"Access and Benefit Sharing and Digital Sequence Information: Unravelling the Knot"

Frison, Christine ; Tsioumani, Elsa

ABSTRACT

Scientific and technological advances in recent decades have significantly altered the nature of bio-based research and development (R&D). The rise of genomics, i.e. the study and editing of entire genomes rather than individual genes, has been accompanied by the birth of bioinformatics, which develops and uses methods and software tools to extract knowledge from biological material. Enabled by advances in computing power and tools that can generate and analyse large quantities of genotypic, phenotypic and environmental data, these developments have allowed for a 'tsunami of genomic information being generated … [with] the potential to be shared with any other laboratory in real time'. Research on sequence data arising from biological and genetic resources has thus taken place alongside research on physical samples of such resources for several decades already. The normative and regulatory frameworks governing them, however, have developed in parallel and largely ignoring each other, alongside a third one: The intellectual property frameworks. The main framework for the collection, storage and sharing of genomic data is the International Nucleotide Sequence Data Collaboration (INSDC), an international collaboration between public databases in the United States, Europe and Japan, which includes sequence data associated with genetic resources both within and outside5 the scope of the United Nations Convention on Biological Diversity (CBD). Going back to the late 1970s, the INSDC provides the connecting infrastructure for the more than 700 public databases of sequence ...

CITE THIS VERSION

Frison, Christine ; Tsioumani, Elsa. *Access and Benefit Sharing and Digital Sequence Information: Unravelling the Knot.* In: Charles Lawson, Michelle Rourke and Fran Humphries, *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge*, Routledge 2022, p. 122-138 http://hdl.handle.net/2078.1/265552 -- DOI : 10.4324/9781003301998-11

Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge

Edited by Charles Lawson, Michelle Rourke and Fran Humphries

Routledge
Taylor & Francis Group
a GlassHouse Book

First published 2023
by Routledge
4 Park Square, Milton Park, Abingdon, Oxon OX14 4RN

and by Routledge
605 Third Avenue, New York, NY 10158

a GlassHouse book

Routledge is an imprint of the Taylor & Francis Group, an informa business

British Library Cataloguing-in-Publication Data
A catalogue record for this book is available from the British Library

Library of Congress Cataloging-in-Publication Data
A catalog record has been requested for this book

ISBN: 978-1-032-29525-1 (hbk)
ISBN: 978-1-032-29527-5 (pbk)
ISBN: 978-1-003-30199-8 (ebk)

DOI: 10.4324/9781003301998

Typeset in Bembo
by Deanta Global Publishing Services, Chennai, India

Contents

Chapter 9

Access and Benefit Sharing and Digital Sequence Information

Unravelling the Knot

Christine Frison and Elsa Tsioumani[1]

Context: Issues, interactions, expectations

Scientific and technological advances in recent decades have significantly altered the nature of bio-based research and development (R&D). The rise of genomics, i.e. the study and editing of entire genomes rather than individual genes, has been accompanied by the birth of bioinformatics, which develops and uses methods and software tools to extract knowledge from biological material. Enabled by advances in computing power and tools that can generate and analyse large quantities of genotypic, phenotypic and environmental data,[2] these developments have allowed for a 'tsunami of genomic information being generated … [with] the potential to be shared with any other laboratory in real time'.[3] Research on sequence data arising from biological and genetic resources has thus taken place alongside research on physical samples of such resources for several decades already. The normative and regulatory frameworks governing them, however, have developed in parallel and largely ignoring each other,[4] alongside a third one: The intellectual property frameworks.

The main framework for the collection, storage and sharing of genomic data is the International Nucleotide Sequence Data Collaboration (INSDC), an international collaboration between public databases in the United States, Europe and Japan, which includes sequence data associated with genetic resources both within and outside[5] the scope of the United Nations *Convention on Biological Diversity* (CBD)[6]. Going back to the late 1970s, the INSDC provides the connecting infrastructure for the more than 700 public databases of sequence data around the world. It also makes a significant piece of the normative puzzle governing research on sequence data arising from biological and genetic resources. The INSDC adheres to a policy of free and unrestricted access with no use restrictions and with the note that data will be permanently accessible.[7] A key prerequisite for publication in many academic journals is submission of the sequence data to the INSDC: The INSDC enables scientists to submit their sequence data and receive an accession number, which is then required by the majority of life science journals for the publication of research results. The practice was first codified in 1996 by the Bermuda

DOI: 10.4324/9781003301998-11

Principles during the Human Genome Project,[8] before becoming a practice of almost-universal application, including through open-access requirements by research funding agencies.[9]

International instruments on access and benefit sharing (ABS) have been developed in the framework of international environmental law and policy, with reference to access to 'genetic resources'[10] for R&D purposes. Developments in biotechnology and the use of sequence data were largely ignored. Marked by the principle of national sovereignty over natural and genetic resources reaffirmed in the CBD,[11] ABS instruments were developed as a reaction to the privatisation of genetic resources through intellectual property, mainly patents and plant breeder rights, and to address the concerns of developing countries about justice and sustainable development.[12] By regulating access to genetic resources, ABS instruments sought to ensure that some portion of the benefits arising from their use, including commercial ones, would flow back to the provider country and the communities that conserved them. Variations of this concept have been applied in several fora addressing access to genetic resources for R&D purposes, in an uncoordinated manner. These include, *inter alia*, the CBD and its 2010 *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity* (Nagoya Protocol),[13] the *International Treaty on Plant Genetic Resources for Food and Agriculture* (ITPGRFA),[14] the ongoing negotiations under the United Nations General Assembly on marine biodiversity beyond national jurisdiction (BBNJ)[15] and, moving beyond the environmental realm, the Pandemic Influenza Preparedness (PIP) Framework under the World Health Organization (WHO).[16]

