

Keep talking while everything gets sequenced: how the Pandemic Agreement, global health, and genetic resource governance are keeping pace with digitisation?

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One of the responses to COVID-19 has been the development of a multilateral instrument under the World Health Organization: the Pandemic Agreement. Aimed at strengthening equity, transparency, and cooperation in public health, it also recognises the principles of One Health and the importance of data and benefit-sharing concerning genomic sequences. Adopted in May 2025, states agreed on a core text but left the details of a Pathogens Access and Benefit-Sharing (PABS) mechanism open for future negotiation. These negotiations took place in a challenging context for the WHO, marked by contestation and difficulties common to other Access and Benefit-Sharing frameworks. Health and environmental governance now appear fragmented and outpaced by the dematerialisation of genetic resources, particularly in the context of Digital Sequence Information (DSI). Once considered a technical issue, DSI has become a central concern across international regimes on health, biodiversity, agriculture, and marine resources. Adopting a critical approach to international law within the context of regime complexes, this paper analyses the emerging PABS mechanism in light of ongoing DSI debates, overlapping institutional frameworks, and legal fragmentation, and asks whether this fragmented architecture can still uphold equity and respond effectively to global crises such as pandemics and biodiversity loss.

Keywords: *Pandemic Agreement, Pathogen Access and Benefit Sharing, Regime complex, Digitisation, DSI, Genetic resources*

1 INTRODUCTION

Adopted in May 2025 and accompanied by operational modalities still subject to negotiation in its annexes, the Pandemic Agreement represents a promising step towards a

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more coordinated and equitable approach to pandemics. Yet, it still poses considerable challenges. Developed under the auspices of the World Health Organization (WHO) and drafted in the post-COVID-19 context, this instrument seeks to strengthen equity, transparency, and cooperation in global public health. As most other international treaties consider biological entities in their scope, the Pandemic Agreement also emphasises the importance of the rapid sharing of genomic sequence data, together with the benefit-sharing mechanisms related to their use.

The negotiations have unfolded in a difficult environment for the WHO and have been further influenced by broader challenges in multilateralism. In particular, they mirror the persistent ‘hotspots’ present in other access and benefit-sharing (ABS) regimes related to the use of genetic resources and their digital equivalents, especially with the rise of Digital Sequence Information (DSI). These tensions are intensified by the fragmentation of governance across the various instruments and institutions in health, biodiversity, agriculture, and marine genetic resources.

What initially appeared to be a relatively technical issue regarding DSI has evolved into a central site of political, ethical, economic, and, to some extent, ontological debate about the very definition and scope of genetic resources. It has increasingly become a source of tension, as recently demonstrated during the protracted discussions over Pathogen Access and Benefit Sharing (PABS) information in the Intergovernmental Working Group (IGWG), a subdivision of the World Health Assembly, which is mandated to develop key components of the Pandemic Agreement, particularly regarding the provisions of its Article 12. Additionally, DSI continues to impact debates within the ABS framework, for example, with the inception of a multilateral mechanism under the CBD (see below) or the recent collapse of the process on the extension of the multilateral system at the latest session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in November 2025.

This article examines the negotiations surrounding the WHO Pandemic Agreement and its annex within the broader ABS regime complex, adopting a critical international law perspective.¹ The analysis focuses in particular on ongoing debates on DSI, overlapping institutional frameworks, and legal fragmentation, and ultimately questions whether such a fragmented architecture can uphold equity and respond effectively to global challenges such as pandemics and biodiversity loss.

2 FRAMING THE DSI IN THE ENVIRONMENTAL AND GLOBAL HEALTH REGIMES

2.1 Brief history of the DSI conundrum

Digitisation of genetic resources has been one of the major bottlenecks in the recent ABS negotiations. Signals from various forums, where governance mechanisms for genetic resources data – often referred to as Digital Sequence Information – are negotiated, show very striking similarities, particularly in ways to share the benefits arising

1. Kal Raustiala and David G Victor, ‘The Regime Complex for Plant Genetic Resources’ (2004) 58 *International Organization* 277; Karen J Alter and Sophie Meunier, ‘The Politics of International Regime Complexity’ (2009) 7 *Perspectives on Politics* 13 <<https://www.cambridge.org/core/journals/perspectives-on-politics/article/politics-of-international-regime-complexity/37B14B427A95988E48D9F5D3CDB13403>> accessed 12 December 2025.

from their use and call for more coherence across regulatory silos.² Divergent paths and competing mechanisms can be observed in various international legal instruments governing genetic resources, whether through *lex specialis* instruments (for pathogens, seeds, or marine genetic resources) or for all genetic resources under the Convention on Biological Diversity (CBD)³ and its Nagoya Protocol.⁴

For a long time considered a technical detail, the idea gradually pervaded that biodiversity and genetic resources governance might be missing the point by focusing only on physical samples without considering the digital information extracted from their material shell.⁵ Many observers and parties believed that the CBD and other associated treaties, such as the ITPGRFA, may become obsolete because they fail to capture an essential fraction of the utilisation of genetic resources. While the debate over the legal impact of the dematerialisation of genetic resources had existed since at least the CBD's inception,⁶ it did not emerge in the formal discussion as a 'negotiation agenda item' until 2016. Since then, all international treaties dealing with genetic resources have incorporated DSI into their agendas. However, they have not effectively produced a clear or coordinated governance solution for tackling digitisation.⁷ After nearly a decade of discussions, landmark decisions have recently been made under the CBD. In 2022, Decision 15/9 of the 15th Conference of the Parties of the CBD opened the way towards developing a multilateral solution to the DSI conundrum. This was followed by Decision 16/2 of the 16th Conference in 2024, which established the building blocks for a multilateral mechanism governing digital information.⁸ This complex decision encompasses key features, including a dedicated fund (the 'Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information'). It paves the way for various possible governance options in order to operationalise a multilateral mechanism.⁹

2. Sylvain Aubry and others, 'Bringing Access and Benefit Sharing into the Digital Age' (2022) 4 Plants, People, Planet 5; Scarlett Sett and others, 'Harmonize Rules for Digital Sequence Information Benefit-Sharing across UN Frameworks' (2024) 15 Nature Communications 8745 <<https://www.nature.com/articles/s41467-024-52994-z>> accessed 10 October 2024.

