The Future of Pathogen Access and Benefit Sharing under International Law

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The sharing of pathogen samples and their associated genetic sequence data (GSD) is crucial for global pandemic prevention, preparedness and response. It enables global surveillance, risk assessment and the research and development of pandemic-related products. The sharing of related benefits is also seen as key to ensuring more equitable global access to the fruits of science. These issues, collectively known as Pathogen Access and Benefit Sharing (PABS), remain a major point of contention in the ongoing Pandemic Agreement negotiations.

The recent discussions at the Intergovernmental Negotiating Body (INB) concerning draft Art. 12, which deals with the PABS System, have proven challenging. The opportunity for countries to incorporate their preferred language into the revised draft of the negotiating text prepared by the INB Bureau resulted in a complex amalgam of text and brackets within brackets, revealing the persistence of profound disagreements between the delegations. With only a little time remaining until the official May deadline for negotiations, there is a need to consider different legal scenarios that may ensue for PABS with regard to the procedure and form of the instrument.

In this post, I explore potential scenarios regarding the establishment or absence of the new PABS System, and their implications under international law. At the time of writing, the presented scenarios are hypothetical and ultimately dependent on the political will to find international consensus.

Scenario 1: Status quo (no PABS System)

The first scenario examines the legal situation in the absence of the PABS System, either due to the failure to agree on a pandemic agreement, or during the period awaiting its entry into force.

In this scenario, the Pandemic Influenza Preparedness (PIP) Framework would continue to apply to the sharing of Influenza Viruses with Pandemic Potential (IVPP). Under the PIP Framework, countries share influenza samples with the World Health Organization's (WHO) laboratory network (GISRS); in exchange, recipients commit to provide, through WHO, benefits related to their use, which includes annual Partnership Contributions and pandemic-related products. Although the PIP Framework is not a legally binding instrument, it relies on Standard Material Transfer Agreements as contracts that legally bind their parties (including pharmaceutical industry) to the access and benefit sharing commitments. However, the enforceability of such contracts and the dispute resolution clauses contained therein remains to be tested.

The PIP Framework only applies to influenza samples. Without a PABS instrument established through the Pandemic Agreement, the global health community would lack a specialized legal framework for the sharing of other pathogens with pandemic potential and benefits related to their use. The GSD of pathogens, whose use has expanded due to the improvement and lower costs of sequencing technologies and which remains outside the scope of existing legal frameworks, would continue to be shared on digital platforms, such as GISAID and GenBank, subject to their respective policies.

Concurrently, Parties to the Nagoya Protocol to the Convention on Biological Diversity (CBD) see pathogens and related digital sequence information (DSI, a placeholder term which includes GSD) as falling within its remit, potentially requiring case-by-case bilateral negotiation of access and benefit-sharing arrangements based on the principles of Prior

Informed Consent (PIC) and Mutually Agreed Terms (MAT). The Parties to the CBD are also working to develop a multilateral benefit-sharing mechanism for DSI, which could become operational in 2024.

The sharing of pathogens and their GSD would thus not occur in a legal vacuum. However, the absence of a (functional) PABS System could result in higher transaction costs and decreased legal certainty for pathogens with pandemic potential. The Pandemic Agreement negotiators will also have to consider the possibility of pathogen GSD soon falling under the scope of the CBD's multilateral mechanism for DSI. While very much a work in progress, the latter is likely to focus on biodiversity protection and may not be adequately designed to facilitate risk assessment, rapid access to data and development of pandemic-related products, the crucial aspects of global pandemic prevention, preparedness and response.

Scenario 2: The PABS System is established

As part of a treaty

In the second scenario, the PABS System, as part of the Pandemic Agreement, would be adopted as a convention under Art. 19 of the WHO Constitution.

Firstly, the material scope of the PABS System would have to be defined and clarify whether it would apply to pre-determined families of viruses, or, as the revised draft of the negotiating text proclaims, to all known and novel pathogens with pandemic potential (defined by criteria such as transmissibility and/or virulence, and their potential to cause a public health emergency of international concern (PHEIC)). A definitive answer to these concerns will affect the legal relationship between the PABS System and other frameworks in this field. Secondly, the terms of future PABS contracts with pharmaceutical companies would have to be defined, including the scope of benefits and dispute resolution clauses. There is also a practical concern about WHO having to sign contracts with a vast number of pharmaceutical companies and actually being able to enforce their terms (see here for a useful expert commentary on practical concerns with regard to the language proposed by the INB Bureau).

According to the revised draft of the negotiating text, benefits envisaged in PABS contracts would include monetary contributions to the PABS System, capacity strengthening, and real-time contributions of vaccines in an emergency. Transfers of technology and know-how are only listed as voluntary contributions. Users of the system (including for non-commercial purposes) could also be asked to acknowledge the providers of data in publications and contribute to open science and scientific collaboration.

