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A Fair Solution for Access and Sharing of Benefits of Digital Sequence Information? Decision for the CBD COP in November 2024

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A decision is expected from the Conference of the Parties of the Convention on Biological Diversity (CBD) by 1 November 2024 on a solution to the fair and equitable sharing of benefits from the use of digital sequence information (DSI) on genetic resources. There are different forms of non-monetary and monetary benefits from the use of DSI that are being considered. This paper argues that for monetary benefit sharing, the focus should be on when DSI is used commercially, as part of products or services. Calculations should be based on revenue that includes sales and intellectual property licencing.

La Conférence des parties à la Convention sur la diversité biologique (CDB) devrait prendre une décision d'ici le 1er novembre 2024 sur une solution au partage juste et équitable des avantages découlant de l'utilisation des informations numériques sur les séquences (DSI) des ressources génétiques. Différentes formes d'avantages non monétaires et monétaires découlant de l'utilisation des DSI sont envisagées. Ce document soutient que pour le partage des avantages monétaires, l'accent devrait être mis sur l'utilisation commerciale des DSI, dans le cadre de produits ou de services. Les calculs doivent être basés sur les revenus qui comprennent les ventes et les licences de propriété intellectuelle.

Se espera una decisión de la Conferencia de las Partes del Convenio sobre la Diversidad Biológica (CDB) para el 1 de noviembre de 2024 sobre una solución al reparto justo y equitativo de los beneficios derivados del uso de la información de secuencias digitales (DSI) sobre recursos genéticos. Se están considerando diferentes formas de beneficios monetarios y no monetarios derivados del uso de la DSI. En este documento se sostiene que, en lo que respecta a la distribución de los beneficios monetarios, la atención debe centrarse en los casos en que la DSI se utiliza con fines comerciales, como parte de productos o servicios. Los cálculos deben basarse en los ingresos, que incluyen las ventas y las licencias de propiedad intelectual.

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I. Introduction

The stakes are high for the upcoming Conference of the Parties (COP) of the Convention on Biological Diversity (CBD), to be held on 21 October – 1 November 2024 in Cali, Colombia, which is expected to decide on a solution for the fair and equitable sharing of benefits from the use of digital sequence information (DSI) on genetic resources.

The outcome in the COP will make waves in ongoing negotiations in other multilateral fora that are also addressing questions on regulating access and benefit sharing from the use of DSI.

The COP will decide on the modalities for operationalizing a multilateral mechanism for the fair and equitable sharing of benefits from the use of DSI. A technical working group of the CBD that met on 16th August 2024 is forwarding a recommendation for the COP that is heavily bracketed, signalling important and continued divergences.

Among the noteworthy options that appear in the recommendation is an obligation for users of DSI that generate revenues/profits/turnover from its use (i.e. sales from a product or service that required the use of DSI) to pay into a fund a percentage of the revenues/sales/profits as monetary benefit sharing.

A glaring omission in the options is to require users of DSI on genetic resources to share benefits from the exploitation of intellectual property rights (IPRs). While reference to "revenues" for a product or service could include revenues from licensing IPRs, without a direct agreement to refer to such revenues, there will not be legal certainty on the applicability of the obligation to contribute to the fund.

II. Tensions in legal regimes shaped by competing interests

The tensions between trade liberalisation, the regulation of access to and use of natural assets and biodiversity, and the expansion of IPR protection, have remained unsettled despite significant analytical work and intense debates during the last three decades. This is explained by several factors. Countries and firms diverge in their technology capabilities and ability to capture the benefits of the production and trade in products derived from biodiversity – i.e. biotechnology, pharmaceuticals, cosmetics - as well as of economic rents based on the exploitation of IPRs. The bulk of Earth's biodiversity is concentrated in developing countries that struggle with trade-offs in advancing policies on biodiversity conservation, use, poverty reduction, and industrialisation, while most of those countries lack the technological capability needed to derive value from genetic resources. The contributions of indigenous and local communities and their knowledge about conservation and uses of biodiversity are not adequately valued and can be misappropriated, although the new World Intellectual Property Organization (WIPO) International Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, when it enters into force, may contribute to identifying instances of misappropriation. [1]

In addition, the relevant multilateral legal regime is complex, with a myriad of international agreements on environmental, trade, human rights, and IPRs of which some countries are party but not others, with ambiguities in the provisions and contradictions and disagreements on interpretation, divergences in the enforceability of obligations across agreements, problems of non-compliance and reliance on private contracts to define benefits to be shared from the utilisation of genetic resources. Despite efforts to promote synergies among those instruments for their coherent implementation,[2] there are significant divergences in priorities and views on how they should interact and evolve.

