-sharing) within the value chain might be possible. WiLDSI brought experts together from a range of different fields to investigate various technical aspects of the DSI issue and to provide input on possible solutions. This expertise covered DSI and its traceability as well as database infrastructure, economics and possible financing mechanisms, legal aspects, including intellectual property law, and potential socio-economic impacts. These experts developed a series of white papers on these respective topics.

The key outputs<sup>1</sup> of the WiLDSI project are

- 1) the final WiLDSI white paper on [“Finding Compromise on ABS & DSI in the CBD: Requirements & Policy Ideas from a Scientific Perspective”](#) which proposes five open access policy options for DSI;
- 2) this technical annex which is a compilation of the various white papers and technical inputs to the project;
- 3) the three workshop reports from [Bonn](#) (January 2020), [Brussels](#) (March 2020), and the online private sector workshop (July 2020).

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<sup>1</sup> The WiLDSI project outputs can be found here: <https://www.dsmz.de/collection/nagoya-protocol/digital-sequence-information>

The technical annex is presented in a series of white papers that were drafted in the first phase of the WiLDSI project (October 2019-March 2020), which address scientific/technical, economic, legal, and socio-economic aspects of the DSI issue and potential benefit-sharing models.

**White paper 1** looks at the database infrastructure and considers the acceptability of theoretical changes to the INDSC's open access policy. Such changes in response to outcomes of international discussions on DSI would be voluntary. This paper indicates that some changes might be expected to have neutral implications for the database infrastructure and data submitters but very positive effects for provider countries. Other changes, such as some ABS-relevant tagging of data, establishment of licensing conditions or the introduction of access restrictions, would be expected to be regarded positively by provider countries but very negatively by important data submitters and INDSC policy makers.

With respect to the economic aspect, in **white paper 2**, the issue of cost and benefits for the various stakeholders is identified as being a key consideration in the development of any benefit-sharing mechanism. Questions about who contributes to the system, who pays, when and how need to be negotiated, taking into account the needs of various stakeholder groups and general concerns, such as legal certainty, sustainable use of data, fairness and equity etc.

**White paper 3** addresses existing innovative financing instruments (IFIs), which could inform the benefit-sharing options for DSI, especially in terms of value creation with value chains. Relevant considerations for developing sustainable instruments include transparency, legal certainty and the motivations for stakeholders to participate in the mechanism.

**White paper 4** shows that there is much which can be learnt from the legal system. Especially patent law, where open access to DSI is maintained but benefit-sharing for patent holders is ensured, can potentially offer insights into how legal certainty can exist in the context of open access system for data. The use of standards for the handling and presentation of data has been shown to be necessary in this regard.

A detailed analysis of existing multilateral models is provided in **white paper 5**. These models, which include multilateral benefit-sharing systems, clearinghouse mechanisms and patent pools all have their weaknesses and strengths and elements which might be informative in the international DSI discussions. Irrespective of the model chosen, trust and control issues have been identified as being central issues.

**White paper 6** discusses the societal benefits arising from the generation, sharing and use of DSI, e.g. in the identification and preservation of genetic material, plant breeding and food security but points at the considerable costs associated with the generation, duration, storage and research with these data. Given the critical and growing importance of DSI, it proposes that there is a need for more investment in the relevant infrastructure and identifies the potential for further investments in capacity building and technology transfer, which would allow more use of DSI in developing countries and emerging economies. **White paper 7** shows that researchers from such countries also rely on DSI and especially the main open access DSI database infrastructure, the International Nucleotide Sequence Database Collaboration (INDSC), for their research.

Finally in **white paper 8**, a number of different potential models for benefit-sharing for DSI were identified and considered in detail, including micro levies, subscription, public-private partnerships, impact bonds and certification systems. This white paper focuses on the concept of shared/ social responsibility of all stakeholders for biodiversity conservation as well as the generation of sustainable and effective (monetary) benefit sharing.

## 1. Introduction

### 1.1 Background and Context

#### *The International Discussion on DSI*

The 15<sup>th</sup> Conference to the Parties (COP) to the Convention on Biological Diversity (CBD) will take place next year in Kunming, People's Republic of China.<sup>2</sup> At the COP, the Parties will negotiate the Post-2020 Global Biodiversity Framework (Post-2020 Framework) (GBF) and define the international biodiversity targets for the next 10 years. Within the GBF negotiations, an important issue will be Digital Sequence Information on Genetic Resources (DSI), which has been on the agenda of the CBD and its *Nagoya Protocol* (NP) on *Access to Genetic Resources and the Fair and Equitable sharing of Benefits Arising from their Utilization* since 2016. At the 14<sup>th</sup> COP, which took place in Sharm El Sheikh, Egypt in November 2018, the CBD made a decision that put in place a science-policy process to inform the COP's discussions on DSI. It requested that the open-ended working group (OEWG) established under decision 14/34 to prepare the Post-2020 Framework to also consider the outcomes of the science-policy process and to make recommendations to the 15<sup>th</sup> COP on how to address DSI in the context of the Post-2020 Framework.<sup>3</sup>

Much of the controversy around DSI centres on whether DSI falls within the definition of “genetic resources” or not, whether the use of DSI from open access databases is subject to benefit-sharing obligations, whether the use of DSI from open access databases undermines the existing bilateral access and benefit-sharing (ABS) regime under the CBD and its NP, and whether open access to DSI can be regarded as a form of benefit-sharing. Divergent positions have emerged, typically along the lines of developing countries and economies in transition, which are in favour of benefit-sharing obligations for DSI, and more industrialised countries with well-developed and strong research and development sectors, which typically support continued open access to DSI. The latter have taken the position that DSI does not fall within the scope of the CBD or its NP and is therefore not subject to benefit-sharing obligations unless this is expressly provided for in mutually agreed terms (MAT) relating to physical material.

#### *DSI and the scientific community*

DSI and open access are regarded by many members of the research community as being essential across the life sciences. There is significant concern in the research community that policy solutions for DSI could have significant impacts on research worldwide, especially if DSI was to be regulated according to the bilateral ABS model. As such, it is essential that the scientific community engage actively in the international discussions around DSI and provide input on possible policy solutions.

### 1.2 The WiLDSI project

The WiLDSI project (*Wissenschaftsbasierte Lösungsansätze für Digitale Sequenzinformation*, Science-based solutions for DSI in preparation for COP 15) is an interdisciplinary research project funded by the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF) to enable the scientific community to contribute to the international

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<sup>2</sup> This meeting has now been postponed from October 2020 to fall 2021 due to the COVID-19 pandemic.

<sup>3</sup> <https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf>



discussion on DSI. This project was led by the Leibniz Institute-German Collection of Microorganisms and Cell Cultures (Leibniz Institute DSMZ) and the Leibniz Institute of Plant Genetics and Crop Plant Research (IPK Gatersleben). It commenced in September 2019 and will conclude with COP15.

### ***Objectives of the WiLDSI project***

The objective of the WiLDSI project was to provide scientific input for policy makers in Germany and the European Union (EU) on the international discussion on DSI. Specifically, it aims to:

- Identify and describe in detail one or more approaches (scenarios) in which both open access to DSI is possible for non-commercial research purposes and at the same time sustainable benefit-sharing is made possible.
- Evaluate the feasibility of these various options and whether they will result in the flow of benefits (monetary) from the users of DSI to providers.
- Engage with the scientific stakeholder community in Germany and Europe, including actors from both academia and industry, on DSI in order to raise awareness and integrate the perspectives and concerns of these stakeholders into the outputs of the project.

In the development of the proposed policy options, three main assumptions were made:

1. open access to DSI should be preserved and maintained i.e. any policy option should ensure that open access to sequence databases is guaranteed on a permanent basis;
2. monetary benefit-sharing would be required in any option; and
3. non-monetary benefits need to be quantified, valued and communicated, including through the systematical analysis of the global use and re-use of DSI, i.e., via an interactive bioinformatics platform.<sup>4</sup>

DSI was considered from various technical perspectives by the contributing experts, including:

- I. the scientific-technical perspective, including the character of DSI and its traceability as well as existing database infrastructure;
- II. the financial aspect, including DSI value chains and possible financing mechanisms;
- III. the legal aspect, especially from the perspective of intellectual property law; and
- IV. the socio-economic aspect, which concerns the impact of the different interests of the countries of origin.

This annex report presents the outputs (in the form of white papers) of this technical analysis.

The final WiLDSI White paper for the proposed open-access policy options for DSI “Finding Compromise on ABS & DSI in the CBD: Requirements & Policy Ideas from a Scientific Perspective” was officially launched online on October 7<sup>th</sup>, 2020 and can be found at the WiLDSI project website.<sup>5</sup>

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<sup>4</sup> The WiLDSI project will soon publish and release an interactive and accessible online platform to visually demonstrate and quantify use and re-use of DSI by scientists worldwide.

<sup>5</sup> Further information and documents for the October 7<sup>th</sup> launch can be found here:

<https://www.dsmz.de/collection/nagoya-protocol/digital-sequence-information/dsi-policy-options-webinar-2020>

### ***Inputs to WiLDSI and project activities***

The WiLDSI project was an interdisciplinary research project, involving various experts from various fields, including science, database infrastructure, international law and regulation, finance, and development policy. These experts formed the Steering Committee and provided their inputs on technical issues and the proposed policy options (see below for the list of the WiLDSI Steering Committee members). The steering committee met three times in person (in September and November 2019 as well as March 2020) and participated regularly in calls to discuss the technical issues and the ongoing development of the policy options. In order to gain additional expertise additional members were invited to join the Steering Committee in April 2020.

Input from scientific and industry stakeholders was obtained through three workshops. These workshops involved a total of approx. 150 stakeholders at the national (German) and EU level.

The first workshop, **“Digital Sequence Information, Open Access, and Sustainable Benefit Sharing: Scientific Input to International Policy Decisions”**, was held on 21-22 January 2020 at the Zoological Research Museum Alexander Koenig in Bonn. The workshop helped raise awareness among the scientific stakeholder community in Germany concerning the political debate surrounding the DSI issue as well as offered the participants a platform to voice their opinions and contribute early brainstorming around monetary and non-monetary benefit-sharing options.

The second workshop, **“Digital Sequence Information, Open Access, and Sustainable Benefit Sharing: Scientific Input to International Policy Decisions”** was held on 10-11 March 2020 at the NH Collection Brussels Centre, Brussels, Belgium. The workshop was jointly organized by the the WiLDSI project and co-hosted by a Horizon 2020 Project, the European Virus Archive (EVA) and the EVA institutes, DSMZ, the National Institute for Public Health and Environment (RIVM, Netherlands) and the Pasteur Institute (France). The work done by the WiLDSI project up until that point led to the development of three potential scenarios for how DSI could be handled in a new policy framework. These scenarios were presented at the workshop and used for the basis of discussion and assessments of pros and cons.

Due to the COVID-19 pandemic, the third workshop on **“Scientific industry input on five open access policy options for DSI”** was held virtually on July 13, 2020 and aimed to proactively engage and gather input from European scientific private sector stakeholders on policy ideas surrounding DSI. The focus of this workshop was to discuss and test the feasibility of five potential open-access policy options for DSI that were developed through extensive research conducted by the WiLDSI project experts over the past nine months as well as knowledge acquired from the two prior WiLDSI scientific stakeholder workshops.

The detailed reports, information and outcomes of the workshops are available on the WiLDSI project website.<sup>6</sup>

In addition to the project activities, various members of the WiLDSI Steering Committee were invited as experts to participate in several outreach events:

- Five experts from the WiLDSI project attended the First Global Dialogue on DSI in South Africa in November 2019.

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<sup>6</sup> <https://www.dsmz.de/collection/nagoya-protocol/digital-sequence-information>

- Three experts from the WiLDSI project attended an informal dialogue on Digital Sequence Information (DSI) in Brazil in December 2019.
- Three experts from WiLDSI project attended the BfN DSI round table in Jan 2020.
- Three WiLDSI project members participated in the virtual Chile briefing in June 2020
- One WiLDSI member participated in the Annual General Meeting of the CGIAR Genebank Managers virtual policy session on genetic resources in October, 2020.
- One WiLDSI member participated in the UNDP global virtual ABS webinar series in October-November, 2020.

## 2. Technical Outputs

A series of white papers were developed by the steering committee members on technical issues related to their expertise. The full white papers can be found below in the Project Annex 4. Below is a short summary of the key findings in each of these white papers.

### 2.1 The scientific-technical perspective, which includes the character of DSI and its traceability as well as the infrastructure of databases

The core DSI infrastructure, the International Nucleotide Sequence Database Collaboration (INSDC) is a permanent open access platform for DSI with 15 million users worldwide. It provides enormous societal good and connects >1,700 scientific databases and platforms.<sup>7</sup> In addition to the INSDC, large publication databases connect open access literature to the scientific results and datasets found in the INSDC and the surrounding infrastructure. Further DSI infrastructures such as the Global Biodiversity Information Facility (GBIF), International Bar Code of Life (iBOL), Global Genome Biodiversity Network (GGBN), and many others build upon and support this system.

The INSDC is not under any formal obligation to make changes to its open access policies or infrastructure in order to address issues decided upon by the COP. Nevertheless, it is likely that some changes to the status quo will be called for in the discussions on DSI. The WiLDSI project looked into hypothetical changes that could be made to the existing database infrastructure and the acceptability of these hypothetical changes according to different stakeholders.

#### ***What changes could be made to existing database infrastructure in response to access and benefit-sharing requirements and the discussions on DSI?***

Any changes to the INSDC infrastructure would be likely to elicit varying responses from different stakeholder groups. In particular, the changes involving ABS-relevant tagging of data, establishment of licensing conditions or the introduction of access restrictions on data would elicit strongly negative responses from people who submit data to these databanks. Such changes could, on the other hand, elicit very strong positive responses from provider countries.

There are also hypothetical changes that could be made that could elicit strongly positive responses from provider countries while at the same time being neutrally evaluated by data submitters. These types of changes probably offer the best possible chances for possible changes to existing infrastructure that would be acceptable across the board. Such changes might include changes to terms and conditions, governance structures and non-monetary benefit-sharing.

<sup>7</sup> Rohden, F., Huang, S., Dröge, G., and Scholz, A., (2020) Combined Study on Digital Sequence Information (DSI) in Public and Private Databases and Traceability. Secretariat of the Convention on Biological Diversity. Montreal, Canada. <https://www.cbd.int/meetings/DSI-AHTEG-2020-01>.

The acceptability of changes to the database infrastructure findings were explored through an exercise in which hypothetical changes were made to the existing INDSC databases under eight broad categories. The changes were rated for their acceptability on a score from highly unacceptable through to highly acceptable from the perspective of defined stakeholders.

**For more details, see white paper 1 by Dr. Guy Cochrane (EMBL-EBI).**

## **2.2 The economic aspect, including DSI value chains and possible financing mechanisms**

The WiLDSI project assumes that monetary benefit-sharing will be required for DSI, which necessitates consideration of value chains and how monetary benefits can be generated in an open access system as well as how such benefits could be distributed.

Although the word “open”, at first glance, seems to stand in direct contradiction to an income-generating system, the assumption is made that open does not necessarily mean that data is free of any obligations. The WiLDSI project considered how income can be generated without losing open access to DSI for academic research.

The need was identified to look at the difference between traceable (i.e tracking NSD usage) and non-traceable (i.e. no tracking of NSD usage) benefit-sharing systems and to ask how these could function and what the value of these different approaches would be.

### ***How can a traceable system make money?***

Even when stakeholders (provider country, academic users, industrial users, collections) have different views on DSI, some of their priorities for such a system may be similar with respect to:

- the need for legal certainty;
- the freedom to operate and sustainable use of DSI;
- low transaction costs, predictable conditions and cost effectiveness;
- fairness and equity for all actors; and
- transparency in governance of any system and the distribution of benefits.

One of the main considerations for any system will be the associated costs.

All types of users (from the R&D process and value chain) can and should participate in the development of any benefit-sharing system. Any system needs to have incentives for actors to participate, including on both the user and provider sides and take a balanced approach to be taken to public and private rights.

There may be a false binary distinction between traceable and non-traceable systems. A fully multilateral system may be too oversimplified. The operationalization of the bilateral system, for example, could combine continued open access and exchange with fair/correct benefit-sharing upon the development of a commercial product and commercial. This could be inspired by pools, genetic resources pools, genetic diversity pools defines the terms and conditions of access and use (can be based on model contracts) connecting the relevant provider countries and possible users, setting a fee for a commercial product.

Key parameters that need to be considered and operationalized in a fee/payment model are:

- on what is a fee applied, meaning that there is a clear material scope that maintains the link between the ‘DSI’ and the related genetic resources of R&D process and excludes use

and sharing. The value in the commercial product directly linked to the 'DSI', i.e. which is materially or directly based on it;

- when is the fee set, set up-front and with predefined rates, while independent from whether the 'DSI' actually leads to commercial development or a commercial product, at commercialization or at the end of the R&D process or at the start of the (commercial) development phase. Alternatively upfront fee with predefined rates is paid. Another option that could be looked at is the ability to actually measure the value of the non-monetary benefit sharing which is being applied, with the ability for users of "DSI" to demonstrate this value and receive credits for such non-monetary benefit sharing. Time limited
- by whom is it to be paid.

Two options are considered in more detail, namely a collaborative or pooling model and a subscription system.

**For more information, see white paper 2 by Aysegul Sirakaya (University of Ghent, ABS-int).**

***What could a system look like that does not require tracking of NSD usage and what would be its value?***

Innovative finance instruments (IFI) are defined as institutions that link different elements of the financing value chain in order to mobilize, pool, channel, and allocate resources. There could be a variety of potential formats that could deliver innovative finance for DSI. Examples include IFIs operating at a global level, novel ways of channeling traditional donor funding, the role of corporate social responsibility, the use of bonds for leveraging private sector investment for sustainable development, impact bonds, certification schemes etc.

In the development of IFIs, a key consideration is understanding why various actors engage in these processes. These may not necessarily be tied to immediate profits, even for corporate actors. Regulatory certainty, avoidance of potential antitrust issues, long term market growth and overall social license can all provide relevant motivations.

There are also a wide range of potential payment categories, e.g. grants and voluntary trust funds, mandatory payments through ties and levies, micro-levies, subscriptions, public-private partnerships, results-based finance, long-term donor pledges to issue bonds, etc.

IFIs can inform the discussion on DSI. It is suggested that in this context, any IFI would have to take into account specific criteria, namely, the ability to raise funds from private sector partners, require a direct financial return to the funder, include an element of regulatory intervention, include an element of voluntary participation and engagement, and not just deliver money but include other elements that encourage etc.

A needs-based assessment of funding needs for bioinformatics training, sequencing centers or new INSDC partner databases in developing countries would also be necessary.

In terms of process, relevant goals and milestones for developing a cooperative system would need to be identified and these may necessarily involve trade-offs. Decision-making processes and criteria of equity and fairness would also need to be discussed.

**For more information, see White paper 3 by Torsten Thiele (Potsdam Institute for Advanced Sustainability Studies).**

## 2.3 Lessons learned from existing legal systems

### ***What can be learnt from NSD Disclosure in the Patent System?***

A great deal of experience has been gained through the patent system with respect to the traceability of intangible assets. The patent system establishes a link between material and DSI while creating legal certainty and maintaining both open access to data and ensuring benefit-sharing for innovators.

The articles of the Patent Cooperation Treaty (PCT) are specified in more detail in the PCT Regulations and PCT rules, which include specific rules relating to nucleotide and/or amino acid sequences and disclosure. The World Intellectual Property Organization (WIPO) has developed standardized practices for NSD in close collaboration with INDSC, to ensure that existing database infrastructure and the patent system are interoperable. The relevant standards are ST. 25 and ST.26 and they provide general guidance for the presentation, publication and communication of information related to intellectual property rights (IPR). This facilitates the harmonization of practices by industrial property offices regarding electronic data processing. WIPO Standard ST.25 provides for standardization of the presentation of nucleotide and amino acid sequence listings, specifically requiring that sequences in patent applications are assigned a separate sequence identifier. This prevents tracing back of information on the specific sequence, such as the origin of the sequence or the biological material because a new sequence is issued. A transition to ST26 is proposed by 2022, whereby incoming patented DSI will automatically be formatted to be INDSC compatible and tracing will be enabled.

Other legal issues considered relevant to the DSI issue include considerations about protection of databases, copyright and contracts.

Databases in the European Union, for example, are protected under the EU Directive under certain circumstances. These rights are *sui generis* and do not include any copyright for software used to create the database. They also do not protect the content of the databases, such as databases containing DSI. Copyright may protect databases in some countries.

There is also some discussion around copyright and DSI. This debate was strong in the 1990s, especially regarding synthetic sequences. In recent times, there has been renewed interest in this issue and copyright protection on DSI. Lessons learned with respect to copyright, e.g. on licensing, may also be informative.

**For more information, see white paper 4 by Prof. Claudia Seitz (Universities of Ghent and Bonn).**

### ***What is the value of examining existing multilateral models and what can we learn from them?***

There are already a number of multilateral models that exist, which could serve as a source of inspiration for the discussion on DSI. Three different categories of models are:

- Benefit-sharing models, e.g. the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and its Multilateral System (MLS);
- innovative funding models, e.g. the Global Alliance for Vaccines and Immunization (GAVI), Crop Trust etc.; and
- collaborative licensing mechanisms, e.g. the CRISPR pool, Global Initiative on Sharing All Influenza Data (GISAID) and the Pandemic Influenza Preparedness (PIP) Framework, etc.

This white paper analyses various models systematically, including a profile of the stakeholders, the uptake, strengths/incentives, weaknesses/challenges among others.

Collaborative licensing mechanisms, which include patent pools (PP) and clearinghouses (CH) allow for some traceability and can offer transparency, match-making and negotiating platforms as well as allowing for technology exchange and royalty setting. They are often used in the context of IPR and have demonstrated the ability to lower transaction costs, overcome blocking positions and allow stakeholders to avoid costly litigation. These models require close collaboration among actors with widely diverging interests. It is not clear whether such models could apply in the benefit-sharing context. One parallel is that the different actors with diverging positions do have to negotiate how they will contribute to and license the pooled resource.

In the context of multilateral models, further consideration needs to be given to:

- the risk that bilateral investment treaties may also be applicable to the innovative funding mechanisms and cause problems;
- who the donors are and why they participate;
- the role of leadership;
- the role of incentives to join; and
- trust.

Trust and control are identified as key issues for benefit-sharing with respect to genetic resources and DSI as some countries may want to maintain control of their genetic resources (assets), i.e. through a bilateral model. Governance of any multilateral solution will have to build and enhance trust in the system, although this is challenging given the heterogeneity of the stakeholders and the nature of the models.

**For more information, see white paper 5 by Prof. Esther van Zimmeren (Univ. of Antwerp).**

## **2.4 The socio-economic aspect**

The decision of the 14<sup>th</sup> COP on DSI noted the societal benefits arising from open access and the use of DSI. Data flow is a key element of life sciences and open access thus plays an essential role in this. The EU and Member States' long-term strategies widely support open access, which is reflected in the large financial and infrastructure commitments, FAIR (Findable, Accessible, Interoperable, and Reusable) principles and the European Open Science Cloud (EOSC).

***What do scientists in research intensive countries say about the use and importance of DSI for research?***

Gene banks have an important role in preserving and distributing genetic material and information for research purposes. This information includes passport data and increasingly DSI, which complements traditional passport records. The social relevance of these gene banks and the associated research, for example on crop plants, is enormous. There are significant costs associated with the preservation of physical material, generating and storing data, and conducting research, which can amount to many millions of euros annually.

FAIR principles play an important role with respect to the generation, storage and sharing of the data. Data are provided by and for the entire research community, allowing re-use and monitoring of genetic diversity. Hypothesis development and the determination of function are only possible

through comparison of large amounts of data, making data sharing and accessibility to data essential.

Even in research intensive countries, there are limitations on data storage as well as analysis and transfer capacities. This indicates the need for better storage and linking of data and knowledge around the world, coupled with ongoing training for scientists.

**For more information, see white paper 6 by Dr. Jens Freitag (Leibniz Institute of Plant Genetics and Crop Plant Research).**

### ***What do scientists in developing and emerging economies say about the use and importance of DSI for research?***

The majority of the DSI in the INDSC databases comes from, i.e. is geographically sourced from, the USA, China, Canada, and Japan.<sup>8</sup> This may be unexpected as these are usually regarded as “user” and not “provider” countries. At the same time, more than half the 15 million users of the INDSC are not from the countries which host and finance the databases. This indicates that DSI is relevant for and used by the international scientific community worldwide. For this purpose, the WiLDSI project investigated the use and importance of DSI for researchers in developing and emerging economies (South Africa, India, Colombia and Brazil) through a survey and semi-structured interviews.

DSI is essential for the researchers who participated in the study. They intensively use open access databases, such as GenBank, BOLD, EMBL-EBI, the Joint Genome Institute (JGI) and regard open access as a pre-condition for their research.

Of those researchers who had already had some experience with the NP and its implementation, they expressed concern about the potential negative impacts on their research that might arise from taking a bilateral “Nagoya Protocol” approach to access to DSI. In this respect, their concerns seem closely aligned with those of researchers in developed countries.

The study also highlighted the potential for more benefit-sharing with these countries, e.g. through increased availability of domestic sequencing facilities, training in bioinformatics, increased research funding, data sharing and technology transfer.