3. Convention on Biological Diversity, adopted 5 June 1992, entered into force 29 December 1993. 1760 UNTS 79.

4. 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), adopted 29 October 2010, entered into force 12 October 2014. UNEP/CBD/COP/DEC/X/1.

5. Aubry and others (n 2); Sarah Laird and others, 'Rethink the Expansion of Access and Benefit Sharing' (2020) 367 Science 1200.

6. RJ Pistorius and JCaC van Wijk, 'The Exploitation of Plant Genetic Information: Political Strategies in Crop Development' <<https://dare.uva.nl/search?identifier=6e15b4d7-7cf6-489f-ba-ba-54cb0a43769c>> accessed 25 July 2024; Peter Schei and Morten Tvedt, "'Genetic Resources" in the CBD The Wording, the Past, the Present and the Future'.

7. CBD (2016) CBD/COP/DEC/XIII/16 <<https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-16-en.pdf>>.

8. See details below; CBD (2022) CBD/COP/DEC/15/9 <<https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf>>; CBD (2024) CBD/COP/DEC/16/2 <<https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf>>.

9. CBD (n 8) COP/DEC/16/2, Annex; Bruna Gomes Maia and Sacha Bourgeois-Gironde, 'Analysis of the Working Group's Recommendations and COP-16 Decision 16/2 on Digital Sequence Information' (2025) 11 Global Policy 1 <<https://onlinelibrary.wiley.com/doi/abs/10.1111/1758-5899.70013>> accessed 24 June 2025; Pablo Orozco and Amber Hartman

Meanwhile, the parallel development of major sequencing capacity and the generation of massive data (DSI) have mainly proceeded untouched by these debates. Following the suboptimal global response to the COVID-19 pandemic,¹⁰ the Pandemic Agreement, agreed upon in May 2025, is carving legal provisions within the scope of the CBD and is confronted with the same scientific and legal issues over digitisation.¹¹ It is, therefore, crucial to consider recent developments in environmental governance, particularly regarding DSI, to understand the stakes for digitised global health better, particularly when crafting a new pathogen ABS (PABS) system.

2.2 What then is DSI? Provided that no one asks me, I know

Paraphrasing St. Augustine may provide a reasonable insight into the DSI conundrum in environmental and global health law: a decade-old debate without agreed-upon boundaries.¹² Interestingly, while prompting a lot of ‘hot air’, the terminology related to omics data remains unstable. At least two acronyms are commonly used in various negotiation fora to refer to slightly overlapping concepts: Genetic Sequence Data (GSD) and Digital Sequence Information (DSI). Article 4.2 of the Pandemic Influenza Preparedness Framework (PIP framework)¹³ defines GSD as the ‘order of nucleotides found in a molecule of DNA or RNA’. So far, GSD is almost exclusively used in the context of the PIP framework while diffusing into other ABS discussions. GSD has been gradually replaced during the Pandemic Agreement negotiations, resulting in a reference to ‘sequencing information’.¹⁴

However, it is unclear whether focusing solely on GSD adequately addresses current practices in modern biology or biomedicine. The growing importance of non-DNA-based data should be carefully considered; it may include high-throughput metabolomics surveys, protein structures for biomedical applications, and nutrition. Various definitions of DSI have been suggested: *stricto sensu* comprises DNA and RNA (thereby being equivalent to GSD), whereas *lato sensu* can encompass proteins, metabolites, or even other phenotypic data, structural data, and metadata data, as well

Scholz, ‘The Cali Fund Promises Conservation Benefits, but Only If Countries and Businesses Take Action’ (2025) 1 Nature Reviews Biodiversity 276 <<https://www.nature.com/articles/s44358-025-00050-z>> accessed 9 July 2025.

10. Mark Eccleston-Turner and Harry Upton, ‘International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility’ (2021) 99 The Milbank Quarterly 426 <<https://onlinelibrary.wiley.com/doi/abs/10.1111/1468-0009.12503>> accessed 12 December 2025; Thomas J Bollyky, Lawrence O Gostin and Margaret A Hamburg, ‘The Equitable Distribution of COVID-19 Therapeutics and Vaccines’ (2020) 323 JAMA 2462 <<https://jamanetwork.com/journals/jama/fullarticle/2765944>> accessed 12 December 2025.

11. Adam Strobeyko, ‘When Science Meets Sovereignty: Regulating Infrastructures for Pathogen Genetic Sequence Data’ (Social Science Research Network, 29 May 2025) <<https://papers.ssrn.com/abstract=5315993>> accessed 23 June 2025; Pierre Walckiers, Christine Frison and Sylvain Aubry, ‘A Roadmap to Equity in Pandemic Preparedness, Prevention and Response’ (2024) 14 Journal of Global Health 03031 <<https://jogh.org/2024/jogh-14-03031>>.

12. Saint Augustine and Former Master Henry Chadwick, *St. Augustine’s Confessions* (OUP 2017).

13. Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits, adopted 24 May 2011. A64/VR/10.

