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INTERNATIONAL SHARING OF PATHOGENS AND GENETIC SEQUENCE DATA UNDER A PANDEMIC TREATY

**WHAT LINKAGES WITH THE NAGOYA PROTOCOL AND THE
PIP FRAMEWORK?**

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ABBREVIATIONS AND ACRONYMS

ABS	Access and Benefit-Sharing
AHTEG	Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources
BMEPP	Biological Material with Epidemic or Pandemic Potential
CBD	Convention on Biological Diversity
COP	Conference of the Parties
DSI	Digital Sequence Information
GISRS	WHO Global Influenza Surveillance and Response System
GSD	Genetic Sequence Data
IHRs	International Health Regulations
INB	Intergovernmental Negotiating Body
INSDC	International Nucleotide Sequence Database Collaboration
IVTM	Influenza Virus Tracking Mechanism
MAT	Mutually Agreed Terms
PIC	Prior Informed Consent
PIP Framework	WHO Pandemic Influenza Preparedness Framework
SBI	Subsidiary Body on Implementation
SII	Specialised International Instrument
SMTA	Standard Material Transfer Agreement
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHA	World Health Assembly
WHO	World Health Organization
WHO BioHub	WHO BioHub System for Preparedness and Response to Epidemics and Pandemics

TABLE OF CONTENTS

EXECUTIVE SUMMARY	5
1. INTRODUCTION AND BACKGROUND	7
2. WHAT ARE THE MAIN ISSUES IN THE EXISTING INTERNATIONAL LEGAL FRAMEWORK?	8
2.1. The unsettled status of pathogen-sharing under the CBD and its Nagoya Protocol.....	8
2.2. The gaps in the regulation of pathogen-sharing under WHO instruments	11
2.3. The applicability of the international ABS framework to genetic sequence data.....	12
3. NAVIGATING THE SYNERGIES AND TENSIONS BETWEEN THE NAGOYA PROTOCOL, THE PIP FRAMEWORK, AND A PANDEMIC TREATY	14
3.1. Reconciling ABS in biodiversity and public health	14
3.2. Can the PIP Framework and a new pandemic treaty be considered as SIs under article 4.4 of the Nagoya Protocol?	16
3.3. Delimiting the scope of application of a new pandemic treaty	20
4. CONCLUSION AND OPTIONS FOR NEGOTIATORS.....	22

EXECUTIVE SUMMARY

On 1 December 2021, the delegates of WHO member States agreed to start negotiations on an international instrument applicable to the issue of pandemic preparedness, prevention, and response. Once these negotiations begin, it is likely that the intergovernmental negotiating body will consider the adoption of rules governing the cross-border sharing of pathogens with epidemic or pandemic potential, as well as the distribution of the benefits arising from their utilisation in public health research and development activities, as part of the new instrument.

However, there are likely to be significant interactions between any provision on pathogen- and benefit-sharing under a pandemic treaty and other applicable international instruments, including the 2010 Nagoya Protocol to the Convention on Biological Diversity (CBD) and the WHO Pandemic Influenza Preparedness (PIP) Framework. Analysing the interface between the pandemic treaty and these instruments is therefore important for avoiding the development of conflicts of norms at the level of international law, as well as to prevent inconsistencies and improve legal certainty at the level of domestic implementation.

What are the main issues?

First, there are potential tensions between a multilateral approach to benefit-sharing issues, which appears more appropriate for a public health instrument (and was indeed adopted by the PIP Framework), and the bilateral approach of the Nagoya Protocol. This does not mean that the two approaches are fundamentally at odds. However, the proposed pandemic treaty must be able to strike a balance between a multilateral approach and the respect of key access- and benefit-sharing (ABS) principles, including the respect of prior informed consent, mutually-agreed terms for pathogen-sharing, and fair and equitable benefit-sharing.

Secondly, and relatedly, a pandemic treaty must avoid the risk of a conflict of norms vis-à-vis the Nagoya Protocol, as this will also build legal certainty at the level of domestic implementation. In practice, the new treaty would have to comply with the requirements set in article 4.4 of the Nagoya Protocol and pay particular attention to the draft indicative criteria for identifying a specialised international instrument (SII) that are currently being discussed by the CBD's Subsidiary Body on Implementation.

Finally, the delimitation of the scope of application of the future treaty's pathogen-sharing provisions would help avoid potential gaps in the international ABS regime, but also determine the extent of normative interactions between the treaty and other governance instruments, including the PIP Framework and existing transnational partnerships and platforms. Key choices would relate, for example:

- to the type of pathogens covered by the new regime;
- to the inclusion of benefit-sharing obligations in relation to the sharing of genetic sequence data (GSD);
- to the presence of specific thresholds that would trigger the applicability of the treaty's ABS provisions; and
- to the applicability of such provisions to commercial research and development activities, in addition to non-commercial ones.

How could negotiators address the interface between the pandemic treaty, the Nagoya Protocol, and the PIP Framework?

At least in theory, the Nagoya Protocol does not completely forestall the development of a multilateral pathogen-sharing mechanism under a pandemic treaty that guarantees both timely access to pathogen samples and GSD and the fair and equitable sharing of technologies, knowledge, and medical countermeasures. However, it would be necessary for negotiators to consider those design options that would make it more likely for the two instruments to be considered compatible, and build legal certainty at the level of domestic implementation. These would entail, *inter alia*:

- the preference for a legally-binding treaty;
- a clear delimitation of the pathogen- and GSD-sharing practices to which the instrument would apply;
- the respect of principles of legal certainty, fairness, and equity in the development of access- and benefit-sharing procedures; and
- a wider treaty architecture which responds to a One Health approach and includes forms of public participation and accountability.

In addition, it would be important for the new treaty to explicitly acknowledge the requirements set in article 4.4 of the Nagoya Protocol for the identification of an SII (including any indicative criteria subsequently agreed under the CBD), and for the WHO to encourage the adoption of an explicit decision of the COP to the CBD supporting the consideration of the pandemic treaty as an SII.

Lastly, negotiators should be mindful of the potential trade-offs that might arise from an excessive delimitation of the treaty's scope of application. While a narrower scope could facilitate consensus and avoid an excessive dilution of the treaty's object, it would almost certainly maintain some of the existing gaps and tensions in the current international framework for pathogen-sharing, and thus limit the added value of the new instrument.

1. INTRODUCTION AND BACKGROUND

The idea of a so-called ‘pandemic treaty’ has been vocally supported by actors including heads of states and governments, ministers, the European Council President and the WHO Director-General, mainly as a consequence of the governance gaps and inefficiencies that have been laid bare during the international response to the COVID-19 pandemic.¹ In December 2021, during a special session of the World Health Assembly (WHA), WHO member States agreed to start negotiations on the new instrument and establish an intergovernmental negotiating body (INB) for the purpose, with the outcome expected to be presented at the 77th WHA in 2024.²

One of the most important thematic clusters that would likely be considered by the INB for a pandemic treaty concerns the adoption of rules governing the cross-border sharing of pathogens (ie, organisms causing disease to their host, whether viruses, bacteria, or eukaryotic organisms) with pandemic potential, as well as the distribution of the benefits arising from their utilisation in cross-border research and development activities.³ In theory, the aim of these rules would be to strengthen public health surveillance, preparedness, and response by facilitating the international sharing of pathogens and ensuring that any monetary or non-monetary benefits (eg, vaccines, drugs, licensing agreements on favourable terms) are shared with the Party originally providing the samples (or the wider international community, according to each country’s public health risk and need).

In practice, however, there are likely to be significant interactions between any provision on pathogen sharing under a potential pandemic treaty and other existing international instruments that are already applicable to specific pathogens, or to genetic resources more generally. It cannot be excluded that some of these interactions may result in trade-offs, particularly as the objectives and approaches adopted by the relevant instruments may not be entirely compatible. For example, the public health interest towards enabling rapid access to biological samples for surveillance, early warning, and drug development purposes may at times conflict with the necessity of ensuring that such access is granted on conditions that are previously and mutually agreed with the provider.