[1] See N. Syam and C. Correa, "Understanding the New WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge", Policy Brief, No. 131 (Geneva, South Centre, 2024). Available from https://www.southcentre.int/policy-brief-131-3-july-2024/.

[2] For example, efforts in the World Trade Organization (WTO) on the agenda item on the relationship between the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the CBD, and the review of TRIPS Article 27.3(b) have been unsuccessful for more than 20 years, and the recent agreement in WIPO.

III. Digital Sequence Information

The digitisation of biological information ignited a new debate on regulation under existing environmental law. The CBD of 1993 establishes that countries have national sovereignty over their genetic resources. Hence, they can decide the terms for access to them (CBD, Article 15), requiring prior informed consent (PIC) and sharing of benefits -including for indigenous and local communities in accordance with national policies and legislation- from the commercial use of genetic resources, in the form of monetary and non-monetary benefits. [3]

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD was adopted in 2010, establishing an international regime that covers access and benefit sharing for genetic resources and their derivatives and associated traditional knowledge pertaining to indigenous and local communities. While the basis for establishing access conditions tied to PIC and benefit sharing has relied on physical access to the genetic resource, with advances from research and development in biotechnology and the utilisation of DSI of such resources, physical access is no longer required for their utilisation or replication. [4]

This brings into question the application of access and benefit-sharing obligations of the CBD and the Nagoya Protocol in the case of access to and use of DSI, with different approaches being pursued at the national level. Given the value of utilisation of DSI for biodiversity conservation and for the development of commercial products, the parties to the CBD and the Nagoya Protocol have discussed as of 2015 whether DSI was covered or not under those instruments. The negotiating positions on this subject have been shaped by different policy approaches, research, and commercial interests, leading to persistent substantial disagreements. [5]

IV. In search of a solution

In 2022, parallel negotiations ensued on DSI and the Kunming-Montreal Global Biodiversity Framework,[6] resulting in an agreement to develop a solution so that benefits from the use of DSI on genetic resources would be shared fairly and equitably. An important decision was adopted in that year,[7] which states that the Parties agree "to establish, as part of the Kunming-Montreal Global Biodiversity Framework, a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund". As part of this compromise, nine criteria were defined as potential elements of the solution: (a) be efficient, feasible and practical; (b) generate more benefits, including both monetary and non-monetary, than costs; (c) be effective; (d) provide certainty and legal clarity for providers and users of DSI on genetic resources; (e) not hinder research and innovation; (f) be consistent with open access to data; (g) not be incompatible with international legal obligations; (h) be mutually supportive of other access and benefit-sharing instruments; (i) take into account the rights of indigenous peoples and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold. [8]

The decision also establishes that benefits arising from the use of DSI can be monetary and non-monetary, and should, in particular, be used to support the conservation and sustainable use of biological diversity and, *inter alia*, benefit indigenous peoples and local communities. It was also agreed that a multilateral approach to benefit sharing from the use of DSI could be adopted, considering the nine criteria noted above, instead of the contract-based approach in the CBD and the Nagoya Protocol for defining fair, equitable and mutually agreed terms for benefit sharing.

[3] Biological resources include "genetic resources, organisms or parts thereof, or any other biotic component of ecosystems with actual or potential use or value for humanity" (CBD Article 2).
[4] There is no internationally agreed definition of DSI on genetic resources, which is the term used in the context of the CBD and other fora. A press note from the CBD Secretariat dated 16 August notes that "in this context DSI refers to information on the basic building blocks of life that are encapsulated in DNA". Available from https://dev-chm.cbd.int/doc/press/2024/pr-2024-08-16-dsi-en.pdf. However, this terminology has not been agreed so far.
[5] The relevant decisions and documentation on DSI in the context of the CBD and the Nagoya Protocol to the CBD is available here: Relevant decisions and documents (cbd.int).