14. Walckiers, Frison and Aubry (n 11).

as traditional knowledge.¹⁵ Issues related to the scope of DSI are also addressed in parallel with the status of genetic resources, whether by incorporating their immaterial dimensions or not, potentially leading to a ‘shift in the [ontological] understanding of what constitutes a genetic resource’.¹⁶

The lack of precise terminology, while contributing to some legal uncertainty, has also fostered a degree of constructive ambiguity in the recent CBD negotiation rounds, which probably helped to reach an agreement on a possible multilateral solution.¹⁷ Meanwhile, terminological instability also has legal consequences for operationalising benefit sharing. In the current PABS discussion, a very similar discussion to the one at the CBD preceding the COP16 is taking place: protracted discussions on the exact scope and use of terms range from considering a ‘narrow’ scope (namely, GSD) to all possible associated data or derivatives.¹⁸ Interestingly, the tensions between allowing access to data and/or derivatives from a genetic resource and conditioning that access to benefit sharing are not entirely solved. As Lawson puts it: ‘a closed domain for information under the ABS schemes will directly conflict with the open domain required by the information sharing obligations’.¹⁹ While there is a global consensus to agree on the importance of accessing data for pandemic preparedness, there is a fine line between allowing -free- or -open- access, which must be considered carefully.²⁰

In this context, the reasons for not defining DSI precisely can be twofold: by not having a clear scope for the DSI that must be shared under the agreement, providers may likely negotiate some margins in case they effectively do not want to share everything (for example sharing environmental DNA containing pathogen sequences, but not the full strains’ genomes of unique species), while users can benefit from an unprecise definition to simply reduce the cases where a benefit may be triggered (for example producing treatments against a prion-based disease like Kuru, while amino-acid sequences may be excluded from the DSI definition and, therefore, possibly exempt from benefit-sharing obligations). Negotiators know this very well: they would not spend so much time negotiating precise definitions if it were not crucial for an

15. Wael Houssen, Rodrigo Sara and Marcel Jaspars, ‘Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use’ (2020) CBD/DSI/AHTEG/2020/1/3; Chidi Oguamanam, ‘Indigenous Peoples Rights in Equitable Benefit-Sharing over Genetic Resources: Digital Sequence Information (DSI) and a New Technological Landscape’ in Dwight Newman (ed), *Research Handbook on the International Law of Indigenous Rights* (Edward Elgar Publishing 2022).

16. CDB, Report of the Ad Hoc Technical Expert Group on Synthetic Biology (2015). UNEP/CBD/SYNBIO/AHTEG/2015/1/3; Christine Frison and Elsa Tsioumani, ‘Access and Benefit Sharing and Digital Sequence Information: Unravelling the Knot’ in Charles Lawson, Michelle Rourke and Fran Humphries (eds), *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (Routledge 2022).

17. CBD (n 8) COP/DEC/16/2; CBD (n 8) COP/DEC/15/9; see also ITPGRFA (2025) IT/GB-11/25/17.2. 3–4; Maia and Bourgeois-Gironde (n 9).

18. World Health Organization, Third Meeting of the Open-Ended Intergovernmental Working Group on the WHO Pandemic Agreement, Report of the Meeting, 18 November 2025, A/IGWG/3/4.

19. Charles Lawson, Fran Humphries and Michelle Rourke, ‘The Future of Information under the CBD, Nagoya Protocol, Plant Treaty, and PIP Framework’ (2019) <<https://onlinelibrary.wiley.com/doi/abs/10.1111/jwip.12118>> 22 *The Journal of World Intellectual Property* 103.

20. Colin J Carlson and others, ‘The LISTEN Principles for Genetic Sequence Data Governance and Database Engineering’ (2025) 57 *Nature Genetics* 2099 <<https://www.nature.com/articles/s41588-025-02270-7>> accessed 9 October 2025.

instrument's effectiveness. While ambiguity may sometimes help reach agreement, for example, the BBNJ Agreement and the Cali Fund incorporate DSI while leaving its precise definition to be clarified later, it also risks undermining its very purpose when applied in practice.²¹

3 DSI IN GLOBAL HEALTH: NOTHING IS AGREED, EVEN AFTER EVERYTHING IS AGREED

Formally speaking, pathogen-related DSI, or more accurately, pathogen-derived omic data, constitutes a specific subset derived from the CBD scope whose main property is its association with the biological function of being pathogens to humans.²² Pathogens, particularly human pathogens, represent a relatively small subset of the global omic data generated, with, for example, an estimated share of 3 per cent of the European Nucleotide Archive database.²³ The Pandemic Agreement proposes to limit its scope to 'pathogens with pandemic potential',²⁴ with some relatively vague provisions that call for attention regarding zoonotic spill-over and antimicrobial resistance. Meanwhile, precise definitions of both 'pathogens with pandemic potential' and 'PABS material and Sequence Information' remain to be established in the annex yet to be negotiated (the annex being a prerequisite to the agreement's processing towards ratification) by the IGWG.²⁵ The WHO R&D Blueprint has been undertaking parallel work to prioritise relevant pathogens for public health or pandemic emergencies. It short-listed '28 Viral Families and one core group of bacteria, encompassing 1652 pathogens'.²⁶ Interestingly, this coalition of experts also conceptualised an explicitly unknown threat by naming it 'pathogen X', defined as 'an unidentified or unspecified, unknown pathogens with the potential to induce a Public Health Emergency of International Concern (PHEIC in the WHO parlance) or pandemics in the future'.²⁷ This appears to be a very relevant concept to pandemic preparedness that has not yet effectively materialised in the legal text of the Pandemic Agreement draft.

Although considered a relatively small subset compared to other biodiversity data, access to omic data/DSI during pandemics has proven essential for a rapid and coordinated response to the COVID-19 pandemic and is likely to remain

21. Felix Ekardt and others, 'Legally Binding and Ambitious Biodiversity Protection under the CBD, the Global Biodiversity Framework, and Human Rights Law' (2023) 35 *Environmental Sciences Europe* 80 <<https://doi.org/10.1186/s12302-023-00786-5>> accessed 12 December 2025; Solomon Sebuliba and Katherine G Sammler, 'Governing Biodiversity: Ambiguity and Fragmentation in the BBNJ Agreement' (2025) 270 *Ocean & Coastal Management* 107913 <<https://www.sciencedirect.com/science/article/pii/S0964569125003758>> accessed 12 December 2025.

22. World Health Organization, Pandemic Agreement, adopted 20 May 2025, World Health Assembly Resolution WHA78.1, art 4(a).

23. Sett and others (n 2).

24. WHA78.1 (n 22) arts 4 and 12.

25. WHA78.1 (n 22) 2.

26. WHO, 'Pathogens Prioritization. A Scientific Framework for Epidemic and Pandemic Research Preparedness' (WHO R&D Blueprint 2024).