This paper focuses on the interactions that may arise between the proposed pandemic treaty, the 2010 Nagoya Protocol⁴ to the Convention on Biological Diversity (CBD),⁵ and the Pandemic Influenza

¹ See for example ‘EU Supports Start of WHO Process for Establishment of Pandemic Treaty: Council Decision’ (*consilium.europa.eu*, 20 May 2021) <<https://www.consilium.europa.eu/en/press/press-releases/2021/05/20/eu-supports-start-of-who-process-for-establishment-of-pandemic-treaty-council-decision/>> accessed 2 November 2021; and ‘WHO Director-General’s Remarks at the Press Conference with President of the European Council to Discuss the Proposal for an International Pandemic Treaty’ (*who.int*, 30 March 2021) < <https://www.who.int/director-general/speeches/detail/who-director-general-s-remarks-at-the-press-conference-with-president-of-the-european-council-to-discuss-the-proposal-for-an-international-pandemic-treaty>> accessed 20 November 2021.

² World Health Assembly (WHA) Decision SSA2(5) ‘The World Together: Establishment of an Intergovernmental Negotiating Body to Strengthen Pandemic Prevention, Preparedness and Response (1 December 2021) Doc WHA74(16).

³ The need for a new multilateral instrument encompassing provisions relating to “the rapid and timely sharing of pathogens, specimens and genome sequence information for surveillance and the public health response, including for the development of effective countermeasures,” was for example endorsed in the 2021 Report of the Review Committee on the Functioning of the International Health Regulations (2005) During the COVID-19 Response. See ‘WHO’s Work in Health Emergencies. Strengthening Preparedness for Health Emergencies: Implementation of the International Health Regulations (2005)’ (5 May 2021) WHA Doc A74/9 Add.1, 16.

⁴ Nagoya Protocol to the Convention on Biological Diversity, 29 October 2010, UN Doc UNEP/CBD/COP/DEC/X/1.

⁵ Convention on Biological Diversity, 5 June 1992, 170 UNTS 79.

Preparedness Framework (PIP Framework) adopted by the WHO in 2011.⁶ The Nagoya Protocol represents the main multilateral agreement governing access to genetic resources and benefit-sharing (ABS), and its potential implications for public health have been widely discussed in recent years. For its part, although it only applies to influenza viruses with pandemic potential, the PIP Framework is widely recognised as a best practice for international pathogen- and benefit-sharing, and its likely influence on any new system of ABS under a pandemic treaty cannot be overstated.⁷ Analysing the interface between these instruments is therefore important for avoiding the development of conflicts of norms at the level of international and domestic law alike, which could undermine the coherent interpretation and application of the new treaty.

The paper is structured as follows. First, the paper briefly summarises the main issues relating to the current regulation of pathogen-sharing in international law, illustrating the relevant provisions of the Nagoya Protocol, the 2005 International Health Regulations (IHRs),⁸ and the PIP Framework. Secondly, the paper discusses the synergies and tensions that might emerge in the current international legal framework for ABS during the negotiation of a pandemic treaty. Finally, the paper provides a conclusion which briefly summarises the options that the negotiators of such a pandemic treaty might wish to consider, in order to address these synergies and tensions.

For the sake of clarity, it should be noted that the question of which legal form the future instrument may take is still unresolved, as it will be decided by the INB itself during its deliberations. According to the WHO constitution, the options could for example include an international convention or agreement (article 19), a specific set of WHO regulations (article 21), or a non-binding recommendation (article 23) – all of which hold a different legal status under international law.⁹ However, because the expression ‘pandemic treaty’ has been commonly used in the lead-up to the WHA’s Special Session, the present paper will adopt this terminology to refer to the proposed instrument in a generic and non-technical way.

2. What are the main issues in the existing international legal framework?

2.1. The unsettled status of pathogen-sharing under the CBD and its Nagoya Protocol

For most of the 20th century, the notion of pathogen-sharing was undifferentiated from other practices that involved the open access to non-pathogenic biological resources for purposes of research, industrial application, or commercial use,¹⁰ and it largely took place in a legal vacuum. Pathogen-sharing practices could assume a variety of forms, from informal research collaborations involving

⁶ WHO, *Pandemic Influenza Preparedness (PIP) Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* (2nd edition, World Health Organization 2021).

⁷ See for example Anne Huvos, Steven A Salomon and Claudia Nannini, ‘The Pandemic Influenza Preparedness Framework as an Access and Benefit Sharing Mechanism’ in in Sam F Halabi and Rebecca Katz (eds) *Viral Sovereignty and Technology Transfer* (Cambridge University Press 2020).

⁸ WHO, *International Health Regulations 2015* (3rd edition, World Health Organization 2016).

⁹ Constitution of the World Health Organization, 22 July 1946, arts 19-23. Available in WHO, *Basic Documents* (48th edition, World Health Organization 2014).

¹⁰ Michelle Rourke, ‘The History of Accessing and Sharing Human Pathogens for Public Health Research’ in Halabi and Katz (n 7).

scientists of different countries to instances in which access to pathogen samples was obtained through field work conducted by foreign researchers without the permission of national authorities.

This landscape started to change during the 1980s, as international concerns progressively grew about the lack of regulation of bioprospecting activities¹¹ conducted in biodiversity-rich countries by users based in other countries, often based in the Global North. The recognition that provider countries enjoyed some form of property rights over their own biological resources began to be considered as way of addressing the social justice and equity issues raised by the appropriation of such resources by powerful external actors. At the same time, it also came to be seen by governments in the Global North as a compromise solution that was necessary to ensure that Global South countries could commit to safeguarding their species and ecosystems, under the assumption that the economic benefits flowing back to these countries could be reinvested in the conservation sector.¹²

These debates later led to the 1992 adoption of the CBD, which codified three broad objectives (namely, the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources)¹³ and endorsed the principle that States enjoy sovereign rights over the biological resources located in areas under their national jurisdiction.¹⁴ Because the genetic material of pathogenic organisms could be subsumed under the definition of genetic resources contained in article 2 of the CBD, which encompasses all “genetic material of actual or potential value” of “plant, animal, microbial or other origin,”¹⁵ the relevant provisions of the Convention became potentially applicable to pathogens. Particularly important, from this perspective, was article 15, which despite calling on the Parties to “endeavour to create the conditions to facilitate access to genetic resources for environmentally sound uses,” ultimately affirmed national governments’ authority to determine access, pursuant to their domestic legislation.¹⁶ In addition, article 15 provided that such access should be based on the prior informed consent (PIC) of the provider country, and that both access and benefit-sharing should be subjected to the definition of mutually agreed terms (MAT) between the involved parties.

In order to further support the achievement of the objective of fair and equitable benefit-sharing under the CBD, the Convention’s COP subsequently adopted the Nagoya Protocol, which as of today has been ratified by 132 Parties.¹⁷ Building on the approach that was already incorporated in article 15 of the CBD, the Nagoya Protocol reiterated that access to genetic resources should be based on the principle of PIC, and subjected to the domestic ABS legislation and other regulatory requirements of the provider country.¹⁸ Furthermore, the Protocol restated that the terms of this access, including those

¹¹ The Collins Dictionary defines bioprospecting as “searching for plant or animal species for use as a source of commercially exploitable products, such as medicinal drugs.” For a discussion of bioprospecting in relation to its implications for the conservation and sustainable use of biodiversity, see for example Shivcham S Dhillon and others, ‘Bioprospecting: Effects on Environment and Development’ (2002) 31(6) *Ambio* 491.

¹² See for example Fiona McConnell, *The Biodiversity Convention: A Negotiating History* (Kluwer Law International 1996); and Abdulqawi A Yusuf, ‘International Law and Sustainable Development: The Convention on Biological Diversity’ (1995) 2(1) *African Yearbook of International Law* 109.

¹³ Convention on Biological Diversity (n 5) art 1.