The rationale behind ABS is quite simple, but its applications have resulted in complex legal mechanisms with little benefit for developing countries when it comes to conserving genetic resources and bridging the equity and capacity gap in bio-based R&D. This may be due to several factors, including legal, institutional and market-related ones.[17] At the same time, unclear ABS regulations have arguably caused difficulties for academic research;[18] and interlinkages with the patent system remain complex. Indeed the latter fails to support the CBD objective of fair and equitable benefit sharing due to lack of an international requirement for disclosure of origin/source/benefit sharing in patent applications involving the use of genetic resources,[19] although several countries have incorporated a mandatory disclosure requirement in their national ABS or patent laws.[20] Meanwhile, the patenting and similar intellectual property protections over genetic resources are expanding dramatically, with an ever-increasing number of patents covering not only transgenic organisms, but also particular traits, parts and components, as well as breeding methodologies and vectors.[21] Even though a strong open source sharing ethos is driving most of the scientists working with large data to date, as in all technological fields, users tend to strategically patent research tools and sequences that are foreseen to

have commercial applications.[22] As explored below, the patent landscape varies around the globe, with legal debates regarding patent eligibility of genetic sequences continuing to rage in several jurisdictions.[23]

Interactions between international policies governing access to genetic resources and benefit sharing and those governing access to and sharing of sequence data have been limited until recently, when the 'digitalisation' or 'dematerialisation' of genetic resources reached policy arenas. In 2013, then ITPGRFA Secretary Shakeel Bhatti noted that 'the information and knowledge content of genetic material [could increasingly be] extracted, processed and exchanged in its own right, detached from the physical exchange of the … genetic material'.[24] The item was termed 'digital sequence information' (DSI) in the CBD negotiations, although Contracting Parties have noted that it 'may not be the most appropriate term and … is used as a placeholder until an alternative term is agreed upon'.[25] Technical work under the CBD has suggested that the term may refer to nucleic acid sequence reads but also a range of associated data, including information on the sequence assembly, gene expression and phenotypical and behavioural data, among others.[26] The origin of CBD debates on DSI can be traced in the report of the 2015 meeting of the *Ad Hoc* Technical Expert Group (AHTEG) on synthetic biology.[27] Participating experts identified potential adverse effects of synthetic biology for the CBD objective on fair and equitable benefit sharing, including inappropriate access without benefit sharing due to the use of sequence data, and a 'shift in the understanding of what constitutes a genetic resource'.[28] This means that synthetic biology applications may allow for the development of organisms directly from sequence data, without the need for access to the physical genetic resource, bypassing sovereignty-related rights of the provider country and thus CBD benefit sharing requirements where national legislation does not address the issue specifically.[29] At the same time, large-scale sequencing techniques allow the searching of genebank accessions for material containing desired genetic elements for direct use in production or in breeding programmes for plant genetic resources for food and agriculture. In this case, the value lies in the amount of data analysed, rarely in a single accession, without however necessarily acknowledging the previous work of breeders and farmers.[30]

Understanding what constitutes a genetic resource lies at the heart of the highly polarised debate on DSI,[31] which attracted major attention at the 14th Conference of the Parties (COP) to the CBD in 2018, and has received central political importance during the negotiations for a Post-2020 Global Biodiversity Framework to replace the Strategic Plan for Biodiversity 2011–2020.[32] In fact, several countries from the global South declared that there will be no agreement on a post-2020 framework, unless some form of benefit sharing from DSI use is ensured.[33] While most DSI will never yield any economic value, large-scale sequencing increases opportunities for profit making,[34] raising fears of disrespect of benefit sharing obligations and increased privatisation of genetic resources. The issue of the regulation of DSI use has also arisen in

all other ABS-related processes beyond the CBD, having revealed pre-existing weaknesses.[35] The Food and Agriculture Organisation of the United Nations processes has attracted a lot of attention since 2016.[36] Importantly, in the ITPGRFA realm, benefit sharing from the use of genetic sequence data associated with plant genetic resources for food and agriculture in the ITPGRFA's Multilateral System of ABS was identified as the deal breaker, leading to the collapse of six years of negotiations to enhance this System.[37]

Normative issues and legal interpretations

The availability and easy exchange of large amounts of sequence data have the potential to facilitate research on genetic resources, for those actors in countries who have the capacities to analyse and use such data. Many recent advances in biology, medicine and agriculture were achieved by sharing and mining publicly available sequence data. It is due to the success of modern genomics and advances in synthetic biology that concerns were raised about the need to share fairly and equitably the benefits arising from the use of such data. This raises a number of normative issues, regarding both ABS frameworks specifically and the legal and policy framework governing the production of scientific knowledge and the human right to benefit from scientific progress more generally.[38] We address them below, in turn.

DSI, ABS regimes and policy constraints

First, the lack of clarity regarding terminology challenges the dialogue between the diplomatic, policy-making and scientific communities, and undermines legal certainty and consistency across regulatory instruments. The definition of the term DSI used as a placeholder in the CBD negotiations is still not agreed upon, and would probably be unknown to the majority of scientists. In addition, other terms are used in other fora to address the same matter: The term 'genetic sequence data' is preferred in the ITPGRFA and the WHO, while the terms 'resources *in silico*' and 'digital sequence data' have been used in the BBNJ negotiations. Agreement needs to be reached with regard to the terminology used, in coordination with international instruments,[39] as well as the kind and extent of data covered under each term.

When it comes to ABS instruments, the overarching normative issue raised is the need for them to stay relevant and fulfil their objectives, including the conservation and sustainable use of biodiversity. The ABS approach continues to be the mainstream paradigm in multilateral environmental agreements and beyond, despite the fact that it has failed to produce the monetary benefits expected to be channelled towards biodiversity conservation, or to bridge significantly the fairness and equity gap in bio-based R&D. Despite the shortcomings, however, the objective of fair and equitable benefit sharing introduces both legally binding obligations for the parties of these treaties, and

a sharing ethos in international environmental law.[40] While the technicalities of ABS have not facilitated the achievement of this objective for the time being, challenges arising from DSI may provide an opportunity to rethink the model towards 'a new approach for ethically sharing the benefits of science and technology'.[41]

Two interrelated questions and one overall ethical concern stem from the overarching issue above: The patentability of DSI and the possibility of misappropriation of DSI placed in the public domain; and the question of value generation from the use of DSI, and related benefit sharing obligations.[42] As for the overall ethical concern, we would like to open the debate on decolonising science as well as the science-policy interface in international negotiation fora.