27. *ibid.*

equally significant in the future.²⁸ The extension of the pre-existing GISAID (Global Initiative on Sharing Avian Influenza Data) from influenza to COVID-19 serves as a pertinent example of an ad hoc response that requires an institutional framework.²⁹ The hosted viral genome sequences facilitated streamlined access to SARS-CoV-2 genome sequences during the pandemic and, most recently, ensured access to other pathogens, such as Mpox, RSV, or Dengue virus sequences, for the R&D community. Interestingly, while sometimes criticised, controlled access to data on GISAID is standard.³⁰ It operates independently of GenBank within the International Nucleotide Sequence Database Collaboration (INSDC) bulk data and concentrates on guaranteeing a certain degree of transparency and accountability, particularly for authors. Beyond its success and the established practice, the terms of GISAID licenses remain relatively unclear regarding the actual access and sharing of benefits, as well as sovereignty issues and liability.³¹ This is not particularly surprising, given that the ‘GISAID Epiflu terms of use’ were designed in 2011, before most of the debates and controversies over the last decade concerning DSI and the benefit sharing of pathogen genetic resources.³² The extent to which the INSDC databases, GISAID, GISRS or even a possible extension of the WHO Biohub System³³ could serve as a relevant blueprint for implementing the PABS is a complex question. In any case, a significant collective effort would be required to precise both legal and technical terms to reach a trustworthy solution for sharing data that would satisfy all the Pandemic Agreement parties.

28. WHO, ‘Global Genomic Surveillance Strategy for Pathogens with Pandemic and Epidemic Potential 2022–2032’ (WHO 2022) <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8958828/pdf/BLT.22.288220.pdf>> accessed 8 August 2025; Margo A Bagley, ‘“Just” Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good’ (2022) 63 *Harvard International Law Journal* 1; Maximilian Brackmann and others, ‘The WHO BioHub System: Experiences from the Pilot Phase’ (2023) 8 *BMJ Global Health* e013421 <<https://gh.bmj.com/content/8/8/e013421>>.

29. Peter Bogner and others, ‘A Global Initiative on Sharing Avian Flu Data’ (2006) 442 *Nature* 981 <<https://www.nature.com/articles/442981a>> accessed 9 July 2025; Stefan Elbe and Gemma Buckland-Merrett, ‘Data, Disease and Diplomacy: GISAID’s Innovative Contribution to Global Health’ (2017) 1 *Global Challenges* (Hoboken, NJ) 33; Mariana Lenharo, ‘Global “Pandemic Treaty”: Nations Wrestle with How to Fairly Share Virus Data’ [2023] *Nature* <<https://www.nature.com/articles/d41586-023-01986-y>> accessed 20 June 2023.

30. Bogner and others (n 29).

31. Martin Enserink and Jon Cohen, ‘Control Issues’ (2023) 380 *Science* 332 <<https://www.science.org/doi/10.1126/science.ad4114>> accessed 9 July 2025; Meridith Wadman, ‘Critics Decry Access, Transparency Issues with Key Trove of Coronavirus Sequences’ (2021) *Science* <<https://www.science.org/content/article/critics-decry-access-transparency-issues-key-trove-coronavirus-sequences>> accessed 9 July 2025.

32. ‘GISAID’ (2025) <<https://gisaid.org/>> accessed 9 October 2025; Sarah Laird and Rachel Wynberg, ‘A Fact Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and Nagoya Protocol’ [2018] CBD/DSI/AHTEG/2018/1/3.

33. Brackmann and others (n 28); Paul Oldham and Siva Thambisetty, ‘The Pandemic Access and Benefit Sharing System: Four Elements of a Trusted System’ (Social Science Research Network, 26 June 2024) <<https://papers.ssrn.com/abstract=4877517>> accessed 10 July 2025; WHO, ‘WHO BioHub System Technical Consultation Sessions’ (2023) Background note and discussion questions.

4 TOWARDS A MORE COHERENT DIGITALISED REGIME

4.1 Defining a precise scope for the Pathogen Benefit Sharing System

The governance of pathogenic genetic resources is heavily fragmented. It is divided at least among the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Nagoya Protocol,³⁴ the pandemic influenza preparedness (PIP) framework, and the Pandemic Agreement. Thus far, in most instances, pathogenic genetic resources fall within the genepool under the national sovereignty of their country of origin, and access is regulated on a bilateral basis. Interestingly, from a technical standpoint, the distinction between human pathogen genetic resources and human-derived genomic data is subtle, which can sometimes result in confusion. It is widely acknowledged at the institutional and legal levels that human-derived data are excluded from the scope of the CBD.³⁵ That said, the isolation of pathogens (ie strains, metabolites, or sequences) from human (samples) can raise ethical and legal questions that warrant reflection.³⁶ The extent to which the patient, a ‘person of origin’ to paraphrase the CBD, has to be considered, maybe his/her nationality, ethnic background or relationship to the user, may indeed have some practical consequences when it comes to sharing benefits.

Human genomic research has improved dramatically over the past few decades, yet the incorporation of greater equity, particularly regarding modalities of benefit sharing in data governance, is increasingly being discussed. Calls for equity and open access were featured prominently in the early discussions surrounding the Human Genome Project, which took place some 30 years ago,³⁷ essentially predating the DSI debates. It might, therefore, be surprising that discussions about human data governance are now resurfacing. We interpret this as yet another reverberation of the DSI debate that first emerged in biodiversity circles.

The Pandemic Agreement negotiations did not occur in an institutional vacuum; they evolved in complex regulatory environments at the intersection of biodiversity, scientific data, and global health governance regimes.³⁸ The ways the provisions of the PABS may interact with the current biodiversity ABS framework, particularly in their approach to omics data/DSI, will have consequences for other sectors. Having set a possible scope for a coherent PABS (within the CBD and the ABS regime complex, but preferably outside human data), we now dig into the complexity of its potential interaction with the regulatory regime and its increasing fragmentation.