**For more information, see the white paper 7 by Dr. Carmen Richerzhagen (German Institute for Development Policy).**

## **2.5 Potential models to generate sustainable and effective (monetary) benefit sharing**

### ***What could benefit-sharing post-2020 look like that is not based on tracking NSD usage in the INDSC? What value can be delivered by such a system?***

The development of a benefit-sharing system could involve a three step process, starting with a needs-based assessment mechanism, followed by designing a tailored funding approach and then fine-tuning the system through discussions with a wide range of stakeholders, including from the

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<sup>8</sup> Rohden, F., Huang, S., Dröge, G., and Scholz, A., (2020) Combined Study on Digital Sequence Information (DSI) in Public and Private Databases and Traceability. Secretariat of the Convention on Biological Diversity. Montreal, Canada.  
<https://www.cbd.int/meetings/DSI-AHTEG-2020-01>.



public and private sectors. Such a system would be based on various assumptions, such as ensuring that it contributes to the conservation of biodiversity, safeguards open science, is fair and equitable, includes elements of voluntary participation, respects existing bilateral and multilateral benefit-sharing mechanisms, is not conditioned on tracking the actual use of genetic resources/DSI, can raise funds from private sector partners, etc.

Possible models would differ with respect to:

- the degree of regulatory intervention required;
- the stakeholders involved;
- the amount of resources that may be mobilized.

Consideration would need to be given as to whether a new funding structure is created or existing structures can be used, e.g. the Global Environment Facility (GEF).

The potential need for an initial ‘coalition of the willing’ was identified. This could include stakeholders from a range of areas, such as core databanks, donor countries and foundations, relevant corporations who would come together to design and launch such a mechanism.

The following models, which are described in detail, are all aimed at mobilizing the shared responsibility of all stakeholders:

- paying public domain model;
- subscription model;
- micro-levies;
- public-private partnerships;
- bonds; and
- certification schemes.

Irrespective of the type of model, a need for transparency and accountability as well as clear verifiable metrics is necessary to safeguard the incentives for users to participate in such a system and to guarantee the success of the funding mechanism.

It is proposed that a substantial part of the funds should be allocated towards supporting conservation and sustainable use of biodiversity according to the specific identified needs of the countries involved.

**For more information, refer to white paper 8 by Devanshi Saxena, Prof. Claudia Seitz, Torsten Thiele and Prof. Esther van Zimmeren.**

### **3. Conclusion**

These eight white papers provided the background research and inspiration for the policy options white paper released in October 2020. Through discussions and lessons learned from these white papers, the building blocks of the 5 open-access policy options were generated.

## 4. Compilation of 8 White Papers

### White Paper 1: WiLDSI INSDC hypothetical changes in response to theoretical ABS requests

Dr. Guy Cochrane, EMBL-EBI

#### Introduction

This report lays out the findings to date from an exercise carried out by those working in the International Nucleotide Sequence Database Collaboration (INSDC) databases and their governance systems. The exercise forms part of the larger WiLDSI project to explore options for Access and Benefit Sharing systems that retain openness in data via INSDC.

In the exercise, changes to INSDC were imagined that might be requested by those implementing Access and Benefit Sharing (ABS) systems or could be seen to offer something of benefit to ABS implementations. These changes were considered entirely *hypothetically, classified* and, based on their expected impacts to different *stakeholders*, were *scored* for acceptability. The changes, discussions and scores continue to be refined and this white paper should be considered a work in progress.

#### Hypothetical changes

The changes discussed in this report are hypothetical; they have not been made and there is no indication from INSDC that they will be made. The INSDC, a scientific collaboration between the European Molecular Biology Laboratory (an inter-governmental treaty organisation of member states), the National Center for Biotechnology Information (a part of the US Government's National Institute of Health's National Library of Medicine) and the DNA Databank of Japan (a part of the Japanese National Institute of Genetics), is under no formal obligation to make any changes in response to requests from the Convention on Biological Diversity (CBD) or other ABS fora. Furthermore, given that the majority of the data holdings, and of database access, from INSDC databases does not come from CBD-relevant sequences, a reluctance to change INSDC operations based on requirements relating ABS is expected and must be balanced against the global needs and priorities for INSDC. However, the exercise reported here sets out to understand which changes might reasonably be requested and what impacts can be expected if the changes are made.

#### Change classification

Changes have been classified under eight broad headings, in some cases with hierarchical classification of changes within a heading. In some cases, changes are independent of others within a heading; in others (denoted in colored text), the changes presented are mutually-exclusive options.

The 8 broad change categories include:

1. Country of origin (geographical location and/or latitude and longitude)
2. ABS-relevant tagging
3. Terms of use

4. Data licensing
5. Missing data
6. Governance
7. Non-monetary benefits
8. Access restriction

## Stakeholders

In order to estimate impact, a number of classes of stakeholder have been defined (see Table I).

*Table I: Stakeholder definitions*

Stakeholder	Definition	Notes
ABS submitters	INSDC users uploading DSI in scope of CBD/NP	These stakeholders are likely aware of CBD activities and requirements for ABS
General submitters	INSDC users uploading DSI out of, or not known to be in, scope, for CBD/NP	These stakeholders are unlikely to be aware of CBD activities and requirements for ABS
Infrastructure providers	Those that provide informatics infrastructure, such as the INSDC partners and the CBD's ABS Clearinghouse	This group is of a technical nature and concerns only the informatics operations of INSDC and the CBD, in contrast with, for example, the INSDC stakeholder group (below)
Primary data consumers	Those who search, access and retrieve DSI from INSDC databases	This group is defined as excluding secondary database providers (see below); changes acceptable to this group encourage the free use and reuse of sequence data, driving value creation
Secondary database providers	Those who operate databases that consume data from INSDC and re-distribute to users	Changes unacceptable for this user group risk preventing propagation of DSI into secondary resources, from which the greatest reuse of data is achieved and the fullest value is created
Provider countries	Countries asserting ABS requirements relating to biological materials from which DSI is generated	Membership of this group is defined by a nation's sovereignty over the materials that are sequenced rather than the location of the sequencing
INSDC policy makers	Those involved in considerations of policy, governance and the strategy of INSDC	This group ignores all technical implementation issues

## Scoring system

The scoring system uses estimates of acceptability based on interests held by the defined stakeholder groups. Using whole increment scores from -3 to +3, for a given stakeholder group, -

3 represents a change that would be *highly unacceptable*, -2 a change that would be *moderately unacceptable*, -1 a change that would be *slightly unacceptable*, 0 a change that would be *neutral* with respect to acceptability, +1 a change that would be seen as *slightly positive*, +2 a change that would be seen as *moderately positive* and +3 a change seen to be *highly positive*.

For example, change “1. /country and/or /lat\_lon > b. Policy > iii. Opt-out rather than opt-in to /country and/or /lat\_lon usage” shows the scores as shown in Figure I. According to this scoring, the change concerned would be *neutral* with respect to ABS submitters, primary data consumers and secondary database providers, *highly unacceptable* to infrastructure providers and *moderately positive* to provider countries and INSDC policy makers.

Figure I: Scores for change 1.b.iii. An example exploration is provided here.

ABS submitters	general submitters	infrastructure providers	primary data consumers	Secondary database providers	provider countries	INSDC policy makers
0	-2	-3	0	0	2	2

## Preliminary exploration of scores

### *Simplifying the analysis space*

In a preliminary analysis, we choose to ignore the infrastructure provider scores; scores for this group represent complexity and new engineering requirement for the required technical transition which translate almost exclusively to costs, largely for engineering staff salaries and, to a lesser extent, for hardware. While these costs would become important if the given change were accepted, and funds would certainly need to be raised, given the timescales of the decision-making upon, and ultimate implementation of, a future ABS system, we might satisfy ourselves with noting that future costs would be incurred to different levels and that in a second phase we would need to seek these funds. Depending on where infrastructure was implemented, costings and funding sources could be more accurately investigated in this second phase.

In this same analysis, we might also choose to ignore the impacts upon ABS submitters for two reasons: first, while scores against the changes for this stakeholder group are never positive, they are largely at 0 or -1, with only 2 changes at the minimum for the stakeholder group of -2 indicating that this is a stakeholder group for which the changes raise limited acceptability issues; second, given that there is a strong intersect between ABS submitters and provider countries, for most users, compromises at point of submission will be expected given that the change has been implemented to support ABS. For example, if it is an inconvenience for a data submitter from a provider country to provide country information, then this same submitter will very likely know the reason for this inconvenience and the greater chance that the ABS system will work in his/her favor as a result.

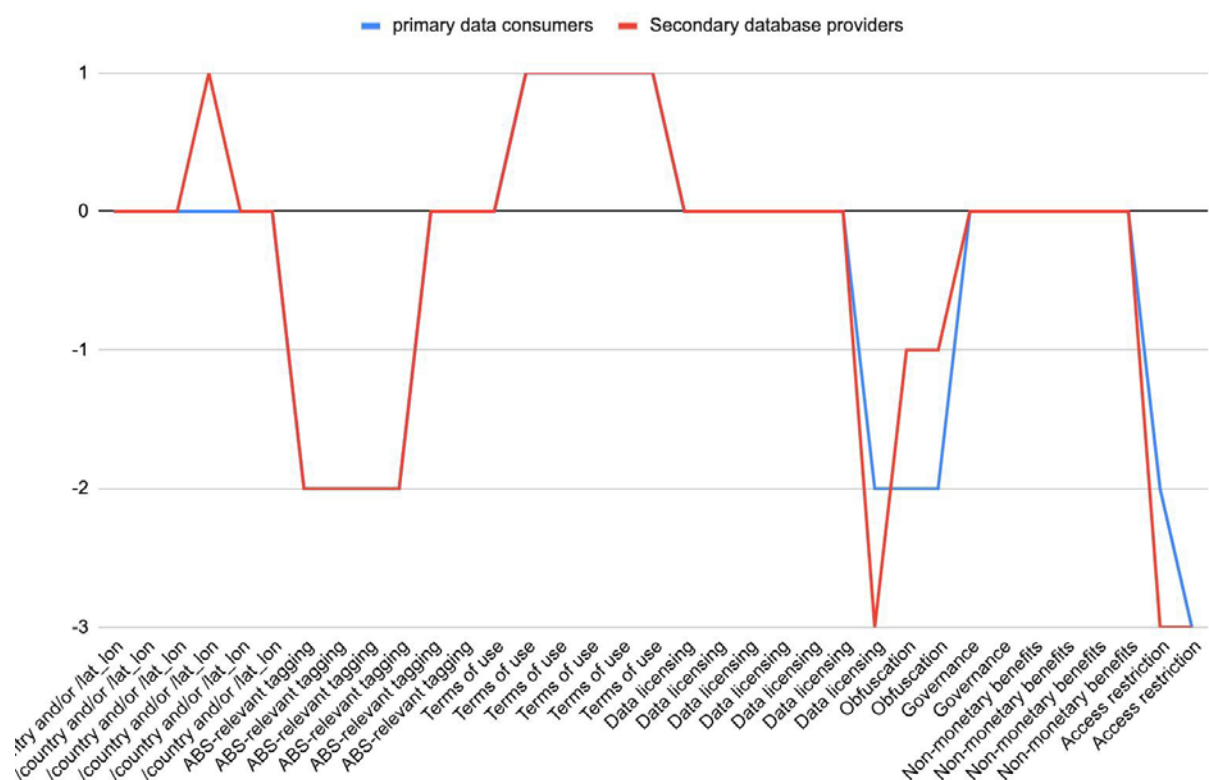
### *Some inverse correlation between the scores for general submitters and provider countries*

Figure II: Broad view of scores: general submitters versus provider countries



21

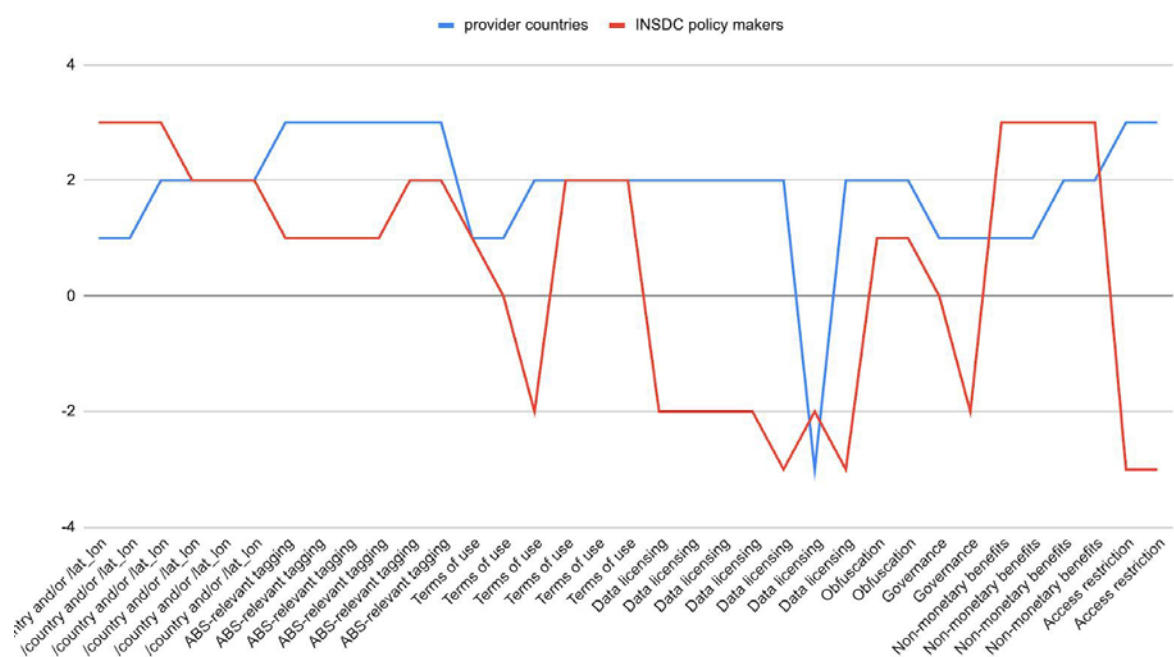
Figure III: Broad view of scores: primary data consumers versus secondary database providers



Benefits to INSDC policy makers and provider countries are mutually achievable

While for some changes, INSDC policy makers see detrimental effects from given changes when provider countries see benefits, for many cases, changes of benefit to INSDC policy makers are also beneficial to provider countries (see Figure IV).

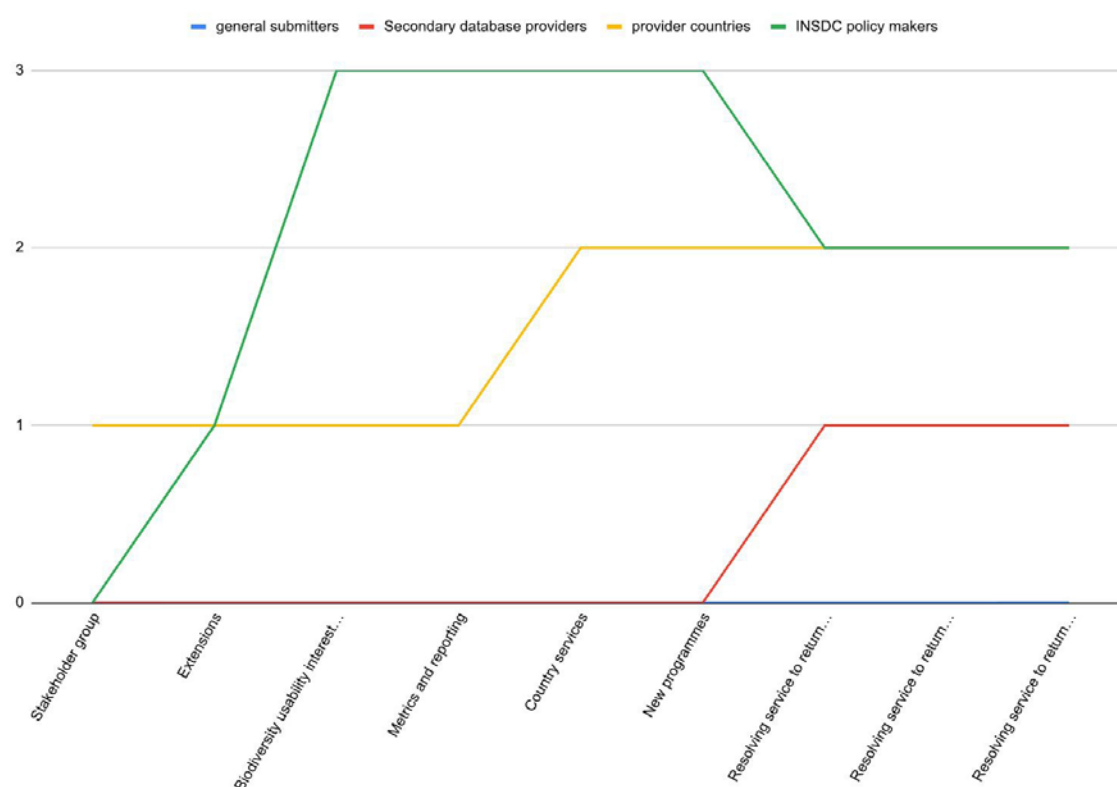
Figure IV: Broad view of scores: INSDC policy makers and provider countries



### *Resolving towards a subset of “opportunity” changes*

Taking these lines of thought together, one can select a number of changes because there is no negative impact (scores  $\geq 0$ ) upon general submitters, secondary database providers or INSDC policy makers, and that there is strong benefit (scores  $\geq 2$ ) for provider countries (see Figure V).

*Figure V: Changes selected for strong benefit to provider countries and no negative impact upon general submitters, secondary database providers or INSDC policy makers*



## **Results**

The exercise showed that changes to country of origin (the fields known as geographical location and lat\_long) was neutrally accepted by the primary data consumers, moderately unacceptable to general submitters, positively acceptable to provider countries and highly positive to INSDC policy makers. Furthermore, ABS-relevant tagging showed a strongly negative response from general submitters whereas provider countries stakeholder group elicited a strongly positive response. Changes to terms of use condition was neutrally accepted by data submitters and positively accepted by provider countries.

## **Conclusion**

The changes examined here are hypothetical; they have not been made and there is no indication from INSDC that they will be made. Furthermore, given that the majority of the data holdings, and of database access, from INSDC databases does not come from CBD-relevant sequences, a reluctance to change INSDC operations based on requirements relating ABS is expected. Also, no

formal request has been officially made as of now. However, the exercise reported here sets out to understand which changes might be requested and what impacts can be expected if the changes were implemented.



## **White Paper 2: How can a (traceable) system make money?**

Aysegul Sirakaya, University of Ghent, ABS-int

### **1. Introduction**

A key request from the countries that are advocating for an explicit recognition of the value of 'DSI' within the context of the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) is the capturing and sharing of value related thereto. While a substantive part of this value is already captured in the non-monetary benefits that are generated by enabling unencumbered access and open exchange of 'DSI' enabling research and development on genetic resources and related DSI, which leads to a progress in natural product research, an explicit policy request has been formulated to also ensure a monetary value sharing or monetary benefit sharing.

In order for such a monetary benefit sharing to take place, a system needs to be developed which conceptually takes into due consideration the key demands from both sides, i.e. from the provider country side and the user side, and by doing so creating an incentive for both sides to link through the system. A system can therefore only generate 'money' if it safeguards the legitimate interests and recognizes these demands of both providers and users. This is essential to ensure benefits are generated by access and utilization of genetic resources and related 'DSI', which can then be shared effectively. If there is no sound basis providing for a balanced system, the likelihood of benefits being generated will go down, which will negatively impact the actual benefit sharing.

### **2. What is demanded from a user and provider country perspective?**

#### **a. International ABS goals**

With the aim of compiling the international ABS principles regulated under the CBD and the NP with additions from various decisions of the Conference of the Parties to the CBD and the NP (COP Decisions), we have previously conducted a review of these international documents on ABS and compiled 11 ABS goals that are prescribed by these documents which are then to be fulfilled by the Parties through their national ABS frameworks. These goals found through the literature review conducted in Sirakaya (2019) are listed hereunder:

1. Predictable conditions (Nagoya Protocol Preamble)
2. Legal certainty (Nagoya Protocol Article 6, COP Decision V/26, VII/19, VIII/4)
3. Transparency (Nagoya Protocol, COP Decision V/26)
4. Fairness and equity in negotiations (Nagoya Protocol, COP Decision V/26)
5. Sustainable use of biodiversity components (CBD Article 1, Nagoya Protocol Preamble, Article 8, Article 9, COP Decisions V/26 and VII/19)
6. Cost-effective measures (Nagoya Protocol Article 6, COP Decisions VII/19, VIII/4)
7. Scientific research based on genetic resources (CBD Article 15.6)
8. Strengthening the ability of Indigenous People and Local Communities to benefit from the use of traditional knowledge (Nagoya Protocol Articles 5, 6, 7, 12, 21, 22, / COP Decision V/26, VI/24) Tech transfer and cooperation to build research and innovation capacity in developing countries (Nagoya Protocol, COP Decisions VIII/4, VII/19 VI/24, V/26)
9. Creating incentives to conserve biodiversity (CBD Article 11, COP Decision VI/24, Nagoya Protocol Preamble)
10. Innovative solutions for transboundary situations (Nagoya Protocol Preamble and Article 11)

A stakeholder survey has been conducted following the identification of the international ABS goals to provide a better understanding regarding the priorities of different stakeholder groups. The

survey has received 220 responses in total with 92 responses from provider countries, 60 from academic users, 31 from industrial users and 37 from collections.

	PROVIDER COUNTRY	ACADEMIC USER	INDUSTRIAL USER	COLLECTIONS
Access	<p>Top 5:</p> <ol style="list-style-type: none"> <li>1. Legal certainty (72%)</li> <li>2. Transparency (61.40%)</li> <li>3. Sustainable use of biodiversity components (61.40%)</li> <li>4. Fairness and equity in negotiations (54.40%)</li> <li>5. Predictable conditions for ABS (52.63%)</li> </ol> <p>Least Important:</p> <p>Innovative solutions for transboundary situations (32%)</p>	<p>Top 5:</p> <ol style="list-style-type: none"> <li>1. Developing and carrying out scientific research based on GR (57.8%)</li> <li>2. Legal certainty (57.8%)</li> <li>3. Cost-effective measures (57%)</li> <li>4. Predictable conditions for ABS (56%)</li> <li>5. Transparency (50%), sustainable use of biodiversity components (50%) and creating incentives for biodiversity conservation” (50%).</li> </ol> <p>Least Important:</p> <p>Tech transfer and cooperation to build research and innovation capacity in developing countries (40%)</p>	<p>Top 5:</p> <ol style="list-style-type: none"> <li>1. Legal certainty (83.33%)</li> <li>2. Predictable conditions for ABS (62.5%)</li> <li>3. sustainable use of biodiversity components (58.33%)</li> <li>4. Developing and carrying out research based on GR (54.17%)</li> <li>5. Providing transparency (50%).</li> </ol> <p>Least Important:</p> <p>Creating incentives for biodiversity conservation (42%)</p>	<p>Top 5:</p> <ol style="list-style-type: none"> <li>1. Legal certainty (78.13%)</li> <li>2. Providing transparency (68.75%)</li> <li>3. Developing and carrying out scientific research based on GR (68.75%)</li> <li>4. Predictable conditions for ABS (62.5%)</li> <li>5. promoting fairness and equity in negotiation (50%)</li> </ol> <p>Least Important:</p> <p>Strengthening the ability of Indigenous and Local Communities to benefit from the use of traditional knowledge ranks the lowest (28.13%)</p>

Benefit-sharing	<p>Top 5:</p> <ol style="list-style-type: none"> <li>1. Transparency (67.27%)</li> <li>2. Legal certainty (63.8%)</li> <li>3. Fairness and equity in negotiation (54.40%)</li> <li>4. Creating incentives for biodiversity conservation (62.1%)</li> <li>5. Sustainable use of biodiversity components (55.17%)</li> </ol> <p>Least Important:</p> <p>Innovative solutions for transboundary situations (34.5%)</p>	<p>Top 5:</p> <ol style="list-style-type: none"> <li>1. Fairness and equity in negotiation (64.4%)</li> <li>2. Cost-effective measures (57%)</li> <li>3. Sustainable use of biodiversity components (56.5%)</li> <li>4. Creating incentives for biodiversity conservation (56%)</li> <li>5. Providing transparency (54.5%).</li> </ol> <p>Least Important:</p> <p>Innovative solution for transboundary situations (43.18%)</p>	<p>Top 5:</p> <ol style="list-style-type: none"> <li>1. Providing legal certainty (62.5%)</li> <li>2. Predictable conditions for ABS (58.33%)</li> <li>3. Providing transparency (58.33%)</li> <li>4. Promoting fairness and equity in negotiation (58.33%)</li> <li>5. Creating incentives for biodiversity conservation (58.33%)</li> </ol> <p>Least Important:</p> <p>Tech transfer and cooperation to build research and innovation capacity in developing countries (37.5%)</p>	<p>Top 5:</p> <ol style="list-style-type: none"> <li>1. Providing legal certainty (69%)</li> <li>2. Developing and carrying out scientific research based on GR (62.5%)</li> <li>3. Predictable conditions for ABS" (59.38%)</li> <li>4. Providing transparency (59.38%)</li> <li>5. Providing fairness and equity in negotiation (59.38%)</li> </ol> <p>Least Important:</p> <p>Strengthening the ability of Indigenous and Local Communities to benefit from the use of traditional knowledge (31.25%)</p>

## b. Key requirements

In order for a system to be supported, users and provider countries have formulated certain key requirements. An effective system should provide for 1) legal certainty, 2) a clear freedom to operate – sustainable use, 3) low transaction costs - predictable conditions – cost effectiveness, 4) fairness and equity (fee) and 5) transparency.

Provider countries equally request legal certainty (including predictability) and low transaction costs. Also ensuring sustainable use is of key relevance to ensure benefit sharing. In addition, fairness and equity as to the fee is also highly relevant for the provide country as the receiving entity. The predictability and cost effectiveness related to receiving payment (of monetary benefits) is specifically linked to the requirement of the users for predictable and fair conditions in relation to the fee to be applied.

This overlap of key requirements of provider countries and users shows that any system that is proposed needs to deliver on – at least – the common key requirements.

### 1. Legal certainty

Preparatory documents to the NP repeatedly mention the need for legal certainty in ABS frameworks. Article 6 of the NP confirms this need as it states that the conditions should be providing legal certainty.