Open questions on patentability

Intellectual property law concerning the patentability of the outcomes of genetic research, including the mapping and isolation of genetic information, is still evolving. With patent law being territorial in nature, there is no global consensus on what should be patentable. Key questions include whether isolated gene sequences are patentable, and the extent to which such gene sequences need to be modified or applied in order to be patentable.[43] In many jurisdictions, the genetic information of living organisms is generally regarded as a substance found in nature and is thus excluded from patentability. Brazil, for instance, excludes living beings or biological materials found in nature from patentability, even if isolated, and this includes the genome or germplasm of any living being.[44] Yet, advances in genetic research are increasingly the subject of patent applications in jurisdictions where R&D is taking place. In the European Union, naturally occurring genetic sequences remain patent-eligible under Directive 98/44/EC,[45] as long as the functionality of the sequence is disclosed, along with the usual requirements of novelty and inventive step.[46] In the United States, on the other hand, the 2013 Supreme Court decision in *Association for Molecular Pathology v Myriad Genetics* held that DNA segments and the information they encode are not patent-eligible simply because they have been isolated from surrounding genetic material.[47] This decision reversed years of prior jurisprudence and confirmed a shift in the broad scope of patentability of genetic sequences.

Patent expansion poses significant obstacles to public research. Researching and negotiating the patents that potentially surround the material and methods of their work in order to obtain 'freedom to operate' are a substantial transaction cost for researchers. Navigating the patent landscape is further complicated by the uncertainty generated by those patent applications that are still pending, the fees usually required for searching patent databases and the lack in many jurisdictions of a disclosure requirement for the rights transferred through licences.[48] As strategic patenting is expected to increase over time, this multi-level complexity has devastating consequences for public sector

researchers, which the addition of ABS legislation can only increase unless carefully designed.

Contradictory legal interpretations regarding benefit sharing from DSI use

With regard to DSI use and benefit sharing, opinions of negotiators diverge as to whether and how the utilisation of DSI should give rise to benefit sharing obligations. Leaving aside the area of human genetic resources,[49] which falls outside the scope of the CBD,[50] this question encompasses legal interpretation issues concerning the scope of each instrument, and implementation concerns involving the identification of users and monitoring/tracking of uses of such data.

Unrestricted access to DSI, in the form of public and open-access databases, can be considered an important form of non-monetary benefit sharing, as long as it is accompanied by measures to ensure its fair and equitable use by actors in developed and developing countries alike, as explored below. However, in view of the increasing use of DSI in bio-based R&D, alongside the potential restriction of its availability through patents, biodiversity-rich developing countries have been calling for the application of monetary benefit sharing requirements to the use of DSI arising from genetic resources.[51] To focus on the case of the CBD and its Nagoya Protocol, and the ongoing negotiations on a Post-2020 Global Biodiversity Framework, debates have centred mainly around the interpretation of the scope of these instruments. Some developed countries oppose any benefit sharing from DSI and argue that the CBD and the Nagoya Protocol have been developed to address exchanges of 'material' resources.[52] Their legal argumentation points to the definition of 'genetic resources' as genetic 'material'.[53] Therefore, exchanges of 'immaterial' information such as DSI would fall outside the scope of the two instruments.

Notwithstanding this narrow textual interpretation, a series of legal arguments support the view that the use of DSI should be linked to benefit sharing obligations, and could do so without overburdening R&D with unpractical measures or requirements. For instance, a teleological interpretation would put forward the need to interpret the instrument's provisions in light of its objective, i.e. fair and equitable benefit sharing.[54] This is a central argument by developing countries, who argue that letting DSI use escape benefit sharing obligations would make the Nagoya Protocol obsolete, and its objective of fair and equitable benefit sharing void. This can be supported by a series of arguments based on textual interpretation. First, it can be argued that DSI use qualifies as 'utilisation' of genetic resources, thus giving rise to benefit sharing obligations under the Nagoya Protocol. In this light, it has been argued that the biological *origin* rather than the biological *form* of the information matters[55] for the definition of utilisation of genetic resources. This means, as former Secretary of the Food and Agriculture Organization of the United Nation's Commission on Genetic Resources for Food and Agriculture José Esquinas

has suggested, that 'a genetic resource is like a book: whether it is in hard copy or in electronic format is irrelevant' (personal communication). Another argument could be made on the basis of the term 'utilisation', defined as R&D on the genetic and/or biochemical 'composition'. 'Composition' could be interpreted to include the information in the transcribed product (protein) too.[56] In effect, the definitions of the Nagoya Protocol appear capable of being interpreted dynamically in the light of relevant technological developments, with a view to including any new technique that 'in fact realizes the value of functional units of heredity'[57] and avoiding the Nagoya Protocol becoming obsolete in a few years' time.[58]

In addition, general principles of international law, notably effectiveness and good faith, support interpretations that contribute to ensuring the full effect of a treaty in line with technological developments. In this regard, it seems 'self-evident that the benefit associated with a genetic resource is often linked to the *information* held within a genetic resource in addition to the physical traits of the specific specimen'.[59] The argument that the value of a resource lies with its genetic information, rather than physical form, is further backed by the fact that early attempts in genetic engineering described the new techniques as permitting a combination of genetic 'information' from different organisms.[60]

Arguing for open access to DSI

On the other hand, developed countries have consistently argued that open access to DSI is an important form of non-monetary benefit sharing and contributes to scientific development globally.[61] The scientific community present in the negotiations has also cautioned against restricting open access.[62]

Maintaining open data and open science remains an important policy objective, particularly in the face of persistent trends to restrict it via property rights.[63] However, in the words of Sylvain Aubry, '"open science" does not necessarily mean "fair science", and "access to" can differ greatly from "utility of" DSI'.[64] We argue that this can be conceptualised through two main criteria, which have not yet been addressed explicitly in the DSI negotiations: The responsiveness and sharing of the outcomes of scientific progress, and the underlying inequalities in capabilities to analyse and use DSI.[65] These two elements could be used to illuminate the debate and enhance the objective of benefit sharing.

