

ARGUMENTS AGAINST THE INEQUITABLE DISTRIBUTION OF VACCINES USING THE ACCESS AND BENEFIT SHARING TRANSACTION

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Abstract Access and benefit sharing (ABS) is a transactional mechanism designed to allow countries to trade access to their sovereign genetic resources for monetary and non-monetary benefits, with the ultimate goal of channelling those benefits into sustainable development and environmental conservation. Arguments about how pathogens are not the sort of genetic resources the world ought to conserve eventually gave way to a recognition that pathogens are indeed sovereign genetic resources under the Convention on Biological Diversity and its Nagoya Protocol, and that the ABS transaction may be an effective way to deliver scarce vaccines to developing nations as benefits received in exchange for shared pathogen samples. This article argues that categorising vaccines as benefits given in exchange for access to pathogen samples creates opposing incentives for providers and users of virus samples and undermines the human right to health because it makes that right a commodity to be bought. The provision of pathogen samples to the global research commons and the fair and equitable distribution of medicines should be two parallel public goods to be pursued as goals in and of themselves. We conclude that the linking of these goals through the ABS transaction should be reassessed.

Keywords: public international law, access and benefit sharing, Convention on Biological Diversity, Nagoya Protocol, access to medicines.

I. INTRODUCTION

Pathogens must continuously change their genetic code to outmanoeuvre their hosts' immune systems. This means that when researching pathogens, such as bacteria and viruses, scientists require new samples of the pathogen from

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This article was presented and workshopped at the 2021 annual meeting of the American Society of International Law as part of the Sixth Annual Detlev F Vagts Roundtable on Transnational Law – Pandemic Vaccines: Market Products or Global Public Goods. The authors wish to thank Gian Luca Burci, Suerie Moon, Beatriz Thome and Yuvraj Dalvi for their invaluable insights and feedback on an earlier version of this paper. We also wish to thank Charles Lawson for his feedback and ongoing support.

different hosts and different geographic locations. This is vital to public health: effectively combating emerging and re-emerging infectious diseases requires a coordinated international response which includes testing, surveillance, risk assessments and the development of strain-specific vaccines and other medical countermeasures. Each of these vital activities relies upon prompt access to pathogen samples. To this end, the international scientific community has been sharing pathogen samples informally for many decades, monitoring the changing genetic sequences of isolates, and hoping to detect a pandemic strain before it starts to take hold in the human population. The soft global norm of informally sharing pathogen samples for scientific research and development has been eroding, and pathogen sample transfer is becoming increasingly legalised.¹ In 2019, the Seventy-second World Health Assembly (WHA) requested the Director-General of the World Health Organization (WHO) to undertake a programme of study on access to pathogen samples (with a specific focus on influenza viruses) and the sharing of benefits associated with their use,² a policy known as pathogen access and benefit sharing (ABS).³

The international ABS legal landscape is dominated by the Convention on Biological Diversity (CBD) and its supplementary agreement, the 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). The Nagoya Protocol is a binding international agreement on Contracting Parties that aims to ensure that the benefits arising from the utilisation of genetic resources are shared in a fair and equitable way.⁴ This is achieved by introducing a form of property rights over biological resources like plants and animals and allowing Parties to govern

¹ C Lajaunie and C Wai-Loon Ho, 'Pathogens Collections, Biobanks and Related-Data in a One Health Legal and Ethical Perspective' (2018) 145 *Parasitology* 688; K Mullis, 'Playing Chicken with Bird Flu: "Viral Sovereignty", the Right to Exploit Natural Genetic Resources, and the Potential Human Rights Ramifications' (2009) 24 *AmUIntlLRev* 944; A Bollinger, 'E-Mers-Gency: An Application and Evaluation of the Pandemic Influenza Preparedness Framework to the Outbreak of MERS-CoV Notes & Comments' (2015) 29 *TempIntl&CompLJ* 1.

