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Digital Sequence Information (DSI) and national measures: approaches and perspectives *By Jorge Cabrera Medaglia*

Digital sequence information (DSI, or genetic sequence data) is an emerging aspect of synthetic biology which involves certain functional genetic sequences being shared by different means. The genetic sequences from plants, animals or micro-organisms could be used to support conservation and sustainable use of biological diversity, to develop and commercialize new products and processes, or for other purposes. The regulation of the use of DSI for both commercial and non-commercial entities may have huge implications for the access and benefit-sharing (ABS) regimen established in the international instruments, ongoing processes and regional and national legislation that implement these conventions. International guidance is needed to promote a coordinated approach to secure fair and equitable sharing of benefits while avoiding a negative impact on the non-commercial benefits arising from the genetic data.

I. Digital Sequence Information (DSI) and benefit-sharing

Digital sequence information (or genetic sequence data) is an emerging aspect of synthetic biology which involves certain functional genetic sequences being shared by different means. The term DSI does not have an internationally agreed meaning and it is considered as a placeholder which originated in the context of the discussions of the Convention on Biological Diversity (CBD) and its Nagoya Protocol (NP).

DSI carries information, as do genes. The genetic sequences from plants, animals or micro-organisms could be used to support conservation and sustainable use of biological diversity, to develop and commercialize new products and processes, or for other purposes. The technological advances in the sequencing (including entire genomes), the increased capacity to store and manage data and falling costs have resulted in amazing quantities of information being stored in thousands of public or private databases. However, when the information has been developed the sources of the material are usually not known. Access to and transfer of this data to third parties (for commercial and non-commercial purposes) can be done with or without a variety of restrictions and conditions depending on the institutional framework, laws and policies governing the provider of the information.

Therefore, the regulation of the use of DSI for both commercial and non-commercial entities may have huge implications for the access and benefit-sharing (ABS) regimen established in the international instruments, ongoing processes and regional and national legislation that implement these conventions.

The issue has become a pressing and controversial topic (especially a North-South one) within the international community. Discussions and potential negotiations are currently taking place in many international fora, especially in the CBD, where several studies have been produced and Ad Hoc Technical Working Groups have been created. DSI has been prominent on the agenda of other international organizations and will be a top issue in the next Conference of the Parties (No. 15) of the CBD. This is scheduled to be held next year when it is expected that some decisions will be taken on how to handle DSI, especially from the perspective of benefit-sharing.

II. The international debate

The conclusion of the Convention on Biological Diversity (CBD) in 1992 represented a fundamental shift in both international law and the approach taken to conserve biological diversity. Whereas genetic resources had previously been the common heritage of humanity, the Convention changed this approach and granted states sovereignty over the genetic resources found within their borders. The thinking was that this would allow states to control access to genetic resources, setting terms that would enable them to profit from the potential value of these genetic resources and their diversity, thus creating incentives to conserve the resources and use them sustainably.

The objectives of the CBD are the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources by appropriate access to them, by appropriate transfer of relevant technologies, and by appropriate funding.

According to the Convention, states have the authority to determine access to genetic resources in areas within their jurisdiction. Parties also have the obligation to take appropriate measures with the aim of sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. Two further principles established under Art. 15 of the CBD are that “access [to genetic resources], where granted, shall be on mutually agreed terms” (MAT) and “shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party” (Prior Informed Consent or PIC). This provides the basic legal framework under the Convention for access and benefit-sharing arising from the utilization of genetic resources.

To facilitate the achievement of the third objective of the CBD the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization were adopted in 2002. Then, in 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Resulting from their Utilization was adopted.

It has been argued that the roots of ABS in the CBD can be traced to colonialism and efforts by colonial powers to gain control of the trade of key commodities for their own benefit. This argument sees part of the rationale behind benefit-sharing as an attempt to avoid the exploitation inherent in many forms of resource extraction with a North-South legacy, which has historically been associated with the unsustainable use of natural resources. The resulting approach allows states to control access by setting terms that allow them to profit from the potential value of their genetic

resources and biodiversity, creating an incentive to conserve and sustainably use these resources.

The Nagoya Protocol on ABS provides a transparent legal framework for the effective implementation of the benefit-sharing obligations of the CBD, giving greater legal certainty for providers and users of genetic resources and helping to ensure benefit-sharing when these resources leave the providing country. By enhancing legal certainty and promoting benefit-sharing, it encourages the advancement of research on genetic resources. This creates incentives to conserve and sustainably use genetic resources, thereby enhancing the contribution of biodiversity to development and human well-being. The Annex to the Nagoya Protocol demonstrates the potential breadth of benefit-sharing and indicates how it may contribute to sustainable natural resource management for development, which could be of relevance to interpreting benefit-sharing in a broader context.