Discussion on the first element can be informed by CBD work on technical and scientific cooperation and technology transfer,[66] and enriched by human rights discourses concerning the right to the benefits of scientific progress. Technology transfer was one of the most contentious issues in the CBD negotiations, reflecting the divide between developed and developing countries.[67] Since the CBD's entry into force, however, it has received limited attention, an exception being the adoption of the programme of work in 2004.[68] Implementation also lags behind, with a core structural challenge being that the owners of technology are mainly private companies or persons.[69] Interlinkages

with intellectual property seem to hamper both policy development and implementation. CBD obligations are further supported by the human right to benefit from scientific progress, enshrined in the *Universal Declaration of Human Rights*[70] and the *International Covenant on Economic, Social and Cultural Rights*,[71] as well as several regional instruments, which raise the issue of the equitable sharing of benefits and transfer of technologies.[72]

The second element can be illuminated by an increasing body of social sciences literature that explores the production of knowledge and research conditions in developing countries.[73] Among this literature, Louise Bezuidenhout and colleagues build on Amartya Sen's capabilities approach to highlight the distinction between 'simply making resources available, and fostering researchers' ability to use them'.[74] An example can be provided by the Regional Centre of Excellence for Root and Tuber in Ghana which 'acquired the latest generation DNA analyzer [in 2015]. But due to lack of funding and expertise, the center is incapable of using the machine. It is now looking for partners to provide the needed funds to get this critical machine functional'.[75] Bezuidenhout and colleagues highlight the persistence of 'deep inequalities' within the 'seemingly egalitarian-inspired open data landscape'[76] and conclude that current data engagement structures 'inadvertently perpetuate marginalization, exclusion and data poverty amongst some communities of scientists'.[77] Such analyses could be used to enrich intergovernmental and multistakeholder discussions on capacity-building, which are currently almost cliché. Bezuidenhout and colleagues for instance argue for the need to shift the debate from how to bridge the digital divide to the importance of identifying the capabilities necessary to share data and exploit those available online within any research setting, in order to develop the resources and expertise needed to transform data into new knowledge.[78] In the same line of thought, Aubry highlights the need for a deeper discussion on 'modalities of DSI generation, curation, storage, and dissemination' and engagement 'with various stakeholders to reduce disparities and encourage accessibility, transparency, and accountability'.[79] Accompanied by a decrease in technology costs and the democratisation of open source analytic pipelines, he argues, this discussion 'may in the long term favor a major reshuffling' of the research landscape.[80] What is essential, however, is to recognise and truly take account of the major imbalance of capabilities in R&D, and science in general, and how this translates into the imbalance of powers in the ABS negotiation fora.

Decolonising science: Recognising the deep-rooted conflict to be reconciled

Pushing the reasoning several steps further, one may question the fact that the current way of presenting and analysing the DSI question is biased from a Eurocentric/Western view. As expressed in Titilayo Adebola and Daniele Manzella's chapter in this volume, the historical development of plant genetic

resources for food and agriculture conservation, sustainable use and ABS rights and obligations is grounded in a decolonial discourse. Recognising the decolonial rationales for ABS, they argue, reinforces the need for effective DSI protection frameworks. In line with Donna Haraway's concept of situated knowledge,[81] Aram Ziai explores the 'eurocentric or even colonial structures in development studies in terms of its knowledge basis and its knowledge production before pointing to possible ways of decolonising development research'.[82] Applying Ziai's approach to the DSI conundrum, one could recognise that it is urgent to disentangle DSI from the Eurocentric epistemological and ontological spaces and make efforts to build collaborative and co-creative benefit sharing mechanisms of caring and sharing. Linda Tuhiwai Smith proposes methodologies to decolonise research[83] that could enrich current discussions in all negotiation fora. While it goes beyond this chapter to dig into this suggested pathway, we would like to highlight one overall ethical question which we believe to be key in answering the issue at stake. In order to do so, we get inspiration from the concept of 'conservation conflict transformation' in the field of conservation theories.[84] Conflict transformation 'addresses both the presenting problem and the deeper social conflicts with the goal of establishing sustainable conflict transformation mechanisms to address future conflicts'.[85] Francine Madden and Brian McQuinn posit that:

> Many conservation conflicts involve deep-rooted conflict. Such conflicts include deeply held values, high stakes, power imbalances, complexity, and a sense of moral superiority that may drive parties to perpetuate the fight, even when they cannot win in the short term.[86]

They use a pyramid showing the three levels of conflict that may exist in the conflict context (top – dispute, middle – underlying conflict and bottom – identity-based/deep-rooted conflict) and the corresponding process used to address conflict at that level respectively (settlement, resolution and reconciliation).[87]

We suggest that the conflict around the use of DSI is generally represented as the top dispute level of the pyramid (dispute), but we argue that the ongoing discussions to settle the issue will not be sufficient to resolve the underlying matter. We posit that rather it is a deep-rooted conflict that lies in the unfair and inequitable use and exploitation of biodiversity reflected in the power imbalance of rights and obligations in the relevant international ABS instruments implemented in former colonial countries and colonialised ones. We further posit that we need to address this question in order to foster a true (and fair and equitable) reconciliation (and more than just a settlement or resolution) between all parties in order to solve the urgent biodiversity loss issue as well as the colonialist history problem. As Madden and McQuinn further state, '[b]eyond the narrow focus on addressing the material losses, analyzing the conflict dynamics and developing appropriate decision-making processes

that address these deeper drivers of conflict would build genuine community receptivity to, commitment in, and ownership of the solutions'.[88]

Outlook

To return to the current intergovernmental policy arena, at the time of writing, benefit sharing from the use of DSI remains one of the politically central and largely unresolved topics in the Post-2020 Global Biodiversity Framework negotiations. While positions remain polarised, a significant amount of technical work and consultations have taken place, both in the form of a series of technical studies commissioned by the CBD Secretariat, and in the context of a series of webinars and a discussion forum organised by the Secretariat at the request of the Co-Chairs of the Working Group on the post-2020 framework. As part of the webinars, an exercise was undertaken to organise and categorise the policy options from different sources and present them in a simple and practical manner. The options range from lack of agreement or agreement not to consider DSI as equal to genetic resources, to addressing access to and benefit sharing from DSI either through a bilateral or through a multilateral mechanism.[89]