There is no harmonised definition or scope of legal certainty within the field of international law. However, it is accepted that the basis of legal certainty dates back to Fuller's principles of legality (Popelier 2000), which are: "sufficiently general, publicly promulgated, not retroactive, clear and intelligible, free of contradictions, relatively constant, so that they don't continuously change from day to day, possible to obey, and administered in a way that does not wildly diverge from their obvious or apparent meaning" (Fuller 1973). Within the field of ABS, Shei and Tvedt (2010) state that: "Legal certainty implies that the persons operating under the law can predict their obligations and rights according to the regime." Legal certainty enables a user to reasonable assume that he has complied with the law.

Also, for the provider country, legal certainty reduces transaction costs and ensures the sustainability of the innovative cycle of use of their genetic resources (and related 'DSI'). Legal certainty is therefore the core requirement for all stakeholders.

### 2. A clear freedom to operate – ensure sustainable use

An important part of the freedom to operate is that facilitated access remains guaranteed and safeguarded, otherwise there is a bureaucratic or financial burden on R&D or any pre-commercial use of 'DSI'. It is important to stress that open access and exchange of data enables continued sustainable use of genetic biodiversity (this also generates incentives for characterization). In addition, the voluntary non-monetary forms of benefit sharing are explicitly recognised, i.e. the value in the sharing of data and of the enabled sustainable use.

Sustainable use of biodiversity components is one of the 3 pillars of the CBD objectives as stated in Article 1. Sustainable use under Article 2 of the CBD is defined as "the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations."

Article 9 of the NP obliges the Parties to direct benefits into sustainable use. Furthermore, Article 8 of the NP on special considerations states that when putting ABS systems in place, Parties should create conditions to promote and encourage research which contributes to sustainable use of biological diversity, including through the use of simplified measures. Under Article 9, sustainable use is exemplified as use that is beneficial for human, plant and animal health as well as food security. The importance of access to genetic resources leading to sustainable use of biological diversity is further emphasised in COP Decisions V/26 and VII/19.

### 3. Low transaction costs – predictable conditions - cost effectiveness

Cost-effectiveness of ABS measures has been repeatedly emphasised in COP Decisions VII/19 and VIII/4 and found its place under Article 6 of the NP.

Coglianese (2012) explains cost-effectiveness as the calculation of the balance between the cost of regulatory option and benefit of a given level of behavioural change or of reduction in the problem due to the regulatory option. This outcome can be based on monetary or non-monetary means such as social or environmental benefits.

The provider country should design regulatory options whose implementation costs do not outweigh benefits. When selecting a regulatory option for ABS, a provider country should think about the cost of fulfilling these requirements both for the user and provider, and the possibility of generating benefits that would outweigh the transaction costs.

One of the elements that could be looked at to ensure predictable conditions is the development of standard contractual clauses or standard contractual frameworks with well-defined terms and conditions. Reference in this regard is also made to the option to look at collaborative models which is dealt with later in the document.

#### 4. Fairness and equity (fee)

Although fair and equitable benefit-sharing is repeatedly mentioned in various international legal instruments and documents, there currently exists no unified definition or common understanding related to their legal meaning and scope at the international level (Morgera 2016). However, fairness and equity by nature and by their literal meaning do emphasise the element of justice (UNEP 1996).

Fairness and equity in negotiations are important for both parties. ABS negotiations within the framework of the NP tend to demonstrate many socio-political differences amongst the stakeholders (De Jonge 2016). Information obtained demonstrates that the users often have higher negotiation skills and expertise than the provider countries (UNCTAD 2014).

In addition, certain unrealistic expectations from provider countries which are detached from the actual value of the genetic resource and related 'DSI' in a final product, might also undermine the fairness and equity from a user perspective. Also, a one size fits all approach to the definition of an applicable fee undermines fairness and equity and a model enabling a diversification in the applicable fee should be considered.

Capacity-building related to negotiation skills and enhancing the understanding the complexities of natural product research (especially with regard to the use of 'DSI' related thereto), as well as standardisation of certain contractual clauses can further support fairness.

#### 5. Transparency

##### Transparency for users

According to Bianchi (2013) "Transparency is associated with a public law paradigm that is transposed onto the international legal system to provide good governance and enhance its overall legitimacy and effectiveness." He adds that transparency can also be associated with legitimacy and accountability. Transparency is ensured when the user knows on what grounds a decision by a competent authority is made. Transparency is most effectively guaranteed when a decision is taken in accordance with well-defined and detailed process stipulated in the law. By doing so, the provider country can also benefit in justifying its decisions.

##### A transparent management of benefit sharing,

Taking into account one of the objectives of the CBD, users have often indicated that any monetary benefit sharing that takes place should be allocated towards supporting conservation and sustainable use of biodiversity. Although users should not try to directly influence the allocation of the monetary benefits shared, however the aims of the ABS system should be respected, e.g. benefits to be directed to conservation and sustainable use of genetic resources. This can be linked to the direct action by users to achieve the CBD objectives and the SDGs. Users can voluntarily take action to contribute to achieving these objectives, e.g. they can create products for smaller markets, and contribute to capacity building.

### **3. Key parameters to be considered and operationalized in a fee/payment model**

The key elements that need to be operationalized for an effective payment system are: on what is a fee applied, when is the fee set, and by whom is it to be paid. Defining these parameters provides more clarity on how a proposed system in the context of the traceable discussion could make money.

#### **a. On what?**

##### **1. (Starting) material**

There is the need for a clear terminology which provides a clear frame around the material scope of 'DSI'. It has been agreed (already during the first Ad Hoc Technical Expert Group, AHTEG) that 'DSI' is a placeholder and is not precise and too open-ended as a term. As an alternative term, some countries have proposed Genetic Sequence Data (GSD), some stakeholders have proposed Genetic Resource Sequence Data (GRSD), others Nucleotide Sequence Data (NSD)<sup>9</sup>. A well-defined term is also essential to keep a clear link between the 'DSI' and the related genetic resources. In the context of the discussions on an all-encompassing multilateral system, there is a substantial risk that the need for a clear and well-defined definition of the term is dismissed as not needed. This would not only create unlimited and unbalanced (payment) obligations, but would also put the subject matter on which benefit sharing obligations are applied outside of the scope of the Nagoya Protocol.

##### **2. Activity**

It has been clearly formulated by policy makers that there should not be any (benefit sharing) obligations imposed on the access and sharing of 'DSI'. The open access and exchange should be safeguarded since this is seen as essential to ensure natural product research. In addition, since the access and sharing of 'DSI' is such an important enabling tool for the further development of innovative products, this is rightfully qualified in itself as an important non-monetary benefit, which is already shared between the different entities active in the innovation ecosystem, as well as with provider countries in the form of socio-economic benefits.

The request for (additional) monetary benefit sharing hence targets the actual value in the commercial product directly linked to the 'DSI'. This request for monetary benefit sharing is based upon the assumption that through new techniques the value lies in the data ('DSI') directly derived from the genetic resource. It is important to point out that recognising that looking at potential benefit sharing on such 'DSI' has merit does not negate the necessary link between the genetic resource and the 'DSI' (as has been pointed out above). In that sense there are similarities between the issue of 'DSI' and 'derivatives' re benefit sharing (cfr infra).

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<sup>9</sup> Reference is made to the actual position papers of the relevant countries and stakeholders for a further background and argumentation related to the proposed alternative term.

Taking into account that in the policy discussions a direct link is made between the monetary benefit sharing on 'DSI' and the commercial product, it could be argued that payments should be set as of the development phase. The development phase has a clear link with the aim to come to a commercial product and hence the generation of monetary benefits. This means that all research activities, including those for commercial research should be without any obligations. This is in line with the requirement to keep open access and especially open exchange since in open innovation systems data might be transferred from an academic entity to a commercial entity, and later again to an academic entity.

A relevant question is whether this can only be applied in a traceable system (through a pooling system/collaborative mechanism the traceability should be fairly easy (to be confirmed in the further assessment of collaborative models)).

It is also important that no obligations on activities outside the scope of the R&D process or activities directly resulting therefrom are applied. This includes that no obligations should be imposed on certain activities conducted in the development phase, e.g. quality control, regulatory & safety studies, species identification (for disease monitoring), which do not qualify as utilization under the NP.

### 3. (Developed/commercial) material/product

The developed commercial material or product on which the fee will be applied should also comply with certain qualification criteria. These qualification criteria ensure that the product is (directly) based upon or integrates the 'DSI', which substantiates the sharing of benefits resulting from (the use of) 'DSI'.

First, the developed material should be materially or directly based upon the 'DSI', not purely be inspired upon or by the 'DSI'. Some even state that only 'DSI' that has actually been integrated in a (modified) organism or product should be captured by possible benefit sharing.

In this regard, reference can be made to some elements which are being discussed in the context of the WIPO IGC negotiations. This includes a definition of “(materially/directly) based on”, i.e. meaning that the genetic resource (and/or associated TK) must have been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the genetic resource (and/or associated TK). This is stricter than “derived from” and shows that in an IP context a material/direct link with the genetic resources is needed, which can be informative as a qualifier to establish a link between 'DSI' and benefit sharing. “Based on” includes any genetic resources that were involved (but with application of the “materially/directly” qualifier in the development of the invention). The term “materially/directly” indicates that there must be a causal link between the invention and the specific genetic resource. In practical terms, this means that only those genetic resources without which the invention could not be made, are to be considered. Those GRs, which may be involved in the development of the invention, but which are not material to the claimed invention, are not relevant.

This can also be applied to the qualification of the (commercial) material or product, which includes (the use of) 'DSI' on which benefit sharing might be due. Only in case the 'DSI' has been necessary or material to the development of the (commercial) product, this 'DSI' is seen as material and benefit sharing might apply. Only the 'DSI' without which the (commercial) product could not have been made can be subject to the benefit sharing obligations.

Some national laws refer to ‘adding value in the final product’. In the position of Brazil as notified on 3 June 2019, it is clearly stated that “the Genetic Heritage should be one of the main elements adding value to the product”. The position further states that “this means that in some cases there may be a finished product developed from a genetic resource that won’t share benefits because the genetic resources present in the finished product is not ‘crucial to the existence of its functional features or its commercial appeal’”. This seems to be a translation of ‘materially based upon’. The concept of ‘added value’ also enables to diversify and ensure real and realistic value sharing.

Such a system provides for a fair and correct calculation basis for the benefit sharing due for the use of ‘DSI’, and provides an incentive to use and share as much DSI as possible (which is in line with the current scientific practice), which will further enhance the probability of the development of an actual valuable product, which would result in (higher) benefit sharing re the relevant ‘DSI’.

This also avoids unfair royalty stacking since no fees are due on the ‘DSI’ which does not comply with the qualifier.

Secondly a clear cut-off point should be applied to the application of a monetary payment. In this regard reference can be made to the issue of derivatives (conceptually ‘DSI’ has certain similarities to a derivative, since a derivative is also not qualified as a genetic resource, and solely regarded in the context of benefit sharing, with the need for a direct link between the genetic resource and the derivative). Specific reference can be made to the discussion related to benefit sharing on derivatives. First reference is made to the fact that derivatives are defined as “naturally occurring compounds”. This reasoning can be applied to the issue of data, as being different from information. This means that no additional benefit sharing is to be applied in case further information which results from substantial human intervention is used. Doing so would undermine (the need for) a (direct) link between the genetic resource and the ‘DSI’ related thereto. Secondly, it has been clearly stated that for R&D activities on derivatives to fall in the scope of ABS obligations, there must be an ascertainable level of continuity between the R&D activities conducted using a derivative and (obtaining the derivative from) the genetic resource. If we apply this principle to the issue of ‘DSI’, any activity with ‘DSI’ which does not fit this continuity cannot incur benefit sharing obligations.

#### **b. When is the fee to be set?**

As pointed out above re the key requirements the fee applied should ideally be based on a realistic calculation basis, which takes into account the real value of the ‘DSI’ it is related to, and as it has been integrated in a final (commercial) product. In private licensing reference can be made to the added value of the trait as calculation basis for royalties. Unfortunately, also the transaction costs seem to increase, as well as the complexity of the traceability with the level of qualification of real value which is required to be taken into account. This appears as a paradox in the traceable system.

You can set the applicable fee 1) upfront with predefined rates, 2) at commercialization or - as an option in between - 3) at the start of the (commercial) development phase.

The fee could be set as an upfront fee with predefined rates. A predefined fee is different from a subscription fee in that it will only be applied at the trigger point (while a subscription fee is payable independent from whether the ‘DSI’ actually leads to commercial development or a commercial product). The predefined fee provides clarity and legal certainty and does not entail transaction costs. The downside is that this rate will not take into account the specificity of a real case, nor is it related to the real value of the ‘DSI’ in relation to the final (commercial) product, or does it enable to diversify. (there also seems to be a risk of unwarranted royalty stacking).



With an upfront fee with predefined rates (but only paid later), more legal certainty seems to be provided in cooperation schemes which start with academic use, since the academic users (which will not pay since access and academic research remains open and free of any payment), know what the additional price tag on the 'DSI' applied in the specific R&D process, will be in case of commercial licensing. Commercial users will then know upfront (as soon as it is licensed, acquired or a cooperative R&D agreement is entered into) what the price will be to be. This system is similar to the system currently provided for in the national law in Brazil with a fee due on a final (commercial) product.

The fee could be negotiated at the end of the R&D process, i.e. at commercialization. Such a fee can take into account the specificity of a real case and can be related to the real value of the 'DSI' in relation to the final (commercial) product. However, it is unlikely that a fair price will be agreed upon, since the user has no more bargaining power (in addition to being under time pressure to accept a fee). In addition, the transaction costs can be high.

You have more of a negotiation in a model which is neither fully upfront in defining the applicable fee or completely at the end of the R&D process, i.e. at the start of the (commercial) development phase. Negotiation on the actual fee (to be paid at actual commercialization) could be done as soon as the development starts to enable differentiation. This provides an incentive for a correct fee, since the (intended) user most probably still has several options about which genetic resource and related 'DSI' will be included in the development activities and decide not to continue the (commercial) development with that genetic resource and/or 'DSI' for which no workable fee can be defined or agreed upon. Such a differentiation is not feasible and choice not available if a predefined rate is applied or when the negotiation only takes place at the actual commercialization.

In a collaborative or pooling model, you could further operationalize this model and potentially distinguish, i.e. the more essential 'DSI' has been for the commercial product, the higher the fee is that will be applied for this 'DSI' compared to another 'DSI' (this system is also applied in patent pools); or a fee is only applied for the DSI used and not for the DSI not used. This is of course dependent upon the effective application of traceability. A collaborative model could enable combining the advantages of an upfront fee with predefined rates, but at the same time taking into consideration certain specificities of the actual scope of the model.

A fee which is defined at the commercial stage of the R&D process, also seems to provide effective safeguards for free and open access and exchange, both for academic and commercial research. Open exchange is especially safeguarded if all research activities, including characterization and commercial research activities prior to the development phase are exempted from any payment.

Another option that could be looked at is the ability to actually measure the value of the non-monetary benefit sharing which is being applied, with the ability for users of "DSI" to demonstrate this value and receive credits for such non-monetary benefit sharing.

A further stakeholder review can be done with the private sector to get a better view on the (delta) of possible workable fees.

Another issue that could be looked at is the limitation in time of the application of fees to provide for a balanced system (cfr the limited duration of private IP rights).

In a non-traceable context, you can look at the payment of a subscription fee. Such a subscription fee can be applied in a comprehensive multilateral system or as fee to subscribe to a specific multilateral system (this would work as an FTO fee for the material and technology covered by this

specific collaborative (multilateral) system). The different subscription fees are then to be defined and or negotiated in every separate multilateral system.

With regard to subscription models, it is important to point out that users will need options to withdraw from the subscription (this creates specific issues with regarding to the continuation of existing rights); as well as legal certainty that the rules of the subscription will not become less favorable.

**c. By whom is the fee to be paid?**

Taking into consideration that the intent to ensure unencumbered access and research should be safeguarded, academic users should not have any payment obligations. The focus of the potential monetary benefit sharing obligations seems to be on commercial users. However, since the payment should be as much as possible directly linked to the commercial product (and the value of the 'DSI' related thereto), only commercial use (commercial development or a final commercial product, as defined above) by commercial entities should trigger a payment obligation.

The distinction between academic users and commercial users is not always black and white. In case use starts as non-commercial, and then becomes commercial (*at development*), albeit that no payment is due for academic users, transparency on the potential fees that will apply as soon as the research goes into (commercial) development would enable effective R&D cooperation agreements between academic users and commercial users.

**4. Operationalised ABS system**

**a. Introduction: risk of false choice + decoupling with genetic resources**

It seems that there is a false binary distinction between traceable and untraceable, or put differently the status quo with PIC and MAT and a fully multilateral system.

A traceability system goes back to PIC and MAT at the beginning of the chain and can work in principle, both technically and legally. However, in practice it will not provide for a functioning system taking into account the key requirements of both users and providers as set out above; users and provider countries will dismiss this as complicated and with a high transaction cost. This will hence provide support for what seems to be the only logical solution, i.e. a fully (one size fits all) multilateral system.

The multilateral (untraceable system) is however too simple; it is promoted as the only system in which there is no need for traceability and every possible use can be covered by one subscription fee. This is an utopic solution that will not be supported since all control (for provider countries and for potential users) is gone and the diversity of types of use and differences in value related thereto is not taken into consideration. There is hence a risk of an all-encompassing scope (with an alleged lack of need for a clear and well delimited definition). In addition, an all-encompassing model would also create an interference between public rights and private rights (private property and proprietary rights). For all these reasons, the one fee for all uses will result in no easy buy in. A logical consequence is that you give up bilateral approach for genetic resources as well. This however does not seem the intent, and countries will want to add a fully multilateral system for DSI above and beyond a bilateral system on genetic resources. This disconnect is however not legally correct (cfr infra) and creates a false assumption of easy workability.

In an all-encompassing multilateral model, there is a risk of a disconnect between a genetic resource and (the related) 'DSI' (which would not be compatible with the NP, because it would make a system apply to DSI as such). In addition, the DSI to which is will apply will be defined broader than the scope of the NP, which is legally impossible. Within the context of the CBD and the NP, the information chain is and needs to be anchored on the genetic resource origin, with ownership and access conditions firmly on the country providing the genetic resource. This means that the country providing the genetic resource has to define the conditions on benefit sharing related to 'DSI' (or agree with how the conditions are defined in a more collaborative model) in direct relationship with the underlying genetic resource.

We have to overcome this 'false choice' and should include an assessment about the possibility to have systems in between a purely bilateral system based on PIC and MAT and a fully multilateral system, i.e. collaborative models.

#### **b. Conceptual proposal: a collaborative model operationalizing access and benefit sharing**

##### The case for a collaborative model

A collaborative system operationalizes the bilateral system and should combine enabling broad access (continued open access and exchange), with a fair/correct benefit sharing for the development of a commercial product and commercial use. One of the key conceptual elements is that the legal basis of such a mechanism remains bilateral, following the basic principles of the NP.

A collaborative model will most likely take the form of a clearing house mechanism or a cluster of clearing house mechanisms.

Another example of a system in between a purely bilateral or fully multilateral system – operationalizing the bilateral system, could be inspired by pools, genetic resources pools, genetic diversity pools (comparable to patent pools) containing all relevant/essential 'DSI' (potentially also the related genetic resources) for a crop, product, technology, sector... This pool defines the terms and conditions of access and use (can be based on model contracts) connecting the relevant provider countries and possible users, setting a fee for a commercial product. This is diversified and takes into account differences in value for users. Private patent pools often do not work properly since the patent estate from parties is too differentiated. There seems more similarity between the rights in collaborative model in the context of the NP, since the public rights, i.e. the sovereign rights in the 'DSI' are pooled.

Collaborative models create a technical dialogue, which provides a sound basis for consensus building between users and provider countries. All types of users (from the R&D process and value chain) can and should participate. This creates an opportunity to talk with stakeholders that want a solution, and it creates "examples of solutions", which will be an incentive for other pools or clearing house mechanisms. The focus on a certain type of biological diversity or use thereof makes a discussion easier, and hence makes a workable and acceptable result ensuring a balanced and sound basis for payment of monetary benefits more probable.

In addition to lowering transaction costs, while at the same time acknowledging legitimate control, as well as taking into consideration legitimate differences (as to value and hence benefit sharing calculations), collaborative models may also help to simplify or harmonize national ABS laws.

As such a cluster of different multilateral systems comes into existence. Every multilateral system can be recognised as a specialized instrument. In order to facilitate the conception of multilateral systems and the recognition as a specialized instrument, these can be based on model frameworks or contracts.

Provider countries are not obliged to join, but If some provider countries have joined a certain multilateral system and agreed on a certain fee, there is an incentive for other provider countries to join (otherwise their 'DSI' is not used and there is no income). In addition, also for users there is an incentive since the genetic diversity is higher in the "genetic diversity pool".

Some might indicate that such a cluster of multilateral systems is complex, but the status quo is much more complex, and the fully multilateral system is too simple and appears as the representation of an unrealistic utopia, disregarding realities and complexities of use of 'DSI' (and related genetic resources).

## **5. (intermediate) conclusions**

To provide elements for an answer to the question how a traceable model can provide money into the system, put differently, how it can ensure effective and fair (monitory) value sharing, we need to take into due consideration the key requirements which have been identified by users and provider countries. This is of key importance since in a traceable system you want to reach an effective and fair agreement, otherwise no effective money will be shared.

Key parameters that need to be looked at and where several options arise are related to the questions on what is a fee applied, when is the fee set, and by whom is it to be paid. These questions are to be compared to the assessment provided by the untraceable group.

In order to operationalize the bilateral (traceable) model, it is proposed to look at collaborative models. This paper already provides some arguments in favour of such collaborative models, to be further discussed. These collaborative models are also assessed and compared in the context of the untraceable study and will be looked at into more detail in a second step.

## **White Paper 3: What could a (monetary) benefit-sharing system look like that does not require tracking of NSD usage? What value is delivered by such a system?**

Torsten Thiele, Potsdam Institute for Advanced Sustainability Studies (IASS)

### **Introduction**

This paper discusses ways to deliver and share benefits of NSD by looking at potentially comparable existing mechanisms in other areas. The assumption is that as the Nagoya Protocol aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way, provider countries, in particular from the developing world, could benefit from support mechanisms that would facilitate their ability to use NSD.

### **Overview over existing known financing mechanisms**

Innovative financing instruments (IFIs) are financing schemes that generate and mobilise funds. Rifat Atun in a recent paper<sup>10</sup> listed ten instruments for the health sector that fulfilled the inclusion criteria for the paper and between 2002 and 2015 these generated about US\$8.9 billion in revenues and disbursed US\$7.5 billion. These were (in alphabetical order): the Advanced Market Commitments Pilot for Pneumococcal Disease (AMC), the Affordable Medicines Facility for Malaria (AMFm), the Airline Solidarity Levy (Airline Levy), the Children's Investment Fund Management that financed the Children's Investment Fund Foundation (CIFF), Debt2Health, the GAVI Matching Fund, the International Finance Facility for Immunisation (IFFIm), the Japan International Cooperation Agency ODA Loan Conversion Program for Polio (ODA Loan Conversion), PRODUCT(RED), and the World Bank Investment Partnership for Polio International Development Assistance Buy-Back Program (IDA Buy-Back).

A recent study defined innovative financing mechanisms as institutions such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and GAVI that link different elements of the financing value chain to mobilise, pool, channel, and allocate resources.<sup>11</sup> Three integrated innovative financing mechanisms: GAVI, Global Fund, and UNITAID—have reached a global scale.<sup>12</sup> These three financing mechanisms have innovated along each step of the innovative finance value chain—namely resource mobilisation, pooling, channelling, resource allocation, and implementation—and integrated these steps to channel large amounts of funding rapidly. Resources mobilised from international innovative financing sources are relatively modest compared with donor assistance from traditional sources.

Initiatives such as the World Bank Health Results Innovative Trust Fund, the Grand Challenge mechanisms in health, and the Global Innovation Fund supported by the Governments of Australia, Sweden, the UK, and the USA provide new opportunities for channelling traditional donor funding in novel ways.

The scope of innovative financing for development is also broad and diverse. The CSR Law in India mandates companies with a certain turnover and profitability to spend 2 per cent of their

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<sup>10</sup> Atun, R, Silva, S., Knaul, F.M. (2017) Innovative financing instruments for global health 2002–15: a systematic analysis. Health Policy. Lancet Glob Health.

<sup>11</sup> Girishankar, N (2009) Innovating development finance: from financing sources to financial solutions, World Bank, Washington (Policy research working paper 5111) <http://elibrary.worldbank.org/doi/abs/10.1596/1813-9450-5111>

<sup>12</sup> Rifat, A, Knaul, M.K., Akachi, Y, Frenk, J, (2012) Innovative financing for health: what is truly innovative? The Lancet, Volume 380, Issue 9858, 8–14 December, Pages 2044–2049.

net profit in support of social and environmental objectives. Bonds can leverage private sector investment for sustainable development. For example, the Women's Livelihood Bond leverages private sector investment to support women's livelihoods.<sup>13</sup> The World Bank considers innovative financing approaches that generate funds by tapping new funding sources or by engaging new partners, including approaches that "enhance the efficiency of financial flows by reducing delivery time and/or costs" and "make financial flows more results- oriented". These include Impact investments are intended to generate positive social and environmental impact alongside a financial return. An interesting example is the world's first development impact bond (DIB) in healthcare is focused on improving the quality of care among private maternity care providers in Rajasthan. Partners include USAID, UBS Optimus Foundation, Palladium, PSI, HLPPT and MSD for Mothers. Impact bonds are an innovative way of financing international development. They are 100% focused on outcomes and have the potential to leverage private philanthropic capital to address some of the world's greatest challenges.<sup>14</sup>

For this impact bond, the upfront funder, UBS Optimus Foundation will provide up to USD 3.5 million initial working capital so service providers can begin their work with private facilities in Rajasthan.