4.2 Building incentives to limit fragmentation: towards a coherent PABS

The significant subtraction (terrestrial biodiversity *minus* human pandemic pathogens), or, more precisely, the addition of a supplementary layer of regulatory complexity to

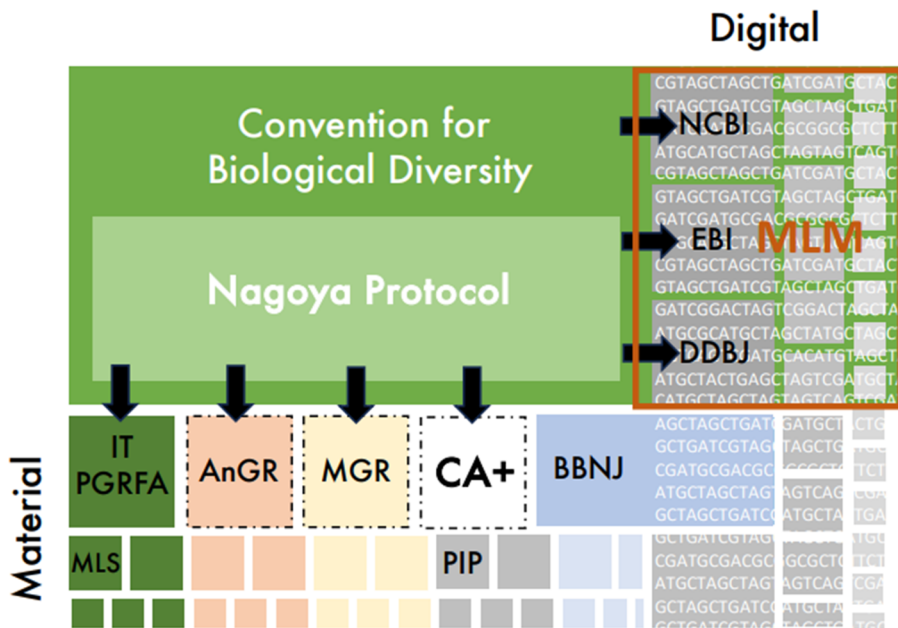
34. Nagoya Protocol (n 4), art 8.

35. Lawson, Humphries and Rourke (n 19).

36. Bagley (n 28); Ann M McCartney and others, ‘Benefit-Sharing by Design: A Call to Action for Human Genomics Research’ (2024) 25 Annual Review of Genomics and Human Genetics 369 <<https://www.annualreviews.org/content/journals/10.1146/annurev-genom-021623-104241>> accessed 24 January 2025.

37. John Sulston and Georgina Ferry, *The Common Thread* (Bantam Press 2002).

38. Strobeyko (n 11); Stephanie Switzer and others, ‘Negotiating Pathogen Access and Benefit-Sharing (PABS): Recommendations and Priority Issues’ (OSF, 7 August 2025) <https://osf.io/9r3g7_v1> accessed 8 August 2025.



Notes: The multiplication of sub-sectorial instruments that extract specific subsets and try regulating them ad hoc (vertical arrows) and the split between material and digital resources. Some of the major databases are provided as examples: NCBI, National Center for Biotechnology Information; EBI, European Bioinformatics Institute; DDBJ, DNA Data Bank of Japan. ITPGRFA, International Treaty for Plant Genetic Resources and Agriculture; MLS, Multilateral System; AnGR, Animal Genetic Resources; MGR, Microbial Genetic Resources; CA+, refers to the WHO CA+, preceding the WHO Pandemic Agreement; PIP, Pandemic Influenza Preparedness Framework; BBNJ, Biodiversity Beyond National Jurisdiction; MLM, Multilateral Mechanism drafted in the CBD COP 16.

Figure 1 Trimming forces applied to the Convention for Biological Diversity and its Nagoya Protocol gene pool

every subset of genetic resources, is a symptom of the increasing strain on the ABS framework.³⁹ Despite repeated calls for greater consistency and support among ABS treaties, agreements, and conventions,⁴⁰ governance of genetic resources is becoming increasingly fragmented, resulting in a more complex and convoluted overarching regime.⁴¹

We attempt to illustrate these forces in two dimensions (Figure 1):

- The first stream tends to multiply sector-specific instruments with scopes addressing specific subsets of stakeholders' concerns (horizontally in Figure 1).

39. Walckiers, Frison and Aubry (n 11).

40. Sett and others (n 2); Switzer and others (n 38).

41. Sebastian Oberthür and Justyna Pożarowska, 'Managing Institutional Complexity and Fragmentation: The Nagoya Protocol and the Global Governance of Genetic Resources' (2013) 13 Global Environmental Politics 100 <https://doi.org/10.1162/GLEP_a_00185>.

This is not a new process; ad hoc solutions are formally acknowledged in Article 4 of the Nagoya Protocol, but multiplying ‘specialised regimes’ may weaken the visibility, efficacy, and efficiency of the ABS framework. In this context, one may question the relevance of creating new sector-specific instruments if they are to share the same underlying principles and objectives as pre-existing instruments, and if they are to reproduce the same weaknesses and lack of effectiveness.

- The second stream has been triggered by the digitisation of genetic resources (vertically in Figure 1). The many issues underlying the digitisation of genetic resources, such as the speed and scale of sequencing and the impossibility of adopting a bilateral approach to benefit sharing, have not been sufficiently addressed.⁴²

Interestingly, although this two-dimensional map provides a clear overview of the ongoing fragmentation within the genetic resources’ regime complex, it does not fully capture the fragmentation’s detailed granularity. Indeed, the only consistent feature within the genetic resource regime is its continual and increasing fragmentation, a well-recognised phenomenon in global environmental governance.⁴³