¹⁴ *ibid*, art 3.

¹⁵ *ibid*, art 2.

¹⁶ *ibid*, art 15.1-2.

¹⁷ Nagoya Protocol (n 4) art 1.

¹⁸ *ibid*, art 6.1.

relating to the sharing of the benefits that may arise from it, must be mutually agreed by the Parties – and if necessary, by the indigenous and local communities who might have established rights over the relevant genetic resources.¹⁹

Although it is relatively uncontroversial that, much like in the CBD, pathogens represent genetic resources for the purposes of the Nagoya Protocol, this instrument did not introduce additional provisions to recognise their specific characteristics, nor did it explicitly clarify whether Parties, in adopting (or amending) their domestic ABS laws, should include pathogens within their scope. At the same time, in article 8(b), the Protocol acknowledges that legal frameworks for ABS may interact with the response to “present or imminent emergencies that threaten or damage human, animal, or plant health”, and that in this case Parties should take into consideration the need for “expeditious access to genetic resources and expeditious fair and equitable sharing of benefits,” including treatments.²⁰ In its Annex, the Protocol also lays out a non-exhaustive list of monetary and non-monetary benefits that could form part of bilateral ABS agreements, many of which could be articulated from a public health perspective, such as, *inter alia*:

- royalties and licence fees in case of commercialisation;
- sharing of research and development results;
- collaboration in scientific research and development programmes and product development; and
- strengthening capacities for technology transfer.²¹

Moreover, the Protocol implicitly recognises the possibility that specialised international instruments (SIIs) are negotiated outside of the CBD’s regime to regulate ABS practices relating to specific subsets of genetic resources, thus potentially including pathogens (article 4). Whereas article 4 as a whole does not intend to create a normative hierarchy between the Protocol and other international instruments, article 4.2 explicitly requires that any SII entered into by the Protocol’s Parties “is supportive to and does not run counter to the objectives of” the CBD and the Protocol itself (namely, the conservation of biological diversity, the sustainable use of its components, and fair and equitable benefit-sharing).²² If an SII is consistent with these objectives, and does not run counter to them, the Protocol does not apply to the Parties to the SII and with respect to the specific genetic resources covered by it (article 4.4).²³

Although initially slow, the uptake (or updating) of national ABS laws seeking to implement the provisions of the Nagoya Protocol has grown in recent years.²⁴ Inevitably, however, the ambiguous scope of the Protocol on issues of pathogen-sharing has percolated on these domestic measures. For example, the responses provided to a 2021 survey conducted on behalf of the WHO Director-General illustrate that while some countries have included pathogens in their national ABS frameworks, many

¹⁹ *ibid*, art 5.1 and 5.2.

²⁰ *ibid*, art 8(b). In its preamble, the Protocol explicitly mentions the 2005 IHRs and notes “the importance of ensuring access to human pathogens for public health preparedness and response purposes.”

²¹ *ibid*, Annex.

²² *ibid*, art 4.2.

²³ *ibid*, art 4.4.

²⁴ ‘Information Provided by Parties to the Nagoya Protocol on the National Implementation of Article 8(b) and other Relevant Provisions of the Protocol’ (24 September 2018) UN Doc CBD/NP/MOP/3/INF/4. See also Nicolas Pauchard, ‘Access and Benefit Sharing under the Convention on Biological Diversity and Its Protocol: What Can Some Numbers Tell Us about the Effectiveness of the Regulatory Regime?’ (2017) 6 *Resources* 1 (2017). To access the CBD clearing-house on ABS, see ‘Access and Benefit-Sharing Clearing-House’ < <https://absch.cbd.int/en/> > accessed 23 November 2021.

others have not. This has reportedly created discrepancies in the application of the Protocol and potentially discouraged scientific cooperation, owing to the high transaction costs of concluding bilateral ABS agreement and the increased complexity and fragmentation of the system.²⁵ Many of the respondents lamented the lack of an “harmonized system across countries”, “unclear domestic guidelines”, and extensive delays in sample sharing caused by uncertainty over the implementation and requirements of the Nagoya Protocol.²⁶ In particular, such conclusions quoted extensively from a separate WHO report on influenza virus sharing, which in 2020 had found that the sharing of influenza virus samples within and outside the GISRS was being increasingly impacted by national ABS requirements introduced in the implementation of the Nagoya Protocol.²⁷ The delays in pathogen-sharing, which were caused by the need for laboratories and/or vaccine producers to negotiate bilateral material transfer agreements for samples of seasonal influenza viruses or associated candidate vaccine viruses, often took several months to resolve.²⁸

2.2. The gaps in the regulation of pathogen-sharing under WHO instruments

Even before the adoption of the Nagoya Protocol, it had become clear that the CBD’s approach to ABS could represent a hindrance to the timely sharing of pathogens for purposes of public health research and development. However, although the idea of international collaboration to detect and respond to public health events emerged as an important component of the 2005 IHRs, the sharing of biological samples for global health research purposes was only indirectly covered by some of its provisions, including those relating to notification and information-sharing (articles 6-7), collaboration and assistance (article 44), and transport and handling of substances and materials (article 46).²⁹

For influenza viruses with pandemic potential, a specific framework was therefore adopted by the WHO in 2011 to update the long-standing practices and processes of its network of influenza public health laboratories, known as the Global Influenza Surveillance and Response System (GISRS).³⁰ The PIP Framework recognised that the benefits arising from pathogen-sharing constitute “equally important parts of the collective action for global public health,” and thus identified a principle of ‘equal footing’ in the sharing of pathogens and benefits, that WHO member States committed to.³¹ Although the PIP Framework itself is a non-binding instrument from an international law perspective, it seeks to regulate

²⁵ ‘The Public Health Implications of Implementation of the Nagoya Protocol. Report by the Director-General’ (6 January 2021) Doc EB/148/21, para 18. See also Anthony Rizk and others, ‘Governing Pathogens and Benefit-Sharing (PBS)’ (2020) Global Health Centre Working Paper No 23 < https://www.graduateinstitute.ch/sites/internet/files/2020-12/GHC_WorkingPaper_No_23_Web.pdf> accessed 10 November 2021.

²⁶ ‘The Public Health Implications of Implementation of the Nagoya Protocol’, *ibid*, paras 27-29 and 34.

²⁷ ‘Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. Decision WHA72(12), paragraph 1(a). Report on Influenza Virus Sharing. Report by the Director-General’ (February 2020) paras 15 and 19 < https://cdn.who.int/media/docs/default-source/pip-framework/governance/wha72-12-op1a-report-edited_en1a2d0386-152a-4bbd-b801-9ec5d71e8930.pdf?sfvrsn=80f75c02_16> accessed 20 November 2021.

²⁸ *ibid*, 20-22.

²⁹ WHO (n 8) arts 6-7, 44 and 46. Even when discounting the compliance and implementation issues which continue to surround the IHRs, this shortcoming has recently been flagged by the Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response. See ‘WHO’s Work in Health Emergencies. Strengthening Preparedness for Health Emergencies: Implementation of the International Health Regulations (2005)’ (5 May 2021) WHA Doc A74/9 Add.1, paras 116-117 and 148-149.

³⁰ ‘Global Influenza Surveillance and Response System (GISRS)’ (*who.int*, nd) < <https://www.who.int/initiatives/global-influenza-surveillance-and-response-system>> accessed 20 November 2021.