Certification schemes are incentives to improve production processes and empower consumers to make informed purchasing decisions. They can offer a payment framework, for instance by charging corporates for access to the ratings.

Social enterprises are gaining recognition as a potential source of innovation, including for R&D. They can provide an appropriate format for addressing complex challenges.

Other innovative financing mechanisms, such as payments for ecosystem/environmental services (PES), mechanisms for biodiversity offsetting (e.g. habitat banking), integration of biodiversity into existing fiscal instruments and different mechanisms for leveraging private funding have been suggested. For instance results-based agri environmental measures linking the payment to the provision of a desired environmental outcome, rather than to prescribed management activities, are of increasing interest.<sup>15</sup>

Corporate supply-chain arrangements are another format for innovative arrangements. In 2008 Mondelēz International – Europe's largest biscuit producer - launched the Harmony initiative. The initiative focuses on sustainable agriculture and biodiversity protection by targeting its own wheat supply chain. The headline target of the initiative was to have 75% of their Western European biscuits to be made with Harmony wheat by the end of 2015.

An example of a mechanism involving governments as members and finance actors as observers is the International Platform on Sustainable Finance (IPSF). The IPSF aims to scale up the mobilisation of private capital towards environmentally sustainable investments through coordination on approaches and initiatives for the capital markets (such as taxonomies, disclosures, standards and labels), that are fundamental for private investors to identify and seize environmentally sustainable investment opportunities globally. The IPSF operates in an informal and inclusive setting with a Steering Committee, working groups and a secretariat.

INSPIRE—the International Network for Sustainable Financial Policy Insights, Research, and

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<sup>13</sup> Akhtar, S et al (2017) Innovative Financing for Development in Asia and the Pacific Government policies on impact investment and public finance for innovation. ESCAP

<sup>14</sup> <https://www.convergence.finance/news-and-events/news/21DGf2v0MmUcA284AmYcc/view>

<sup>15</sup> Illes, A., Russi, D., Kettunen, M. and Robertson M. (2017) Innovative mechanisms for financing biodiversity conservation: experiences from Europe, final report in the context of the project "In- novative financing mechanisms for biodiversity in Mexico / N°2015/368378". Brussels.

Exchange is a global, philanthropy-supported research network to commission independent, gold-standard research on the financial oversight of climate risks and the promotion of green finance. INSPIRE will aid the members of the Network for Greening the Financial System (NGFS), a network of more than 30 central banks and supervisors, and observer organizations from Africa, Asia, the Americas, and Europe, as they work to enhance the financial system's ability to manage climate-related financial risks and mobilize capital for green and low-carbon investments. The network will be guided by an advisory committee.

In Europe EMODnet provides an example as to how data grants are made available to science organisations on application through an evaluation process that includes the EMODnet Biology Coordination Board. A fully free open access system, potentially with funding support for any data charges may be considered as a form of non-monetary benefit-sharing,

This range of examples serves to show the variety and range of potential formats to deliver innovative finance for NSD. Innovation ecosystems help countries and scientists to modernise their NSD delivery systems by sourcing proven high-impact technologies and “infusing” them with resources and expertise to take them to scale. It is important to understand the various motivations for engagement in such processes. Whilst basic grant giving from public and private donors can be a relevant funding source the benefits of an innovative support structure for instance for corporate funders can encompass a variety of aspects that are not necessarily tied to immediate profits. Regulatory certainty, avoidance of potential antitrust issues, long term market growth and overall social licence can all provide relevant motivations.

### **Potential payment categories**

The below provides a wider list of potential categories of payment formats:

- Grants and voluntary trust funds
- Mandatory payments through taxes and levies
- Micro-levies, subscriptions and other agreed funding mechanisms
- Blended mechanisms
- Public-private partnerships
- Results-based finance
- Innovative financing mechanisms
- Use long-term donor pledges to issue bonds
- Use donor commitments to incentivise activities
- Matching funds
- Loan buy-downs
- Exchange-traded donor funds

These formats can be grouped into

- A) Direct sources of funding
- B) Finance delivery mechanisms
- C) Innovative finance structures that amplify commitments

### **Relevant criteria**

For the purposes of our recommendations I propose we restrict ourselves to mechanisms that

- A) have shown promise to raise funds from private sector partners against some form of agreed, results-based process, thus excluding simple donations
- B) Do not require a direct financial return to the funder
- C) Are not simply based on fiscal coercion, such as taxes, but may include an element of regulatory intervention (micro-levy etc)
- D) Include an element of voluntary participation and engagement
- E) Do not just deliver money but include other elements that encourage, facilitate and optimise finance for NSD solutions

### **Needs-based assessment**

The proposed survey and interviews will provide information based on an assessment of the needs of a sample of countries and researchers. By identifying relevant measures such as funding needs for bioinformatics training, sequencing centers or new INSDC partner databases in developing countries we will not only gain a perspective on the overall quantity and timing of financing required but also information required to potentially tailor the mechanisms accordingly for best results.

### **Next steps proposed**

Decide on relevant goals and milestones for developing a cooperative system. These will include trade-offs that are to be made around issues such as whether it is more important to deliver immediate support to the most disadvantaged or whether the focus will be on building a robust and potentially larger platform over time. Decision-making processes and criteria of equity and fairness would also need to be discussed. Analysing in detail the scientific, regulatory and economic advantages and disadvantages of the top 3 mechanisms will help to clarify to what a degree a cooperative system can be developed that will address in a meaningful way to concerns of those that may find a cooperative approach insufficient to deliver comprehensive benefit sharing.



## White Paper 4: Creating Legal Certainty for NSD in ABS Frameworks: Learnings from NSD Disclosure in the Patent System

Prof. Claudia Seitz, University of Ghent, Belgium; Lecturer, University of Bonn, Germany; Seitz & Riemer, Germany

### I. Content

The following paper consists of two parts: In the first part it focuses on traceability in the patent system and analyses questions of how NSD traceability works in the current patent system, what new requirements are actually planned for NSD traceability and what their current status is.

The second part of this paper shall try to apply the lessons learned from traceability in the patent system, as identified in the first part, within systems beyond the patent system. This part shall focus primarily on the question what can be learned from the experience of the patent system in dealing with such intangible assets for maintaining legal certainty in traceability mechanisms in the ABS context. Besides the patent system, lessons learned from other relevant IP systems, such as the collective management of copyright and the latest developments for the protection of data as trade secrets in the digital environment will also be taken into account. In addition, other possibilities for similar traceability mechanisms beyond the patent system shall be addressed.

### II. Introduction

The disruptive power of the shift from genetic material towards NSD has lead to new legal questions for all legal frameworks. It requires some answers regarding the mechanisms through which access to and utilization of GRs (“Genetic Resources”) and GR characterization data have been regulated. This applies to both IP and ABS frameworks and may require different and customized solutions. Multiple international policy processes are currently addressing the impact of NSD for their respective frameworks.

Whereas in the patent system NSD has been systematically managed and regulated with legal certainty since the beginning of gene patenting in the 1990s, the question of how to address NSD in the context of ABS mechanisms is new and currently debated on a national and international level. Thus, it is of practical value to start the analysis on how to create legal certainty for NSD in ABS frameworks with an assessment of NSD traceability in the patent system. This approach has many advantages:

- *The patent system establishes the link between the material and NSD with legal certainty for those inventions where the patent system requires disclosure.* At the international level, this is addressed by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.<sup>16</sup>
- *The patent system combines open global public access to NSD with the recognition of exclusive rights of innovators who have improved the material which the NSD describes.* Lessons that can be learned for maintaining the important balance between open access and public disclosure to NSD on the one hand and adequate allocation of incentives through the grant of exclusive rights to regulate access will be particularly important to minimize potential constraining effects of ABS frameworks for NSD on scientific research and technological innovation.

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<sup>16</sup> Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure (“Budapest Treaty”), adopted in 1977 and as amended on 26 September 1980, available at: <https://wipolex.wipo.int/en/treaties/textdetails/12244>. The Budapest Treaty has been complemented by Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, as amended on 1 October 2002, available at: <https://wipolex.wipo.int/en/treaties/textdetails/12246>.

- *The patent system has managed to standardize the national practices of dealing with NSD in over 100 countries.* How to minimize transaction costs for GR users from having to comply with diverse operational ABS requirements in different jurisdictions will be another area where lessons can be learned from the past harmonization efforts of IP systems, particularly the patent system.
- *The standardization was developed in close collaboration with INSDC.* A key achievement of the global patent system in managing NSD with legal certainty and operational efficiency was to work directly with INSDC in developing its standards for NSD. The practicalities and benefits of this cooperation should be further elaborated, in order to be imported into the processes for development of ABS standards on NSD. Practical illustrations may give a good resource for this.
- *The patent system has created interoperability in the creation, exchange, search, retrieval and aggregation of NSD in the global system.* Not only are legal and technical standards applied to NSD in the patent system coordinated with INSDC, but the global institutional and information infrastructure of the global patent system is connected to the INSDC databases through standardized practical arrangements between leading patent offices and INSDC databases, which allow for continuous and efficient updating, functioning and management of NSD in both networks of institutions.

Questions how to address NSD in the patent system have already been addressed, for example in the context of patent disclosure obligations. Currently WIPO is working on new standards which shall enter into force in 2022. The application of WIPO Standards ST.25<sup>17</sup> and ST.26<sup>18</sup> for nucleotide sequence listings in patent applications shall be referenced in this context. Other ongoing and future work on initiatives like collective management of rights in the digital environment and digital time stamping will also be referenced.

### **III. General Remarks of NSD under the IP and ABS Systems**

NSD is increasingly replacing biological material in the development of new products and processes based on GR as well as in claims of ownership of these products and processes. The shift from GRs to NSD-based research challenges well-established IP principles and jurisprudence, particularly in the area of patents and copyright as they relate to “genetics”, such as patentability requirements, scope of claims, DNA-based copyrightable works and overlaps between what may be patentable and copyrightable.

The role of NSD under IP systems, such as the patent system, needs to be distinguished from their role under ABS frameworks. As far as IP protection is concerned, NSD is comprised in nearly all research on GR. One of the objectives of generating NSD of GRs may include establishing IP which may form a part of licensing contracts.

Certain interfaces between IP and NSD have already been addressed by WIPO. IP issues regarding NSD which arise in the context of access and benefit-sharing contracts covering NSD subject matter have been described in the “WIPO Guide on IP Issues in Access and Benefit-sharing Agreements”.<sup>19</sup> Related IP issues have been discussed in the WIPO Intergovernmental Committee on Intellectual

<sup>17</sup> WIPO Standard ST.25: Presentation of nucleotide and amino acid sequence listings (December 2009), available at: [https://www.wipo.int/standards/en/part\\_03\\_standards.html](https://www.wipo.int/standards/en/part_03_standards.html).

<sup>18</sup> WIPO Standard ST.26: Presentation of nucleotide and amino acid sequence listings using CML (September 2019), available at: [https://www.wipo.int/standards/en/part\\_03\\_standards.html](https://www.wipo.int/standards/en/part_03_standards.html).

<sup>19</sup> The “WIPO Guide on IP Issues in Access and Benefit-sharing Agreements”, available at: <https://www.wipo.int/publications/en/details.jsp?id=4329>

Property and Genetic Resources, Traditional Knowledge and Folklore. WIPO has developed standards for the presentation of nucleotide and amino acid sequence listings in patent applications, namely ST. 25 and ST.26. Most significantly, WIPO's ongoing capacity building and training activities related to intellectual property and genetic resources address the latest emerging issues in this field.

#### **IV. International Patent Applications**

##### **1. Patent Cooperation Treaty (PCT)**

###### **a) Objective of the PCT**

The Patent Cooperation Treaty ("PCT")<sup>20</sup> assists patent applicants in seeking patent protection internationally for their inventions, helps patent offices with their patent granting decisions, and facilitates public access to technical information relating to those inventions. Whereas national patent applications are not harmonized, international patent applications under the PCT are standardized in the PCT Contracting States ("Contracting Parties").<sup>21</sup> By filing one international patent application (international application, "IA") under the PCT, applicants can simultaneously seek protection for an invention in a very large number of countries.

The PCT as an international patent law treaty, concluded in 1970, provides a unified procedure for filing patent applications to protect inventions in each of its Contracting Parties (all together "International Patent Cooperation Union"). A patent application filed under the PCT is called an international application ("PCT application"). A single filing of a PCT application is made with a Receiving Office ("RO") in one language.

The filing of the international application is followed by a search performed by an International Searching Authority ("ISA"), accompanied by a written opinion regarding the patentability of the invention, which is the subject of the application. It is optionally followed by a preliminary examination, performed by an International Preliminary Examining Authority ("IPEA"). The relevant national or regional authority examines the application and issues a patent in accordance with the applicable national or regional law.

The patent that will be granted based on a PCT application cannot be considered as an international patent since there is no international patent and the PCT system does not result in the grant of patent. A patent is always granted by a national or regional authority according to the applicable law in this country or region. Thus, the objective of the PCT system is not to grant a patent but to standardize national and regional patent applications and their processing. The patent itself is granted or rejected according to the applicable law which may differ from country/region to country/region.

###### **b) PCT Rules on Nucleotide and/or Amino Acid Sequences**

According to Article 5 of the PCT the patent description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. The articles of the PCT are specified in more detail in the Regulations under the PCT ("PCT Regulations"). The PCT Regulations comprise several rules; the current version is of 1 July 2019.<sup>22</sup>

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<sup>20</sup> Patent Cooperation Treaty, done at Washington on 19 June 1970, amended on 28 September 1979, modified on February 3, 1984, and on 3 October 2001 as in force from 1 April 2002, available at: <https://www.wipo.int/pct/en/texts/articles/atoc.html>.

<sup>21</sup> Currently 153 Contracting States have signed the PCT, an overview of the list of Contracting States, available at: [https://www.wipo.int/pct/en/pct\\_contracting\\_states.html](https://www.wipo.int/pct/en/pct_contracting_states.html).

<sup>22</sup> Current Version of the Regulations under the Patent Cooperation Treaty as in force from 1 July 2019, available at: <https://www.wipo.int/pct/en/texts/rules/>.

The PCT Regulations contain several specific rules for nucleotides and amino acid sequences disclosure. Rule 5.2(a) of the PCT Regulations specifies that where an IA “contains disclosure of one or more nucleotide and/or amino acid sequences, the description shall contain an SL complying with the standard provided for in the Administrative Instructions and presented as a separate part of the description in accordance with that standard”.

In addition, Rule 5.3(b) specifies “where the sequence listing part of the description contains any free text as defined in the standard provided for in the Administrative Instructions that free text shall also appear in the main part of the description in the language thereof”. Finally, Rule 13ter.1(a) specifies that where an IA contains disclosure of one or more sequences, the International Searching Authority (“ISA”) may invite applicants to furnish for search purposes, a SL in electronic form.

## **2. WIPO Standards**

### **a) WIPO Standards as general guidance**

WIPO Standards provide general guidance for the presentation, publication and communication of IPR related information. As such, they are not binding regulations. The Standards are expressed in the form of recommendations and are directed to Contracting States and international organizations, in particular to their national or regional industrial property offices, to the International Bureau of WIPO, and to any other national or international institution interested in industrial property documentation and information.

WIPO Standards facilitate the harmonization of practices by industrial property offices regarding electronic data processing in respect of the procedures for filing, examination, publication, granting and registration of industrial property titles. WIPO Standards also facilitate the international transmission, exchange, sharing and dissemination of industrial property information, as well as access to and retrieval of this information.

### **b) WIPO Standard ST.25**

WIPO Standard ST.25 shall provide a standardization of the presentation of nucleotide and amino acid sequence listings in international patent applications.<sup>23</sup> One of the objectives of this Standard is to facilitate searching of sequence data and to allow the exchange of data in electronic form and the introduction of sequence data onto computerized databases. The Standard ST.25 provides minimum data to identify SL in patents. To draw up a single SL acceptable in all Contracting Parties the WIPO Standard ST.25 contains several recommendations.

- Annex C of the PCT Administrative Instructions defines requirements for the submission of sequence listings;
- ST.25 recommends to apply the requirements of Annex C not only to PCT applications but to any patent application (ST.25 is fully equivalent to Annex C);
- SL are normally part of the disclosure (they are filed with the IA);
- The IA may require the applicant to submit SL if the initially submitted SL does not meet the requirements of Annex C and search is not possible (Rule 13ter of PCT);
- Submissions after the filing date do not form part of the IA (initial disclosure) and shall not go beyond the SL initially disclosed as part of the description.

According to the Standard ST.25 each sequence shall be assigned a separate sequence identifier. This identifier will be assigned by WIPO and does not allow tracing back information concerning the specific sequence, such as the origin of the sequence or the biological material.

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<sup>23</sup> The WIPO Standard ST. 25 defines “sequence listing” as a nucleotide and/or amino acid sequence listing which gives a detailed disclosure of the nucleotide and/or amino acid sequences and other available information.

### c) WIPO Standard ST.26

WIPO Standard ST.26 recommends as the standard for the presentation of nucleotide and amino acid sequence listings the use of XML (“eXtensible Markup Language”).

- ST. 26 was developed by the relevant WIPO Committee in collaboration with INSDC;
- the WIPO Secretariat facilitated a Sequence Listing Task Force under the WIPO Committee of WIPO Standards;
- Entry into force is envisaged for 1.1.2022;
- WIPO Secretariat will facilitate a two year global transition period to move all incoming DSI in the global patent system for ST.25 to ST.26;
- applies to national and international applications does only require submission of a SL on XML (no SL on paper or in electronic format).

In order to facilitate the transition from ST.25 to ST.26, WIPO is developing a NSD management tool named “WIPO Sequence”. The software provides the patent applicant with a possibility to enter NSD and will then automatically format it according to ST.26 in compatibility with INSDC Function Keys (or convert an SL from ST.25 to ST.26), which will allow that SL to be submitted and processed in all Contracting Parties.

Lessons could be learned for creating consistent practice for the Contracting Parties in the context of the CBD and NP. At present the draft tool only allows the entry and processing of NSD if the user first enters the bibliographic data of the patent application in a proceeding module of the tool. The transition period between ST.25 and a fully harmonized handling of all NSD according to ST.26 will be two years (2020-2021) and preparations for the transition period have already begun following the approval of the latest biennial work program by the WIPO General Assembly.

## V. Potential Traceability Tools Beyond the Patent System

### 1. Protection of NSD Databases?

In addition to database content, tools for accessing or using the content can be proprietary. For some GRs, private or proprietary databases that could hold critical information necessary to extract maximum value from public databases are growing.

In the EU there is a customized form of legal protection of databases under EU law. The current Directive 96/9/EC on the legal protection of databases<sup>24</sup> was adopted in 1996 and has been evaluated for the second time in 2018 giving specific and separate legal rights and limitations to certain computer records.<sup>25</sup> This EU Directive provides a protection for databases as the collections of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means. Database rights are specific *sui generis* laws on the copying and dissemination of information in computer databases. Rights afforded to manual records under EU database rights laws are similar in format, but not identical, to those afforded to artistic works under copyright laws.

The EU Directive protects databases by rights which are similar to copyright if they are original. Non-original databases such as compilations of applicable laws or scientific publications can also be protected if the investment in obtaining, verifying and presenting the data was substantial. This protection is known as the *sui generis* right, i.e. a specific property right for databases that is unrelated to other forms of protection such as copyright.

<sup>24</sup> Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, OJ L 77, 27.3.1996, p. 20-28, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31996L0009>.

<sup>25</sup> For further information on the evaluation and the evaluation process see the information of the EU Commission, Digital Single Market, Protection of databases, available at: <https://ec.europa.eu/digital-single-market/en/protection-databases>.

The Directive applies to both analogue and digital databases. The special *sui generis* protection for databases, however, is provided separate from general copyright law and does not require an original or creative work. Such databases may not be creative but they require a quantitatively or qualitatively substantial investment in terms of resources and/or time spent. In comparison to the requirements for the application of a copyright there is no creativity needed in connection with the database. Thus, even non-creative databases are protected by the EU Directive. The creativity which is a condition for a copyright is replaced by the substantial investment.

The TRIPS Agreement<sup>26</sup> requires that copyright protection extends to databases and other compilations if they constitute intellectual creation by selection or arrangement of their contents, even if some or all of the contents do not themselves constitute materials protected by copyright. Several countries act in accordance with this requirement, as databases are protected by copyright if this condition is met, and there is no separate IP right which protects databases. The *sui generis* protection of databases is recognized only in a small number of jurisdictions, mainly but not only in the EU. There are also *sui generis* protection of databases on a national level, e.g. in the UK or in Russia, whereas in other countries do not recognize database rights, e.g. USA, Australia or Brazil. According to the general principle of territoriality, the scope of protection of database rights is limited to the territory of the applicable law which protects the database.

The *sui generis* protection of databases may also protect databases of GR information such as DSI databases. The EU Directive, however, does not provide protection for software used to create the database nor for material or information contained in the database. Thus, the GR or DSI database may be protected by the *sui generis* protection of the EU Directive if the requirements comprised in the EU Directive are fulfilled. The content of such a database, e.g. the DSI itself, is, however, not protected by the *sui generis* protection of databases.

## **2. Copyright Protection of NSD?**

Copyright protection of NSD has not yet been sufficiently thematized and studied. However, an analogy to computer software programs may be drawn. Source codes of computer programs can be protected under copyright. As such limited similarities between computer algorithms and certain types of coding DNA sequences and their encoding functions may be drawn. Especially in the field of synthetic biology where new genetic sequences are created an analogy could be justified, because the sequences have been synthesized through human creativity.

In terms of copyright requirements regarding the originality of authorship the similarities to source codes are not obvious. While at the moment no existing copyright law mentions genomic sequence data or other characterization data of genetic resources as protectable innovations, an extensive debate on copyright protection of engineered DNA sequences took place in the 1990s and is recently being picked up again in light of the DSI/NSD discussions emanating from the ABS fora and WIPO's work on big data, AI and database protection. In such debates, it has been suggested that, subject to relevant requirements, certain NSD might fit under the category of literary works if they have a kind of a language that can be expressed in codes. It has been argued that genetic sequence data might be protected by copyright if the nucleotide sequences are not dictated by functionality.

Some sequencing companies are already protection some of their NSD under copyright in certain jurisdictions. This trend has the advantages that

(1) it has a less restrictive effect on the use of NSD by science, technology and industry, while keeping incentive for innovation and equity in allocation of benefits in place, and

(2) extensive lessons could be learned from licensing of copyright works in the collective management of copyright for light, legally certain and transactionally efficient traceability systems and licensing solutions.

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<sup>26</sup> Agreement on the Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), into effect since 1 January 1995, available at: [https://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm).

The second part of this paper will explore such lessons learned for traceability, which may supplement those learned from the patent system.

### **3. Digital Time Stamping**

WIPO is currently assessing the tool of digital time stamping as one mechanism of WIPO's response to digital transformation. This is one of the possible services WIPO could provide in support of innovation which is increasingly being driven by data. Digital time stamping means electronic signed certifications that prove the existence of a digital file at a specific date and time. The advantage of this tool is that it is accurate and may not be tampered. The certification of existence and possession of a digital file shall be provided by a trusted Time Stamping Authority ("TSA").

Currently WIPO aims to become a free of charge provider of an online Digital Time Stamping Service to innovators and may issue a certificate of existence and possession of a digital file but will not receive or store the original file or data. This will remain with the user of the service locally on their computers. This tool could be used to trace back information. WIPO, however, will only certify the existence and possession of the digital work at a specific point in time and will not ascertain or arbitrate the ownership of the original work.

The advantage of this tool provided by WIPO would be that WIPO could address gaps in the markets for digital time stamping services to countries where such a service is not available. WIPO would run its time stamping services as a trusted TSA for which technical feasibility is already confirmed as long as the WIPO TSA infrastructure complies with accepted international standards. The technology which could be used would be a Public Key Infrastructure ("PKI"). WIPO plans to test this service in a pilot project in 2020/21 and aims to establish the business and technical infrastructure in 2020 for the launch of the initial service.

The target use cases that could be addressed by this service could be (1) the management of trade secrets and other undisclosed information, (2) the management of preparatory works before IP filing, such as patents, and (3) the management of IP-related legal documents, such as licenses or non-disclosure agreements.

### **4. Contractual Tools for Traceability**

As a contractual tool for traceability established models of contractual licensing agreements for digital content could be used. A licensing system could be implemented through smart contracts. The system of smart contracts could also be combined with classical digital rights management tools which are commonly used in the context of copyright. The expression 'digital rights management' (DRM) has been introduced in the texts of the provisions of the relevant international treaties (the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT)) in the EU Directives (in particular, in the Information Society (Copyright) Directive) and in the national laws implementing them. This system could be combined through simple 'technological protection measures' (TPMs) and standardized 'rights management information' (RMI) which are the relevant expressions used in the international treaties, the EU Directives and national laws. DRM usually means the combination of TPMs and RMI, although it is frequently used also as a reference just to TPMs, and sometimes just to RMI. Through the use of such established techniques, negative impacts off traceability can be minimized in combination with the use of private law contractual tools.

## White Paper 5: Systematic Legal and Governance Analysis of Various Exemplary Models

Prof. Esther van Zimmeren, Univ. of Antwerp

### Introduction

The objective of this short report is to describe various models that could be an interesting source of inspiration for identifying a spectrum of multilateral solutions which could enable more effective benefit sharing in line with the CBD/NP for genetic resources and potentially also for DSI. Moreover, the description of the models may also be used to identify appropriate governance mechanisms that would provide sufficient incentives for stakeholders to support the model (politically and financially) and to participate in the model as providers and users. For each of the models I focus on a systematic set of factors that are a mix of legal and governance issues. I have categorized the models in three groups (1) benefit sharing model; (2) innovative funding models and (3) collaborative licensing mechanisms (i.e. patent pools and clearinghouses). In particular for this last group I draw on my earlier extensive research with respect to the biomedical sector, including the development of a typology for IP clearinghouses and empirical research (survey on the interest, experience with and perception of such models). In particular the third group of models also has some “traceable” features, which could be helpful for the other WILDSI subgroup.