The policy options were accompanied by a set of criteria for their evaluation, related for instance to effectiveness, feasibility, good governance and coherency.[90] The policy options and the criteria were then addressed in an online discussion forum organised by the Secretariat, with the note that it was informal and not part of the DSI process mandated at the 14th COP to the CBD. In the pre-COVID era, the 14th COP to the CBD had established a science- and policy-based process to address DSI during the intersessional period leading up to the 15th COP to the CBD, which included commissioning a series of technical studies, the establishment of an AHTEG and consideration of the AHTEG outcomes by the Working Group on the post-2020 framework.[91]

However well-intentioned these options may be, we argue that they will only allow settlement of the top of the pyramid dispute, instead of the deep-rooted conflict. Partly in line with the legal interpretation exercise carried out by A. Bendimred and C. Frison,[92] a recent publication by Margo Bagley analyses these options and proposes an interesting way forward to get the negotiations out of the current jam. Focusing on a pragmatic approach, Bagley suggests that 'DSI should be considered as within the scope of the Nagoya Protocol but subject only to benefit sharing obligations, not PIC access limitations'.[93] This makes perfect sense in regard to the impossibility of tracking DSI uses. This article also suggests that all parties have to make an effort to find a solution to the current political conundrum, stating that '[o]nly if all sides choose to be more cognizant of the legitimate perspectives and concerns of others, is a just, viable, and sustainable solution likely to be reached'.[94] While we agree on the direction, we would like to highlight that

all involved parties are not benefitting from the same capabilities, power and means to make this effort in the same way. In line with a decolonial approach to science, we believe that Western countries have a responsibility to acknowledge that the current imbalance results from the colonial history, and that therefore, more efforts and responsibilities should be carried by those countries in finding a 'just, viable and sustainable solution', a fair and an equitable one, we will add.

While webinars and consultations have certainly created a common understanding of DSI-related issues and have arguably maintained the momentum regarding the need to resolve the issue at the 15th COP to the CBD, scheduled to be held in Kunming, China, in 2022, divergence of negotiating positions remains. We conclude on the following policy-relevant recommendations, some of which are supported by largely converging scholarly effort:

- Addressing the issue in the CBD and Nagoya Protocol framework, in coordination with other ABS-related fora, to maintain the regulatory relevance of these instruments in view of technological developments.[95]
- Specifically addressing the challenges that the regulation of DSI use may pose for the architecture of the Nagoya Protocol, which was conceived without specific consideration of the information component of genetic resources, possibly through a multilateral mechanism.
- Allowing for enhanced degrees of harmonisation and multilateralism to ensure responsive, inclusive, efficient and fair governance of access to DSI and sharing of the benefits of its use, taking also into consideration that lack of a multilateral solution may lead to restrictive national laws.
- Making use of the opportunity that the DSI debate offers to reconsider the ABS architecture in the context of fair and equitable knowledge production and scientific progress globally.
- Open up the colonial issue related to biodiversity conservation and use, in order to develop fair and equitable biodiversity conservation and use policies that address the deeper drivers of the DSI conflict. Doing so could be a means to fully hear and embrace the developing countries' (and Indigenous Peoples' and local communities') views on biodiversity governance, remembering the key role they are playing in biodiversity conservation and co-evolution.

We conclude by pointing out that the current negotiation blockade is detrimental to developing countries. The longer the negotiations are at a standstill, the more sequencing takes place under no regulatory framework, the less the global South benefits from a fair and equitable sharing of the benefits arising from the use of DSI, which increases even more the imbalance between parties in the negotiation playing field. This clearly does not point to a just, fair or equitable treatment, let alone a sustainable one.

Notes

1 In alphabetical order, equivalent contribution to the article. Both authors are white female independent researchers from European universities who have attended most CBD and ITPGRFA meeting as observers since 2004 and 2000 respectively. We do not claim to speak on behalf of any of the stakeholders involved in the analysed issues. We disclose this information in an attempt to ensure transparency for a decolonised research. Christine Frison has received funding from the Belgian Fund for Scientific Research – FNRS (grant n°1.B.172.18F). Elsa Tsioumani has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie grant agreement No 101029634 (SynBioGov).

2 W. Diniz and F. Canduri, 'Bioinformatics: An Overview and Its Applications' (2017) 16 *Genetics and Molecular Research* gmr16019645.

3 Peter Phillips, Stuart Smyth and Jeremy de Beer, 'Access and Benefit-Sharing in the Age of Digital Biology' in Chidi Oguamanam (ed.), *Genetic Resources, Justice and Reconciliation* (CUP, 2018) p. 181.

4 Sarah Laird, Rachel Wynberg, Michelle Rourke *et al.*, 'Rethink the Expansion of Access and Benefit Sharing' (2020) 367 *Science* 1200, 1200.

5 Such as human genome sequences.

6 (1992) 1760 UNTS 79 (CBD).

7 *Ad Hoc* Technical Expert Group on Digital Sequence Information on Genetic Resources, *Combined Study on Digital Sequence Information (DSI) in Public and Private Databases and Traceability* (2020) CBD/DSI/AHTEG/2020/1/4, [5] and Annex; Soren Brunak, Antoine Danchin, Masahira Hattori *et al.*, 'Nucleotide Sequence Database Policies' (2002) 298 *Science* 1333, 1333–1334. Note, however, the GenBank statement that 'some submitters may claim patent, copyright, or other intellectual property rights in all or a portion of the data they have submitted. NCBI [the National Center for Biotechnology Information of the United States National Institutes of Health, which is part of the INSDC] is not in a position to assess the validity of such claims, and therefore cannot provide comment or unrestricted permission concerning the use, copying, or distribution of the information contained in GenBank': available at <https://www.ncbi.nlm.nih.gov/genbank> (28 February 2022). In addition, it is to be noted that more than 50 per cent of nucleoside sequence data deposited to the INSDC come from four countries – the USA, China, Canada and Japan.