The establishment of the PABS System would also constitute an opportunity to establish international ground rules for the sharing of pathogen GSD, currently subject only to individual platform policies. The main points of contention include the degree of openness of the new GSD sharing system and its primary purpose: whether the system's primary aim should be to facilitate rapid data sharing and access, or to promote accountability by requiring user registration, verification, and acceptance of terms and conditions of use. According to the revised draft of the negotiating text, WHO would be tasked with developing legally binding terms of reference for databases forming part of the system.

All users of the system would have to be notified of benefit sharing obligations and have legal obligations under the PABS System. Note that the users of the system would not necessarily have to be located in the same countries which actually signed and ratified the agreement, potentially opening the way to transnational application.

The final draft text of the Pandemic Agreement containing the PABS System would have to be submitted to the World Health Assembly (WHA), consisting of 194 WHO Member States, for consideration. While Article 19 of the WHO Constitution requires a two-thirds majority of valid votes, the treaty would most likely have to be adopted by consensus to ensure universal political buy-in. Although the possibility of making reservations on the text had been previously excluded, the revised draft of the negotiating text allows such a possibility. However, it is unlikely that reservations on PABS, which is likely to be deemed

central to the object and purpose of the treaty, would be allowed.

Once adopted, the Pandemic Agreement would be opened for signature for a defined period of time and would enter into force once the pre-determined number of ratifications (forty in the revised negotiating text) is met. Art. 25 of the Vienna Convention on the Law of Treaties (VCLT) also envisages "provisional application" of a treaty pending its entry into force if "(a) the treaty itself so provides; or (b) the negotiating States have in some other manner so agreed." However, such a possibility appears not to be considered in the revised draft of the negotiating text.

Once it is adopted and enters into force, the PABS system would still have to be recognized as a specialized international instrument (SII) within the meaning of Art. 4(2) of the Nagoya Protocol to the CBD, which states that:

> *"Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol."*

Pending its entry into force and recognition as a SII by the Parties to the Nagoya Protocol, the legal status quo (Scenario 1) would continue. Once adopted and recognized as a SII, the PABS system would take international legal precedence for matters falling under its scope on the basis of the principle *lex specialis derogat legi generali*. Even then, the scope of the specialized agreement would determine its application; for instance, if the PABS System only applies to specific pathogens or category of data ('genetic'), other pathogens and PHEIC-relevant data could still fall under the scope of the CBD multilateral mechanism.

As a WHO regulation

Another scenario concerns the possibility of PABS (or the Pandemic Agreement as a whole) being adopted as a regulation under Art. 21 of the WHO Constitution. Such a possibility has been raised by some delegations. Having already mentioned some of the issues surrounding the material scope of the PABS System, I focus on the procedural implications of choosing a WHO regulation over an international treaty.

In accordance with Art. 21 of the WHO Constitution, regulations can be adopted by the WHA on five specific grounds, which include preventing the spread of diseases (Art. 21(a)). The important role of PABS in surveillance, risk assessment, and research development of and access to pandemic-related products, points to the possibility of using Art. 21(a) as a legal basis for PABS or the Pandemic Agreement as a whole, should such a need arise.

According to Art. 22 of the WHO Constitution, Regulations do not require ratification and enter into force at the same time for all Member States that do not "opt out" by notifying WHO Director-General of their rejection or reservations within a set period of time. WHO Member States agree that regulations are legally binding for them. The International Health Regulations (IHR), the main legal instrument currently governing global pandemic response, have been adopted under Art. 21 of the WHO Constitution.

The appeal of universality stemming from the legal nature of WHO regulations is thus understandable. However, as noted by Gian Luca Burci, legal advisers of foreign ministries would face questions about how to prepare internally for entry into force, implementation and the applicability of the law of treaties to such an instrument. The possibility of rejections and reservations to a PABS regulation could also mean that WHO Member States could become subject to different obligations. Therefore, the effectiveness of a regulation would ultimately depend on a firm political commitment by WHO Member States to implementing and complying with the WHO regulation.

The PABS System adopted under a regulation would still have to be recognized as an SII within the meaning of Art. 4(2) of the Nagoya Protocol to the CBD. The universality of such an instrument could contribute to its recognition as an SII by the Nagoya Parties. However, since the potential transformation of the Pandemic Agreement into a WHO regulation in the final months of negotiations would be a far-reaching

change, it would likely necessitate more time before the status quo (Scenario 1) is changed.

Conclusion

These scenarios illustrate some legal considerations negotiators will face in the final stretch of the Pandemic Agreement negotiations. Ultimately, political factors will likely determine which scenario unfolds and whether it is followed by effective implementation. The legal solutions should prioritize legal clarity, be forward-looking, and be able to adapt in light of scientific and technological change. For the system to actually function and remain effective, special attention should be paid to the enforceability of its provisions, settlements of disputes, and incentives envisaged for various participants in the system.

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