Veille citoyenne d'information sur les OGM et les semences

Digital sequence information: Appropriating life without touching it?

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Digital sequence information (DSI) has long been a source of tension between countries in the "*Global North*" and the?"*Global South*". The latter provides the majority of the physical genetic resources containing this DSI, whilst the North, thanks to its bioinformatics capabilities, carries out most of the exploitation and financial capitalisation of this information. Thus, by linking biological functions to digitised genetic sequences, the North files numerous patent applications and captures the lion’s share of the profits, in violation of international conventions and treaties. In an attempt to legalise this new form of biopiracy, a pledge to share these benefits equitably – the Cali Fund – was formalised in 2024. It remains, however, ineffective, failing to address a major injustice.

Podbrushkin

This article is part of a series devoted to intellectual property (patents, plant variety rights, trademarks, licences, etc.). It differs, however, in that it focuses on DSIs, not as a form of intellectual property, but as a legal concept that has become central today.

Digital sequence information (or DSI) is not defined by any international legal text[ii]. Nor has any agreement been reached on the name of this new virtual subject of international law, with the term GSD (Genetic Sequence Data) also being used in certain international meetings. This semantic issue is historically complex[iii]. For the sake of simplicity, we will refer to it here as "*DSI*". Most of these GSDs[iv] are freely accessible *via* public databases[v]. These genetic components of physical biological resources, originating mainly from countries in the Global South ("*South*"), are now attracting significant scientific and economic interest, particularly from multinationals in the wealthy countries of the Global North ("*North*")[vi]. These DSIs are fuelling an exponential surge in patent applications since the cost of genome sequencing fell dramatically in the 2010s. Such

commercialisation of DSIs further contributes to the distortion of the concept of "*invention*", whose original meaning of "*creation of the mind*" is already undermined by its application to living organisms[vii].

From physical resource to digital resource

DSIs constitute an undefined set of digital data derived from the genetic sequencing of living organisms (plants, animals, microorganisms). Stored in computer databases, these DSIs are used as raw material for the development of certain products in the pharmaceutical and agro-industrial sectors (often combined within the same entity) as well as in the cosmetics industry. They are also used by the public research sector, increasingly often under contract with private companies. Thanks to these databases, there is no longer any need to access the physical biological resource in order to study its genetic characteristics and attempt to appropriate them.

The appropriation of genetic resources is now taking place less and less *via* physical material, but primarily *via* DSIs. Thanks to highly sophisticated bioinformatics tools, the Northern industry cross-references databases with, in the case of the seed sector, other databases listing the characteristics of physical plant samples. It then files patent applications for organisms containing sequences presented as modified by patentable genetic modification techniques, whose functions are assumed and which express the said characteristics. If we take the well-known examples of stevia (production of ultra-sweet substances) or the neem tree (production of medicinal oil), whose current commercial exploitation relies on the patentability of the chemical synthesis of components from these plants[viii], this could now be achieved using the DSI contained in these plants and available in databases.

In silico processes at the origin of "*inventions*"…

The European Patent Office (EPO) is responsible for examining European patent applications for "*inventions*" involving DSI in accordance with the criteria applicable to all technical fields[ix]: technical character, novelty, inventive step, industrial applicability and sufficiency of description. A simple genetic sequence characterised solely by its digital representation and lacking any function or "*technical effect*" is not patentable as such. However, if it is demonstrated that it is associated with disease resistance in a plant, or that it codes for a pathogenic virus[x], it may be patentable.

When assessing the novelty and inventive step of "*inventions*" based on DSIs, the EPO, which we consulted, states that it takes into account *the* entire "*state of the art*" available prior to the filing date of a patent application, including sequences from public databases. If the association of a sequence and its function is already disclosed in a database, a claim for an "invention" relating to that sequence may be rejected for lack of novelty, and obvious variants will generally fail to meet the requirement of inventive step. Regarding the criterion of sufficient description, an "*invention*" based on DSI may be considered sufficiently disclosed (without the deposit of biological material) if the genetic basis of the claimed feature is clearly described, enabling its reproduction using established techniques. In other words, if cross-referencing information from two or more databases allows a function to be attributed to a sequence, it is theoretically possible to obtain a patent on such an "*invention*", and even to claim any product containing that sequence – any organism – even if the latter has not been physically produced.