### Models

#### **Benefit Sharing Model**

*The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and its Multilateral System (MLS)*

- a. Short description model: the ITPGRFA aims at “the conservation and sustainable use of plant genetic resources for food and agriculture [PGRFA] and the fair and equitable sharing [hereafter ABS] of the benefits arising out of their use, (...) for sustainable agriculture and food security” (Article 1). It does so by establishing rules for the management of seeds at a global scale, i.e. through a Multilateral System of Access and Benefit-sharing (the MLS, Treaty Articles 10 to 13). The MLS functions as a virtual common basket of “seeds” where “recipients” (researchers, breeders, farmers) may access PGRFA at “providers” (generally national or international genebanks) using a standard contract (the Standard Material Transfer Agreement or SMTA) upon specific conditions of access and of benefit-sharing, including financial ones.
- b. Domain/field of application: Article 12.3(a) specifies that “access shall be provided solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses” (emphasis added). Access is facilitated only for the 64 crops and forages listed in Annex I to the Treaty, although there is an ongoing negotiation to enlarge this list to all PGRFA.
- c. Status: the ITPGRFA entered into force on 29 June 2004. To date, there are 145 Contracting Parties. However, the Treaty has only really started to be operational around the years 2010-2011, once its main tools and mechanisms had been developed and adopted by its Governing Body: the Standard Material Transfer Agreement (SMTA) and the Benefit-Sharing Fund (BSF) as main operationalizing tools of the Multilateral System of Access and Benefit-sharing (MLS); and the Compliance Committee, the Funding Strategy, the Third Party Beneficiary, the Global Information System (GLIS) as instruments developed for the implementation of the whole Treaty obligations, including the obligations deriving from the



MLS. The rather slow implementation process and the difficulties in reaching sufficient efficiency (Frison et al 2011), inter alia in generating money for the BSF, has lead contracting parties to reopen the negotiation of the functioning of the MLS in 2013 (at its fourth Governing Body). Negotiations are still ongoing in trying to “enhance the MLS” and generate more money to the BSF. The coming Governing Body meeting (November 2019) will be decisive for the future of the MLS.

- d. Type of model/legal mechanism: the MLS is a sort of clearinghouse mechanism (see also below) but for physical seeds. Its funding mechanism depends largely on whether new varieties are protected with IPRs, thereby recognizing (and strengthening) the various IP mechanisms on seeds as contributing positively to breeding R&D. It functions with a standard contract to avoid bilateral contractual negotiations and the possible unfair imbalance of power in its negotiation.
- e. Link to public international legal instrument: the MLS is based on the ITPGRFA and functions in harmony with the CBD/NP on Access and Benefit-sharing (Treaty Article 1.1). PGRFA falling outside the scope of the MLS are to be accessed under the terms and conditions of the NP. This covers, inter alia, in situ peasants’ varieties.
- f. Initiative: the 15 international research centers of the Consortium of International Agricultural Research Centers (CGIAR) took the initiative of designing the facilitated exchange mechanism. The MLS is developed based on the exchange practices occurring under the CGIAR rules. These rules were then adapted and adopted during the first governing bodies (Interim governing body in 2004 and first governing body in 2006) of the Treaty under the SMTA.
- g. Profile stakeholders: states, national (whether public and private) and international genebanks, collections and research institutions (such as the CGIAR or the Global Crop Diversity Trust), farmers’ communities, commercial actors such as the seed industry and breeders, as well as non-profit actors such as NGOs. Main users of MLS material are researchers and breeders.
- h. Administration: Governing Body of the Treaty, which meets every two years. The Secretariat of the Treaty ensures the day-to-day management.
- i. Licensing Practices: N/A for now, but the proposed subscription system might be assimilated to a kind of licensing mechanism. However, the actual features of such a subscription model are still quite uncertain, as various proposals have been made (i.e. recipients (particular categories of stakeholders, to be defined) may access material (to be defined) for a certain period of time (to be defined, approx. 10 years) against the payment of a lump sum (to be defined) to be paid back to the BSF.
- j. Uptake: Main users of the MLS are public researchers and breeders (both public and from small and medium enterprises) both from developed and developing countries. Big seed companies have their own genebanks to carry out their R&D breeding processes and avoid accessing MLS material to avoid any payment obligation. Main providers are CGIAR centers and big national genebanks of contracting parties.
- k. Strengths/incentives: the commonization of seed management at a global scale enables more sharing of seeds, which is crucial for their conservation and adaptation to climate change. Sharing of practices, technology, knowledge is also key and facilitated through this global mechanism.
- l. Weaknesses/challenges: the funding mechanism of the MLS relies mostly on IPRs over seed varieties being commercialized on the market. Moreover, the scope of the MLS does not cover all PGRFA, thereby enabling some key (rich) stakeholders to bypass the system by accessing seeds elsewhere (and not pay back money into the MLS). As a consequence, little money is feeding the BSF and little benefit-sharing projects are implemented in developing country as counter-payment for them having provided most of the diversity held in genebanks.

- m. Trust issues: serious distrust exists among stakeholders from the South (States, NGOs, farmers' communities etc.) in the implementation of the MLS (see e.g. Six et al., 2015). They consider that they have contributed a lot to the MLS by providing most of the genetic diversity held in national and international genebanks participating in the MLS, but that very little (monetary and non-monetary) benefit-sharing have returned back to them. They are reluctant to widen the scope of the MLS annex I list of crops to all PGRFA as long as there is not fairer return. Debates over DSI have significantly increased distrust as Northern countries argue that DSI fall outside of the scope of the Treaty, thereby enabling to use genetic information (eventually originating from MLS material) without the related benefit-sharing obligation (and therefore without payment to the MLS).

## **Innovative Funding Models**

*Global Alliance for Vaccines and Immunization (GAVI) (focus on International Finance Facility for Immunisation)*

- a. Short description model: international organization created in 2000 with the support of the Bill & Melinda Gates Foundation to improve access to new and underused vaccines for children living in the world's poorest countries by making them more easily available, more affordable and the provision more sustainable. GAVI has generated development aid through five mechanisms, (i) the International Finance Facility for immunization (IFFI), a public-private partnership; (ii) Advanced Market Commitments (AMCs) for pneumococcal vaccines - \$1.5 billion to incentivise vaccine production and availability in developing countries; (iii) GAVI Matching Fund- Matches contributions by private sector investors through support from the UK government and the Bill & Melinda Gates Foundation; (iv) loan buydowns - provides GAVI with low interest loans for its immunization efforts; and (v) INFUSE (Innovation for Uptake, Scale and Equity for Immunization) which works as an incubator for innovating start-ups.
- b. Domain/field of application: Health sector- immunizations. Currently 58 countries are eligible for vaccine support from GAVI which is down from 74 countries in the first phase. The eligibility is determined on the basis of GNI per capital in the last three years.
- c. Status: the GAVI alliance was established in 2000. In 2005 GAVI and IFFI came together at a G8 summit. AMCs were also launched in 2005. The GAVI Matching Fund was launched in 2011. Loan buydowns and INFUSE were launched in 2016
- d. Type of model/legal mechanism: IFFI uses the principle of 'frontloading' of funds, i.e. leveraging long-term funding (20 years) by states to attract short-term funding from private investors. The long term funding is leveraged and Vaccine bonds are launched in the capital markets for private investors. These funds can be used to conduct immunization drives (Doust-Blazy 2014:31).
- e. Legal basis public international law/link with international organization: no
- f. Initiative: IFFI is an initiative of the British government which uses the long term borrowing capacity of States (UK, France, Norway, Italy, Sweden, South Africa and Spain) to collect funds on the market and finance immunization programmes in 70 countries (Doust-Blazy 2014:8).
- g. Profile stakeholders: States, GAVI partners/International organisations such as WHO, UNICEF, Gates Foundation and World Bank, GAVI eligible countries and eligible populations, vaccine industry.
- h. Administration: The GAVI Board is composed of governments from donor and developing countries, representatives from the health sector such as vaccine industries, research institutes, representatives from WHO, UNICEF, World Bank as well as Gates Foundation as well as independent experts.
- i. Licensing Practices: not applicable

- j. Uptake/success of the model: IIFI has been issuing bonds since 2006. The bond have been rated highly because of the “high credit quality of its donors”, “politically compelling mandate to support immunizations” and “its conservative financial policies and financial and risk management by the World Bank” (IFFIM).
- k. Strengths/incentives: (1) support from high credit donors, such as governments and the Gates Foundation; (2) focused mandate; (3) the Partners Engagement Framework (PEM) (2016) based on four key principles: country-focus; transparency; accountability and differentiation. In the past, it was difficult to determine what the funding that was allocated to partners was spent on, for what purpose and with what outcome. Under PEM partners and countries know exactly who is doing what, how much funding is allocated to each partner, what the expected deliverables are and how they are progressing.
- l. Weaknesses/challenges: (1) for some countries like Japan and US, it has been difficult to accommodate mechanisms like IFFI and AMs in their budgets, because more restrictive budget score-keeping rules (Atul et. al. 2017:725); (2) funds like GAVI and the Global Fund shift donor focus from funding global health financing to financing specific diseases – this approach has been criticized (Clinton & Sridhar 2017:329).
- m. Trust issues: with regard to AMCs, there are concerns about the quality of drugs developed under such commitments and the concern that the pricing of drugs is not based on purchasing capacity of developing countries (ICAD-CISD 2007:2). The lack of transparency on “strengthening health systems”, which is one of the objectives of GAVI and a fund disbursement area, has been criticized (Storeng 2014)

*Airline Solidarity Levy UNITAID <https://unitaid.org/#en> (Headquarters: Geneva, hosted by WHO)*

- a. Short description model: a tax on airline tickets levied by France in 2006, which was later adopted by other countries as well (including Cameroon, Chile, Congo, Guinea, Madagascar, Mali, Mauritius, Niger, and the Republic of Korea). The tax is mandatory in France and 9 other countries as of 2017 (Dousté-Blazy & Fillip 2017), but not in all countries that contribute to UNITAID. The finance so generated is directed to UNITAID, primarily a drug purchasing facility whose mission is to provide long-term access to quality drug treatment for HIV/AIDS, tuberculosis and malaria. UNITAID has also collaborated with leading travel agencies and distributors to institute a voluntary donation by travelers. The minimal levy in France is €1 for European economy class and €10 on business class tickets and €4 on international economy class and €40 on business class (Müller 2008).
- b. Domain field of application: health sector: UNITAID invests in innovations for better diagnostics for diseases such as HIV aids, tuberculosis, Hepatitis C, malaria and works with governments for better access to medicines for these diseases. “A growing number of our projects address more than one disease, maximizing the effectiveness of health systems as a whole, and more than half of our portfolio is linked to antimicrobial resistance.” (UNITAID)
- c. Status: the tax is operational since 2006 and has generated approximately \$350 million in 2007. Since then revenues have been declining, reaching \$106.7 million in 2015. This corresponds to cycles of economic growth and downturn following the economic crisis (Atul et. al. 2017:724). The revenue generated is still high amongst innovative financing instruments. The tax generated 88.7% of UNITAID’s revenues in 2015 (Atul et. al. 2017:722). UNITAID is working on enlisting more countries.
- d. Type of model/legal mechanism: micro-tax
- e. Legal basis public international law/link with international organization: no public international law instrument, but UNITAID is a hosted partnership of the World Health Organization.

- f. Initiative: The levy was the initiative of France, Brazil, Chile, Norway and UK. In 2004, it was proposed by the Leading Group on Solidarity Levies to Fund Development in 2004. The group has since expanded and comprises of 66 countries and several international and non-governmental organizations (Leading Group).
- g. Profile stakeholders: states, international organizations and non-governmental organizations.
- h. Administration: The contributions are received at the national level and then paid to UNITAID. UNITAID has an executive committee comprising of 12 members that takes all decisions. The WHO acts as a trustee of UNITAID's finances. Projects funded by UNITAID are implemented by partners such as the Global Fund to fight AIDS, tuberculosis and malaria, Doctors without Borders and the Clinton Foundation (ICAD-CISD 2007:2).
- i. Licensing Practices: not applicable
- j. Uptake/Success of the model: the number of countries that levy the airline tax is increasing. In 2015, the model was replicated by 4 countries that decided to levy a micro-tax on gold (Mali), oil (Congo), bauxite (Guinea) and uranium (Niger) (Dousté-Blazy and Phillip 2017). This is paid into the UNITLIFE fund for malnutrition. In addition to the airline tax, since its establishment in 2006 UNITAID has received about US \$3 billion in contributions from donors. Its main donors are France, the United Kingdom, Norway, the Bill & Melinda Gates Foundation, Brazil, Spain, the Republic of Korea, and Chile.
- k. Strengths/incentives: the levy has no effect on air traffic and provides a consistent source of finance. There is a direct link between the levy and the intended purpose. UNITAID's structure is streamlined which limits overhead costs to 5% (Dousté-Blazy 2014:7).
- l. Weaknesses/challenges: increased costs of airline travel which is a hindrance for many economy class travelers. Opponents of the levy argue that it distorts competition as other modes of transport are not taxed similarly (Barbière 2016). It has been proposed that in exceptional cases, governments can make the contribution on behalf of the passengers using climate finance (Müller 2008:5). Challenges include competition from other funding opportunities such as climate projects; enlisting more donor countries and organizations; and reliance on project implementing partners (Dousté-Blazy 2014:17).
- m. Trust issues: [further research required]

*World Bank Health Results Innovation Trust Fund (WBHRITF) (Headquarters World Bank: Washington, D.C.)*

- a. Short description model: a multi-donor trust fund that supports results based financing (RBF) for maternal and child health and nutrition. Funds are released either to patients when they take actions such as immunizations or to healthcare providers when they meet targets (Morgan 2010).
- b. Domain field of application: health sector- maternal and child health.
- c. Status: operational since 2007. It has evolved into the Global Financing Facility Trust Fund (GFF) since 2014 - which also follows the RBF model. Its objectives have expanded to include reproductive health and adolescent health and nutrition. It is operational in 29 countries.
- d. Type of model/legal mechanism: pay-for-performance model. The WBHRITF administers three types of grants Country Pilot Grants, Knowledge and Learning grants, Impact evaluation grants. The grants are disbursed after verification that the services have been delivered. The GFF provides financing for government's plans to implement SDG 2 and 3.
- e. Legal basis public international law/link with international organization: no public international law instrument, but the grants are administered by the World Bank.

- f. Initiative: The HRITF was started in 2007 by the Governments of Norway and the United Kingdom. It is administered by the World Bank and is linked to the funding from the International Development Association.
- g. Profile stakeholders: donor states, implementing states, impact evaluation bodies such as the World Bank Institute and the African development bank.
- h. Administration: The grants are administered within the World Bank's operational framework.
- i. Licensing Practices: not applicable
- j. Uptake/Success of the model: The fund has provided \$400 million in grants and about \$2 million in loans to RBF programs in 29 countries (RBF Health).
- k. Strengths/incentives: focus on rigorous impact evaluations.
- l. Weaknesses/challenges: the programs are still at their early stages and impact assessments are underway. The World Bank reported on the basis of 7 completed impact evaluations showing that it is challenging for implementers to understand the complexity involved in the RBF mechanism which affects incentives. Moreover, continuous incentives need to be offered to guarantee the effectiveness of the program and inspire behavioral changes (Kandpal 2017:15).
- m. Trust issues: [further research required]

*Global Innovation Fund (GIF)* <https://www.globalinnovation.fund/> (Headquarters London)

- a. Short description model: GIF is a hybrid-investment fund that supports development related innovations. It also uses blended finance by mixing outcome based grants, technical assistance, debt and equity.
- b. Domain field of application: innovators that propose new business models, policy practices, technologies, behavioral insights or other projects at any stage, i.e. pilot, test or scale. The project must be able to show measurable and verified impact, especially on people living with a wage of under \$2 per day. The primary region of investment is South and South East Asia but there are a few projects in East and West Africa.
- c. Status: launched in 2014.
- d. Type of model/legal mechanism: "grants, loans (including convertible debt), and equity investments ranging from £30,000 to £10 million" (Department of International Development 2014).
- e. Legal basis public international law/link with international organization: not applicable
- f. Initiative: GIF was launched in 2014, with the support of US Agency for International Development, UK's department for International Development, Australia's Department of Foreign Affairs and Trade, Swedish International Development Agency and Global Affairs Canada. It also has co-financing partnerships with South Africa's department of science and technology and the Indian Rural Electrification Corporation and with Unilever in 2018 (GIF 2018:9).
- g. Profile stakeholders: state agencies, corporate partners, for-profit or non-profit.
- h. Administration: GIF is governed by a Board that comprises of academics, impact investors and development experts.
- i. Licensing Practices: not applicable
- j. Uptake/Success of the model: GIF is currently funding 38 innovations across various geographies in various sectors. Less than 10% of the applications for funding received are accepted.
- k. Strengths/incentives: strong focus on measuring impact.
- l. Weaknesses/challenges: making a choice between relative values while selecting projects, e.g. prioritizing health, education or income outcomes.

- m. Trust issues: preventing corruption and ensuring transparency and accountability in administration is a key challenge. Several researchers caution against blended finance and in general, “the private turn in development finance” because of the over-extension of the public sector in leveraging private sector investments and the investment law implications (See Van Waeyenberge 2016:44-46; Cotula and Tan 2018; Tan 2019). [further research required]

*Global Fund for AIDS, Tuberculosis and Malaria (GFATM) (Headquarters: Geneva)*

- a. Short description model: a public private partnership created under G8. GFATM receives funds from a variety of instruments such as PRODUCT(REDD) Trademark, Debt2Health, Affordable Medicines Facility for Malaria (AMFM) and other forms of private sector mobilisation (Douste-Blazy 2014:34). RED is a licensed trademark that seeks to engage the private sector in raising awareness and funds to help eliminate HIV/AIDS. It is licensed to a wide variety of partner companies, including Apple, Armani, American Express, GAP, Converse, Bugaboo, Canon, Nike, Hallmark, Starbucks, which contribute a share of their profits to GFATM. Debt2Health is debt forgiveness where a country is allowed to redirect a portion of its loan repayments towards health projects (Communities Delegation 2018:10). The debt settlement mechanism provides partial debt relief to developing countries on the condition that they invest in a Global-Fund-approved project to fight HIV/AIDS, tuberculosis and malaria. AMFM is resource mobilisation and allocation.
- b. Domain field of application: health sector, the fund is set up for targeting tuberculosis, malaria and HIV/AIDS.
- c. Status: created in 2002. The fund generated \$922.2 million through innovative financing instruments (IFIs) which amounted to 2.9% of its total revenues (Atul et. al. 2017:724).
- d. Type of model/legal mechanism: the Fund has three year funding cycles. In each cycle donor funds are allocated to eligible countries. There is a technical review and approval of funds and evaluation and oversight throughout the implementation process. In addition to Debt2Health, Global Funds plans to invest in budget support and blended finance/loan buy-down mechanism and social impact bonds (35th Global fund board meeting) (Communities Delegation 2018).
- e. Legal basis public international law/link with international organization: not applicable
- f. Initiative: the fund has emerged out of G8 partnership of countries. It was endorsed by the G8 in 2001 in the Italy conference after which a Working Group was formed to establish the fund. The RED concept was founded in 2006 by U2 frontman and activist Bono, together with Bobby Shriver of the ONE Campaign.
- g. Profile stakeholders: government donors (largest contributors US, France, UK, Germany, Japan and the European Commission), civil society, technical and development partners, private and non-governmental partners, implementing partners, friends of the Global Fund (organisations).
- h. Administration: the Fund is governed by the Global Fund Board composed of representatives from donor countries, NGOs and communities affected by tuberculosis, malaria and HIV/AIDS. The Fund is governed by its bylaws and the applicable laws of Switzerland (Art. 1, ByLaws of the Global Fund). The World Bank is its trustee since 2002 and responsible for its financial accountability (Ko Sy et. al. 2014:5).
- i. Licensing Practices: PRODUCT RED - licensing fee
- j. Uptake/Success of the model: 93% of the funds raised are from public donors. The contributions of private sector doubled in 2019. As of June 2019, donors contributed \$7.9 billion (Global Fund- Results Report 2019). In October 2019, new pledges were made to the Global Fund up to \$14 billion to the Global Fund. (RED) has generated more than \$600 million for the Global Fund and in October 2019 it committed \$150 million to the Fund.

- k. Strengths/incentives: systems of accountability and internal auditing.
- l. Weaknesses/challenges: in case of results based financing models, such as social impact bonds, there will be a need for periodic monitoring and evaluation. “lack of integration of monitoring structures with other donor initiatives to manage the grants and the discordance between grant performance ratings and disbursements of performance-based incentives, which an analysis partly attributed to the complexity of using composite instead of individual performance measures” (Meghani and Basi 2015). Product Red is less beneficial when annual budgeting is necessary (Meghani and Basu 2015).
- m. Trust issues: in 2013, the fund reported abuse of its fundings resulting in suspension of aid by several governments, after which the fund underwent restructuring (Hanefeld 2014:55).

Crop Trust <https://www.croptrust.org/> (Headquarters: Bonn (since 2013, before Rome)

- a. Short description model: Crop Trust is an autonomous body that enables a seed sharing system allowing researchers to access genetic material. The ITPGRFA identifies 25 priority crops that are important for food security. Crop Trust with the help of its Endowment Fund provides long term grants for conservation of these crops.
- b. Domain field of application: the Endowment fund is used to conserve the 25 crops listed in Annex I and other material in accordance with Art. 15 of the Treaty as well as 11 Genebanks (CGIAR Platform).
- c. Status: Crop Trust has been functional since 2004. In 2016 its Endowment Fund was valued at \$300 million dollars. Approximately 95% of the funding is from governments and the rest is from the private sector.
- d. Type of model/legal mechanism: maintenance grants for eligible seed collections via the Endowment Fund (Art. 3- Crop Trust Constitution).
- e. Legal basis public international law/link with international organization: ITPGRFA, Art. 15 (Ex Situ collections of plant genetic resources for food and agriculture).
- f. Initiative: it was founded in 2004 by Biodiversity International on behalf of the CGIAR and the UN Food and Agriculture Organization (FAO) to help support the ITPGRFA in a sustainable way, through a Crop Diversity Endowment Fund
- g. Profile stakeholders: states, private sector investors
- h. Administration: Crop Trust is an independent international legal entity since 2004. Its Executive Board (as per Art. 5 of its Constitution) oversees the operations of the Trust. The Board is also related to the Governing Body of the ITPGRFA which means that it receives overall policy guidance from the Governing Board (Art. 7 of Crop Trust’s Constitution) and is an essential element in the funding strategy of the Treaty. It also receives advice from a Donor’s Council on fundraising and other financial matters.
- i. Licensing Practices (single v. multi-option licensing schemes): N/A
- j. Uptake/Success of the model: 28 countries have signed/acceded to Crop Trust’s establishment agreement.
- k. Strengths/incentives: The relationship of the Executive Board with the Governing Board of the Plant Treaty. The integration of these two bodies provides coherence in their functioning as their objectives are the same. It also builds trust among donors.
- l. Weaknesses/challenges: There are concerns about the merits of ex-situ conservation for diversity as well as Crop Trust’s practice of taking seeds from farmers for free and making them available for both public and private plant researchers (De Wit 2015:633).
- m. Trust issues: the weakness identified above risks creating distrust amongst farmers. Compare also: ITPGRFA.

## Patent Pool (PP) and Clearinghouse (CH) Models

### *Some general observations on PPs & CHs*

PP and CH models have been considered widely as an effective tool to deal with fragmented landscapes of intellectual property rights (IPRs). Such models could act as a “one-stop-shop” (offering transparency, match-making, negotiating, technology exchange and royalty setting) multilateral model for IP owners and IP users resulting in lower transaction costs, clearing blocking positions and avoiding costly litigation.

The prevailing PP model is a relatively rigid model as it focuses primarily on pooling relevant patents related to a specific technology or technical standard (e.g. MPEG2, DVD). PPs are, hence, generally specifically tailored models often closely linked to a technical standard and with a rather homogenous group of stakeholders. Moreover, as PPs tend to require a close collaboration between competitors, specific guidance was provided by various competition authorities (e.g. US, European Commission) as to the set-up of these models, their institutional design and their licensing practices (e.g. Fair, Reasonable and Non-Discriminatory (FRAND) licensing terms). This is quite different for the benefit sharing issues that we are considering within the WiLDSI report. Nonetheless, I believe that a short comparative analysis of several pools could be relevant as a source of inspiration in particular with respect to some of the governance challenges involved in setting up such models (convincing patent owners/providers/donors to join the model). In addition, it may be interesting to note that several initiatives to set up a pool model in the end have become more of a clearinghouse model (e.g. MPP), which offers more flexibility and is less risky from a competition law perspective (see Figures 1 and 2).