DSI has also become a critical part of discussions, negotiations and the implementation of other conventions and instruments, including the 2001 Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA); the FAO Commission on Genetic Resources for Food and Agriculture; the World Health Organization (particularly in the context of the Pandemic Influenza Preparedness Framework); and in the process for negotiating a legally binding instrument for the Areas Outside of Any National Jurisdiction (ABNJ), among others. In the case of the ITPGRFA last Governing Body (December 2019) the lack of consensus on how to address genetic information was one of the main reasons the negotiations for the enhancement of the benefit-sharing system of the Treaty failed.

III. Divergent views¹

So far there is a wide range of views and positions advocated by national governments, the research sector, academia and non-governmental organizations active in the CBD discussions, and elsewhere. These center on the following points:

1. Scope

Some stakeholders are of the opinion that DSI do not and should not fall within the remit of CBD and the Nagoya Protocol. Due to the definition of genetic material/resources, they believe DSI do not fall within the scope of PIC but can be covered by MAT associated with the utilization of genetic resources. Statements that DSI already fall within the definition of genetic resources and access can thus be subject to PIC and MAT procedures.

Despite differences of opinion on whether DSI should or could be regulated at the access stage, there seems to be a general recognition that parties at the very least have the right to regulate benefit-sharing through MAT where the use of DSI is the result of the utilization of a genetic resource.

2. Definition

A further discussion is how the term DSI could be defined, and indeed whether it should be defined. The question of the definition of DSI is necessarily linked to whether it falls within the scope of ABS, and whether and how benefits should be shared. For some, if DSI is to be

¹ The author acknowledges the information provided by Mr Fred Perro-Welch, Center for International Sustainable Development Law Senior Research Fellow on this particular issue.

regulated, then the term needs to be defined clearly in order to assess what is within the scope of regulation, and what is not. There are also unsolved positions on the appropriate terminology to be used. Here the proposals include digital sequence data, genetic sequence data, genetic resource sequence data, genetic information, genomic sequence data, natural information, nucleotide sequence data on genetic resources, sequence information, sequence data, and sequence information derived from genetic resources. For others there is no need for a further definition as, based on the negotiating history of the CBD, DSI is already included in the concept of genetic resources and countries are regulating DSI on this basis. Alternatively, a more detailed definition of genetic resources should be elaborated.

3. Benefit-sharing

Some stakeholders put an emphasis on the non-monetary benefits currently provided by open access to DSI through, for example, genetic sequence repositories and the scientific research that results. Regulated access to DSI would impede these valuable non-monetary benefits, and that could outweigh the relevance of monetary benefits to the CBD objectives of conservation and sustainable use of biodiversity. Others emphasize that excluding DSI from the scope of regulation would undermine the viability of the third objective of the CBD and the objective of the NP, as access to DSI can increasingly be used as a substitute for access to tangible genetic resources. Some conclude that without agreement on benefit-sharing from the commercial use of DSI it can be expected that more countries will regulate all access to DSI, limiting non-commercial access and its benefits in the process.

IV. National responses

An interesting recent study² on how domestic measures are addressing DSI identified four main approaches to addressing DSI in domestic measures:

- Some countries address DSI only in conjunction with the utilization of a physical genetic resource. In other words, when access to a genetic resource is granted, some countries include conditions on the use of DSI that could originate from that genetic resource as part of PIC and MAT.
- Others have domestic measures in place that seem to suggest that PIC and MAT would be required to access DSI independently of access to a physical genetic resource.
- In another group of countries, even though there are no access requirements for DSI, benefit-sharing is required from its utilization. In other words, benefit-sharing obligations are triggered by utilization rather than access.
- Some countries may also address DSI in relation to benefit-sharing and research and development through other measures, such as compliance and monitoring mechanisms.

As the study points out, independently of how and whether DSI is addressed in domestic measures, every party can include provisions in MAT on the use of DSI, even when their domestic measures do not cover or address DSI. However, clear limitations exist to taking a bilateral approach to dealing with DSI through contracts, particularly when it is published in publicly accessible databases.

² Margo Bagley and others, "Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development", prepared by the Secretariat of the Convention on Biological Diversity, January 2020. Available from <https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf>.