² Seventy-second World Health Assembly, 'Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits' (28 May 2019) WHA72 (12); Seventy-second World Health Assembly, 'The public health implications of implementation of the Nagoya Protocol' (28 May 2019) WHA72(13).

³ Alternatively referred to as 'pathogen and benefit-sharing' (PBS) in A Rizk *et al.*, "'Everybody Knows This Needs to Be Done, but Nobody Really Wants to Do It': Governing Pathogen- and Benefit-Sharing (PBS)' (Graduate Institute of Geneva 2021) <https://www.graduateinstitute.ch/sites/internet/files/2020-12/GHC_WorkingPaper_No_23_Web.pdf>. It is interesting to note that this report of 'the largest study on this issue' wholeheartedly accepts ABS as the only option in the public health space and uses the language of 'pathogen and benefit-sharing', rather than the traditional 'access and benefit-sharing'. The implication of this shift in language could suggest that when it comes to pathogens, access is (or should be) implied.

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 (adopted 29 October 2010, entered into force 12 October 2014) UN Doc UNEP/CBD/COP/DEC/X/1 (Nagoya Protocol) arts 5 and 6.

access to those genetic resources according to domestic laws and by ensuring that justice, environmental concerns, and sustainable development are incorporated into the transfer of those genetic resources from provider countries to resource users.⁵ This exchange of access to sovereign genetic resources in return for benefits associated with their use ‘is a market-based approach aimed at preserving biodiversity’,⁶ designed to address the market failure of environmental conservation.⁷ The market failure is that there are greater short-term incentives to exploit biological resources than there are to conserve them over the long term. The ABS solution is to create obligations on the users of biological resources to share the (ideally financial) benefits generated through their use and for the State to then channel those benefits into biodiversity conservation.⁸ The idea of the ABS mechanism has now been extended beyond biodiversity conservation into international public health governance.

Both the CBD and the Nagoya Protocol take a transactional approach to accessing genetic resources in exchange for associated benefits,⁹ the default transaction occurring bilaterally between user and provider parties,¹⁰ with provision for multilateral ABS arrangements.¹¹ At the multilateral level, in 2011, the WHO adopted the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (hereafter, ‘PIP Framework’), codifying the use of the ABS transaction in the public health space, albeit multilaterally with the WHO mediating a constellation of transactions between Member State providers and third party users of influenza viruses with human pandemic potential.¹² The ABS mechanism in the PIP Framework links access to influenza viruses that were previously treated as common goods to benefits such as access to

⁵ *ibid* Preamble, arts 1 and 9.

⁶ C Richerzhagen, ‘Effective Governance of Access and Benefit-Sharing under the Convention on Biological Diversity’ (2011) 20 *Biodiversity and Conservation* 2243, 2243.

⁷ C Lawson, ‘Regulating Access to Biological Resources: The Market Failure for Biodiversity Conservation’ (2006) 24 *Law in Context* 137.

⁸ C Lawson, M Rourke and F 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 *QMJP* 7.

⁹ ‘A critical element of ABS is its trans-national nature. At least two countries are involved in every ABS transaction – a “source country” (from which genetic resources are obtained) and a “user country” (which has jurisdiction over the user).’ M Walløe Tvedt and T Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD* (IUCN 2007) 2.

¹⁰ Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993) 1760 UNTS 79 (CBD) art 15.

¹¹ Nagoya Protocol (n 4) art 10. Note that Article 10 is specifically about a global multilateral system but recognises that ABS can occur through ‘modalities’ other than the default bilateral transaction.