8 Kathryn Maxson Jones, Rachel Ankeny and Robert Cook-Deegan, 'The Bermuda Triangle: The Pragmatics, Policies, and Principles for Data Sharing in the History of the Human Genome Project' (2018) 51 *Journal of the History of Biology* 693, 697–699.

9 CBD/DSI/AHTEG/2020/1/4, above n. 6, pp. 16–17.

10 CBD, Art. 2 defines 'genetic resources' as 'genetic material of actual or potential value', and 'genetic material' as 'any material of plant, animal, microbial or other origin containing functional units of heredity'.

11 CBD, Preamble and Arts. 3 and 15.1.

12 Michael Halewood, Isabel López Noriega and Sélim Louafi, 'The Global Crop Commons and Access and Benefit-Sharing Laws: Examining the Limits of International Policy Support for the Collective Pooling and Management of Plant Genetic Resources' in Michael Halewood, Isabel López Noriega, Sélim Louafi (eds.), *Crop Genetic Resources as a Global Commons* (Routledge 2013) pp. 5–6; Elsa Tsioumani, *Fair and Equitable Benefit-Sharing in Agriculture: Reinventing Agrarian Justice* (Routledge, 2021) pp. 1–2.

13 Conference of the Parties to the Convention on Biological Diversity, *Report of the Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity* (2010) UNEP/CBD/COP/10/27, [103] and Annex (Decision X/1, Annex 1, pp. 89–109) (Nagoya Protocol).

14 (2001) 2400 UNTS 303.
15 See United Nations, 'Intergovernmental Conference on Marine Biodiversity of Areas beyond National Jurisdiction', available at <https://www.un.org/bbnj> (28 February 2022).
16 World Health Assembly, *Sixty-Fourth World Health Assembly* (2011) WHA64/2011/REC/1, p. 8 (Resolution WHA64.5) and Annex 2 (*Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*) (PIP Framework). See also Sylvain Aubry, Christine Frison, Jorge Medaglia *et al.*, 'Bringing Access and Benefit Sharing into the Digital Age' (2022) 4 *Plants, People, Planet* 5, 6; Margo Bagley, '"Just" Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good' (2022) p. 1 available at <https://www.researchgate.net/publication/357028113_Just_Sharing_The_Virtues_of_Digital_Sequence_Information_Benefit-Sharing_for_the_Common_Good> (28 February 2022).
17 Laird *et al.*, above n. 3, p. 1200.
18 Ibid.
19 There is currently no explicit requirement related to fair and equitable benefit sharing in international instruments such as the World Trade Organization's *Agreement on Trade-Related Aspects of Intellectual Property Rights* (*Marrakesh Agreement Establishing the World Trade Organization* (1994) 1867 UNTS 154, Art. II and Annex IC), the argument being that intellectual property protection benefits society as a whole by promoting innovation: Martha Chouchena-Rojas, Manuel Ruiz Muller, David Vivas and Sebastian Winkler (eds.), *Disclosure Requirements: Ensuring Mutual Supportiveness between the WTO TRIPS Agreement and the CBD* (IUCN and ICTSD, 2005) pp. 10–11.
20 World Intellectual Property Organization, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* (2nd edition, WIPO, 2020) Annex.
21 Keith Aoki, '"Free Seeds, Not Free Beer": Participatory Plant Breeding, Open Source Seeds, and Acknowledging User Innovation in Agriculture' (2009) 77 *Fordham Law Review* 2275, 2279–2287.
22 Eric Welch, Margo Bagley, Todd Kuiken and Sélim Louafi, *Potential Implications of New Synthetic Biology and Genomic Research Trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture*, A Study Commissioned by the Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture (FAO, 2017) p. 16; Paul Oldham, 'Digital Sequence Information – Technical Aspects' (2020) pp. 22–23 available at <https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Final_Report_technical_aspects_of_DSI.pdf> (28 February 2022).
23 Florian Rabitz, Jesse Reynolds and Elsa Tsioumani, 'Emerging Technologies in Biodiversity Governance: Gaps and Opportunities for Action' in Ingrid Visseren-Hamakers and Marcel Kok (eds.), *Transforming Biodiversity Governance* (Cambridge University Press, forthcoming).
24 Secretariat of the International Treaty for Plant Genetic Resources for Food and Agriculture, *Report of the Secretary* (2013) IT/GB-5/13/4, [3].
25 Conference of the Parties to the Convention on Biological Diversity, *Report of the Fourteenth Meeting of the Conference of the Parties to the Convention on Biological Diversity* (2018) UNEP/CBD/COP/14/14, [258] and Decision 14/20, Preamble.
26 *Ad Hoc* Technical Expert Group on Digital Sequence Information on Genetic Resources, *Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources* (2018) CBD/DSI/AHTEG/2018/1/4, [23] and Annex ([2]).
27 *Ad Hoc* Technical Expert Group on Synthetic Biology, *Report of the Ad Hoc Technical Expert Group on Synthetic Biology* (2015) UNEP/CBD/SYNBIO/AHTEG/2015/1/3, [31] and [66(i)]. See also Conference of the Parties to the Convention on Biological Diversity, *Synthetic Biology: Updated Reports* (2014) UNEP/CBD/COP/12/20, [31].

28 UNEP/CBD/SYNBIO/AHTEG/2015/1/3, Ibid., [52]. A recent study states that surveyed countries do not report having received monetary benefit sharing from DSI although important benefits arise from the use of DSI: See *Ad Hoc* Technical Expert Group on Digital Sequence Information on Genetic Resources, *Fact-Finding Study on How Domestic Measures Address Benefit-Sharing Arising from Commercial and Non-Commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development* (2020) CBD/DSI/AHTEG/2020/1/5, pp. 25–30.

29 National ABS laws and ABS agreements can address these matters as sequencing does require access to the physical materials. The problem arises with unregulated third party and other access where national ABS laws and ABS agreements have not specifically addressed these issues when dealing with the source physical materials. This is particularly problematic for the reuses of sequence data that are not subject to national ABS laws and ABS agreements (including legacy and orphaned materials).