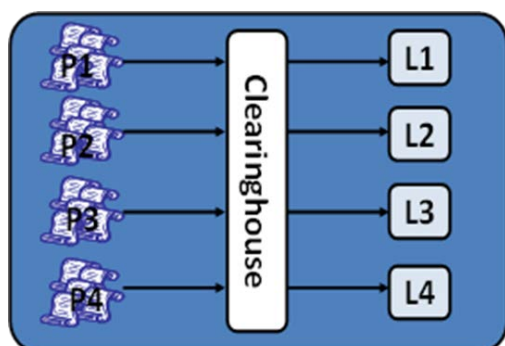


Figure 1. Simplified Clearinghouse Model

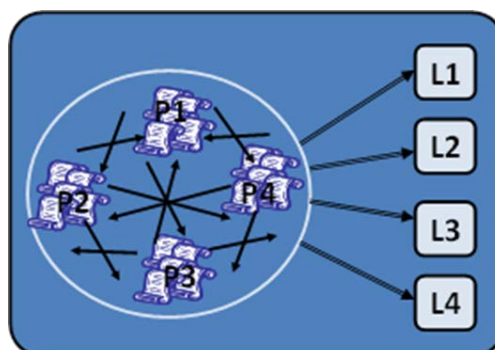


Figure 2. Simplified Patent Pool Model

(P= patent owner, L = licensees)

In the pool model the patent owners “sit together”, negotiate and determine the conditions under which they will contribute and license to the pool model, on the one hand, and the conditions under which the patent pool will be (sub)licensing out to individual licensees, on the other hand. In most early pools in the consumer electronics and ICT-sector all participating patent owners also had an interest in getting access to the pooled technologies (both provider to the pool and user/licensee). Those pools mostly related to one key technical standard requiring access to a set of essential patents in order to ensure compatibility with the standard and interoperability between products. In those pools, patent owners were rather homogeneous. Therefore, they had an incentive to negotiate reasonable terms for the sublicense granted by the patent pool. From interviews with experts who had been involved in setting up several pools, I learnt that in a few cases a single key patent owner (in one case this was a university) had a very different business



model from the others, which had resulted in extremely hard and time-consuming negotiations. Moreover, in more recent initiatives to set up pools for instance with respect to standards related to the Internet of Things, it has turned out much harder to employ the pool model to get access to fragmented patent rights, as the stakeholders are extremely heterogeneous and have widely diverging interests.

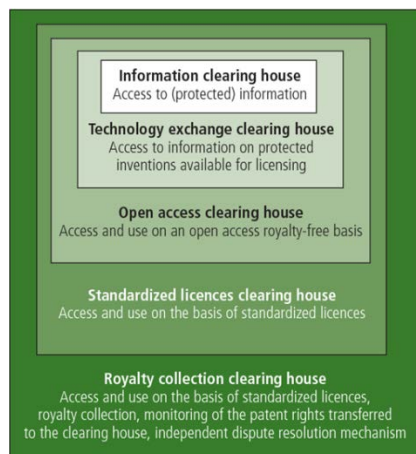
Furthermore, whereas the pool model has worked quite well in the consumer electronics and ICT sector, it has been much more complicated to set up similar models in other sectors such as the biomedical sector. Even a very experienced patent pool administrator, such as MPEG LA, which has initiated various attempts for pools in the field has not been very successful. van Zimmeren et al, 2011 shows that in this sector patent owners are unwilling to trust this type of intermediaries with key IP assets. They preferred to keep control and engage in bilateral transactions (high transaction costs) rather than entrusting a multilateral system with (potentially) very valuable assets (lower transaction costs).

In my opinion, *trust* and *control* are also key issues in exploring innovative models for benefit sharing for genetic resources and DSI. Key biodiversity countries in the South will want to keep control of their (potentially) very valuable assets, which they believe they can do through a bilateral model. They will not be inclined to trust a multilateral model, as their past experiences (see for instance the trust issue in the Section above on the ITPGRFA) with a multilateral system for benefit-sharing has not resulted in substantive monetary and non-monetary benefits. Therefore, the actual governance of the multilateral solutions that we will propose is essential for building and enhancing trust in the system (see also MPP model below, which initially had difficulties in getting some from important pharmaceutical patent owner). Identifying trust- building mechanisms is, however, not easy in this context due to the heterogeneity of the stakeholders and the multi-sided nature of these models.

In my work on clearinghouses, I have identified a typology of different clearinghouse models. Perhaps this typology could also be helpful in thinking about the potential role of a clearinghouse (more advanced than the current ABS clearinghouse<sup>27</sup>) in supporting more effective and sustainable benefit sharing. Below you find figure 3 which illustrates the variety of clearinghouse models. This typology was based on theoretical and empirical research focused on the biomedical sector, but not exclusively on this sector (e.g. agriculture).

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<sup>27</sup> The ABS clearinghouse (for now) seems to be operating only as an information clearinghouse (see Art. 14 NP and Annex JOINT MODALITIES OF OPERATION FOR THE CENTRAL CLEARING-HOUSE MECHANISM, THE BIOSAFETY CLEARING-HOUSE AND THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, CBD/COP/DEC/14/25, 30 November 2018, available at <https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-25-en.pdf>. Its role in monitoring the utilization of the genetic resources (Art. 17(1)(a)(iii) NP is limited to an information provision function.



**Figure 3. Typology of Clearinghouse Models**

### *Consumer electronic & ICT pools (MPEG2, DVD)*

- a. Short description: since the '90s many pools have been established in the consumer electronics and telecommunications sector in order to provide a one-stop-shop to clear fragmented patent rights and hence reduce transaction costs, prevent blocking positions and limit the risk of litigation. These PPs were often initiated in parallel to the ongoing standardization activities, where relevant patent owners were already collaborating and negotiating.
- b. Domain/field of application: consumer electronics, information and communications technology. These are highly fragmented markets: in some cases access to hundreds or even thousands of patents could be essential for complying with the technical standard concerned.
- c. Status: many PPs are operational in this sector and the early pools are generally considered very successful generating reasonable royalty levels for the patent owners and fair and reasonable licensing terms for the users. The PP model has been very well received. However, as indicated above, the more complicated the technology in this sector is becoming and the link with IoT with a large variety of stakeholders has rendered it harder to set up new pools in this field.
- d. Type of model/legal mechanism: PPs generally closely linked to a technical standard
- e. Legal basis public international law/link with international organization: not applicable
- f. Initiative: the first PPs initiated in this sector were primarily the initiative of a number of key patent owners who were inspired by older pools that emerged in the beginning of the 20 Century in the US. The MPEG2 pool resulted in the establishment of MPEG LA as a administrating agent. Nowadays, the initiative for new pools is primarily taken by MPEG LA and other patent pool administrators who issue a call for interested patent owners.
- g. Profile stakeholders: the pools that were set up in the 90s involved primarily patent owners who were also downstream manufacturers of the related products. Therefore, they had an incentive to determine reasonable licensing terms. For more recent pool initiatives, some of the key patent owners do not have any manufacturing activities and, hence, their incentives in participating in the pool (and in the standardization process) are very different.
- h. Administration: the PPs has gradually been professionalized and now several PP administering companies (such as MPEG LA) exist that issue calls, drive the negotiation process, offer support with the identification of relevant patents and are responsible for licensing out to third parties. Some pools are, however, administered by one of the key patent owners (however, need for so-called "Chinese Walls").

- i. Licensing Practices: competition law requires that users can also license relevant patents outside the patent pool model. Most pools offer licensing options that allow for tailoring to the type of use, field of application, number of products, etc.
- j. Uptake/Success of the model: the model is widely considered a successful model and has been “copied” by many later patent pools. It has also often been suggested to apply to patent pool model in the biomedical sector, where the uptake has, however, been less successful.
- k. Strengths/incentives: (1) one-stop-shop model resulting in a reduction of transaction costs, prevention of blocking positions and limitation of the risk of litigation; (2) reasonable royalties; (3) without the PPs it would have been impossible to produce products compatible with the technical standards without infringing on hundreds of patents.
- l. Weaknesses/challenges: transposing the model to other sectors and technologies has been very difficult and also in the consumer electronics and ICT sector setting up pool models with a more diverse set of stakeholders has created problems.
- m. Trust issues: it appears that thanks to its long-held experience with setting up pools and its expertise in the administration of PPs MPEG LA has been able to build a good reputation in the sectors concerned. Nonetheless, its attempts to build a similar track-record in the biomedical sector has not been very successful.

#### *CRISPR pool*

- a. Short description: MPEG LA has issued a call to start negotiations with key patent owners for a PP for CRISPR-Cas gene editing technology.
- b. Domain/field of application: gene editing technology – this is an area where a lot of research and development is ongoing and where the patent landscape is becoming increasingly more complex. As CRISPR-Cas is a platform technology with potentially many different applications in various fields, the technology could be quite suitable for setting up a pool, as even as there is no (de jure/legal) technical standard that is being established, important (de facto) scientific standards are emerging in the field.
- c. Status: the call for setting up the pool is pending and negotiations are ongoing
- d. Type of model/legal mechanism: PP for platform technology
- e. Legal basis public international law/link with international organization: not applicable
- f. Initiative: MPEG LA; several key patent owners have confirmed that they are participating in the negotiations for setting up the pool.
- g. Profile stakeholders: universities, research centres, spin-off companies, companies in many different sectors
- h. Administration: MPEG LA
- i. Licensing Practices: multi-option licensing schemes
- j. Uptake/Success of the model: thus far quite limited due to ongoing patent litigation between Berkeley and Broad/MIT
- k. Strengths/incentives: MPEG LA has expressed an interest in considering ethically responsible licensing terms in the licensing conditions.
- l. Weaknesses/challenges: uncertainty patent law in the area of gene editing.
- m. Trust issues: as long as the patent litigation is not settled, it will be hard get the key patent holders on board.

*Global Initiative on Sharing All Influenza Data (GISAID) and Pandemic Influenza Preparedness (PIP) framework* <https://www.gisaid.org/>

- a. Short description model: GISAID operates an open access database (accessible on registration and acceptance of terms of use) for sharing influenza virus sequences, related

clinical and epidemiological data associated with human, avian and animal viruses. GISAID operates within the WHO PIP framework which brings together Member States, industry, other stakeholders and WHO to implement a global approach to pandemic influenza preparedness and response; strengthening the sharing of influenza viruses with human pandemic potential and increasing the access of developing countries to vaccines and other pandemic related supplies.

- b. Domain field of application: influenza viruses with human pandemic potential
- c. Status: GISAID is operational since 2008.
- d. Type of model/legal mechanism: GISAID open access clearinghouse; Epiflu Database access agreement. The PIP framework ensures that an adapted form of the virus is made available to vaccine manufacturers. In return for receiving the viruses the manufacturers need to sign an agreement with WHO (SMTA) and commit to setting aside specific quantities of antivirals or vaccines for donation or purchase by WHO. In addition, manufacturers need to contribute to the Partnership Contribution (\$28 million a year used for strengthening global and country capacity to respond to pandemics and to build up a response fund (PIP Framework infographic).
- e. Legal basis public international law/link with international organization: link with the WHO PIP Framework
- f. Initiative: GISAID's creation shows how innovative models such as GISAID can depend on the initiative of one individual, Peter Bogner, a studio executive with a background in creating and licensing media content and in philanthropic work for organizations such as the United Nations and UNICEF. Bogner provided the main share of funding for setting up GISAID and was key to the development of the licensing mechanism that defines the GISAID data sharing policy. As chief executive, he remains closely involved in the initiative to this day. The initiative was launched at the 2008 World Health Assembly.
- g. Profile stakeholders: individual philanthropists, researchers, vaccine manufacturing companies, governments, WHO, national health agencies
- h. Administration: the GISAID Initiative receives administrative support from Freunde von GISAID e.V. a registered non-profit association (GISAID). The database is hosted by Germany.
- i. Licensing Practices: a non-exclusive, worldwide, royalty-free, non-transferable and revocable license. The core provisions of the Data Access Agreement include that users: (1) will share their own data and allow other users to access it; (2) that they will not share or distribute data submitted directly to the GISAID sharing mechanism to other non-GISAID servers or to individuals/institutions who are not registered GISAID users; (3) that they will credit the use of others' data in publications; (4) that they will make best efforts to collaborate with the originating laboratory and involve them in analyses and further research involving the data; (5) that they will analyse findings jointly; and (6) that they will maintain common access to technology derived from the data so that it can be used not only for research but also for the development of medical interventions such as diagnostics, vaccines, or antivirals. GISAID users have the right to develop a commercial product on the basis of data obtained through GISAID, but they may not impose any terms on the data itself (which remains the sole property of the contributor), and they must also seek to collaborate with the data contributors (Elbe & Buckland-Merrett, 2017).
- j. Uptake/Success of the model: GISAID has over 6,500 active users and data from 800 laboratories (GISAID).
- k. Strengths/incentives: Elbe & Buckland-Merrett (2017) argue that GISAID is making at least five key contributions to global health: (1) collating the most complete repository of high-quality influenza data in the world; (2) facilitating the rapid sharing of potentially pandemic virus information during recent outbreaks; (3) supporting the World Health Organization's biannual seasonal flu vaccine strain selection process; (4) developing informal mechanisms for conflict resolution; and (5) building greater trust with several low-income and middle-

income countries key to pandemic preparedness. With these contributions GISAID provides support in tackling three key challenges in influenza virus data-sharing: (i) scientists may hesitate to share data on viruses because they are concerned about other researchers then using this data to publish scholarly articles more quickly than they can do themselves. (ii) governments might interfere with the international exchange of information because of concerns about the negative economic ramifications of being identified as the source country of an international outbreak or they may wish to retain ownership over any potential intellectual property associated with the data and will be keen to ensure that they can secure access to new vaccines or medicines subsequently developed on the basis of that cooperation. (iii) who will provide sustainable funding and material infrastructure for hosting the virus data (Elbe & Buckland-Merret, 2017). Laird & Wynberg emphasize the importance of the identification of contributors, which allows tracing of genetic information about viruses which is useful during emergencies (Laird and Wynberg 2018:42).

- l. Weaknesses/challenges: (1) difficulties with monitoring access to the database and lack of clarity on what should be monitored - users or also products developed using the data in the database; (2) the WHO PIP Framework Review group in 2016 expressed concerns about “fairness and equity in benefit sharing” and “free-riding” with respect to sharing of viruses;<sup>28</sup> (3) future leadership and institutionalization of GISAID; (4) the ongoing negotiations around the PIP Framework as to the question of whether NSD (as opposed to physical specimens) should also be governed by the framework (proved to be too sensitive to be resolved during the initial negotiations for the PIP framework) (Gostin et al., 2014); (5) unclear whether the success of the model could be extended to other fields (points 1-2 based on GISAID website; 3-5 based on Elbe & Buckland-Merret, 2017)
- m. Trust issues: GISAID is regarded as having successfully built greater trust with several low-income and middle-income countries key to pandemic preparedness by including proper safeguards in the access agreement allowing for the retention of ownership of potential intellectual property rights related to the data and ensuring access to new vaccines/medicines. (Elbe & Buckland-Merret, 2017; Shue & McCauley, 2017).

### *International Licensing Platform Vegetable*

- a. Short description: There has been increasing discussion about patents on vegetable plant traits: proponents of such patents claim that they foster innovation, knowledge-sharing and continued investments in research and development. Opponents argue that such patents are unnecessary because of the IP protection offered by plant breeders’ rights and that patents impede the work of breeders because they can no longer gain access to biological materials, or can do so only after a delay or at a high cost. In order to respond to the needs of breeders eleven companies have worked together to establish the International Licensing Platform Vegetable with an aim to provide plant breeders around the world with faster, more efficient and cost effective, guaranteed access to crucial vegetable plant traits that are currently covered by patent claims by ILP member companies. The ILP Vegetable provides a straightforward, easy way for vegetable breeders to license the traits they need at a fair and reasonable cost. The members of the ILP Vegetable will make all of their patents related to vegetable plant traits accessible to their fellow members under the conditions of the ILP.
- b. Domain/field of application: vegetable plant traits
- c. Status: introduced in November 2014

<sup>28</sup> <https://www.gisaid.org/references/statements-clarifications/gisaid-comments-on-the-preliminary-findings-of-the-pip-framework-review-group-2016-25-september-2016/>, Genetic Sequence Data, Finding 3.

- d. Type of model/legal mechanism: the way that the ILP has been set up seems to be in line with a technology exchange clearinghouse where the platform offers a ground to connect people, but the actual licensing process happens at a bilateral level.
- e. Linked to public international legal instrument: not applicable
- f. Initiative: 11 companies including Agrisemen, Bayer, Bejo, Enza, Holland-Select, Limagrain, Limgroup, Pop Vriend, Rijk Zwaan, Syngenta and Takii, which comprise both listed companies and family businesses from Switzerland, Germany, Japan, France and The Netherlands.
- g. Profile stakeholders: universities, research centres, companies, plant breeders
- h. Administration: ILP
- i. Licensing Practices: (information from website ILP) If a member of the ILP Vegetable wants to take a license for a patented trait of a fellow member, he starts bilateral negotiations. These negotiations can lead to a license agreement. This agreement can be based on the so-called Standard License Agreement: a standard agreement provided for by the ILP Vegetable, but it may also deviate. In the event that negotiations don't lead to an agreement within three months after the start, the case can be submitted to independent experts. The method of decision-making by the experts is based on the so-called Baseball Procedure. Both members submit their license fee proposal to the secretary of the ILP Vegetable with all the arguments, why they think that their proposal is reasonable. This could be a proposal for a royalty percentage or - if both parties agree - a lump sum. After receiving figures from both members, the secretary exchanges the two proposals between the two members involved with the possibility to come to an agreement within three weeks. If no agreement can be reached, the decision is referred to the independent experts. These independent experts will choose among the proposals the most reasonable proposal and then a Standard License Agreement including the chosen proposal will be executed. This system encourages both parties to propose reasonable positions, because an unreasonable position will be rejected in favor of a more reasonable proposal. Furthermore the cost for the baseball arbitration must be paid by the member whose proposal has not been selected by the independent experts.
- j. Uptake/Success of the model: it is unclear to what extent the model has been successful and to what extent already licenses have been granted. Moreover, no public information seems to be available regarding the role and success of the Baseball Procedure.
- k. Strengths/incentives: the Baseball procedure is often mentioned as a potentially very interesting asset for this type of mechanisms as it could reduce transaction costs in the negotiations.
- l. Weaknesses/challenges: (1) even though a lot of the relevant documents including standard agreement, members agreements, etc. are publicly available, not a lot is known about the actual functioning of the model and its success; (2) uncertainty patent law in the area of essentially biological processes and the products thereof in Europe.
- m. Trust issues: [further research required]

#### *Medicines Patent Pool (MPP) (Headquarters: Geneva)*

- a. Short description: the MPP is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries by way of a pooling mechanism. The licenses permit generic pharmaceutical companies to manufacture and distribute patented medicines in developing countries. The licenses also provide the freedom to develop new treatments such as fixed-dose combinations – single pills composed of several medicines – and special formulations for children. Competition between low-cost manufacturers brings prices down.

- b. Domain/field of application: initially the MPP was focusing on making HIV, hepatitis C and tuberculosis medicines available to low- and middle income companies. Due to the success of the model, the MPP is currently exploring opportunities for addressing new markets and additional diseases.
- c. Status: the MPP was founded in 2010
- d. Type of model/legal mechanism: the model is generally referred to as a patent pool model but it does not comply with the typical features of a patent pool. The current head of the MPP has confirmed that the MPP in practice operates more as a technology exchange clearinghouse model.
- e. Legal basis public international law/link with international organization: link with UNITAID and WHO
- f. Initiative: the MPP is founded and funded by UNITAID
- g. Profile stakeholders: pharmaceutical companies, generic companies, civil society organizations
- h. Administration: MPP
- i. Licensing Practice: multiple option licensing schemes and all the licenses and sub-licenses are made available on the MPP website. This very transparent approach is one of the key assets of the MPP model.
- j. Uptake/Success of the model: the uptake of the MPP has been extremely slow in the beginning. Important pharmaceutical companies have been reluctant to join the model. However, a growing number of pharmaceutical companies is collaborating with the MPP and the number of licenses has also been increasing considerably. The MPP's mandate was initially limited to HIV/AIDS and has gradually been extended. At present, the MPP is exploring opportunities to expand further into new disease areas.
- k. Strengths/incentives: (1) sustainable funding model thanks to the support of UNITAID; (2) carefully constructed accountability mechanism; (3) gradual expansion of the mandate over time; (4) transparency concerning the licensing conditions.
- l. Weaknesses/challenges: during the starting phase the MPP encountered (1) quite some resistance from pharmaceutical companies and (2) the MPP was strongly criticized by civil society organizations as they negotiated licensing conditions were considered too advantageous for industry. There are still some pharmaceutical companies that do not want to collaborate with the pool, but the number of partners has steadily been increasing. Moreover, there are a number of companies that can be regarded as strong supporters of the model. The second criticism was partially due to the fact that most civil society organizations had never closely studies licenses or been involved in licensing negotiations. Generally, licensing conditions are considered secret. The MPP publishes all licensing agreements on its website. This has been a game-changer within this type of models and can be considered an important step in creating more awareness, a better understanding and an opportunity for debate amongst stakeholders as to what should be considered reasonable licensing conditions. So in the end, a key challenge for the MPP in the end became one of is key assets.
- m. Trust issues: during a conference at the starting phase of the MPP I met several industry representatives that expressed their irritation about the fact that they had the impression that the majority of the staff members of the MPP were former civil society representatives. This was raising significant doubts as to the neutrality of the MPP, the expertise of staff members in IP law and the capacity of staff members to understand the interests of industry and to engage in efficient negotiations. Even though this might very well only be a perception not based on reality and only amongst a particular stakeholder group, but such a negative perception can be disastrous for building trust in the model and involving key stakeholders. Therefore, the governance of a model and the selection of staff members should be a key point of attention for any model that WiLDSI is proposing. Fortunately, for the MPP those early concerns were overcome while the MPP was gaining

experience and industry representatives had an opportunity to build relations with the pool.

*WIPO Research (Headquarters: Geneva)*

- a. Short description: WIPO Research is a Consortium sponsored by the World Intellectual Property Organization (WIPO) in collaboration with BIO Ventures for Global Health (BVGH). The Consortium aims to accelerate the discovery and product development of medicines, vaccines, and diagnostics to create new solutions for people affected by neglected tropical diseases (NTDs), malaria, and tuberculosis by setting up an open innovation platform. This platform operates by making Intellectual Property available on concessionary terms to researchers everywhere. The commitment to sharing Intellectual Property, however, goes beyond research. Members also commit to the licensing of Intellectual Property contributed to the Consortium.
- b. Domain/field of application: medicines, vaccines, and diagnostics to create new solutions for people in LDCs affected by neglected tropical diseases (NTDs), malaria, and tuberculosis.
- c. Status: established in 2011
- d. Type of model/legal mechanism: The WIPO Re:Search is a cooperative, voluntary arrangement among groups and institutions collaborating towards a common set of principles and objectives but each acting on its own. No legal structure is hereby created. In my opinion, WIPO Re:Search effectively operates as a technology exchange clearinghouse and its Guiding Principles document offers a frame for the bilateral negotiations, which does not fully amount to a standard licenses clearinghouse. The scope of the platform extends to “patent and related registered rights, know-how, manufacturing processes, and regulatory data and the corresponding physical materials such as proprietary compounds and technologies”.
- e. Legal basis public international law/link with international organization: the WIPO Re:Search Consortium is sponsored by WIPO and the WHO provides technical assistance.
- f. Initiative: WIPO
- g. Profile stakeholders: Membership includes providers contributing IP, users who have negotiated a license with providers and supporters, they consist of pharmaceutical companies, academic institutions and product development partnerships. 8 companies provide financial contributions to WIPO Re:Search including Eisai, GSK, Merck, Johnson & Johnson, Novartis, Pfizer, Takeda. Australia and Japan provide financial support through Funds-In-Trust.
- h. Administration: the Partnership Hub is managed by BIO Ventures for Global Health (BVGH).
- i. Licensing Practices: WIPO Re:Search has adopted Guiding Principles that set the minimum standard for members. Membership in the Consortium is open to those that agree in writing to these Guiding Principles. Some of the key Guiding Principles are the following: (1) providers agree to grant users royalty-free licenses to their IP for R&D and for making and selling products, technologies or services for addressing public health needs for any or all NTDs in LDCs; (2) users shall be allowed to retain ownership of and apply for registration of IP protection as they deem fit, but shall be encouraged to license to third parties through WIPO Re:Search under terms consistent with these Guiding Principles. (3) providers will not make any claims to rights in new IP, materials or derivatives of materials generated by a user under a license agreement made pursuant to membership in this Consortium. (4) in case of a conflict members are encouraged to use the services of WIPO’s Arbitration and Mediation Center.
- j. Uptake/Success of the model: WIPO Re:Search has over 141 members across the globe.
- k. Strengths/incentives: (1) the model is specifically tailored to a clear list of diseases; (2) diseases that offer only limited commercial opportunities rendering it more attractive to



making relevant IP available through the open innovation platform (3) has managed to attract the support of some of the major pharmaceutical companies; (4) broad scope of IP rights; (5) flexible model; (6) WIPO Re:Search creates a market for underutilized assets; (7) governance mechanism tailored to specific groups of “members” that are well-represented within the mechanism.