Meanwhile, the regime complex can be navigated by several actors who will not necessarily be involved, affected, or impacted by it in the same way.⁴⁴ The complexity of a regime is likely to favour some actors while undermining others’ capabilities. Many different actors, mainly states and international organisations, but also other non-state actors (experts, scientists, non-governmental organisations, interest group representatives, etc) can effectively interact with the (horizontal) sector-specific dimension. They can contribute to shape the modalities, obligations, and liabilities, thereby influencing the hierarchy among instruments, reducing redundancy, and ultimately affecting the overall structure of the so-called ‘spaghetti bowl’.⁴⁵ While both the states and non-state actors⁴⁶ may be influencing the extent of governance fragmentation, the global power dynamics remain unchanged. Recognising the underlying politics of the regime is essential to understanding whether fragmentation – and its associated regulatory loopholes, such as forum shopping and other cross-institutional power plays – has occurred incidentally or is the outcome of a deliberate strategy.⁴⁷ In the case of DSI, regulatory procrastination and the *status quo* were sustained passively, and the rise of omics and GR-derived data accumulated irrespectively. These data are now ready to

42. Aubry and others (n 2); Laird and others (n 5).

43. Fariborz Zelli and Harro van Asselt, ‘Introduction: The Institutional Fragmentation of Global Environmental Governance: Causes, Consequences, and Responses’ (2013) 13 Global Environmental Politics 1 <https://doi.org/10.1162/GLEP_a_00180> accessed 12 December 2025.

44. Alter and Meunier (n 1).

45. *ibid* 14.

46. Jessica F Green and Graeme Auld, ‘Unbundling the Regime Complex: The Effects of Private Authority’ (2017) 6 Transnational Environmental Law 259 <<https://www.cambridge.org/core/journals/transnational-environmental-law/article/unbundling-the-regime-complex-effects-of-private-authority/C64AED9E3020D8824DA42EC71A5AD01E>> accessed 12 December 2025; Amandine Orsini, ‘Multi-forum Non-state Actors: Navigating the Regime Complexes for Forestry and Genetic Resources’ (2013) 13 Global Environmental Politics 34 <https://doi.org/10.1162/GLEP_a_00182> accessed 12 December 2025.

47. Alter and Meunier (n 1).

feed AI training models.⁴⁸ There are clear beneficiaries in the absence of further regulation: DSI users who take advantage of cutting-edge, genuinely ‘open science’. This lag of *de facto* inconsistency in regulating data production in the global genetic diversity regime (at times corrected by national legal initiatives⁴⁹) is very much in line with an ‘instrumental interface conflict’ in Kreuder-Sonnen nomenclature.⁵⁰

On the contrary, the digitisation-related tensions (vertical, Figure 1) appear more like a technical ‘hurdle’ that primarily falls under the remit of experts and, to a certain extent, non-State actors (NGOs, academia, and industry).⁵¹ The State actors and civil society representatives (outside academia) gradually gained expertise and focus on DSI as a governance concern through non-state expertise.⁵² Had the DSI issue remained primarily within the domain of technicians and experts, standardising benefit-sharing obligations across databases, practitioners, and legal instruments might have been more straightforward. Several indications suggest that most DSI users are generally willing to act in good faith, as evidenced by multiple proposals for mutually agreed terminology and guiding principles.⁵³ This has been the case with medical databases or, to some extent, with GISAID. The expert’s framing is particularly relevant in the case of omics (ie. the DSI production), which is a constituted, three-decade-old field with a defined community of practice,⁵⁴ that suddenly had to find its way within a regulatory regime that evolved almost entirely independently from it. This institutional ‘jump’ for scientists was at times problematic, particularly in translating the regime’s

48. Charles Lawson, Elizabeth Englezos and Michelle Rourke, ‘Access and Benefit Sharing Biological Materials for Machines: Artificial Intelligence, Machine Learning and Deep Learning’ (2025) 7 *Plants, People, Planet* 1485 <<https://onlinelibrary.wiley.com/doi/abs/10.1002/ppp3.70007>> accessed 12 December 2025.

49. Margo A 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’ [2020] UN Doc CBD/DSI/AHTEG/2020/1/5.

50. Christian Kreuder-Sonnen, Alexander Schmotz and Michael Zürn, ‘The Complex Effects of Regime Complexity: A Conflict Model’ (2025) *European Journal of International Relations* 13540661251368630 <<https://doi.org/10.1177/13540661251368630>> accessed 12 December 2025.

51. Orsini (n 46); Arne Langlet and Alice Vadrot, ‘Expert Authority Politics in the Marine Biodiversity Complex’ (2024) 24 *Global Environmental Politics* 98 <https://doi.org/10.1162/glep_a_00744> accessed 12 December 2025; Regine Andersen, ‘The Time Dimension in International Regime Interplay’ (2002) 2 *Global Environmental Politics* 98 <<https://doi.org/10.1162/152638002320310545>> accessed 12 December 2025.

52. Houssen, Sara and Jaspars (n 15); Michael Halewood and others, ‘New Benefit-Sharing Principles for Digital Sequence Information’ (2023) 382 *Science* 520 <<https://www.science.org/doi/10.1126/science.adj1331>> accessed 6 November 2023; Elizabeth J Karger and Amber Hartman Scholz, ‘DSI, the Nagoya Protocol, and Stakeholders’ Concerns’ (2021) 39 *Trends in Biotechnology* 110 <[https://www.cell.com/trends/biotechnology/abstract/S0167-7799\(20\)30245-6](https://www.cell.com/trends/biotechnology/abstract/S0167-7799(20)30245-6)> accessed 30 January 2022; Sett and others (n 2); Amber Hartman Scholz and others, ‘Multilateral Benefit-Sharing from Digital Sequence Information Will Support Both Science and Biodiversity Conservation’ (2022) 13 *Nature Communications* 1086 <<https://www.nature.com/articles/s41467-022-28594-0>> accessed 27 February 2022.

53. Carlson and others (n 20).

54. Hallam Stevens, *Life Out of Sequence: A Data-Driven History of Bioinformatics* (University of Chicago Press 2013) <<https://www.degruyterbrill.com/document/doi/10.7208/9780226080345/html>> accessed 12 December 2025.

constitutive legal principles, such as equity, fairness, or benefit-sharing, into current scientific practice.