[6] See CBD/COP Decision 15/4, 19 December 2022, document CBD/COP/DEC/15/4. For an analysis the negotiations, see V. Munoz Tellez, "Proposals to Advance the Negotiations of the Post 2020 Biodiversity Framework", Policy Brief, No. 90 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/policy-brief-90-march-2021/.
[7] Document CBD/COP/DEC/15/9, Decision on *Digital sequence information on genetic resources*, 19 December 2022.
[8] *Ibid*.

Among the issues of contention are how to establish monetary obligations on benefit sharing for DSI users, whether the obligation should apply to all or some users, for example only to users from developed countries, what forms of non-monetary benefits to establish, requirements for public databases, how the contributions to the global fund should be allocated (i.e. on a project basis or direct allocations to countries), and review of the system.

On 16 August 2024, a draft recommendation was agreed by the second meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources to be submitted to the COP 16 of the CBD,[9] to be held on 21 October – 1 November 2024 in Cali, Colombia, on the modalities for operationalizing the multilateral mechanism for the fair and equitable sharing of benefits from the use of DSI on genetic resources. While still heavily bracketed – meaning areas where there is still no consensus -, the draft provides the basis for the negotiation at the CBD COP 16. The negotiation to follow will be difficult. During the Ad Hoc Open-ended Working Group, groups of developing countries such as the African Group and the Latin American and Caribbean Group (GRULAC), expressed at times that their textual proposals were not being adequately reflected in the draft text of the recommendation. But this struggle is not new.

V. DSI discussions in multilateral fora

The multilateral debate for recognition of DSI as part of the CBD and the Nagoya Protocol dates back to 2016. In the World Health Organization (WHO), in the same year, discussions began on the handling of the genetic sequence data (GSD) of influenza viruses with pandemic potential under the Pandemic Influenza Preparedness (PIP) Framework, which is also now a topic of negotiation for the establishment of a Pathogen Access and Benefit Sharing (PABS) System as part of a new WHO pandemic instrument.[10] DSI is currently relevant or under consideration within the Food and Agricultural Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), particularly regarding the enhancement of the Multilateral System for Access and Benefit Sharing, and considering revisions to the Standard Material Transfer Agreement. A Working Group is considering the possibility of developing a specialised approach for DSI on plant genetic resources for food and agriculture under the International Treaty. In the recent meeting of the working group, a policy brief was discussed which suggests that "given the way that DSI has changed the utilisation of genetic resources and information in crop improvement, a new approach to benefit-sharing is justified: an approach that does not imply the tracking of PGRFA material and information along the research and development process of particular products, but that is based on payments linked to the sales of specified classes of products (namely, seeds and other relevant propagating materials), regardless of whether or not specific samples of PGRFA and derived DSI have been used directly for the development of such products."[11]

The inclusion of DSI was debated at length and finally agreed as part of the 2023 Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ Agreement), requiring that DSI on marine genetic resources of areas beyond national jurisdiction is linked to standardised batch identifiers and to inform on the repository or database where the DSI is or will be deposited.[12] The COP of the BBNJ will elaborate on the modalities for the sharing of monetary benefits from the utilisation of DSI, taking into account the recommendations of an access and benefit-sharing committee that is established as part of the BBNJ agreement.

[9] Document CBD/WGDSI/2/L.2, draft recommendation on *Further development of the multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund*, 16 August 2024.

[10] These negotiations are taking place in an Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, see https://apps.who.int/gb/inb/e/e_inb-11.html.

[11] FAO, "Policy brief on digital sequence information/genetic sequence data: Generation, Use and Sharing of Digital Sequence Information in Crop Improvement", Twelfth Meeting of the Ad Hoc Open-Ended Working Group to Enhance the Functioning of the Multilateral System, IT/OWG-EFMLS-12/24/3/Inf.1, August 2024. Available from https://openknowledge.fao.org/server/api/core/bitstreams/46ac5930-7b44-48ed-b698-20218081d5c7/content.

[12] See Article 12 of the BBNJ, available at https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXI-10&chapter=21&clang=_en .

VI. Do not overlook IPRs as a source of monetary benefit sharing

One of the noteworthy options included in the recommendation is the requirement for users of DSI that benefit from the successful commercialisation of a product or service developed making the use of DSI, to pay the global fund a percentage of the revenue obtained through sales.