- l. Weaknesses/challenges: (1) not so successful in expanding the number of participating companies, catalyzing agreements with developing country institutions, responding to requests for financial and technical support from developing country partners, attracting new donors, and demonstrating that partnerships can lead to product development. (2) difficulty in creating and operating a structure that is widely understood, and in shaping a clear long-term vision; (3) need for upgrade of the web-based database; (4) need for clearer metrics to measure the performance of WIPO Re:Search (Mahoney, 2015); (5) strengthening transparency.
- m. Trust issues: [further research required]

### *DSM SNP Nutrigenomics*

- a. Short description: about a decade ago I was involved in an initiative of DSM to explore the opportunity of setting up a clearinghouse model in order to provide a one-stop-shop for getting access to patented SNPs for a reasonable licensing fee. The initial aim was to set up a royalty collection clearinghouse model for IP related to SNPs for an application in the field of nutrigenomics.
- b. Domain/field of application: nutrigenomics
- c. Status: failed
- d. Type of model/legal mechanism: the initial proposal related to a royalty collection clearinghouse. However, during discussions with a number of potential key providers to such a pool, proposals were made to start with an information clearinghouse and then analyze the needs for a more advanced model.
- e. Legal basis public international law/link with international organization: not applicable.
- f. Initiative: DSM had set-up a project group responsible for exploring the opportunities of such a clearinghouse model. They had prepared patent landscapes and organized meetings with potential stakeholders.
- g. Profile stakeholders: public and private SNP patent owners (providers), companies active in nutrigenomics (users)
- h. Administration: not applicable.
- i. Licensing Practices: not applicable
- j. Uptake/Success of the model: despite the support generated within DSM and initial expressions of interest of potential stakeholders, the proposals did not generate sufficient support.
- k. Strengths/incentives: (1) support for the model amongst a few key potential users; (2) access to SNPs was perceived as essential to open up a new commercially potentially very interesting market.
- l. Weaknesses/challenges: (1) uncertainty patent law; (2) provider side of the two-sided platform was not represented in discussions about the need for a clearinghouse model; (3) key users did not want to take the lead or invest in a model which would potentially also benefit competitors.
- m. Trust issues: /

## Librassay Clearinghouse

- a. Short description: MPEG LA, a pioneer in administering patent pools, launched Librassay as the first “licensing supermarket” in the biomedical sector. Librassay offered non-exclusive, non-discriminatory licences to developers and suppliers of commercial products and clinical tests for diagnostics and research tools.
- b. Domain/field of application (incl. some information on industry sector/structure, market fragmentation):
- c. Status: the model was launched in September 2012. Reassured by the reputational effects of MPEG LA’s successful pool licensing programs, nine well-respected US institutions decided to participate in Librassay’s licensing program.<sup>29</sup> MPEG LA actively licensed the Librassay patents to several companies for diagnostic tests, life sciences research products, and medical devices. But ultimately Librassay was suffering of the risks involved in being a lead actor. In several important patent cases the US Supreme Court considerably limited the patent eligibility of diagnostic methods and isolated nucleic acid sequences. As a consequence, the patent thickets and stacking issues surrounding multiplex diagnostic tests that may have supported the market need for a one-stop, non-exclusive licence diminished considerably.
- d. Type of model/legal mechanism: the model that was being set up can be labelled as a royalty collection clearinghouse offering information, match-making services, standard licenses and royalty collection and distribution.
- e. Legal basis public international law/link with international organization: not applicable.
- f. Initiative: MPEG LA
- g. Profile stakeholders: public and private owners of patents essential for developing multiplex diagnostic tests, diagnostics companies, universities, hospitals
- h. Administration: MPEG LA
- i. Licensing Practices: multi-option licensing schemes
- j. Uptake/Success of the model: initial uptake by US research organizations was quite positive, but changes in US patent law policy changed market dynamics and decreased the need for a one-stop-shop licensing mechanisms in the field of application.
- k. Strengths/incentives: initiative by MPEG LA, a pioneer in administering PPs has developed a good reputation in setting up collaborative licensing models.
- l. Weaknesses/challenges: (1) market uncertainty; (2) uncertainty patent law
- m. Trust issues: see strengths

## Some general observations and topics for further research:

- In several papers by legal researchers and at international conferences, experts in investment law have emphasized the risk that bilateral investment treaties may be applicable to the innovative funding mechanisms and may cause problems. We need to carry out further research to get a better understanding as to the extent to which such treaties may be applicable and the type of problems that could be caused (and that could perhaps be overcome by tweaking the financial model or by adapting the governance mechanism).
- Donating countries: the actual countries that seem to be involved as donors in the analyzed innovative funding models is relatively limited. It could be interesting to explore why other

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<sup>29</sup> Johns Hopkins University, Ludwig Institute for Cancer Research, Memorial Sloan-Kettering Cancer Center, National Institutes of Health, Partners HealthCare, The Board of Trustees of the Leland Stanford Junior University, The Trustees of the University of Pennsylvania, University of California, San Francisco and the Wisconsin Alumni Research Foundation.

countries are not involved in and do not support these models. What about Switzerland and Scandinavian countries?

- Importance of leadership: several models show the relevance of strong leadership of sometimes even one key philanthropist (see GISAID), a company or an international organization that takes the lead and leverages its network to establish a mechanism for the benefit of the broader community. Nonetheless, leaders also sometimes fail (SNP Nutrigenomics clearinghouse). Moreover, even perceived bias can create challenges in attracting the necessary support for a new initiative (see MPP). This points again to the need to pay sufficient attention to a balanced governance mechanism; this applies to benefit sharing models, innovation funding mechanisms and collaborative licensing mechanisms.
- All these models are what economists often refer to as so-called “two-sided platforms”. For the models to be feasible, you need to be able to incentivize some key stakeholders to join both at the provider side and at the user side. If the support on any of the sides is lacking, the model will not be successful. Therefore, the governance of the model should safeguard that incentives and safeguarding mechanisms exist at both “sides” of the platform that ensure that providers and users are supporting the development and establishment of the model and will effectively join the model. In many models apart from the providers and users, a third group of supporters/donors is involved. Those donors may be funding companies or countries. It is essential that also their interests are well-represented in the governance of the model.
- Problems with benefit-sharing seems to be resulting in distrust in the ITPGRFA model. This will likely affect the interest and incentives related to any proposal that we will make within the WiLDSI project. Therefore, it seems important to delve somewhat deeper in the trust literature and to identify trust building mechanisms that could be useful in proposing an effective institutional design for our cooperate/traceable multilateral solutions.

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## White Paper 6: Importance of Open Access Gene Banks from the perspective of Crop Plant Research

Dr. Jens Freitag, Leibniz Institute of Plant Genetics and Crop Plant Research, IPK

### Preliminary remarks

The current focus of this white paper is on crop plants, meaning similar work would be required to gain perspectives on microbial resources, farm and wild animals as well as on wild plants and collections to develop a comprehensive overview of the perspective of the scientific community on this issue.

### Gene banks are bio-digital resource centers

A total of approximately 7.4 million Plant Genetic Resources (PGR) accessions are currently held in 1,750 gene banks worldwide. In addition to collecting these resources, these gene banks preserve these resources permanently, ensuring access to and distribution of this material together with associated information. This information increasingly includes molecular and phenotypic information as well as so-called passport data. This information and the PGR provide the basis for plant research. The value of these resources comes from the research done and the subsequent dissemination of the research results. Without research, these resources are meaningless. These socially relevant tasks of gene banks and databases providing and valorizing information cause significant ongoing costs. Using the example of the Federal *ex-situ* gene bank at the Leibniz Institute for Plant Genetics and Crop Plant Research IPK, these amount to approximately 5 million euros annually. This does not yet include research efforts to further characterize the resources in the gene bank. The total budget of the institute accounts to 40 million euros plus approximately another 10 million euros annual for competitive research projects from public funds (regional, national and European funding). The genetic resources themselves and the scientific information gained including all data generated at the Institute are available to the research community worldwide.

Parallel to the described availability of resources and information, which represent the biological diversity itself, the current transformation of gene banks into bio-digital resource centers<sup>30</sup> is ongoing. Precision panels provide a new backbone for basic and practical plant research (for more details see below).

Through the possibilities of high-throughput DNA sequencing using 2<sup>nd</sup> (multi-parallel sequencing) and 3<sup>rd</sup> (single molecule sequencing) generation, the molecular diversity of genetic resources can be systematically digitally captured and exploited. Through initiatives such as the National Research Data Infrastructure (NFDI) of the DFG and the BMBF, these digital resources can be networked with other relevant but not necessarily predicted, i.e. surprising, data sources. Access to these data is following as an absolute prerequisite the FAIR principles, which stands for: Findable, Accessible, Interoperable, and Reusable. More and more researchers worldwide are committed to these principles.

From a scientific point of view, there is therefore only one way: **free access to digital sequence information must be ensured** on a permanent basis in order to enable research and development, the re-use of genetic information and the monitoring of genetic diversity on a permanent basis. The information stored in gene banks and databases is extended and supplemented by numerous

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<sup>30</sup> Martin Mascher *et al.* (2019), Genebank genomics bridges the gap between the conservation of crop diversity and plant breeding, *Nature Genetics*, DOI: 10.1038/s41588-019-0443-6

further experimental approaches and resulting data. Data on genotypes and phenotypes which might become more organ-specific in future providing deeper insights into cellular processes, supplemented with information from plant breeding and with the rising opportunities of Big-Data analysis with feedback information about the genetic performance in specific environments and under different managing practices in agricultural on farm scale. Data provided by and for the research community as it whole.

One of the greatest challenges of current biological research is the experimental and therefore valid description of biological proven gene functions. For the most, gene functions are determined by annotation using comparative analyses predictions across all groups of organisms. Improved functional genomics research is needed to close the gap between predictive and experimentally valid information. This is based on comprehensive, freely available data in databases and their meaningful networking. The experimental validation of gene functions needs a dramatically increase of experimental groups worldwide as well as completely new scientific approaches. The more comprehensive the available data, the more precise the information gained will be. Conversely, restrictions and isolation lead to a loss of plausibility and a decreased quality of scientific information. Cooperation's, joint efforts, the design of standardized processes and open interfaces for e.g. application programming interfaces – APIs of databases and open algorithms as the backbone of soft-ware tools for the analysis as well as an enforcement of open access principles and the requirement to store corresponding experimental data as a prerequisite of publications – all this will increase the value of scientific data for researchers all over the world. Basic principles of free research, including the reproducibility of experimental approaches but also access to and actuality of data in databases, are ensured.

In addition to classical sequence information, integrative approaches, so-called systems biology approaches, are increasingly used in current research. So-called "omics technologies", which deal with genomics, proteomics and metabolomics and generate large amounts of data because they capture and evaluate complete genomes, proteomes or metabolites, are used to elucidate biological relationships. Information technology and the linking of information structures are essential elements of systems biology research in these approaches. Research based on omics data requires sufficient bioinformatic capacities and new methods for data evaluation and networking. Deficits currently lie in insufficient data storage, analysis and transfer capacities. Locally generated raw data is often too large for transmission in a global network. The data stored at different locations and the resulting knowledge models need to be better linked. Currently, there are a large number of differently organized databases and structures: primary databases, annotated data, topic- or institute-specific surveys and many more. But, also the development of software solutions and algorithms that are used to evaluate the data often lag behind the scientific questions. Isolated solutions that lag behind technological possibilities and technological developments or the large number of independently developed software solutions that make it difficult to compare data are no longer up to date.

It is important to build up an international consensus in order to achieve sustainable and globally accessible data management and research. The comprehensive empowerment of researchers worldwide and the associated integration of intellectual potentials must be guaranteed and expanded. The promotion, networking and exploitation of the research community will become a fundamental prerequisite for free research in the 21<sup>st</sup> century. This is the only way to enable science and research to solve future tasks.

The dissemination of technology is therefore a central task and should be carried out jointly and globally. The training of young scientists or the continuous training of already established

researchers are also tasks for the future and would be further hindered by isolation and restrictions. In many countries of the global South, it is initially a question to catch-up these developments. At the same time, established industrialized countries need to make extensive investments in the maintenance, expansion as well as the ecological restructuring of existing research infrastructures. Developments and costs that would be further exacerbated or increased by more restrictive systems and a less free access.

**In order to increase this potential, significantly higher expenditures are needed for research, but also for the development and expansion of infrastructure and the reduction of existing restrictions worldwide.**

### **Example for a barley “precision collection” - a need and cost driver**

In the early-to-mid twentieth century, it became increasingly apparent that crop landraces were slowly being replaced by modern crop varieties and were in danger of disappearing. In order to prevent loss of genetic diversity and biodiversity, the first gene banks were established, with the mission to preserve these plant genetic resources. Nowadays, gene banks function as biorepositories and safeguards of plant biodiversity but most importantly as libraries which turn the genetic plant information and plant material into a freely accessible but nonetheless valuable resource. As such, scientists, plant breeders or even anybody from around the world can request and use the data stored within gene banks around the world for research or plant breeding purposes.

An example of such a precision collection was created at IPK as part of the [BRIDGE](#) project. BRIDGE stands for "Biodiversity informatics to bridge the gap from genome information to educated utilization of genetic diversity hosted in gene banks. Nearly 24,000 barley accessions and thus a large part of the allelic diversity within a species were recorded and characterized<sup>31</sup>. The characterization was based on the analysis of single nucleotide polymorphisms (SNP's). With the ongoing developments in sequencing approaches, such characterization might be based on complete genome sequencing in future even for organisms with giant genomes as barley, wheat or other crops as well. This increases the exploitable scientific value of a collection. At the same time, the effort to preserve and characterize this collection will increase.

Three major challenges for gene banks can be defined which will need attention but will rise costs to run and manage gene banks. Two are caused by the basic demands of managing tens of thousands of precision seed lots, namely the tracking of the identity of accessions, and the need to avoid unnecessary duplications within and between gene banks. The third challenge is that of maintaining the genetic integrity of accessions, due to the inherent drawbacks of using *ex situ* conservation, such as differential survival, drift and genetic erosion in storage and regeneration.

However, a stronger genomic-driven approach towards gene banks might help when taking on these challenges. For example, traditionally, the “passport data” of the gene bank material describe the taxonomy and provenance of accessions. By adding single-nucleotide polymorphisms (SNPs) or complete sequence information in future as defining characteristics of an accession, this genotypic information could serve as molecular passport data to complement and correct traditional passport records, as well as assist with the cleansing and prevention of duplicates and improve the quality and integrity of the collections. By implementing the shift towards bioinformatics and big data

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<sup>31</sup> Sara G. Milner *et al.*; Genebank genomics highlights the diversity of a global barley collection, Nature Genetics (2018). DOI: 10.1038/s41588-018-0266-x



analytics in plant sciences, traditional gene banks, which focus on the preservation of germplasm collections, will be able to transform into bio-digital resource centers, which combine the storage and valorization of plant materials with their genomic and molecular characterization.

Current funding scenarios of gene banks do not yet allow for the systematic generating of molecular passport data for each submitted plant sample at gene banks. However, first steps into the direction of high-throughput genotyping of entire collections have already been taken.

As an outcome of the case-study the creation of the project accompanied web-information-portal BRIDGE was a result. BRIDGE is a data storage for the attained genomic barley information which links to the phenotypic information collated at the Federal *Ex situ* Gene Bank for Agricultural and Horticultural Crop Species at the Leibniz Institute. Whilst BRIDGE is already paving the way towards evolving the Gaterslebener Gene Bank into a “one stop shop for facilitated and informed utilization of crop plant biodiversity”, international collaborations, such as the organization [DivSeek](#), are building the international framework for enabling gene banks, plant breeders and researchers globally to more efficiently process and mobilize plant genetic diversity, thus starting to bridge the gaps between bioinformaticians, geneticists and gene bank curators. Hence, a worldwide network of bio-digital resource centers, sharing data freely and thus help fostering research progress in plant science and plant breeding may become a reality in the near future.

### **Additional Information**

*Wageningen University and Research recently published a [report](#)<sup>32</sup> from a stakeholder perspective. With the genomic revolution a continuously increasing amount of data is being generated. Innovation in different domains and subsectors, ranging from agriculture and biodiversity conservation, to biotechnology and human health, depends on the use of DSI. Access to DSI and related technologies is crucial for any stakeholder and country, in order to reach long term food security objectives, to be able to adapt to climate change, to deal with human health issues, and to contribute to the conservation and sustainable use of biodiversity. Stakeholder consultations in the Netherlands indicate that fair and equitable benefit sharing arrangements - related to the use of DSI - should possibly only be dealt with in a multilateral context.*

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<sup>32</sup> Sipke Joost Hiemstra, Martin Brink and Theo van Hintum (2019), Digital Sequence Information (DSI) - Options and impact of regulating access and benefit sharing - stakeholder perspectives, Centre for Genetic Resources, the Netherlands (CGN), Wageningen University & Research Wageningen

## **White Paper 7: DSI survey on usage and importance of DSI for biological researchers from South Africa, India, Colombia, Brazil**

Dr. Carmen Richerzhagen, German Institute for Development Policy, DIE

### **Country-specific survey on DSI**

#### ***Background***

The political debate surrounding the inclusion of DSI/NSD in the definition of genetic resources under the CBD and the Nagoya Protocol has raised serious concern and criticism among the European institutions and government infrastructures. However, the views or concerns of scientists of the G77 countries, who actually use DSI/NSD in their research, have not been visible in the negotiations so far. In order to understand and analyze the perspective from the scientists and government bodies from these countries with regard to use and relevance of NSD/DSI, we undertook a country-specific DSI survey. The aim of this study was primarily to investigate the use and relevance of DSI among the scientific stakeholder community from four country case studies (Brazil, Colombia, India and South Africa). We were interested in knowing what is required and needed to improve research based on sequencing in these countries. Further, we also wanted investigate the level of awareness among the scientific community in these countries concerning the DSI/NSD issue.

Thirty seven scientists were interviewed between a three month time period from November 2019 to January 2020. These scientists belong to a total of four countries (Brazil 10, Colombia 6, India 8, South Africa 13). The interviews were conducted either personally, by telephone or by filling out an online questionnaire which was in some cases then followed up by a telephonic interview. Additionally, background interviews with four policy experts were also conducted. The countries selected for this DSI survey were based on the following criteria: i) NSD/DSI relevance in the country as provider or user of NSD/DSI, ii) country is a biodiversity hotspot, iii) role of the country in the CBD/Nagoya negotiations, iv) regional representation (Asia, Africa, Latin America).

#### ***Use and importance of DSI/NAD***

All interviewed researchers use DSI/NSD and rely on DSI/NSD in their research. They represent a wide range of scientific disciplines from microbiology and taxonomy to bioinformatics and genomics (see Figure 4). They work in the academic and private sector or for the government. Most of them are involved in basic and applied research, just two mentioned commercial interests (see Figure 4). They use mainly microbes, plants, animals, and fungi for sequencing (see Figure 4). All researchers stated that DSI/NSD is very essential for their research and that without it their research would not be possible. For example, one researcher from Colombia said “Having access and the ability to sequence genetic information is key to us” (Researcher COL, 13.12.2019). A researcher from South Africa said that DSI/NSD is “critical for gaining a full understanding of plant molecular physiology mechanisms” (Researcher SA, 04.12.2019).

All interviewed scientists intensively use open access databases and see open access as a condition to their research. The most mentioned database institution is the National Center for Biotechnology Information (NCBI) in the United States and its Genbank database. Other systems or institutions mentioned are for example the Barcode of Life Data System (BOLD), the European Bioinformatics Institute (EMBL-EBI), the Joint Genome Institute (JGI). Some researchers only use databases if they are open access. In very few cases, researchers have to pay an access fees (e.g., Repbase if commercial users access database). The majority of researchers (21) knows where the sequencing source comes from (origin), the remaining group (16 researchers) states that they sometimes know

the origin. All interviewed researchers, except one, generate sequence data themselves and most researchers (36) indicated that the use of DSI/NSD has increased in the last decade. During the research phase, they store the sequence data locally on in-house computers, servers and databases, in clouds, and/or later they submit to international databases, such as NCBI, Genbank, JGI, ENA. The submission to the international databases is closely linked to a publication. Researchers usually submit the sequence during the writing process (with a later release date) or when the publication is accepted by a journal. Most journals require the data to be stored on publicly accessible online databases before a review process can take place. In case of microbes the deposit in a second collection is required before a publication is accepted by a journal. Researchers indicated that they normally share the sequence data with collaborators. Only very few of them use Material Transfer Agreements (MTAs). Many share the material without any conditions. Sometimes, researchers request the co-authorship or an acknowledgement. Shared data is transferred for example via ftp, Dropbox.

### ***Nagoya 2.0***

16 researchers have some experience with the Nagoya Protocol and its application, 22 interviewees have not. It is obvious that researchers who have experience with the Nagoya Protocol report about their negative experience. Researchers criticize that the process to receive a permit and the channels to follow are unclear and take very long to complete. They complain that the Nagoya regulations impede their research. Some even call Nagoya a “nightmare”. Some researchers in Brazil report that recently access to genetic resources in their countries was facilitated and bureaucratic obstacles have been mitigated.

According to the question if DSI/NSD should fall under the Nagoya Protocol some researchers mention that a certain form of benefit-sharing should take place if the material is used for commercial purposes. However, the majority of researchers with Nagoya experience fears negative impacts on their research (i.e. access restriction), strongly recommend not to apply the Nagoya Protocol to DSI/NSD (“Disastrous - I might as well pack my bags and go home. Forget doing any research”) and suggest that DSI/ABS regulations should rather be structured in a way that it enables research. One researcher sees in a transparent open access system a good opportunity to avoid biopiracy.

The interviewed researchers have many ideas how to improve research based on sequencing. They suggest greater availability of domestic sequencing facilities, more training in bioinformatics, increased research funding, sharing of data and technology. Although the cost of sequencing continue to drop, it is still very expensive for the research facilities in case study countries. Another proposal that was made by a scientists is increased collaborations with large databases such as EMBL in order build up in-country infrastructure with regard to DSI generation, storage and sharing. Some researchers have heard about the political discussions on DSI/NSD and are partly involved in the debates, but the majority of researchers is rather unaware.

### ***Conclusion***

DSI/NSD is not only relevant for researchers in Europe. Researchers around the world are benefitting from the use of DSI. Researchers in Brazil, Colombia, India and South Africa rely intensively on the generation and use of DSI/NSD. Open access is very critical for their research. Since research conditions in these countries are already worse than in many industrialized countries, any restrictions on open access would put these scientists at another disadvantage. However, there is some understanding among the researchers that a certain form of benefit-sharing in case of commercial use would be fair and adequate. Nevertheless, a system must be

found that enables DSI/NSD research through a facilitated access. Researchers who have Nagoya experience are very critical regarding the application to DSI/NSD. Their opinion should be heard when negotiating DSI under the CBD, but they are usually not included in the political discussions around DSI/NSD.

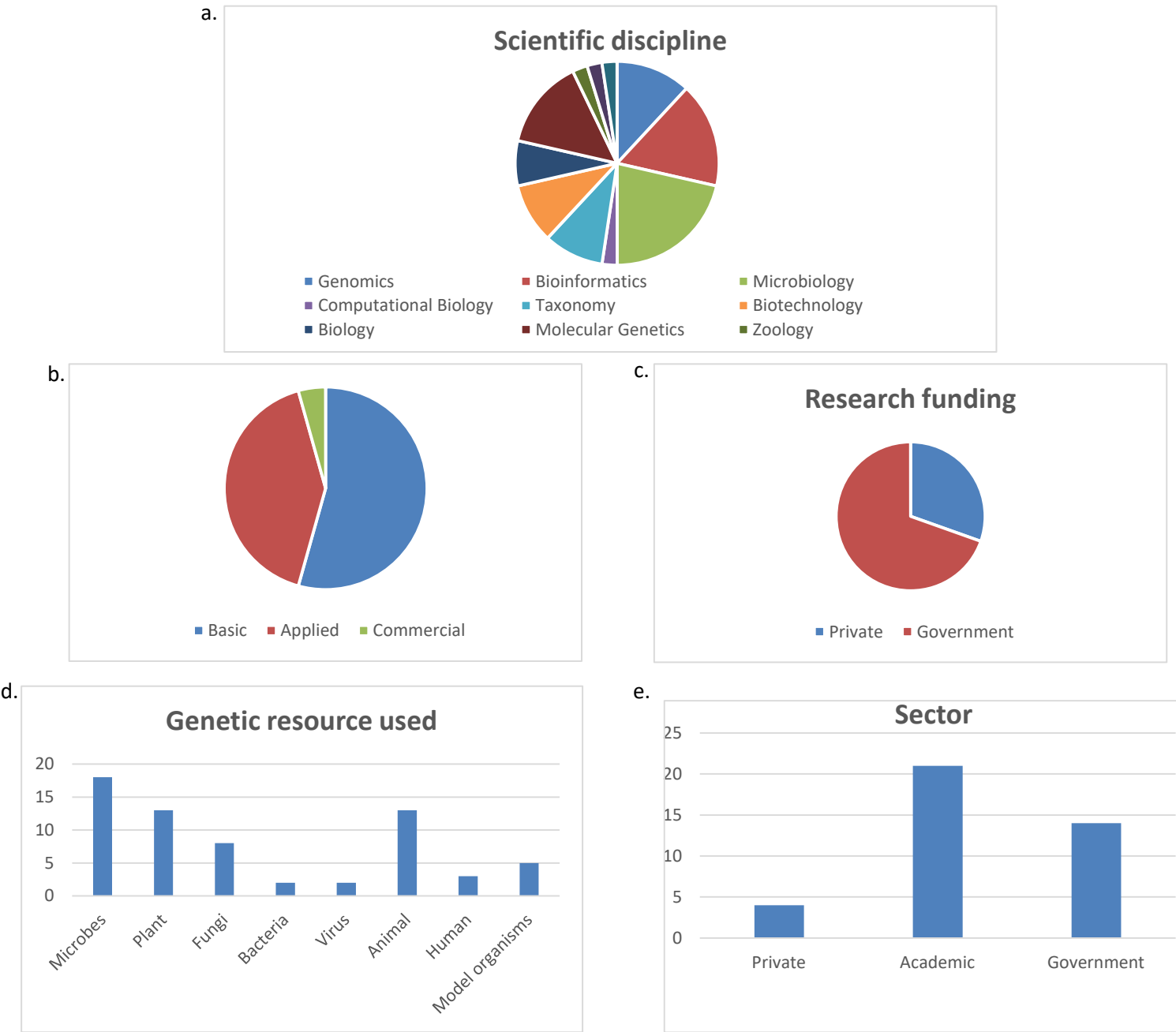


Figure 4. Statistics on the 37 interviewed scientists with respect to; a) scientific discipline, b) focus of research field, c) funding , d) genetic resource used for sequencing, and e) research sector.