30 Sylvain Aubry, 'The Future of Digital Sequence Information for Plant Genetic Resources for Food and Agriculture' (2019) 10 *Frontiers in Plant Science* 1046, pp. 4–5; Michael Halewood, Isabel Lopez Noriega, Dave Ellis *et al*., 'Using Genomic Sequence Information to Increase Conservation and Sustainable Use of Crop Diversity and Benefit-Sharing' (2018) 16 *Biopreservation and Biobanking* 368, 368.

31 Felicity Keiper and Ana Atanassova, 'Regulation of Synthetic Biology: Developments under the Convention on Biological Diversity and Its Protocols' (2020) 8 *Frontiers in Bioengineering and Biotechnology* 310, pp. 16–17.

32 Open Ended Working Group on the Post-2020 Global Biodiversity Framework, *First Draft of the Post-2020 Global Biodiversity Framework* (2021) CBD/WG2020/3/3, [5(b)]. See also Open-Ended Working Group on the Post 2020 Global Biodiversity Framework, *Digital Sequence Information on Genetic Resources* (2021) CBD/WG2020/3/4, [5].

33 Elsa Tsioumani, Asheline Appleton, Lynn Finnegan *et al*., 'Summary of the UN Biodiversity Conference: 13–29 November 2018' (2018) 9 *Earth Negotiations Bulletin* 725, p. 10; Elsa Tsioumani, Lynn Finnegan, Nicole Schabus *et al*., 'Summary of the Eighth Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture: 11–16 November 2019' (2019) 9 *Earth Negotiations Bulletin* 740, p. 11. See also Open Ended Working Group on the Post-2020 Global Biodiversity Framework, *Co-Leads' Report on the Work of the Informal Co-Chairs' Advisory Group on Digital Sequence Information on Genetic Resources* (2021) CBD/WG2020/3/INF/8, pp. 15–16.

34 Aubry *et al*., above n. 15, p. 8.

35 Ibid., pp. 9–10.

36 See, for example, Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture, *Report of the Eighth Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture* (2019) IT/GB-8/19/Report, [37] and Appendix B.4 (Resolutions 4/2019, [14]), [43] and Appendix B.9 (Resolution 9/2019, [5(g)]), [45] and Appendix B11 (Resolution 11/2019, [7]); Commission on Genetic Resources for Food and Agriculture, Report of the Second Session of the *Ad Hoc* Intergovernmental Technical Working Group on Aquatic Genetic Resources for Food and Agriculture (2018) CGRFA/WG-AqGR-2/18/REPORT, [37]–[41]. See also *Ad Hoc* Intergovernmental Technical Working Group on Aquatic Genetic Resources for Food and Agriculture, *Draft Exploratory Fact-Finding Scoping Study on 'Digital Sequence Information' on Genetic Resources for Food and Agriculture* (2018) CGRFA/WG-AqGR-2/18/Inf.10.

37 Tsioumani *et al.* (2019), above n. 32, p. 13; Tsioumani, above n. 11, p. 23.

38 As exemplified with the current COVID crisis and the numerous ethical debates around the lack of accessibility and sharing of research results and pharmaceutical products, often protected by patents.
39 Aubry *et al.*, above n. 15, p. 7.
40 Tsioumani, above n. 11, pp. 134 and 164.
41 Laird *et al.*, above n. 3, p. 1202.
42 Welch *et al.*, above n. 21, pp. 16–22 and 26–35; *Ad Hoc* Technical Expert Group on Digital Sequence Information on Genetic Resources, *Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol* (2018) CBD/DSI/AHTEG/2018/1/3, 56–57.
43 United Nations Conference on Trade and Development, *The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications – A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property* (UNCTAD, 2014) pp. 77–78.
44 Carlos Correa, *Patent Protection for Plants: Legal Options for Developing Countries*, Research Paper No. 55 (South Centre, 2014) p. 13.
45 *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions* (OJ L 213, 30.7.1998), Art. 3. Interestingly, Art. 9 of this Directive delineates the scope of 'protection conferred by a patent on a product containing or consisting of genetic information [as extending] to all material, save as provided in Art. 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function'. In this Article, a very clear and direct link is made between the tangible and intangible elements of a genetic resource. See also Anthony Bochon 'The Directive 98/44 EC for the Legal Protection of Biotechnological Inventions: A Commentary of its Articles' (2008) *Droit and Technologies* available at <https://www.droit-technologie.org/dossiers/the-directive-9844-ec-for-the-legal-protection-of-biotechnological-inventions-a-commentary-of-its-articles> (28 February 2022).
46 Paul Cole, 'Patentability of Genes: A European Union Perspective' (2014) 5 *Cold Spring Harbor Perspectives in Medicine* a020891.
47 *Association for Molecular Pathology v Myriad Genetics*, 569 U.S. 576, 577-578 (2013).
48 Tsioumani, above n. 11, p. 141.
49 Note, however, that the Human Genome Project is an interesting precedent with regard to ethical concerns and moral values in genetic research: See Maxson Jones *et al.*, above n. 7, pp. 700–702.
50 Noting that Malaysia includes human genetic resources in their ABS laws: See *Access to Biological Resources and Benefit Sharing Act 2017* (Malaysia) ss 12(2)(f) and 15(3)(f).
51 Tsioumani *et al.*, above n. 32, pp. 10–11.
52 Ibid.
53 CBD, Art. 2; Nagoya Protocol, Art. 2.
54 A. Bendimred and C. Frison, 'Le Séquençage des Données Issues des Ressources Génétiques: Trouble-fête du Régime International d'Accès et de Partage des Avantages de la Biodiversité' (2022) *Annales de Droit*, in press.
55 Morten Tvedt and Peter Schei, 'The Term "Genetic Resources": Flexible and Dynamic while Providing Legal Certainty?' in Sebastian Oberthür and Kristin Rosendal (eds.), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, 2014) pp. 20–21. Contra Kaspar Sollberger, 'Digital Sequence Information and the Nagoya Protocol: Legal Expert Brief on Behalf of the Swiss Federal Office for the Environment' (2018) p. 11 available at <https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/rechtsgutachten/digitale-sequenzinformationen-nagoya-protokoll.pdf.download.pdf/20180407

_Kurzgutachten%20Digitale%20Sequenzinformationen_Final.pdf> (28 February 2022) who argues that DSI is not covered by 'utilization' but who notes that a historical and teleological interpretation suggests that DSI use can lead to benefit sharing obligations.