³¹ WHO (n 6) sections 1(3) and 2.

the sharing of samples of influenza viruses with pandemic potential ('PIP Biological Materials') through two types of 'standard material transfer agreements' (SMTA 1 and SMTA 2) which in principle cover all the transfers of biological materials involving the GISRS.³² While the SMTA 1 is only applicable to the sharing of samples between laboratories affiliated with the GISRS, SMTAs 2 are concluded between the WHO (acting as the framework's trustee) and any institution outside the GISRS, including private actors who seek to utilise genetic resources for commercial purposes.³³ The SMTA 2 contains a specific benefit-sharing clause, pursuant to which the recipient institution is obliged to select among a series of different benefit-sharing options - ranging from a commitment to donate at least 10 percent of pandemic vaccine production to the WHO to the provision of support to developing countries for the strengthening of their influenza laboratory and surveillance capacity.³⁴

Most recently, the WHO has also launched a non-commercial, pilot testing phase for a 'WHO BioHub System for Preparedness and Response to Epidemics and Pandemics' (WHO BioHub) that aims to apply the logics of the GISRS to all emerging pathogens that may cause a risk to public health security.³⁵ For example, the WHO BioHub mimics the PIP Framework's use of two types of SMTAs to standardise the terms of pathogen-sharing – one applicable to the contributions of biological samples into the BioHub system of laboratories and one regulating their onward transfer outside of the system.³⁶ At the moment, however, the WHO BioHub remains a voluntary initiative, and how it will be incorporated in a wider international legal framework for ABS (or indeed, in a pandemic treaty itself) remains to be seen.

2.3. The applicability of the international ABS framework to genetic sequence data

Finally, the problems surrounding the 'conventional' sharing of microbial samples are by now complemented by those relating to the sharing of their genetic sequence data (GSD),³⁷ which is increasingly generated by laboratories using digital sequencing technologies. GSD can also be shared through bilateral arrangements, but it is more often uploaded to online databases with varying conditions for data access (most notably, the GISAID³⁸ and GenBank³⁹ platforms). From the

³² *ibid*, Annexes 1-2.

³³ More specifically, the SMTA 2 lists a number of potential recipients 'PIP Biological Materials', including "manufacturers of influenza vaccines, diagnostics, pharmaceuticals and other products relevant to pandemic preparedness and response, as well as biotechnology firms, research institutions and academic institutions". See *ibid*, Annex 2, fn 1.

³⁴ *ibid*, Annex 2, art 4.

³⁵ Background documents for the WHO BioHub initiative refer specifically to the notion of 'biological materials with epidemic or pandemic potential' (BMEPPs). These include "clinical samples, specimens, isolates, and cultures –either original or processed of a novel pathogen." See WHO, 'The WHO BioHub' (April 2021) Draft Concept Note 1.0, 2 < [https://cdn.who.int/media/docs/default-source/2021-dha-docs/210617_whobiohubconceptnote_brochure-\(1\).pdf?sfvrsn=5e5a06f3_1&download=true](https://cdn.who.int/media/docs/default-source/2021-dha-docs/210617_whobiohubconceptnote_brochure-(1).pdf?sfvrsn=5e5a06f3_1&download=true) > accessed 10 November 2021.

³⁶ WHO, 'Pilot Testing - WHO BioHub System' (2021) < https://cdn.who.int/media/docs/default-source/campaigns-and-initiatives/biohub/20210923_who-biohub-pilot-testing-package-vfinal-for-webposting.pdf?sfvrsn=313e13b7_4 > accessed 10 November 2021. At present, the only laboratory designated for the WHO BioHub's pilot testing phase is the so-called WHO BioHub Facility in Spiez, Switzerland.

³⁷ Genetic sequences are defined in the PIP Framework as "the order of nucleotides found in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus." See WHO (n 6) section 4.2.

³⁸ 'About Us' (*gisaid.org*, n.d.) < <https://www.gisaid.org/about-us/mission/> > accessed 19 November 2021.

perspective of benefit-sharing, the question of how to compensate countries for making the GSD of a pathogen accessible is particularly controversial, in that in many cases the generation of benefits from such data depends on the value added through subsequent research and development efforts.⁴⁰ At the same time, a system that does not guarantee some form of assistance or international solidarity to countries that are willing to openly share GSD is likely to create significant disincentives to the open sharing of information during a public health emergency, as demonstrated by the recent travel restrictions enacted by many governments in response to South Africa's detection of the so-called Omicron variant of the SARS-CoV-2 virus.⁴¹

The Nagoya Protocol does not explicitly deal with the sharing of GSD, in spite of the fact that digital sequencing technologies and synthetic biology have by now transformed traditional bioprospecting practices – often allowing researchers to access and share genetic information “without the original providers aware of or involved in this process.”⁴² In recent years, the COP to the CBD has thus decided to engage with GSD issues in order to fill what has widely been described as a legal vacuum, including by setting up an Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources (AHTEG) at COP-13 in 2016.⁴³ Whereas this science-policy process is presently ongoing, including with respect to the role of digital sequence information (or DSI) in the post-2020 Global Biodiversity Framework,⁴⁴ the most recent COP decision on the topic was forced to acknowledge the “divergence of views” which still exists among the Parties regarding “benefit-sharing from the use of digital sequence information on genetic resources”.⁴⁵

In the context of the WHO, it has been suggested that article 6 of the 2005 IHRs could be broadly interpreted as encouraging Parties to share GSD as a form of “relevant public health information” following the notification of a public health emergency of international concern, although at present no official position has been taken on the matter.⁴⁶ For its part, the PIP Framework limits itself to recommending that GSD and related analyses of such data be “shared in a rapid, timely and systematic manner with the originating laboratory and among WHO GISRS laboratories.”⁴⁷ Implicitly acknowledging the gap, the recent technical consultations convened by the WHO have hinted at the

³⁹ GenBank is a database maintained by the United States' National Center for Biotechnology Information, which is part of the broader International Nucleotide Sequence Database Collaboration, or INSDC. See ‘GenBank Overview’ ([ncbi.nlm.nih.gov](https://www.ncbi.nlm.nih.gov/genbank/), n.d.) < <https://www.ncbi.nlm.nih.gov/genbank/> > accessed 11 January 2022.

⁴⁰ It has been noted that benefit-sharing obligations “may no longer apply” to GSD “when there is a break in the legal chain between the source of the physical genetic resources and the application of information derived from those physical resources.” See Charles Lawson, Michelle Rourke and Fran Humphries, ‘Information as the Latest Site of Conflict in the Ongoing Contests about Access to and Sharing the Benefits from Exploiting Genetic Resources’ (2020) 10(1) *Queen Mary Journal of Intellectual Property* 7, 20.

⁴¹ ‘Covid: South Africa ‘Punished’ for Detecting New Omicron Variant’ (*BBC News*, 28 November 2021) <<https://www.bbc.com/news/world-59442129>> accessed 29 November 2021.

⁴² ‘Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context Of the Convention on Biological Diversity and the Nagoya Protocol. Note by the Executive Secretary’ (12 January 2018) UN Doc CBD/DSI/AHTEG/2018/1/3.

⁴³ CBD COP Decision XIII/16 ‘Digital Sequence Information on Genetic Resources’ (16 December 2016) UN Doc CBD/COP/DEC/XIII/16, para 4.

⁴⁴ DSI is the label that the COP to the CBD uses to discuss issues relating to genetic sequence data. For the purpose of this paper, GSD and DSI can thus be considered as synonyms.

⁴⁵ CBD COP Decision 14/20 ‘Digital Sequence Information on Genetic Resources’ (30 November 2018) UN Doc CBD/COP/DEC/14/20, para 6.

⁴⁶ See for example Lawrence O Gostin and Rebecca Katz, ‘The International Health Regulations: The Governing Framework for Global Health Security’ (2016) 94(2) *The Milbank Quarterly* 264, 289.

⁴⁷ *ibid*, section 5.2.1.

future inclusion of provisions on GSD in the BioHub initiative,⁴⁸ but any conclusion on the shape this system may take over the coming months appears premature.