¹² M Rourke, ‘Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of “Viral Sovereignty” and the Mark It Left on the World’ in M Eccleston-Turner and I Brassington (eds), *Infectious Diseases in the New Millennium*, vol 82 (Springer International Publishing 2020).

diagnostic kits, vaccines and other medical countermeasures. This transaction was framed as being particularly appealing for developing countries with the world's most vulnerable populations who, in a pandemic, may not be able to secure vaccines through purely commercial arrangements made directly with pharmaceutical companies.¹³ These are also the countries most likely to be the site of emergence of rare (and therefore, at a scientific and transactional level, valuable) influenza strains. The PIP Framework is a pandemic influenza-specific multilateral ABS arrangement that operates on top of the default bilateral ABS transaction of the CBD and Nagoya Protocol.¹⁴ That is, countries can exercise their sovereign authority over their pandemic influenza virus samples by choosing to share their viruses through the multilateral PIP Framework or can enter into a bilateral ABS agreement with a user in accordance with their domestic laws.¹⁵

Either way, be it via the PIP Framework, CBD and/or the Nagoya Protocol, the framing is that of a transaction: the exchange of pathogen samples for a benefit. The transactional approaches encourage developing countries to use their pathogenic genetic resources as bargaining chips to secure access to diagnostics, medicines and vaccines developed with those samples as would be the case in a bilateral ABS agreement. To date, many commentators have praised ABS as a mechanism for delivering justice to LMICs,¹⁶ largely on the basis that the ABS regime created by the CBD and Nagoya Protocol creates legal certainty in respect of the status of genetic resources and traditional knowledge around the world and creates a harmonised legal system for access to said samples.¹⁷

¹³ M Turner, 'Vaccine Procurement during an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1' (2016) 11 *Global Public Health* 322; M Eccleston-Turner and H Upton, 'The Procurement of a COVID-19 Vaccine in Developing Countries: Lessons from the 2009-H1N1 Pandemic' in S Arrowsmith L Butler and A La Chimia (eds), *Public Procurement in (a) Crisis: Global Lessons from the COVID-19 Pandemic* (Hart 2021).

¹⁴ The WHO's 2016 internal review of the PIP Framework states that '[t]he PIP Framework is a multilateral access and benefit sharing instrument that appears to be consistent with the objectives of the Nagoya Protocol ...'. See WHO, 'Review of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits: Report of the 2016 Pandemic Influenza Preparedness Framework Review Group' (18 November 2016) <https://www.who.int/influenza/pip/2016-review/ADVANCE_EB140_PIPReview.pdf>.

¹⁵ See M Rourke and M Eccleston-Turner, 'The Pandemic Influenza Preparedness Framework as a "Specialized International Access and Benefit-Sharing Instrument" under the Nagoya Protocol' (2021) *NILQ* (forthcoming).

¹⁶ R Chennells, 'Toward Global Justice through Benefit-Sharing' (2010) 40 *Hastings Center Report* 3; D Schroeder, 'Justice and Benefit Sharing' in R Wynberg, D Schroeder and R Chennells (eds), *Indigenous Peoples, Consent and Benefit Sharing* (Springer 2009); MZM Nomani, 'The Access and Benefit-Sharing Regime: An Environmental Justice Perspective' (2020) 49 *Environmental Policy and Law* 259.

¹⁷ B Coolsaet *et al.* (eds), 'Introduction: Access Benefit-Sharing and the Nagoya Protocol: The Confluence of Abiding Legal Doctrines' in *Implementing the Nagoya Protocol* (Brill | Nijhoff 2015); E Morgera, 'The Need for an International Legal Concept of Fair and Equitable Benefit Sharing' (2016) 27 *EJIL* 353; J Cabrera Medaglia and F Perron-Welch, 'The Benefit-Sharing Principle in International Law' (2019) 14 *JIPLP* 62.

To this end, the mediating role of the WHO in the PIP Framework is to deliver a more equitable solution that does not just benefit the country of origin or the party accessing the pathogen sample. The ABS transaction applied to pathogens attempts to introduce a market solution to two previously separate problems: 1) the need for public health researchers to secure access to novel pathogen samples and 2) the scarce availability of vaccines and other medical countermeasures during pandemics, where rich countries dominate procurement and leave developing countries to fend for themselves. We argue that these are allocation efficiency problems, and that the market-based solution of ABS that was designed to address the market-failure of biodiversity conservation is not the right approach to addressing them. Instead, the ABS transaction that links these two public health issues together solves neither problem.