56 Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity* (Brill 2014) pp. 59–60. Article 9 of the EU Directive on the legal protection of biotechnological inventions also supports this interpretation: Directive 98/44/EC, above n. 44.

57 Tvedt and Schei, above n. 54, p. 29. See also Joseph Vogel, Nora Álvarez-Berríos, Norberto Quiñones-Vilches *et al.*, 'The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing' (2011) 7 *Law, Environment and Development Journal* 52, 54.

58 Bendimred and Frison, above n. 53.

59 Elisa Morgera, Stephanie Switzer and Miranda Geelhoed, *Study for the European Commission on 'Possible Ways to Address Digital Sequence Information – Legal and Policy Aspects'* (European Commission, 2020) p. 13.

60 Paul Berg, David Baltimore, Sydney Brenner *et al.*, 'Summary Statement of the Asilomar Conference on Recombinant DNA Molecules' (1975) 72 *Proceedings of the National Academy of Science* 1981, 1981.

61 Tsioumani *et al.*, above n. 32, p. 11.

62 See for instance the position of the European Marine Biological Resource Centre, available at <https://embrc.eu/newsroom/news/embrc-position-sharing-benefits-arising-use-digital-sequence-information-genetic> (28 February 2022).

63 Elsa Tsioumani, Mike Muzurakis, Yannis Ieropoulos and Asterios Tsioumanis, 'Following the Open Source Trail outside the Digital World: Open Source Applications in Agricultural Research and Development' (2016) 14 *tripleC* 145, pp. 147–149.

64 Aubry, above n. 29, p. 3.

65 Margo Bagley recognises the need for 'just' sharing of benefit deriving from the use of DSI, but does not fully recognise the overall impact of the initial imbalance of means between various stakeholders in the negotiation fora (resulting from colonial history). Promoting a 'just' sharing without putting all parties on the same level playing field will not equilibrate the balance and enable the fairness and equity principles to be reached. See Bagley, above n. 15, forthcoming.

66 On the basis of relevant CBD provisions, including Arts. 12 and 15–19.

67 Christian Prip, Kristin Rosendal and Morten Tvedt, *The State of Technology Transfer Obligations in Global Environmental Governance and Law: Biodiversity Conservation and Sustainable Use*, FNI Report 4/2015 (Fridtjof Nansen Institute, 2015) p. 9.

68 Conference of the Parties to the Convention on Biological Diversity, *Report of the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity* (2004) UNEP/CBD/COP/7/21, [509] and Annex (Decision VII/29).

69 Prip *et al.*, above n. 66, p. 1.

70 (1948) A/810 (GA res. 217A (III)), Art. 27.

71 (1966) 993 UNTS 3, Art. 15(1)(b).

72 Human Rights Council, *Report on the Right to Enjoy the Benefits of Scientific Progress and Its Applications* (2012) A/HRC/20/26, [66]–[69].

73 See, for example, Louise Bezuidenhout, Sabina Leonelli, Ann Kelly and Brian Rappert, 'Beyond the Digital Divide: Towards a Situated Approach to Open Data' (2017) 44 *Science and Public Policy* 464.

74 Ibid., p. 464.

75 Conference of the Agricultural Research Leaders in West and Central Africa, 'Roots and Tubers Center of Excellence in Need of Support to Operate its USD.5 Million

DNA Analyzer' (July 2021) *CORAF Newsletter* available at <http://coraf.org/newsletters/07-2021/coraf-this-month-july-2021.html> (28 February 2022).
76 Bezuidenhout *et al.*, above n. 72, p. 464.
77 Ibid., p. 473.
78 Ibid.
79 Aubry, above n. 29, p. 7.
80 Ibid., p. 8.
81 See Donna Haraway, 'Situated Knowledges: The Science Question in Feminism and the Privilege of Partial Perspective' (1988) 14 *Feminist Studies* 575.
82 Aram Ziai, 'Decolonising Development Research: Why It Is Urgently Needed and What Steps Must Be Taken' (2021) available at <https://www.convivialthinking.org/index.php/2021/11/04/decolonising-development-research> (28 February 2022).
83 Linda Tuhiwai Smith, *Decolonizing Methodologies: Research and Indigenous Peoples* (Zed Books 1999).
84 Francine Madden and Brian McQuinn, 'Conservation's Blind Spot: The Case for Conflict Transformation in Wildlife Conservation' (2014) 178 *Biological Conservation* 97, 98–99.
85 Ibid., p. 100.
86 Ibid.
87 Ibid.
88 Ibid., p. 99.
89 Secretariat for the Convention on Biological Diversity, 'Policy Options for Access and Benefit-Sharing and Digital Sequence Information: Summary of Webinar' (April 2021) available at <https://www.cbd.int/abs/DSI-webinar/DSIPolicyOptions2021.pdf> (28 February 2022).
90 Secretariat for the Convention on Biological Diversity, 'Criteria to Consider for Policy Options on Digital Sequence Information on Genetic Resources: Summary of Webinar' (April 2021) available at <https://www.cbd.int/abs/DSI-webinar/CriteriaSummaryPaper2021.pdf> (28 February 2022).
91 Conference of the Parties to the Convention on Biological Diversity, *Report of the Conference of the Parties to the Convention on Biological Diversity on Its Fourteenth Meeting* (2018) CBD/COP/14/14, [258] and Decision 14/20, [11].
92 Bendimred and Frison, above n. 53
93 Bagley, above n. 15, p. 54.
94 Ibid.
95 Aubry *et al.*, above n. 15, p. 9.