One of the increasing examples of the use of the current regulatory framework, is the case of Costa Rica. In the opinion of the government DSI is covered under the definition of access to genetic resources of the Biodiversity Law of 1998 and related regulations but in practice for non commercial research it is not regulated (no PIC and MAT are required) and for commercial research benefit-sharing should be established probably through the Global Multilateral Benefit-Sharing Mechanism. Until now no access permit has been granted for the commercial use of DSI/genetic information per se not involving access to the physical material (genetic or biochemical compound).

The questionnaire also concludes that on a case by case basis the Technical Office of the CONAGEBIO (Competent National Authority on ABS) has the power/authority to impose restrictions and prohibitions for the further dissemination/deposit in public databases of genetic information to avoid losing control on the DSI resulting from an authorized access to genetic/biochemical resources by a permit. Some cases have been identified which have used this restriction. For instance, in the permit **No R-CM-089.2010-OT of January 9 2010**, the following restriction was imposed in the permit granted:

"For the DNA (genetic material) extracted from the requested genetic resources the Technical Office of CONAGEBIO **restricts the publication of complete/full genomic information on the national and international databases**, meaning that **entire genomes cannot become public, only the information related with molecular markers**. Likewise, before publishing the sequences of DNA of the molecular markers developed or used for the project purposes, the applicant shall inform in advance the TO and later on submit the number of accession of the sequences" (Unofficial translation).

It is possible that other restrictions/conditions related to the dissemination/deposit/publication of genomes/gene sequences could have been imposed in the access permit, which exact terms could vary on a case by case basis but there is no information on these other cases.

INBio (National Biodiversity Institute) practices³ on ABS contracts can also highlight how DSI related matters can be integrated and regulated under MAT.

For instance in the ABS agreement between INBio, the University of Michigan (U-M) and the University of Harvard (one of the International Cooperative Biodiversity Groups), the following clauses were included in the research collaboration agreement (RCA) negotiated for the project "Discovery of Natural-product based Drugs and Bio-energetic Materials from Costa Rica Biota of September 2009"

- INBio will manage the data related to Samples, Isolates, Extracts, Fractions, and DNA pursuant to its activities under the Statement of Work using its databases; however, each of Harvard and U-M shall be permitted to maintain, in parallel with INBio, data sets that wholly or partially overlap the body of data that is managed by INBio.
- Harvard shall manage the information related to the Research in its databases and shall coordinate with U-M any information that needs to be transferred to NAPIS. Additionally, Harvard shall maintain information updated as long as there is work performed with the Materials.

³³Jorge Cabrera Medaglia, "The Role of the National Biodiversity Institute in the Use of Biodiversity for Sustainable Development – Forming Bioprospecting Partnership", in *Genetic Resources, Traditional Knowledge and the Law*, Evanson C. Kamau and Gerd Winter, eds. (Earthscan, 2009), pp. 243-270.

- Data generated by the Parties in performance of Screens, such as structures and activities of Chemical Entities, will be deposited in **ChemBank by U-M with prior notification to-, and written consent by-, INBio and Harvard. In case a third party has a commercial interest in such information, Harvard, U-M and INBio will require them to negotiate and enter into agreements with Harvard, U-M and INBio.**

In such situations, INBio is the user of the genetic resources (acting here as an intermediary to Harvard and U-M) and the Technical Office (TO) of CONAGEBIO as the Competent National Authority (can) grants or denies the applications submitted by INBio. In accordance with the national legislation all access contracts like this one must be approved by CONAGEBIO. Moreover, the Research Collaboration Agreement was actually endorsed/approved as part of the permit granted by the TO of CONAGEBIO to INBio. The process of revision of the contracts is covered by a confidentiality agreement with the staff of CONAGEBIO.

V. Conclusion

The final internationally agreed solution in different fora – particularly the CBD/NP – has enormous implications for the realization of the third objective of the Convention and the Protocol for the providers of genetic and biochemical resources (including indigenous peoples and local communities and the state) and the users (whether commercial or non-commercial entities).

Huge differences remain between countries on how to address this issue and on what kinds of international, regional and national responses are required to ensure the equity (benefit-sharing) component of the different international instruments. International guidance is needed to promote a coordinated approach to secure fair and equitable sharing of benefits while avoiding a negative impact on the non-commercial benefits arising from the genetic data. In the meantime, countries have undertaken actions in recent years to improve their regulatory frameworks and build capacities among the different actors for their effective implementation. The Nagoya Protocol has undoubtedly served as a catalyst to rejuvenate efforts and initiatives in this field.

DSI is certainly a key issue to consider for these national implementation activities.

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