This article firstly outlines why ABS arose as a solution to address the market failure of extreme biodiversity loss and environmental collapse due to overexploitation: the unjust extraction and exploitation of biological resources (which later came to include pathogens) from developing countries. Secondly, it outlines the history of how the ABS transactional approach has been applied to pathogens through bilateral and multilateral arrangements. The remainder of the article is dedicated to explaining why the transactional approach is unable to deliver equity, fairness or justice to developing countries during a pandemic.¹⁸ Equity, fairness and justice are ostensibly at the heart of the PIP Framework as its stated goal is the creation of a ‘fair, transparent, equitable, efficient, effective system for, on an equal footing: (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits’. Equity, fairness, and justice also form much of the reasoning behind calls to expand the PIP Framework to include other human pathogens, not just the subset of influenza viruses that have human pandemic potential, or to create a new multilateral pathogen ABS agreement modelled on the PIP Framework, with which the WHO is currently engaged.

It is argued that any ABS transactional approach to these issues is at a high risk of failing because the incentive structures are flawed, leading to a loss of trust in the system from provider and user parties, a reduction in overall virus sample sharing and associated innovation, and a false sense of security for developing countries that base their pandemic response plans on the expectation that they will receive benefits in the form of vaccines and antivirals. It concludes by arguing in favour of decoupling these issues: not

¹⁸ For a foundational analysis on the relationship between equity and justice see A Beaver, ‘Aristotle on Equity, Law and Justice’ (2004) 10 *Legal Theory* 33. In respect of the role of equity and justice in international law see B Cheng, ‘Justice and Equity in International Law’ (1955) 8 *CLP* 1, 185–211; for a consideration as to why equity in healthcare resources is morally desirable see N Daniels, ‘Equity of Access to Health Care: Some Conceptual and Ethical Issues’ (1982) 60 *Milbank Quarterly* 1, 55–81.

directly tying the sharing of pathogen samples to the provision of benefits such as vaccines through the ABS transaction. As will be outlined, the ABS mechanism applied to pathogens sometimes creates perverse incentives because it is a market solution for an entirely different problem. The COVID-19 pandemic points to the fact that the marketplace cannot solve all the world's problems and that creating a new market where pathogen samples are exchanged for life-saving vaccines and medicines is not only ill-conceived,¹⁹ but fails to account for the fact that access to vaccines is a social good and a human right in and of itself, regardless of the extent to which an individual government happens to have engaged in ABS transactions with pathogens. Instead, it is concluded that it is preferable to delink these issues, and develop solutions to each problem in parallel, that is: building a strong pathogen research commons, and developing mechanisms to ensure access to vaccines and other medical countermeasures during a pandemic; mechanisms that are not predicated on the exchange of sovereign genetic resources, but on the basis that access to medicines is a human right and a social good.²⁰

II. THE ORIGINS OF THE ABS TRANSACTION

Historically, botanists and natural scientists from the global North travelled to the global South and extracted local biological resources (plants to animal species) without seeking permission from either the local community or the national government. They essentially saw the biological resources of the global South as public goods. These biological resources were then expropriated to the global North where they were used for a range of applications, from medicine to *objet d'art*. Such products were invariably treated as private goods; treating the resources of the South as public goods to capture them within the privatised property regime of the North. The injustice of this situation was neatly summarised by the prominent Indian environmentalist Vandana Shiva, here referring to plant genetic resources:

The North has always used Third World germplasm as a freely available resource and treated it as valueless. The advanced capitalist nations wish to retain free access to the developing world's storehouse of genetic diversity, while the South would like to have the proprietary varieties of the North's industry declared a similarly 'public' good.²¹

¹⁹ J Boyle, *Shamans, Software, and Spleens: Law and the Construction of the Information Society* (Harvard University Press 1997) 127. Boyle was arguing that the Western intellectual property regime disadvantages developing countries and discourages innovation.