3. NAVIGATING THE SYNERGIES AND TENSIONS BETWEEN THE NAGOYA PROTOCOL, THE PIP FRAMEWORK, AND A PANDEMIC TREATY

The previous section illustrates how the international legal framework for pathogen-sharing remains patchy and fundamentally fragmented. In the absence of a coherent, multilateral body of rules, most pathogen- or GSD-sharing activities (with the above-mentioned exception of influenza viruses with pandemic potential) continue to primarily take place through informal bilateral mechanisms, transnational research networks, and other public-private initiatives, as illustrated by the central role played by the not-for-profit GISAID platform in the international sharing of SARS-CoV-2 GSD during the COVID-19 pandemic.⁴⁹ The lack of a globally-agreed legal framework results in a problematic lack of monitoring and transparency over the current practices of, and conditions attached to, pathogen-sharing. In addition, in both national legislation and pathogen-sharing agreements, different pathogens may be subjected to different regulatory frameworks, depending on the level of perceived threat to public health. Lastly, although platforms such as the GISAID are widely praised for facilitating the timely sharing of data among researchers and ensuring the respect of data access conditions such as the acknowledgment of the original data sources, they do not include specific benefit-sharing obligations among their terms of use. This is potentially in contrast with the idea, vigorously promoted by the WHO during the pandemic, that the medical countermeasures developed through pathogen-sharing should represent global public goods.⁵⁰

Although a full discussion of the legal and governance challenges created by the current international legal framework for pathogen-sharing lies beyond the scope of this paper, the likely inclusion of ABS provisions in the negotiations on a pandemic treaty requires – at a minimum – an understanding of how such an instrument could interact with the existing ABS framework under the Nagoya Protocol, as well as with the provisions of the PIP Framework.

3.1. Reconciling ABS in biodiversity and public health

A first challenge to resolve, in the interaction between the various instruments that currently govern pathogen- and benefit-sharing, is represented by what has been effectively summarised as the ‘bilateral’ and ‘transactional’ approach of the Nagoya Protocol, which potentially stands in contract with

⁴⁸ See WHO, ‘WHO BioHub System Technical Consultation Sessions. Session Two: Genetic Sequence Data’ (November 2021) < https://cdn.who.int/media/docs/default-source/campaigns-and-initiatives/biohub/who_biohub_system_gsd-theme-background-document.pdf?sfvrsn=baf67aec_4 > accessed 15 November 2021.

⁴⁹ Amy Maxmen, ‘One Million Coronavirus Sequences: Popular Genome Site Hits Mega Milestone’ (2021) 593 *Nature* 21; and Shruti Khare and others, ‘GISAID’s Role in Pandemic Response’ (2021) 3(49) *China CDC Weekly* 1049.

⁵⁰ See for example ‘WHO Director-General’s Closing Remarks at the World Health Assembly (*who.int*, 13 November 2020) < <https://www.who.int/director-general/speeches/detail/who-director-general-s-closing-remarks-at-the-world-health-assembly--13-november-2020> > accessed 22 November 2021.

the multilateral approach that transpires from both the PIP Framework and the early discussions on a pandemic treaty.⁵¹

As previously mentioned, ABS rules under the CBD and its Nagoya Protocol originate from widespread concerns about the risk that bioprospecting activities in biodiversity-rich countries are conducted without the PIC of such countries and their populations, thus ignoring the general principle of permanent sovereignty over biological resources which is enshrined in article 3 of the CBD. This, in turn, has resulted to access to genetic resources being increasingly subjected to ‘proprietary claims’ on the part of governments – a concept that has also been explicitly extended to pathogens and even to therapeutics developed from such pathogens,⁵² leading some authors to speak of ‘viral sovereignty’.⁵³ By contrast, a public health-driven approach to ABS by necessity emphasises the need for unhindered sharing practices and transparency over cross-border transfers of biological materials, out of recognition that both pathogen samples and the benefits arising from public health research (eg, vaccines, diagnostics, therapeutics) should constitute global public goods. A growing body of literature has emerged in recent years to discuss the tensions that the bilateral, sovereignty-based approach of the Nagoya Protocol has introduced in public health research, mirroring the findings of the WHO’s reports on the topic.⁵⁴

In practice, this does not mean that PIC, the use of MATs, or benefit-sharing provisions become less important in public health. However, all these issues are more likely to be framed from a multilateral perspective, as exemplified by the PIP Framework. In this case, the requirements of PIC and MATs are not negotiated bilaterally for influenza viruses with pandemic potential, but are rather determined *ex-ante* by the provisions of the Framework and its SMTAs. As such, they bind all users who become affiliated with the GISRS, as well as those who wish to negotiate a transfer of PIP Biological Materials outside that system. Similarly, the PIP Framework sets up a common benefit-sharing system which both (a) recognises that public health benefits arising from research on influenza viruses with pandemic potential should be available to all countries; and (b) prioritises the allocation of some important benefits (eg, vaccines and antiviral medicines) to developing countries “according to public health risk and need” (that is, regardless of whether such countries are the original providers of the biological material). In addition, the range of benefit-sharing options that a non-GISRS entity can commit to when concluding an SMTA 2 is also already contained in the standard agreement. As for the common benefit-sharing system, these options again put an emphasis on the role of the WHO as the trustee of

⁵¹ See for example Jerome H Reichman, Paul F Uhler and Tom Dedeurwaerdere, *Governing Digitally Integrated Genetic Resources, Data, and Literature* (Cambridge University Press 2016) 96; and ‘Gian Luca Burci and Frederic Perron-Welch, ‘International Sharing of Human Pathogens to Promote Global Health Security – Still a Work in Progress’ (2021) 25(13) *ASIL Insights* 1 <<http://www.asil.org/insights/volume/25/issue/13>> accessed 20 November 2021.

⁵² It is the well-known case of Indonesia’s refusal to share H5N1 avian flu samples with the GISRS in 2007, which triggered the negotiation of the PIP Framework. See Sam F Halabi and Rebecca Katz, ‘Introduction - Viral Sovereignty, Technology Transfer, and the Changing Global System for Sharing Pathogens for Public Health Research’ in Halabi and Katz (n 7) 10-11 and 16.

⁵³ *ibid.* See also Sam F Halabi, ‘Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research’ (2019) 28 *Annals of Health Law* 101.

⁵⁴ See for example Reichman, Uhler and Dedeurwaerdere (n 51); and Evanson C Kamau and Gerd Winter (eds) *Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law* (Routledge 2013).

the system, and also provide for the possibility of granting licenses to manufacturers in developing countries on a royalty-free, or otherwise ‘fair and reasonable’ basis.⁵⁵

While the two approaches might seem difficult to reconcile in principle, article 4.4 of the Nagoya Protocol leaves space for other international instruments to articulate a health-specific version of ABS provisions. As discussed in section 2.1, this article exempts Nagoya Parties from the provisions of the Protocol with respect to specific genetic resources which may be covered by an SII, provided that such an instrument is consistent with, and does not run counter to, the objectives of conservation, sustainable use of biodiversity, and fair and equitable benefit-sharing. From this perspective, it should be noted that while the approach of the Nagoya Protocol to benefit-sharing is mostly bilateral, this does not mean that the Protocol’s notion of benefit-sharing as such should always be seen as bilateral too. In fact, in the case of public health emergencies, the notion of ‘benefit’ could *de facto* be broadened to include those non-monetary benefits that do not necessarily accrue to the original provider of genetic resources, but rather improve the capacity of the international community as a whole to prevent and respond to epidemics and pandemics.⁵⁶ This is implicitly recognised by other provisions of the Protocol, and most notably by article 10, which envisions the possibility of a global multilateral benefit-sharing mechanism for all those genetic resources “that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent”.⁵⁷

In addition, while article 8(b) of the Protocol only applies to situations of “present or imminent emergencies that threaten [...] health, as determined nationally or internationally,” in practice it may be seen as allowing countries to create differential regulatory regimes for the sharing of pathogens with epidemic or pandemic potential, either as part of their general ABS legislation or when derogating from it – for example, in order to implement the obligations of a future pandemic treaty.