## White Paper 8: Benefit Sharing post-2020: A Proposal for Cooperative Solutions to Effectively Deliver Benefits from Genetic Resources and NSD

Devanshi Saxena (Univ. of Antwerp), Prof. Claudia Seitz, Torsten Thiele, and Prof. Esther van Zimmeren

**Starting point: How can a cooperative, multilateral approach deliver funding and enable effective benefit sharing in the context of the use of genetic resources and Nucleotide Sequence Data (NSD)?**

**What could benefit-sharing post-2020 look like that is not based on tracking NSD usage in the INSDC? What value can be delivered by such a system?**

### 1. Introduction

Scientific research using genetic resources and NSD can help to deliver multiple benefits to society, including new products and processes, and can contribute to **realizing the Sustainable Development Goals**. Traditional research methods of characterizing biodiversity are increasingly being supplemented and replaced by approaches based on DNA sequencing<sup>33</sup> and the aggregation of the resulting sequence data with other datasets. Such work is highly promising and underlines the value of biodiversity. It underscores the need for all countries to **conserve biodiversity and support open science**.

Open science requires that scientific publications are openly accessible online for free, as far as possible and as soon as possible. It obliges researchers to make research data – resulting in whole or in part from public funding – easily accessible online and ensures that scientific information (publications and data) are preserved for future generations and that access to scientific information (publications and data) is facilitated. **All global researchers – be it public or private researchers, researchers located in developing countries, emerging economies and developed countries – heavily rely on the advantages entailed in open science.** Open science requires FAIR research data management (i.e. data that is Findable, Accessible, Interoperable and Re-usable), Text and Data Mining (TDM) and technical standards that enable re-use incentive schemes. Databases, such as INSDC, that ensure free access to the data under FAIR terms, are thus essential in enabling open science and in strengthening global value creation through research and development. Therefore, **we should safeguard and support the well-functioning of such databases, while at the same time exploring opportunities as to how such databases may help more effective, inclusive and sustainable value sharing.** The transition to a sustainable open science-based bio-economy requires a range of capacities and technologies and it comes at a cost. It is part of the **social responsibility of all those acting in this space to support this effort, which could be described as a stewardship payment.**

Almost ten years after the adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (October 2010), some countries have made steady progress in establishing legislative, administrative or policy measures on access and benefit-sharing and in putting in place the necessary institutional arrangements. However, for now most of those mechanisms have only resulted in limited monetary benefit sharing. Yet, the biodiversity emergency is eminent. Only if we address the biodiversity emergency in an urgent and comprehensive way<sup>34</sup> including through finance<sup>35</sup> can we deliver a global sustainable bio-economy

<sup>33</sup> Leray, M. et al (2019), GenBank is a reliable resource for 21st century biodiversity research. *PNAS*

<sup>34</sup> Laffoley, D. et al. (2019), Eight urgent, fundamental and simultaneous steps needed to restore ocean health, and the consequences for humanity and the planet of inaction or delay. *Aq Conserv* <https://doi.org/10.1002/aqc.3182>.

<sup>35</sup> Claudet, J et al. (2019), A Roadmap for Using the UN Decade of Ocean Science for Sustainable Development in Support of Science, Policy, and Action 2019, One Earth

in the long term. A cooperative approach focuses on how best to deliver this transition pathway with the **fullest and earliest engagement of all countries**, including in particular developing countries with biodiversity hotspots or those that are vulnerable to climate change and biodiversity loss.

In order to enable effective and sustainable benefit-sharing post-2020, we propose a three step process that can be operated by countries, the CBD and/or the funding structure (see below Section 3). As a *first step*, a **needs-based assessment mechanism** should be developed to identify what particular funding is required in which countries and at what level, be it at local research capacity, data infrastructure and connectivity, biodiversity monitoring, etc. Or perhaps the needs extend across the entire value-chain of the emerging bio-economy. A *second step* would be to **design a tailored funding approach** that would aim to deliver the funding needed to the relevant parties. This tailored funding approach can draw from the spectrum of solutions that we propose in Section 2. As a *third step* the proposed approach needs to be **fine-tuned through discussions with a wide range of public and private partners** so as to bring in not only more private funds but also to optimize output, timing and risk-sharing tools.

Several studies focusing primarily on the health sector have compared different models and institutions that may generate and mobilize funds that link different elements of the financing value chain to mobilize, pool, channel, and allocate resources.<sup>36</sup> Some blended financing mechanisms have reached a global scale, others are multilateral but cover only a limited number of countries. Models such as GAVI, the Global Fund and UNITAID have innovated along each step of the innovative finance value chain—namely resource mobilization, pooling, channeling, resource allocation, and implementation and governance—and integrated these steps to channel large amounts of funding. Nevertheless, resources mobilized from international financing mechanisms are relatively modest compared with donor assistance from traditional sources. Moreover, most of the mechanisms heavily draw on public funds for so-called “frontloading purposes” to limit the risks of private investors.

In Section 2 we propose a spectrum of potential solutions based on a comparative analysis of a number of different models in other areas (see Annex Comparative Analysis Examples Models; hereinafter Annex) that show how such thinking has been applied in those areas. None of these models provide a simple solution that can be easily transferred to biodiversity, but they show the potential to maximize the amount of funds, to incentivize additional private sector engagement (incl. corporate users of genetic resources and NSD, health insurance companies, financial investors in the sector including pension funds as well as technology and data businesses, impact investors, foundations and philanthropists) and to establish transparent and effective governance mechanisms. With this proposal we aim to **strengthen shared social responsibility for the conservation of biodiversity and effective and sustainable benefit sharing, on the one hand, and to engage more private sector investors, on the other hand**. Such an increased engagement by the private sector requires, however, **a clear focus on objectives, short- and long-term results, impacts<sup>37</sup> and returns**. This underlines the importance of proposing a broad spectrum of potential models out of which tailor-made solutions can be developed after a careful needs-based

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<sup>36</sup> See for instance Girishankar, N. (2009), *Innovating development finance: from financing sources to financial solutions*, World Bank, Washington (Policy research working paper 5111), <http://elibrary.worldbank.org/doi/abs/10.1596/1813-9450-5111> and Rifat, A. et al. (2012), Innovative financing for health: what is truly innovative? *The Lancet*, 380:9858;2044-2049.

<sup>37</sup> Results include performance and outcomes that are expected from the funding project and directly follow from it. Impact includes outcomes that follow from the project, not necessarily directly. These can be positive or negative and need to be assessed periodically and as they arise.

assessment. In identifying potentially interesting models we started off from the following **ten premises**:

1. Models should be apt to contribute to the conservation of biodiversity, to safeguard open science and to back the Sustainable Development Goals (SDG 13, 14, 15 and 17);
2. Models have the potential to respond to concerns of different stakeholders about fair and equitable benefit sharing;
3. Models include an element of voluntary participation and engagement reflecting the shared social responsibility of all stakeholders with respect to the conservation of biodiversity;
4. Models respect the existing bilateral and multilateral benefit sharing mechanisms, will operate in parallel and should facilitate effective benefit-sharing for the use of NSD;
5. Models are not conditioned on tracking the actual use of the genetic resources/NSD, but focus on the generation and mobilization of funds to safeguard the conservation of biodiversity, open science and sustainability;
6. Models are initially focused on delivering funding linked to benefit sharing for the use of NSD, but have the potential to be extended to benefit sharing for the use of physical material;
7. Models have shown their potential to raise funds from private sector partners on the basis of a carefully designed results-based process, thus excluding simple donations and emphasizing the importance of measurable goals and solutions and the evaluation of short- and long-term results and impacts;
8. Models do not always require a direct financial return to the funder;
9. Models are not simply based on fiscal coercion (general taxation), though they may include an element of regulatory intervention;
10. Models do not just deliver funds but include other elements that encourage, facilitate and optimize finance for the conservation of biodiversity, open science and sustainability.

Figure 5.Ten Premises for the Selection of Models

## 2. Spectrum of Models

We have identified a variety of solutions that diverge in terms of the degree of regulatory intervention required, the stakeholders involved, the amount of resources that may be mobilized, etc. The models are ordered according to the degree of regulatory intervention that is required to set up the model. Starting off with the Paying Public Domain, the Subscription Model and the micro-levy that all require some kind of explicit legal or policy basis at the national or international level we then shift towards more voluntary funding mechanisms. Such models are often referred to as “innovative finance mechanisms” as they go beyond pure public/taxpayer funding to engage other partners and concepts. The complete spectrum of solutions is explicitly aimed at mobilizing the shared responsibility of all stakeholders.

### *Paying Public Domain Model*

**What?** The *Domaine Public Payant* or Paying Public Domain (PPD) is a legislative scheme that introduces a fee for the use or economic exploitation of NSD without removing them from the public domain. In essence, it is a kind of copyright model to pay royalties for objects that have always been part of the public domain or that have entered the public domain. Funds received under this type of scheme were so far used by state administrative agencies for the promotion of cultural heritage conservation and exchange activities. The PPD model has been developed to provide financial means for nations to protect and preserve their cultural heritage, mainly folklore, traditional knowledge and traditional cultural expressions in the public domain.

**Who?** The initiative can be taken by individual countries at the national level. The DPP model has for instance been introduced (and withdrawn) for the conservation of cultural heritage in several countries and is still in place in several countries in South America and Africa. The model has been

suggested at different occasions at UNESCO and WIPO (not (yet) included in any international convention) and has been studied by other UN organizations. If it would be established at the international level through a multilateral mechanism, the implications of this model need to be assessed further.

**How?** The DPP system has not yet been discussed in the CBD context. Some elements of the DPP system, however, may be transferred to the CBD mechanism. With regard to the calculation of the royalties the charge could (i) be perpetual or limited in duration and (ii) vary according to the category (replacing works by genetic resource/NSD).

### *Subscription Model*

**What?** In the negotiations on the enhancement of the functioning of the so-called “Multilateral System of Access and Benefit-sharing” (the MLS) of the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA), a subscription model has been proposed to replace the current system of more product-based payment provisions. The ITPGRFA establishes rules for the management of seeds at a global scale, i.e. through the MLS whereby Contracting Parties have agreed to renounce their sovereign rights and put (specific) PGRFA into the MLS while recipients may access PGRFA using a standard contract (the Standard Material Transfer Agreement or SMTA) upon specific conditions of access and benefit-sharing, including financial ones.

The subscription model in essence consists of a subscription (option) whereby a user becomes a subscriber to the MSL by paying an annual subscription fee. During the period of the subscription, users have access and use rights without any further limitations. The ITPGRFA discussions on the subscription model also covered the differentiation of subscription fees (i.e. subscription per crop, crop group, all crops; or a subscription to be based on a percentage of size, profit or turnover). Reference in this regard can also be made to the Global Initiative on Sharing All Influenza Data (GISAID) Pandemic Influenza Preparedness (PIP) Framework whereby a weighted formula is applied to a sales band allocated to a user.

**Who?** The proposed ITPGRFA subscription model was not formally adopted since no final agreement could be reached at the last ITPGRFA Governing Body meeting. The model was, however, quite well received by different stakeholder groups and can be introduced as part of other multilateral or collaborative systems, for instance in the context of the CBD.

In this context specific voluntary multilateral systems can be developed through a bottom-up approach involving all relevant provider countries and users and characterized by vertical diversification (in this regard reference is also made to art 19 of the Nagoya Protocol which prescribes Parties to encourage development and use of sectoral and cross-sectoral model contractual clauses). Such a system could initially be developed as a ‘coalition of the willing’; countries would have a right, but not an obligation to join. A functioning system which safeguards effective use and benefit generation and sharing will create an incentive for other countries to join. The specific multilateral systems can be recognized as specialized instruments under the Nagoya Protocol. The system would be governed by an international body or as a separate (potentially public-private partnership) legal entity.

**How?** In order to establish a subscription model, countries need to renounce their sovereign rights by making NSD available under a multilateral system with a well-defined material scope. In order to have a system which is as effective as possible and which provides legal certainty by safeguarding sustainable use of genetic resources and related NSD, an opt-in for physical material can be considered.



In order to safeguard legal certainty and low transaction costs (for both provider countries and users), the vertical diversification could be combined with a certain degree of horizontal integration, defining key principles and conditions, general terms and potentially standard clauses or modules. Further research is required to determine whether such horizontal principles and conditions, terms and modules could be included in and adopted as a procedural or technical Annex as provided for in Article 30 CBD (potentially combined with a decision on a more precise terminology as a basis for potential (additional) monetary benefit sharing).

The terms and conditions of such a multilateral system, including the standard MTA or other mechanism to access this multilateral system, will need to be defined. In addition, the basis for the calculation and parameters to differentiate the subscription fee(s) (see also above ITPGRFA), including potential cut-off criteria (i.e. time limitations, thresholds as to the products related as the calculation basis) to ensure a balanced and fair fee will need to be defined.

Please note: the use of the term 'subscription' fee might be confusing for some stakeholder and may give the impression that actual access is conditioned upon the payment of a fee. Since open access is a key condition of any proposed solution, 'lumpsum' fee might be a more apt term than 'subscription' fee.

#### *Micro-levy Model*

**What?** Micro-levies are small fees imposed by individual countries that can be used to deliver funds into mechanisms such as the Global Environment Facility (GEF). The prime example for micro-levies is the tax on airline tickets first levied by France in 2006 and later imposed by many other countries (e.g. Cameroon, Chile, Congo, Guinea, Madagascar, Mali, Mauritius, Niger, and the Republic of Korea). The finance so generated is directed to UNITAID, a drug purchasing facility for HIV/AIDS, tuberculosis and malaria medicines. UNITAID has used its leverage by negotiating with leading travel agencies and distributors to institute voluntary donations by travelers. A hybrid or pseudo form of micro-levy on national seed sales was implemented in the genetic resources context by Norway for national payments to the Benefit Sharing Fund (BSF) of the ITPGRFA. The micro-levy has a strong potential to increase shared social responsibility by all stakeholders involved, as the actual levy paid is rather low, whereas it may generate considerable funding at the macro-level.

**Who?** The initiative can be taken voluntarily by individual countries at the national level (see also subscription model 'coalition of the willing') and gradually expanded through a multilateral policy approach, whereby the CBD stimulates its members to adopt legislation for such micro-levies.

**How?** The micro-levy could be linked to products or services that are either directly related to research and development on genetic resources and NSD or it could be totally unrelated (cf. airline levy for the purchase of medicines). An example of the former could be to attach the levy to sequencing machines, products used in the sequencing process, etc. Or the micro-levy could be linked to sales of resulting products (provided appropriate definitions can be determined) as was done for national seed sales of Annex I species in Norway for contributions to the BSF of the ITPGRFA.

### *Public-Private Partnership Model with a Results-Based Approach*

**What?** Any form of partnership arrangement between the public and private sector that has its own legal format and funding approach. Such cooperation can for instance include public guarantees of payments, private donor grant support in cash or in-kind, and financial products so as to deliver lower-cost “blended” finance to support specific tailor-made projects aimed at biodiversity conservation. Such partnerships can be designed to offer a broad variety of instruments adapted to the needs of the proposed project, such as outcome based grants, technical assistance, debt, equity and guarantees. A good example of this type of partnerships that is widely supported is GAVI, the Global Alliance for Vaccines and Immunization. GAVI operates through mechanisms such as the International Finance Facility for Immunisation (IFFIm), Advanced Market Commitments, loan buydowns, the GAVI Matching Fund and INFUSE (incubator for innovative start-ups) and thereby manages not only to engage a broad range of partners but also deliver large amounts of financial support. Other interesting examples are the World Bank Health Results Innovation Trust Fund (WBHRIT) and the Green Climate Fund.

**Who?** A number of institutions have experience with such an approach and could be considered to act as coordinating agent in the biodiversity data context. GEF is for instance already a CBD partner and has experience with various blended finance mechanism. It could be a partner in exploring the possibility to introduce new public-private partnerships targeted to a particular biodiversity target and explicitly linked to facilitating effective and sustainable benefit sharing. Individual countries or groups of countries can make partnership proposals for a particular biodiversity target, bring together public funds enabling frontloading to attract private investors to participate in the mechanism.

**How?** These partnerships often appear to be most trusted if backed by key international organizations. For instance GAVI partners with states and the vaccine industry, but also with the WHO, UNICEF and the World Bank. A strong country-focus, a governance mechanism based on principles of transparency, accountability and differentiation also seem essential. For instance, it is desirable that the Board is composed of representatives of governments from donor and developing countries, representatives from industry, research institutes and universities, representatives from relevant international organizations such as the CBD and the World Bank as well as private donor foundations and independent experts. Moreover, the success of the WBHRIT shows the importance of rigorous independent impact evaluations, supervisions and reporting. For the operationalization of these partnerships the availability of three types of trust funds such as those operated by the World Bank are important: recipient executed trust funds, bank executed trust funds and financial intermediary funds. The latter is a special type of trust fund used when the World Bank partners with other multilateral development banks or UN agencies

### *Impact Bond Model*

**What?:** Bonds, i.e. funds borrowed cost-effectively in the capital markets and immediately available to deliver upfront payments, can leverage private sector investment for sustainable development.<sup>38</sup> Impact bonds are targeting a specific and growing group of impact investors and are intended to generate clearly identified positive social and environmental impact alongside the financial return. A variety of such bond formats exist, from climate, green and blue bonds<sup>39</sup> to social and sustainability bonds. This type of financing model can generate funds by tapping new funding

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<sup>38</sup> Akhtar, S. et al (2017), ‘Innovative Financing for Development in Asia and the Pacific Government policies on impact investment and public finance for innovation’. ESCAP

<sup>39</sup> [https://www.4climate.com/dev/wp-content/uploads/2019/04/Blue-Bonds\\_final.pdf](https://www.4climate.com/dev/wp-content/uploads/2019/04/Blue-Bonds_final.pdf)

sources and can be designed to enhance the efficiency of financial flows by reducing delivery time and/or costs as well as make financial flows more results- oriented. In our specific case this could for instance be linked to the operation of the INSDC database and to particular targets that could be reached by the database.

**Who?** The issuer of a bond can be a country, a municipality, government-backed entities, companies and banks, with the multilateral finance institutions being most active to date. Impact bonds need to be linked to clear and verifiable metrics<sup>40</sup>, such as the impact on biodiversity, particular key event/thresholds, etc. and there should be an external third-party verification process.

**How?** The issuer of the bond creates a special purpose vehicle (SPV) to receive the investor's money. The issue may also have a guarantor, i.e. another institution, usually of a better credit rating, to insure that funds will be repaid. The funds are invested in eligible projects. The issuer pays interest during the term and then repays the principal amount at maturity (for instance 5 or 10 years later). In the case of projects that inherently lack cashflows the repayments will need to be secured against funding commitments from other sources.

#### *Certification Model*

**What?** Certification schemes are incentives to improve production processes and empower consumers to make informed purchasing decisions. They can offer a payment framework, for instance by charging corporates for access to ratings. For instance the Global Fund for AIDS, Tuberculosis and Malaria (GFATM) receives funds from public sector partnership PRODUCT(RED). RED is a 'consumer marketing initiative', a licensed trademark that seeks to engage the private sector in raising awareness and funds to help eliminate HIV/AIDS. It is licensed to a wide variety of partner companies, including Apple, Armani, American Express, GAP, Converse, Bugaboo, Canon, Nike, Hallmark, Starbucks, which contribute a percentage of the profits generated from the sale of RED products to the GFATM.

**Who?** Certification schemes can be initiated by private individuals (cf. RED was founded by Bono and Bobby Shriver of the ONE Campaign), individual companies, groups of companies, states, private donors, international organizations. A certification scheme for biodiversity could be initiated by GEF as a public-private partnership, with the direct involvement of other relevant stakeholders.

**How?** One can imagine a GREEN counterpart aimed at generating funds to help conserve biodiversity feeding into GEF. The GREEN trademark can be licensed to companies selling a variety of products/services provided they comply with certain standards related to biodiversity conservation and sustainable use. The percentage of the profits generated should, however, be more substantial than for RED, as this has been a key point of criticism for RED. Companies should in any case not profit more from 'cause related marketing' than they contribute. Moreover, companies that use the certificate or license the trademark need to comply with good governance requirements, such as transparency on the percentage that is given to the fund. If the scheme is administered by a neutral agent such as a public-private partnership initiated by GEF, it may be relatively easier to apply strict reporting and accountability requirements than when it is a private sector initiative. However, such requirements should not interfere with incentives to start licensing the GREEN trademark. This model appears less reliable as a stand-alone instrument, but could complement other models mentioned above.

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<sup>40</sup> [https://bluenaturalcapital.org/wp2018/wp-content/uploads/2019/03/BNC-Framework\\_final.pdf](https://bluenaturalcapital.org/wp2018/wp-content/uploads/2019/03/BNC-Framework_final.pdf).

In the table below, some key features of each of the models are included.

**Table 1.Overview Key Features Spectrum of Models.**

<b>Models</b>	<b>Initiative</b>	<b>Funders</b>	<b>Incentives</b>	<b>Governance challenge</b>
Paying Public Domain	National	Users of objects in public domain	Maintaining works in the public do-main while ensur-ing financial flows to support their creation and con-servation	IP protection for public domain works may raise controversy; so far only national, international debate ongoing
Subscription	International multilateral	Users - subscribers	Legal certainty; low transaction costs (i.e. no track and trace); fairness (provided fair differentiation; cut-off criteria); higher likelihood to generate users (and hence benefits)	Tailoring (specific) multilateral models; realizing fairness; building coalition of the willing
Micro-levy	National; international multilateral	Users sequencing technologies in the public and private sector	Small contributions by many feed into large impact	Engagement stakeholders if levy unrelated to objective
PPPs	International multilateral	Companies, donors and public bodies	Efficiencies, timing, blending	Results-based approach; equitable representation; transparency, accountability
Impact Bonds	National, local, corporate	Public and private investors	Limited risk to private investors; measurable societal impact	Precise identification triggering event/threshold; transparency, accountability
Certification	International multilateral	Consumers GREEN products/services and companies	Societal impact; marketing	Transparency; accountability

If the user needs-based approach provides information as to the particular needs of developing countries (and their scientists) (see step 1 explained in Section 1) then these models would offer an opportunity to direct and immediately fund such requests. The models can be tailored to the particular needs, sector, technology, etc.

In contrast, a traditional benefit-sharing model would require first the delivery of benefits (which may take many years) and would then deliver funds potentially to recipient countries but not necessarily to specific needs in relation to biodiversity and NSD. Moreover, the models all have the potential to offer a combined solution to enable effective and sustainable benefit sharing for NSD and physical material.

### **3. How to Operationalize these Models for the Biodiversity Context?**

In the CBD context the funding mechanism in place uses an MoU with GEF. **This may offer a potential entry point to start building a broader spectrum of solutions and to deliver further funding. There are, however, a range of alternative entry points**, including linkage to other funding mechanisms that may be considered as interrelated in terms of the subject area such as the Green Climate Fund. **A stand-alone new funding structure or structures should also be considered** as it would allow to bring together an initial 'coalition of the willing', that is stakeholders from a range of areas, including for instance some of the core databanks, willing donor countries and foundations, relevant corporations and others to design and launch such a mechanism. A stand-alone mechanism could choose from multiple legal and governance formats, ranging from for instance a private foundation to an entity hosted by or set up as an international institution.

For building a funding structure with strong support by (potential) users and other stakeholders, transparency and accountability regarding the administration of the funding and the allocation of the funds are essential. Comparative empirical research of similar models has shown that **due respect for transparency and accountability requirements and clear verifiable metrics are needed to safeguard the incentive for users to participate in such a system and, hence, to guarantee the success of the funding mechanism.**

A substantial part of the funds should be allocated towards supporting conservation and sustainable use of biodiversity through specific identified needs of developing countries, potentially supplemented with a general biodiversity fund whereby funds are transferred as such to the different provider countries (linked for instance to actual contributions (of physical material or NSD) or levels of biodiversity).

With regard to NSD and the importance of open access databases as an enabler for value creation, **part of the funds should be allocated to further enhancement of the databases.** Those databases are the key infrastructure for scientists worldwide, including the scientific community in provider countries.

Multilateral models that apply an **inclusive, bottom-up approach** responsive to the needs of all stakeholders and ensuring **fairness and equity** for provider countries and users are needed for **building trust in post-2020 benefit sharing.**

## 5. WILDSI Steering Committee Members

### Scientific Expertise

Dr. Amber.H.Scholz (Leibniz Institute DSMZ, Germany)

Dr. Jens Freitag (Leibniz Institute of Plant Genetics and Crop Plant Research (IPK), Germany)

Fabian Rohden (Leibniz Institute DSMZ) *(Former)*

Dr. Upneet Hillebrand (Leibniz Institute DSMZ, Germany)

### Database Expertise

Dr. Guy Cochrane (European Bioinformatics Institute (EMBL-EBI), United Kingdom)

### Legal Expertise

Prof. Esther van Zimmeren (University of Antwerp, Belgium)

Prof. Claudia Seitz (University of Ghent, Belgium; Lecturer, University of Bonn, Germany; Seitz & Riemer, Germany)

### Financial Expertise

Torsten Thiele (Potsdam Institute for Advanced Sustainability Studies (IASS), Germany)

### Development Expertise

Dr. Carmen Richerzhagen (German Institute for Development Policy (DIE), Germany) *(Former)*

Dr. Jean Carlos Rodrigues (German Institute for Development Policy (DIE), Germany)

### Regulatory Expertise (External Advisors)

Thomas Greiber (German Federal Agency for Nature Conservation, BFN)

Marliese von den Driesch (Federal Office for Agriculture and Food, BLE)

Alicja Kozłowska (Policy Officer ABS, European Commission)

### Ad Hoc External Advisors (from April 2020)

Dr. Mery Piña (Pasteur Institute, France)

George B. Haringhuizen, (National Institute for Public Health and Environment (RIVM), Netherlands)

Prof. Ibon Cancio (University of the Basque Country and EMBRC-Spain)

Dr. Paul Oldham (One World Analytics, United Kingdom)

### Ad Hoc Industrial Representatives (from April-July 2020)

Szonja Czorgo, (Euroseeds, Belgium)

Dr. Matthew Downham (AstraZeneca, United Kingdom)

Dr. Markus Wyss (DSM Nutritional Products, Switzerland)

Dominic Mulydermans, (CropLife, Belgium)