… which encourage biopiracy

The EPO also states that it follows the recommendations of recital 27 of Directive 98/44, according to which, "*whereas if an invention is based on biological material of plant or animal origin or if it*

uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known". For a DSI to be subject to this requirement to provide information on geographical origin, the database from which it was sourced by the patent applicant must provide information linking it to some physical material and its place of collection. However, this remains highly unlikely given the current management of DSI by most databases worldwide. In any case, this would be of little use, since recital 27 specifies that *"this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents*".

The ITPGRFA (International Treaty on Plant Genetic Resources for Food and Agriculture), which also seeks to establish rules on benefit-sharing for DSIs[xi], nevertheless prohibits any intellectual property rights (IPR) over seeds or plants derived from the collections of its multilateral system. The Convention on Biological Diversity (CBD), for its part, requires free and informed prior consent before any access to a genetic resource, consent which may be conditional upon a ban on such IPRs. Only the absence of a strict obligation to indicate the origin of DSIs in any patent application currently allows these restrictions to be circumvented. The current formal recommendations, as they are not binding, are nothing more than wishful thinking.

Furthermore, in May 2024, WIPO adopted a Treaty aimed at regulating the use of genetic resources through the mandatory disclosure of their geographical origin in patent applications[xii]. Whilst its objective is to ensure the equitable sharing of benefits, this Treaty nevertheless poses a threat of biopiracy by WIPO regarding DSIs. The Treaty does, in fact, contain an obligation to disclose the origin of "*material of plant, animal, microbial or other origin containing functional units of heredity*" where the invention is based on such material. This obligation could therefore only apply to inventions based on the physical forms of genetic material, and not on its genetic parts and components, as in the ITPGRFA. This is interpreted by Northern countries, for whom DSIs are not genetic components of biological materials but products of research, as a *de facto* exclusion from the definition of genetic resources under this WIPO Treaty. All patents relating to DSIs contained in genetic resources would thus contribute to a situation of biopiracy[xiii]. To date, no member of the European Patent Convention (which gave rise to the EPO for European Union member states) has ratified this Treaty, with Malawi currently being the only country in the world to have done so.

Sharing the benefits of DSIs: a deadlock similar to that of IPRs

The widespread dissemination of DSIs *via* databases poses numerous problems. It is, for example, very difficult to prove that genetic information incorporated into a database was already known, contained in biological resources and/or associated with indigenous knowledge in its country of origin. This makes it almost impossible to challenge certain patents on the grounds of lack of novelty when an "*invention*" is based on such "*information*"[xiv]. Furthermore, this lack of traceability prevents the sharing of benefits with the provider – who is therefore unknown – of this information.

The Nagoya Protocol does indeed provide for the sharing of benefits arising from the use of genetic resources. However, as this sharing is bilateral between the provider of the physical material and its user, it is not suited to DSIs. Indeed, the considerable number of DSIs, their digital nature and consequently their irreversible circulation on an international scale across thousands of open-access databases for millions of users, makes such an adaptation impossible. This is why COP15 proposed a multilateral system[xv] to be implemented through the Cali Fund[xvi] decided at COP16, which is intended to be funded on a voluntary basis – which is the main problem – by the primarily industrial users of DSI. The financial mechanism, which could involve the payment of 0.1% of turnover or 1% of the user's profit, is expected to be decided at COP17 in Yerevan (Armenia) in

October 2026. However, industry in the Global North remains broadly opposed to such a benefit-sharing system, as it considers that the use of DSIs does not constitute a direct use of physical resources and should therefore not be subject to these obligations[xvii]. Patent applications filed by this industry on the basis of these DSIs therefore currently benefit only the industry itself.

Other international instruments seek to establish benefit-sharing rules for DSIs. This is notably the case with the BBNJ Agreement on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction[xviii] as well as the WHO (World Health Organisation). They could opt for the system to be decided by the CBD or develop their own mechanism, or even a combination of the two, at the discretion of the industry players called upon to contribute.

Intellectual property rights in a vacuum

There are currently several points of contention surrounding the issue of DSIs, reflecting the application of intellectual property rights to innovations that are far removed from practical use. On the one hand, the decisions of patent offices apply only in the countries that adhere to them, as is the case with the EPO, which remains focused on patentability criteria and the existence of a demonstrated effect (function) of a sequence, whether or not identified in a database. On the other hand, there is an international law that claims to seek to protect biodiversity, as well as its custodians and providers, by promoting the equitable sharing – despite the ineffectiveness of the Cali Fund – of the benefits derived from DSIs with the countries providing genetic resources.