Noteworthy, fragmentation is a well-documented issue,⁵⁵ and several calls for ‘mutual supportiveness’⁵⁶ have been sketched in the CBD decision 16/2, the Pandemic Agreement Article 12(4) or the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (GRATK) Article 2.⁵⁷ But the extent to which these provisions do effectively address either of the tensions of fragmentation and redundancy remains unclear. The strong path-dependency of the public international lawmaking process also helps explain the fragmented approach to governance in environmental and global health sectors, encompassing its principles, practices, and interpretive rules. In this regard, a balance must be struck between the principle of ‘systemic integration’, which holds that the interpretation and application of treaties must take into account ‘any relevant rules of international law applicable in the relations between the parties’, and the generally established principle *pacta tertiis nec nocent nec prosunt*.⁵⁸ According to the latter, obligations in international law can bind only those parties that have consented to them. Treaty interpretation must, therefore, be limited to the instruments to which the parties have subscribed, which restricts the applicable materials in fragmented legal regimes such as ABS,⁵⁹ where no systematic coherence exists due to divergences between the parties to the various instruments, depending on signatories, reservations, and the involvement of third parties (Supplementary Figure 1). While many instruments within the regime address different aspects of biodiversity or global health – often with significant overlap – they may ultimately share a common objective: promoting equity in the global governance of DSI.⁶⁰

Ultimately, our analysis of the DSI debates reveals an interesting example of conflicting forces operating within an increasingly fragmented regime complex: one under constant scientific and political pressure, with each strain driven by distinct groups of actors who appear neither coordinated nor aligned in their approaches or language. In the next section, we will explore how more explicit recognition of these tensions could help foster a positive outcome for governing genetic resources, particularly for urgent challenges like the biodiversity crisis and its possibly linked next pandemic.

55. Raustiala and Victor (n 1); Kal Raustiala, ‘Institutional Proliferation and the International Legal Order’ in Jeffrey L Dunoff and Mark A Pollack (eds), *Interdisciplinary Perspectives on International Law and International Relations: The State of the Art* (CUP 2013); Oberthür and Pożarowska (n 41).

56. CBD (n 8) COP/DEC/15/9, para 9(h); Switzer and others (n 38).

57. WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, adopted 24 May 2024, Geneva. GRATK/DC/7. 7.

58. Vienna Convention on Law of Treaty, adopted 23 May 1969, entered into force 27 January 1980. 1155 UNTS 331, arts 31(3)(c) and 34; Christine Frison and others, ‘Policy Paper from EcoLAWgy at the Eleventh Session of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), Agenda Item 9.2 on the Enhancement of the MLS’ <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5823182> accessed 11 December 2025.

59. Richard K Gardiner, *Treaty Interpretation* (2nd edn, OUP 2015); Campbell McLachlan, ‘The Principle of Systemic Integration and Article 31(3)(C) of the Vienna Convention’ (2005) 54 *The International and Comparative Law Quarterly* 279.

60. BE (Bob) Kreiken and BJM (Bas) Arts, ‘Disruptive Data: How Access and Benefit-Sharing Discourses Structured Ideas and Decisions during the Convention on Biological Diversity Negotiations over Digital Sequence Information from 2016 to 2022’ (2024) 87 *Global Environmental Change* 102892 <<https://www.sciencedirect.com/science/article/pii/S0959378024000967>> accessed 26 July 2024; Halewood and others (n 52).

4.3 Effective legal regime or incantatory environmental policy?

There is likely no straightforward legal or institutional solution to the DSI crisis nor a simple pathway to ultimately reforming the ABS framework.⁶¹ Nevertheless, several targets have been identified for improving the situation. Some scholars advocate institutional reforms, such as extending the CBD's new multilateral approach to establish a digital clearinghouse across instruments, which could enable more efficient and transparent benefit sharing.⁶² Other possible solutions included targeting downstream infrastructure, such as databases, and leveraging the relatively standardised field (at least concerning pathogens' genomic data) to create a Global Scientific Commons.⁶³ Finally, some legal solutions have been suggested, drawing on the distinct legal provisions in various instruments and seeking to achieve convergence in how the mutual supportiveness obligations are structured and interpreted.⁶⁴

These three approaches – financial, structural, and legal – not only demonstrate the intellectual richness that the fields of ABS and DSI have reached, but also highlight the significant divide between scientific-legal expertise and the entrenched political barriers that prevent these solutions from being fully considered and developed across various negotiating forums. Given the fragmentation of the regime complex described here, the most likely solution to achieve in a reasonable time frame is to craft efficient mutual supportiveness. A combination of legal (Switzer) and targeted institutional engineering (Strobeyko) to capture major data flows may reach a critical mass that allows for *de facto* standardised DSI-related practices in a fairer way. Meanwhile, as demonstrated by the recent failure to expand the multilateral system of the ITPGRFA, resolving the DSI crisis is unlikely without at least a minimum level of (geo)political goodwill.⁶⁵

In fact, failing to share pathogen data during a pandemic poses significant collective risks. While it may seem obvious, it remains a crucial consideration in formulating global health solutions: a shared anthropocentric imperative underlies this entire discussion. This is perhaps the biggest peculiarity of the DSI debate: the vast majority of actors agree that sharing data is beneficial. Whether and how this sharing must be justly recompensed remains another question and must be appropriately regulated. If this common ground were taken more seriously, it could be argued that the solutions proposed for addressing digitisation have lacked ambition. Exploring options such as a new, comprehensive DSI convention or a complete overhaul of intellectual property rights by changing the ways the genomic information has been patented for the last four decades⁶⁶ may prove to be ground-breaking but relevant paths forward.

61. Laird and others (n 5).

62. Charlotte Blom and others, 'From Frameworks to Finance: How Sharing Benefits from the Use of Digital Sequence Information Can Evolve to Contribute to Biodiversity Conservation' (2025) 43 *Nature Biotechnology* 1599 <<https://www.nature.com/articles/s41587-025-02820-8>> accessed 12 December 2025; Scholz and others (n 52).