A glaring omission in the proposed options is to require users of DSI on genetic resources to share benefits from their exploitation of IPRs. Even if there is mention of "revenue" obtained through sales, it is not clear that this would include usage-based royalties received from IPR licensing. Many nucleic acid and amino acid sequences are claimed in issued or pending patents in many countries worldwide, and this information is contained in both public and commercial databases. One study estimates that about 5% of published nucleic acid and 29% of amino acid sequences have been patented or are under the patenting process worldwide, with the United States contributing over 70% of the patent sequences, followed by the United Kingdom and Japan.[13] There is a growing number of patents granted for products and processes in industrial biotechnology and sectors such as pharmaceuticals that generate value from the use of DSI on genetic resources.

The CBD COP should also consider requiring that payment be made into the global fund of a percentage of the net gross revenue generated from the licensing of intellectual property –i.e. patents, trade secrets, trademarks, and copyrights– when these reach a certain threshold. At the least, negotiators should discuss the merits and drawbacks of requiring users of DSI on genetic resources to share benefits from charges for the use of IP (royalties) they have received, in addition to sales revenues. This element would be important to include for advancing equity in the design of a multilateral benefit-sharing system for the use of DSI on genetic resources. The requirement to share monetary benefits from revenues obtained from the exploitation of IPRs should be in addition to sharing monetary benefits from revenues from sales of products or services as well as non-monetary benefits.

In seeking solutions for more fairness in the sharing of the value that is derived from the utilisation of DSI on genetic resources, the question of value from intellectual property exploitation should not be overlooked by negotiators and academia. The work by J. Vogel and others based on the concept of "bounded openness", more recently developed in a research paper published by the South Centre[14], is a concerted effort in this direction.

It is also critical that negotiators get the right solution for benefit sharing relating to the use of DSI from genetic resources in the context of the CBD and the Nagoya Protocol. Ongoing negotiations in other multilateral fora, such as the World Health Organization, and the Food and Agriculture Organization's Treaty on Plant Genetic Resources for Food and Agriculture, that are also addressing questions on regulating access and benefit sharing from the use of DSI, are likely to be directly influenced by the decisions of the COPs of the CBD and the Nagoya Protocol on this subject.

In the interim, until the multilateral system for the fair and equitable sharing of benefits from the use of DSI on genetic resources is fully operational, developing countries can continue to regulate access and benefit sharing of DSI on genetic resources at the national or regional level as part of the implementation of the CBD and the Nagoya Protocol.

VII. Final remarks

The final decision on the inclusion of DSI as part of the obligations of the CBD and the Nagoya Protocol is expected in November 2024.

[13] See G. Gann Xu, Amie Webster, Ellen Doran, "Patent Sequence Databases", *World Patent Information*, Vol. 24, Issue No. 2 (2002), pp. 95-101. Available from https://doi.org/10.1016/S0172-2190(02)00004-2.

[14] Joseph Henry Vogel, Natasha C. Jiménez-Revelles, Xavier A. Maldonado-Ramírez de Arellano, *Decision 15/9 and the Nagoya Protocol: Who should get what in the Multilateral Benefit-Sharing Mechanism?*, Research Paper, No. 210 (Geneva, South Centre, 2024). Available from https://www.southcentre.int/research-paper-210-30-september-2024/.

The key question is how fair sharing of benefits from the use of DSI of genetic resources can be done in a manner that does not hinder access and sharing of DSI. The multilateral system that the CBD COP develops should put access and benefit sharing on equal footing, meaning that both outcomes are prioritised equally. The main approach being considered in the negotiations is to link benefits to the commercial applications of DSI, which relies on the value of the final products that have used DSI. In this, intellectual property rights - in particular patents and trade secrets - can play a role in the final product value, in revenues from sales but also revenues from royalties from licensing. Hence, the negotiations should explicitly include this element.

Other aspects of intellectual property rights also deserve reflection and are not addressed in this paper. These include the effects of patents and trade secrets on genomic and proteomic inventions (from humans and other species), evaluation of the licensing practices for these inventions for research, innovation and broad dissemination and use of the innovations, and the different national approaches on admissibility of patent claims and trade secret protection.

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