3.2. Can the PIP Framework and a new pandemic treaty be considered as SII under article 4.4 of the Nagoya Protocol?

In recent years, the WHO’s own assessments have reinforced the idea that the Nagoya Protocol and a new SII applying to pathogen-sharing would not be mutually incompatible. Already in 2016, in a study conducted by the WHO Secretariat in response to a request made by the Executive Board, it was noted that:

“the implementation of the Nagoya Protocol is an opportunity to develop an agreement or framework for the sharing of pathogens that affect human health and the equitable distribution of benefits arising from their use.”⁵⁸

⁵⁵ It has been argued that the multilateral approach to ABS enshrined in the PIP Framework is not necessarily less transactional than the bilateral approach of the Nagoya Protocol, as it still treats genetic resources as ‘tradable commodities’ or ‘bargaining chips’ used to secure some monetary or non-monetary benefit. See Mark Eccleston-Turner and Michelle Rourke, ‘Arguments Against the Inequitable Distribution of Vaccines Using the Access and Benefit Sharing Transaction’ (2021) 70(4) *International & Comparative Law Quarterly* 825.

⁵⁶ This interpretation is supported by, *inter alia*, the wording of article 8(b) of the Nagoya Protocol, and it has also been voiced by some of the respondents to a 2016 survey of the WHO Secretariat. See WHO Secretariat, ‘Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications. Study by the Secretariat’ (2016) 23 < https://www.who.int/influenza/Nagoya_Full_Study_English.pdf > accessed 10 November 2021.

⁵⁷ Nagoya Protocol (n 4) art 10.

⁵⁸ WHO Secretariat (n 56) 25.

The implicit assumption is that such an instrument should be recognised as an SII for the purposes of article 4.4 of the Nagoya Protocol, given its likely compatibility with the requirements set therein. The same study – which involved a survey of WHO member States and other relevant stakeholders – found that most respondents believed the PIP Framework to be consistent with article 4.4 of the Nagoya Protocol, thus suggesting the opportunity to harmonise the current system for pathogen- and benefit-sharing by modelling any new instrument on this topic after the PIP Framework. This view was also backed by the IHR Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, which recommended the use of the PIP framework or other existing agreements as a template for creating new agreements applicable to new infectious agents.⁵⁹

Even if the visions of benefit-sharing articulated in the Nagoya Protocol and in public health are not incompatible, however, the current fragmentation of the ABS regime still requires an effort to address the potential for conflicts of norms at the level of international law, as well to delimit the scope of application of the respective instruments. This is because the legal uncertainty that could result from the adoption of a pandemic treaty could be a significant breeding ground for the development of further inconsistencies at the level of domestic legislation, compounding the implementation challenges that have already been highlighted with respect to the PIP Framework and pathogen-sharing practices more broadly.

With respect to the issue of conflicting norms, no formal normative hierarchy exists between the Nagoya Protocol and other international agreements (article 4.1). and the Protocol also states that its obligations should be implemented in a mutually supportive manner with those instruments that are relevant for it (article 4.3). In addition, although it is unclear whether non-binding instruments such as the PIP Framework qualify for the purposes of these provisions, article 4.3 explicitly recognises that

“Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.”⁶⁰

Nevertheless, the potential overlap between ABS provisions under the Nagoya Protocol and those enacted in the implementation of instruments such as the PIP Framework or the proposed pandemic treaty by itself can create legal uncertainty – as demonstrated by some of the experiences shared in the 2021 study of the WHO Director-General.⁶¹ This is why a definition of what constitutes an SII for the purposes of article 4.4 of the Nagoya Protocol becomes particularly important, as it may help national decision-makers and users of pathogen samples understand in which cases it is only the SII, and not the Protocol, that should regulate the process of pathogen- and benefit-sharing.

The question has been debated for some time, particularly as article 4.4 does not create a decision-making procedure by which an SII can be recognised, and is rather meant as a guidance for countries in the adoption of domestic ABS legislation. Some instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)⁶² adopted by the Conference of the Food and Agriculture Organization of the United Nations (FAO) in 2001 and the PIP Framework itself, have

⁵⁹ ‘Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response. Report by the Director-General’ (13 May 2016) WHA Doc A69/21.

⁶⁰ Nagoya Protocol (n 4) art 4.3.

⁶¹ ‘The Public Health Implications of Implementation of the Nagoya Protocol’ (n 25) para 34.

⁶² International Treaty on Plant Genetic Resources for Food and Agriculture, 3 November 2001, 2400 UNTS 303.

been generally assumed to constitute SII, even though the non-binding nature of the latter has sometimes been considered problematic. The ITPGRFA has been explicitly defined as an SII in the implementing ABS legislation of several Parties to the Nagoya Protocol,⁶³ and the same has been done by the European Union with respect to the PIP Framework.⁶⁴ Some have even suggested that the GISRS as a whole could be considered as an SII, in order to facilitate the sharing of pathogen samples that do not have epidemic or pandemic potential (eg, seasonal influenza viruses, for which the PIP Framework's SMTAs do not apply), although this view remains controversial.⁶⁵

Most recently, however, the Chair of the Subsidiary Body on Implementation (SBI) of the CBD has prepared a draft recommendation containing a set of indicative criteria for the identification of SII under Article 4.4.⁶⁶ Provided that the recommendation is adopted at the next meeting of the SBI (taking place in January 2022 in Geneva) and then endorsed by the COP to the CBD serving as meeting of the Parties to the Nagoya Protocol, WHO member States negotiating a pandemic treaty might have access to an important tool for ensuring the compatibility of the latter with article 4.4 of the Protocol.

First, the draft recommendation considers an SII to be an *intergovernmentally or internationally-agreed* instrument, but not necessarily a binding one.⁶⁷ A pandemic treaty, especially if negotiated as a convention or international agreement (under article 19 of the WHO Constitution) or through a regulation (under article 21 of the WHO Constitution, similar to the 2005 IHRs) would fulfil this criterion. An instrument adopted through a different procedure, for example a recommendation pursuant to article 23 of the WHO Constitution (ie, similar to the PIP Framework), would also qualify. However, the 'soft' nature of a recommendation could potentially create uncertainties regarding the simultaneous applicability of the Nagoya Protocol's ABS requirements, particularly as it would be difficult to identify who the Parties to a non-binding instrument are. From such a standpoint, a legally-binding treaty would make it necessary for its Parties to seek executive or legislative approval to ratification, depending on their domestic procedures. This, in turn, would give the treaty the same legal and political weight of the Nagoya Protocol, especially for those countries that have already ratified the latter. In addition, by requiring the adoption of implementing legislation at the national level, a legally-binding would also force countries to amend or complement their ABS laws to better account for the specificities of pathogen-sharing (something which would also be consistent with the special considerations allowed by article 8(b) of the Nagoya Protocol).⁶⁸

Secondly, the draft recommendation requires an SII to be a *specialised* instrument, meaning that it should apply to either: (a) "a specific set of genetic resources and/or traditional knowledge associated

⁶³ WHO Secretariat (n 56) 24.

⁶⁴ Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014, OJ L 150/59, preambular para 16.

⁶⁵ WHO Secretariat (n 56) 24-25. For a critical view, see 'African Group Comments on the Report on WHA72(12) OP1(a)' <https://cdn.who.int/media/docs/default-source/pip-framework/governance/africanunion_comments_wha7212reports.pdf?sfvrsn=b1c4dea8_3> accessed 21 November 2021.

⁶⁶ 'Specialized International Access and Benefit-Sharing Instruments in the Context of Article 4, Paragraph 4, of the Nagoya Protocol. Draft Recommendation Submitted by the Chair' (10 August 2021) UN Doc CBD/SBI/3/L.6.

⁶⁷ *ibid*, Annex, para 2.

⁶⁸ Given the possibility that the proposed pandemic treaty only applies to pathogens with epidemic or pandemic potential, this solution would not necessarily solve some of the outstanding issues relating to the sharing of viruses that lack such potential, such as seasonal influenza viruses. For these viruses, it has for example been suggested that a specific SMTA should be developed as part of the PIP Framework, in order to exclude them from the application of national ABS laws based on the Nagoya Protocol's requirements.

with genetic resources which would otherwise fall under the scope of the Nagoya Protocol”; or (b) “specific uses of genetic resources and/or traditional knowledge associated with genetic resources, or to specific purposes, which require a differentiated and hence specialized approach”.⁶⁹ By applying to pathogens and/or research and development for purposes of epidemic or pandemic prevention and response, a pandemic treaty could also fulfil this requirement (potentially even more so if its scope was restricted to specific classes of pathogens, or if it laid down a narrow set of criteria for identifying them).