63. Strobeyko (n 11).

64. Switzer and others (n 38).

65. Elsa Tsioumani and others, 'Summary of the Eleventh Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture: 24–29 November 2025' (2025) 9 *Earth Negotiations Bulletin* 1 <<https://enb.iisd.org/sites/default/files/2025-12/enb09880e.pdf>> accessed 11 December 2025.

66. Brad Sherman, *Intangible Intangibles: Patent Law's Engagement with Dematerialised Subject Matter* (CUP 2024).

Navigating towards more reasonable ambitions, other scholars and we have been suggesting improving cross-instrumental dialogue through the creation of a multi-stakeholder committee under the remit of the United Nations Environmental Program that could help foster the kind of legal mutual supportiveness, promote standardisation of benefit-sharing practices across silos and eventually buffer the fragmentation of the DSI regime complex.⁶⁷ Within the context of the Pandemic Agreement, such a committee could play a significant educational role for all parties, helping to prevent the repetition of discussions that have already been extensively addressed in other forums (for example: Is track and tracing of DSI working? Are bilateral contracts an efficient solution for the digital world? What is a specialised instrument according to the Nagoya Protocol? How effectively can one distinguish between non-monetary and monetary benefits? etc).

Given the fragmentation that exists also at national levels across ministries, experts rarely follow more than one or two ABS instruments. In response, scholars began forming informal discussion groups to coordinate, share knowledge, and develop coherent propositions (iDSI group, DSI Scientific Network, PABS discussion group, etc). The actual impact of these groups and their formal contributions is difficult to assess; however, there is certainly room for improvement across all areas. In particular, how technical and legal working groups are structured and integrate legal and scientific expertise needs improvement. Again, a platform like the multi-stakeholder committee dedicated to DSI could facilitate this process.

Taking a step back from the purely legal and institutional perspective, the vote for a Pandemic Agreement at WHA78 (to be distinguished from a consensual decision) that includes a still-to-be-defined (P)ABS mechanism is likely highly significant for contemporary trends in global governance. As demonstrated by the 2015 Paris Climate Agreement and its subsequent COPs, the significance of this milestone lies less in its legal strength or scientific coherence and more in its influence on the global political landscape.⁶⁸ Particularly during times of crisis in global health and at the WHO, the significance of reaching ‘any’ agreement sends a strong political signal from the negotiators. However, the actual ability of this ‘incantatory global governance’ to perform adequately in case of a future pandemic remains to be tested.

67. Aubry and others (n 2).

68. Stefan C Aykut, Edouard Morena and Jean Foyer, “‘Incantatory’ Governance: Global Climate Politics’ Performative Turn and Its Wider Significance for Global Politics’ (2021) 58 International Politics 519 <<https://doi.org/10.1057/s41311-020-00250-8>> accessed 24 January 2025.

5 CONCLUSION AND OUTLOOK

We have observed a similar phenomenon in at least three ABS agreements: the CBD,⁶⁹ the ITPGRFA⁷⁰ and the Pandemic Agreement:⁷¹ on the one side, the difficulty of bringing the peculiarities and technicalities of modern scientific practice to the negotiating field, and on the other side, the rapid politicisation of technical elements to feed into a pro-market narrative that may often be distinct from the narrative initially defended by scientists or open-access supporters, who believe in upholding an ideal of unbiased science in good faith.⁷² The discussion on DSI, including pathogen-related data, navigates between these two difficulties without explicitly addressing the actual issues related to intellectual property rights and patenting, which may ultimately have been the primary trigger of mistrust among the parties. A future-proof, ethically sound, and politically viable legal environment that considers adapted ABS modalities is necessary for the stability of the ABS framework and to ensure that environmental and public health challenges can be effectively addressed in a fair and equitable manner. Multiple calls for reflexivity, new normative frameworks, and transdisciplinarity across the various ABS instruments systematically collide with institutional inertia, competing interests, and ever-growing legal complexity. This may ultimately raise questions about the capacity of these institutional arrangements, the regime they constitute, and their foundational norms to address urgent global challenges effectively.

SUPPORTING INFORMATION

Supplementary Figure 1 The overlap between signatories of treaties dealing with genetic resources (last updated 15/12/25)

Supplementary Table 1 Summary table of the data used for Supplementary Figure 1

69. Charlotte Blom and others, 'From Frameworks to Finance: How Sharing Benefits from the Use of Digital Sequence Information Can Evolve to Contribute to Biodiversity Conservation' (2025) 43 *Nature Biotechnology* 1599 <<https://www.nature.com/articles/s41587-025-02820-8>> accessed 11 December 2025; Anis Bendimred and Christine Frison, 'Séquençage des données issues des ressources génétiques: trouble-fête du régime international d'accès et de partage des avantages du Protocole de Nagoya' (2022) 83 *Annales de droit de Louvain* 381; Frison and Tsoumani (n 16); Elisa Morgera, Stephanie Switzer and M Geelhoed, 'Study for the European Commission on "Possible Ways to Address Digital Sequence Information – Legal and Policy Aspects"' [2020] Consultancy project conducted for the European Commission.

70. Christine Frison, *Redesigning the Global Seed Commons* (Routledge 2018); Frison and others (n 58); Pierre Walckiers, 'Conflicting Scientific Narratives at the Convention on Biological Diversity and Other Fora: Analysis and Contradiction in the Discussions on Dematerialization of (Plant) Genetic Resources' (2024) 4 *Journal of Environmental Law & Policy* 22 <<https://grassrootsjournals.org/jelp/0401m00387.html#status>> accessed 3 June 2024.

71. Walckiers, Frison and Aubry (n 11).

72. Sabina Leonelli, *Data-Centric Biology: A Philosophical Study* (University of Chicago Press 2016); Alex Alexis, 'Les controverses sur le séquençage numérique des ressources génétiques à la Convention sur la diversité biologique. Regards pragmatiques sur le droit international en train de se faire' (2023) *Cahiers Droit, Sciences & Technologies* 37; Walckiers (n 70).