The various industrial players in the North who file numerous patent applications based on DSIs will use these rights in the traditional manner (as bargaining chips, in infringement actions, in litigation, for licensing, etc.). But their patent portfolios, which are set to become vast, will also, for many of them, cover industrialists, indigenous peoples and farmers in the Global South, from where the majority of the biological material underlying these DSIs originates. It is therefore conceivable that an Indonesian farmer might have to pay royalties to a multinational that has exploited a DSI derived from his own traditional varieties, or might no longer have any right to use them, or that a Kenyan community might have to do the same for a therapy based on an anti-malarial plant originating from its territory, where it is already used for this purpose.

Unless an urgent response is provided to the industry's use of DSIs – which is intense, daily and legally effective – the situation will persist. This would notably entail making restrictions on the patentability of genetic resources, including their genetic components, mandatory, as well as a contribution to the Cali Fund. Otherwise, the issues of biopiracy and the sharing of benefits derived from these DSIs risk remaining the primary sources of contemporary injustice in the field of intellectual property.

ii Denis Meshaka, "Despite negotiations in 2024, disagreements over DSIs persist", *Inf'OGM*, 7 March 2025.

iii Convention on Biological Diversity, "Submission from the secretariat of the Commission on Genetic Resources for Food and Agriculture: exploratory fact-finding scoping study on *'digital sequence information*' on genetic resources for food and agriculture", 17–29 November 2018.

iv Secretariat of the Convention on Biological Diversity, "Combined Study on Digital Sequence Information in Public and Private Databases and Traceability", 29 January 2020.

v Three major databases are considered the key players: the EMBL-EBI (European Molecular Biology Laboratory – European Bioinformatics Institute), the DNA DataBank of Japan (DDBJ) and GenBank, hosted by the National Center for Biotechnology Information (NCBI) in the United States.

Together, these databases form the International Nucleotide Sequence Database Collaboration (INSDC).

vi The concept of the Global North/Global South refers more to a historical and economic structuring of power relations than to a legal or geographical categorisation.
Countries that can be considered part of the Global North, with strong technological and scientific capabilities: the United States, the European Union, Canada, Japan, Australia and New Zealand.
Countries that can be considered part of the Global South, rich in biodiversity: Kenya, Nigeria, South Africa, Brazil, Mexico, Peru, China, India, Indonesia, the Philippines.
Certain hybrid countries combine high biodiversity with technological and scientific power: China, India, Brazil, South Africa, but also the United States.

vii Denis Meshaka, "Patents on life: extension through language and law", *Inf'OGM*, 27 March 2026.

viii Convention on Biological Diversity, "Study to identify specific cases of genetic resources and traditional knowledge associated with genetic resources that are in transboundary situations or for which it is not possible to grant or obtain prior informed consent", 9–14 November 2020.
Eric Meunier, "Des vitamines et additifs produits par des OGM", *Inf'OGM, le journal*, no. 174, January/March 2024.

ix Denis Meshaka, "Patents, living organisms and GMOs/NGTs", *Inf'OGM*, 25 March 2026.

x Researchers have developed a monoclonal antibody against the Ebola virus using the virus's genetic sequence from GenBank, thereby eliminating the need for physical samples from the country of origin (PCT patent application WO2016123019).

xi Denis Meshaka, "Deadlock over Digital sequence information within the ITPGRFA Agreement", *Inf'OGM*, 29 September 2025.

xii WIPO, "Diplomatic Conference for the Conclusion of an International Legal Instrument on Intellectual Property Related to Genetic Resources and Traditional Knowledge Associated with Genetic Resources", 13–24 May 2024.

xiii K.M. Gopakumar, "WIPO opens more widely the door to biopiracy", *Inf'OGM*, 6 November 2024.

xiv Denis Meshaka, "Patents on life: extension through words and law", *Inf'OGM*, 27 March 2026.

xv Denis Meshaka, "COP15 : accord a minima sur les ressources génétiquescord a minima sur les ressources génétiques", *Inf'OGM*, 22 December 2022.

xvi Convention on Biological Diversity, COP16 in Cali, "Decision 16/2, Digital Sequence Information on Genetic Resources", 1st November 2024.

xvii IFPMA, "Opening statement at COP 16: Multilateral mechanism (MLM) for digital sequence information (DSI)", 21 October 2024.

xviii United Nations, "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", 2024.