Finally, the draft recommendation considers an SII to be *mutually supportive* with the Nagoya Protocol, including with respect to aspects such as, *inter alia*:

- (a) Consistency with biodiversity conservation and sustainable use objectives;
- (b) Fairness and equity in the sharing of benefits;
- (c) Legal certainty with respect to access to genetic resources or traditional knowledge associated with genetic resources, including, as appropriate, the application of prior informed consent, and to benefit-sharing;
- (d) Full and effective participation of indigenous peoples and local communities concerned;
- (e) Contribution to sustainable development, as reflected in internationally agreed goals;
- (f) Other general principles of law, including good faith, effectiveness and legitimate expectations.⁷⁰

For some of these aspects, particularly those under (e) and (f), the mutual supportiveness of a pandemic treaty with the Nagoya Protocol is likely to be uncontroversial. For (b), the respect of the requirement of fairness and equity in benefit-sharing should be assured, provided the future treaty contains a benefit-sharing system at least comparable to the one contained in the PIP Framework.⁷¹ The fact itself that the new instrument would set up a multilateral system of pathogen- and benefit-sharing would also provide legal certainty for the purposes of (c), for example by addressing the current fragmentation and loopholes of the international legal framework for ABS and by improving the traceability and transparency of current sharing agreements (similarly to what the GISRS and the Influenza Virus Tracking Mechanism, or IVTM, have done under the PIP Framework).⁷² Finally, for (a) and (d), the answer may depend in large part on the wider scope and regulatory approach of the treaty. For example, with respect to (a), such mutual supportiveness may hinge on whether the treaty also incorporates specific ‘One Health’ provisions relating to the sale of live wild animals and to human encroachment in potential hotspots of zoonotic disease emergence.⁷³ In a similar vein, in the context of (d), the need for mutual supportiveness would arguably suggest the introduction of mechanisms of public participation in the treaty’s architecture, and at the very least it would also require some clarity regarding the applicability of the treaty’s provisions to issues that are traditionally regulated under the Nagoya Protocol, such as ‘conventional’ bioprospecting activities conducted in biodiversity-rich

⁶⁹ ‘Draft Recommendation Submitted by the Chair’ (n 66) Annex, para 3.

⁷⁰ *ibid*, Annex, para 4.

⁷¹ Incidentally, it should be noted that equity and fairness have been recently proposed as key principles of the WHO BioHub initiative, thus signalling the attention of the WHO to questions of mutual supportiveness with the existing international legal framework for ABS. See ‘What Are the Guiding Principles of the WHO BioHub System?’ (*who.int*, 2021) <<https://www.who.int/initiatives/who-biohub#principles>> accessed 25 November 2021.

⁷² WHO (n 6) section 5.3. For a discussion of the IVTM’s impact, see Rizk and others (n 25) 25–29.

⁷³ For a similar recommendation, see for example Jorge E Vinuales and others, ‘A Global Pandemic Treaty Should Aim for Deep Prevention’ (2021) 397(10287) 1791–1792.

countries for public health purposes (eg, field work to collect pathogen samples or to harness local knowledge about traditional remedies and substances).

3.3. DELIMITING THE SCOPE OF APPLICATION OF A NEW PANDEMIC TREATY

As mentioned in the previous section, an important question that will likely come into play during discussions on the proposed pandemic treaty relates to its scope of application. With respect to the specific issue of pathogen- and benefit-sharing, the question of 'scope' can be framed in different ways. First, it can refer to the type of pathogens covered by the treaty's provisions and their biohazard level. In addition, it can refer to the treaty's possible applicability to the sharing of GSD, in addition to the physical sharing of pathogen samples. Finally, it can also refer to the temporal scope of the treaty. In other words, would the treaty's ABS provisions be triggered only when there is an international determination of a 'public health emergency of pandemic potential', as some have suggested? Would the applicability of the treaty depend on the identification of an emerging pathogen with epidemic or pandemic potential, to use the 'BMEPP' terminology proposed in the WHO BioHub initiative? Or would the treaty's pathogen-sharing provisions mirror the PIP Framework, and thus apply to all sharing activities relating to the covered pathogens (regardless of what is provided for in other parts of the treaty)?

Obviously, each of these decisions will have an impact on the interface between the proposed pandemic treaty and other relevant instruments, including not only the Nagoya Protocol and PIP Framework but also the various partnerships and platforms that currently support pathogen- and GSD-sharing practices, ranging from the GISAID to the framework that has been developed under the Global Health Security Initiative to facilitate the sharing of non-influenza pathogens between GHSI members.⁷⁴

First and foremost, the question of which pathogens would be covered by a new regime would also determine the relationship between the 2005 IHRs, the PIP Framework and the pandemic treaty itself. The previous sections have already emphasised that a future treaty would likely borrow significantly, in terms of underlying principles and regulatory approach, from the PIP Framework. Given the entrenched structures and procedures of the PIP Framework, however, it seems unclear whether the proposed treaty could go as far as to replace the PIP Framework, for example by developing an overarching regime applicable to all pathogens with epidemic and pandemic potential. Moreover, it has been argued that the PIP Framework's benefit-sharing system is only possible because of the specific characteristics of influenza viruses and the fact that there are both a pre-existing market and a well-established production capacity for influenza vaccines, in contrast to emerging pathogens for which the financing and industrial base would have to be built from scratch.⁷⁵ At the same time, an expansion of the pandemic treaty's scope to include influenza viruses with pandemic potential could occur at a later stage, for example through an amendment or protocol which simply incorporates the Framework in the treaty. This approach would have the advantage of removing one potentially controversial item from the initial negotiations. In addition, provided that the pandemic treaty is negotiated through a standalone process or as a WHO regulation, it would elevate the status of the PIP Framework to that of a legally-

⁷⁴ For a discussion of the GHSI framework, see Maria Julia Marinissen and others, 'Sharing of Biological Samples During Public Health Emergencies' in Halabi and Katz (n 7) 167-168.

⁷⁵ 'Review of the Pandemic Influenza Preparedness Framework. Report by the Director-General' (10 April 2017) WHA Doc A/70/17, Annex, 37.

binding international law instrument, thus mitigating any residual concern about the latter's relationship to the Nagoya Protocol.

Secondly, when it comes to GSD-sharing, the relevance that the practice has assumed in the context of the SARS-CoV-2 virus and the early interest shown by the WHO BioHub initiative towards exploring the issue suggest that there may be a growing momentum for including GSD within the scope of the proposed pandemic treaty. From this perspective, the proposed treaty may represent a significant opportunity to start filling the legal vacuum which continues to surround GSD-sharing in international law as well as shaping the contours of a future regulatory regime for GSD – especially if parallel negotiations on DSI under the CBD will continue to be deadlocked beyond the upcoming COP-15 in Kunming, China. For example, the proposed treaty could solidify the idea the GSD-sharing for public health purposes constitutes a global public good. This approach is being currently integrated in the SMTAs developed by the WHO BioHub initiative, as in these documents the WHO undertakes to, *inter alia*, “upload BMEPP genetic sequence data that it generates, in a timely manner, to one or more publicly accessible genetic sequence databases (e.g. GISAID, INSDC Databases)”.⁷⁶ Relatedly, the future treaty would also have to decide on whether to incorporate the WHO BioHub System in its architecture, transforming what is currently labelled as a voluntary initiative for non-commercial sharing into the non-influenza equivalent of the GISRS, developing a traceability mechanism to mirror the PIP Framework's IVTM, and even preparing SMTAs for commercial sharing practices.

Lastly, the definition of a specific ‘threshold’ that would trigger the applicability of the pathogen-sharing provisions of the proposed pandemic treaty would also present important implications for the interplay between the new regime and the Nagoya Protocol. For example, if multilateral ABS obligations under a pandemic treaty could only arise as a result of an international determination of a public health emergency of epidemic or pandemic potential, national ABS laws implementing the Nagoya Protocol would likely remain applicable to most pathogen-sharing activities not covered by the PIP Framework. By contrast, if negotiators wished to make a new pathogen- and benefit-sharing regime applicable regardless of a formal international determination of a public health emergency, they should advance a clear definition of what biologicals material should be considered as having ‘epidemic or pandemic potential (BMEPP)’ and thus falling under the scope of the proposed treaty's pathogen-sharing system (or assign the WHO the responsibility to do so, based on agreed general principles). For instance, it should be noted that the draft concept notes of the WHO BioHub initiative have been referring to BMEPP to indicate “clinical samples, specimens, isolates, and cultures – either original or processed of a *novel pathogen*.”⁷⁷ A similar approach, however, could be problematic, in that it would exclude several known viruses that have epidemic or pandemic potential from the scope of a future treaty. For some of these viruses, such as Ebola, Zika, or the Middle East respiratory syndrome coronavirus (MERS-CoV), there have already been instances in which the countries affected have refused to share biological samples for public health purposes, including by explicitly referring to the benefit-sharing requirements of the CBD and its Nagoya Protocol.⁷⁸

⁷⁶ WHO (n 36) SMTA 1, art 3.1.3.

⁷⁷ WHO (n 35) fn 1.

⁷⁸ For a discussion, see Halabi and Katz (n 52); and Halabi (n 53).

4. CONCLUSION AND OPTIONS FOR NEGOTIATORS

This paper has not taken a position regarding the desirability of a pandemic treaty over other types of approaches to the regulation of pathogen-sharing in international law. In fact, various alternative options have been proposed over the years, with the aim of improving the coordination between the framework sets forth by the Nagoya Protocol and the needs for a timely sharing of pathogens and benefits during public health emergencies. As noted in the 2016 study of the WHO Secretariat, these options could entail, *inter alia*: (a) the extension of the scope of the PIP Framework to all viruses (ie, beyond influenza viruses) with pandemic potential; (b) the use of the PIP Framework as a model for an entirely new instrument dedicated only to pathogen- and benefit-sharing; and (c) the reliance on the development of supportive domestic legislation – for example through the use of public health exemptions to ‘conventional’ ABS based on article 8(b) of the Nagoya Protocol. In many ways, even the recent WHO BioHub initiative could be implemented through a recommendation of the WHA, thus following the experience of the PIP Framework instead of being incorporated in a pandemic treaty.

What is clear, however, is that once the negotiating process for a pandemic treaty gets under way, this process would represent a unique opportunity to address the current gaps and overlaps in the international legal framework for pathogen-sharing. This paper has suggested that some of the key issues to be overcome by the negotiators, in terms of the treaty’s interaction with the Nagoya Protocol and the PIP Framework, include the following:

- potential tensions between a multilateral approach to benefit-sharing issues, vis-à-vis the bilateral approach of the Nagoya Protocol;
- the nature of the pandemic treaty as an SII for the purposes of article 4.4 of the Nagoya Protocol; and
- the delimitation of the scope of application of the future treaty’s pathogen-sharing provisions.

Inevitably, tackling each of these issues would require more than the solution of a legal question. For example, the sovereignty-based approach of the CBD and the Nagoya Protocol is the result of the complex negotiating histories of these instruments and of the political preferences which shaped them. The interests of many biodiversity-rich countries would probably remain strongly oriented towards maintaining control over their genetic resources, unless the future treaty adequately dealt with these countries’ concerns relating to biopiracy and benefit-sharing. If anything, the current inequities in the global distribution of vaccines against COVID-19 have only aggravated such concerns, and could concur to shape the type of benefits that are sought in exchange for access to pathogen samples and GSD during the negotiations.

In other words, a request for strong commitments to health equity is likely to constitute an important negotiating leverage over the coming months. The demands could entail substantial investments to improve regulatory systems and increase laboratory capacities in provider countries, as well as a functioning multilateral mechanism for the expedited, equitable, and affordable sharing of vaccines, diagnostics, and treatments. For middle-income countries that have strong local production capabilities in the pharmaceuticals sector, access to intellectual property and transfers of technology and processes could also represent desirable forms of benefit-sharing, although such measures would likely

raise the risk of normative conflicts with other international law instruments in the area of intellectual property, such as the World Trade Organization's TRIPS Agreement.⁷⁹

From a legal perspective, the Nagoya Protocol would not pose rigid obstacles to the development of a multilateral benefit-sharing system. However, it would be necessary for negotiators to also consider the draft indicative criteria that are being discussed by the CBD's SBI, in order to avoid any doubt regarding the status of a pandemic treaty as an SII for the purposes of article 4.4 of the Nagoya Protocol.⁸⁰ This would entail, *inter alia*: (i) a preference for a legally-binding instrument which also incorporates the WHO BioHub system in its provisions (to avoid uncertainty as to the status of material transfer agreements under the latter); (ii) a clear delimitation of the pathogens (and GSD-sharing practices) to which the instrument would apply; (iii) the respect of principles of legal certainty, fairness, and equity in the development of access and benefit-sharing procedures; and (iv) a wider treaty architecture which responds to a One Health approach and includes forms of public participation and accountability. In addition, it would be important for the new treaty to explicitly acknowledge article 4.4 of the Nagoya Protocol, for example in its preamble. Furthermore, WHO member States and the WHO itself should promptly share information about the negotiations with the COP to the CBD (serving as the meeting of the Parties to the Nagoya Protocol) and support the adoption of an explicit decision of the latter recognising the pandemic treaty as an SII. Although non-binding, such a decision could represent an important political statement, and it would encourage the Nagoya Protocol's Parties to follow suit. Finally, it is evident that improving the mutual supportiveness of the two regimes would also in large part depend on a commitment by governments to promptly harmonise their domestic ABS legislation in response to the adoption of the new instrument.

By means of conclusion, the delimitation of the scope of the treaty is likely to represent one of the thorniest aspects of the negotiations, both practically and politically. Whereas a narrow framing could help negotiators achieve consensus on a smaller number of items on which there is already some agreement, it would also risk maintaining existing lacunae in the international legal framework for pathogen- and benefit-sharing, and thus reduce the added value of the new instrument. Some examples of such a narrow framing could include, *inter alia*:

- a focus on the sharing of 'novel' pathogens, thus maintaining the status quo ante for viruses such as Ebola, Zika, or MERS-CoV;
- subordinating the application of the treaty's ABS provisions to the international determination of a public health emergency of pandemic potential;
- limiting the treatment of GSD issues to questions of data access (eg, the choice of the databases to which GSD generated from the processing of biological materials is to be uploaded), without addressing broader questions of benefit-sharing arising from the utilisation of GSD; and
- restricting the applicability of pathogen-sharing provisions to non-commercial research and development.

Achieving some consensus on the items listed above could improve the capacity of the international community to respond to a future pandemic, at least when compared to a business-as-usual scenario. However, it would leave many of the key elements of the current ABS framework unaddressed, and it would also maintain some of the tensions introduced by the Nagoya Protocol. For example, linking the

⁷⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) 1869 UNTS 299, Annex 1C.

⁸⁰ This invitation is also explicitly included in the SBI's draft recommendation. See 'Draft Recommendation Submitted by the Chair' (n 66) para 2.

application of the pandemic treaty's ABS provisions to the international determination of a pandemic would not increase legal certainty in pathogen-sharing *before* outbreaks, that is, when it is usually most needed for public health research and surveillance. In other words, failing to leverage the window of opportunity created by the ongoing COVID-19 pandemic for a coordinated restructuring of the international legal framework for pathogen- and benefit-sharing could be problematic, as it might lead to a treaty that is from the outset too limited in scope, and potentially in need of reform.



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