²⁰ A Kamradt-Scott, 'The Politics of Pandemic Influenza Preparedness' in C McInnes, K Lee and J Youde (eds), *The Oxford Handbook of Global Health Politics* (Oxford University Press 2020) 544.

²¹ V Shiva, *The Violence of the Green Revolution: Third World Agriculture, Ecology, and Politics* (Zed Books; Third World Network 1991) 257.

Unfortunately, this is not merely a historic injustice; such exploitative practices continue to this day.²² The ABS transaction in the CBD was a compromise that ensured access to genetic resources occurred using the favoured market-based solution of the time, trading sovereign rights in genetic resources for money or other benefits.²³

A. Indonesia and H5N1: The ABS Transaction Applied to Pathogens

In 2006, in response to the threat posed by H5N1 avian influenza virus, the WHA passed Resolution 59.2, which called upon WHO Member States to '[d]isseminate to the WHO Collaborating Centers information and relevant biological materials related to highly pathogenic avian influenza and other novel influenza strains in a timely and consistent manner'.²⁴ At the time, Indonesia had the highest number of infections and deaths from H5N1.²⁵ Indonesia wavered between sharing and refusing to share samples with the WHO's network of collaborating influenza laboratories that had been sharing influenza samples informally since the 1950s,²⁶ the Global Influenza Surveillance Network (GISN), claiming that Indonesia had sovereign authority over the samples isolated within their territories.²⁷

This was the first time the CBD was explicitly applied to human pathogens in an international arena.²⁸ Indonesia's contention was that under the CBD 'access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources'²⁹ and any access granted 'shall be on mutually agreed terms'.³⁰ Indonesia therefore claimed that they were under no obligation to share samples of H5N1 with the wider international community despite Resolution 59.2 which disregarded any sovereign rights countries have over their genetic resources codified under the CBD in 1992, and the fact that the

²² 'As a result of this free-for-all, those in the South today sometimes face high barriers to access to goods based on the biodiversity of their own territories.' D Schroeder and T Pogge, 'Justice and the Convention on Biological Diversity' (2009) 23 *Ethics & International Affairs* 267.

²³ Lawson, Rourke and Humphries (n 8) 8–10.

²⁴ Fifty-ninth World Health Assembly, 'Application of the International Health Regulations (2005)' (26 May 2006) WHA59.2.

²⁵ WHO, 'Cumulative number of confirmed human cases for avian influenza A(H5N1) reported to WHO, 2003-2015' (2015) <http://www.who.int/influenza/human_animal_interface/EN_GIP_20150106CumulativeNumberH5N1cases_corrected.pdf?ua=1>.

²⁶ WHO, 'Global Influenza Surveillance and Response System (GISRS): Technical and Scientific Resource for WHO Public Health Policy Making' (2015) 1 <http://www.who.int/csr/disease/OP_GISRS_FINAL.pdf>.

²⁷ Art 15.1 of the CBD (n 10) 'recogniz[es] the sovereign rights of States over their natural resources' and affirms that national governments have 'the authority to determine access to genetic resources'.

²⁸ Rourke, 'Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of "Viral Sovereignty" and the Mark It Left on the World' (n 12).

²⁹ Art 15(5) Convention on Biological Diversity.

³⁰ Art 15(4) Convention on Biological Diversity; C McInnes and K Lee, *Global Health and International Relations* (John Wiley & Sons 2012) 193.

International Health Regulations (2005), on which this Resolution was based, did not actually specify that countries should share samples.³¹

This framing helped Indonesia highlight the inequity of being expected to share virus samples with the WHO but not being afforded fair access to the vaccines and antivirals developed using those samples,³² in much the same ways as other genetic resources were being exploited by users in developed countries.³³ This framing also led these issues to be connected in the form of the ABS transaction for the first time. A framing that was supported by the WHO with the implementation of the PIP Framework in 2011 which ‘recognise[s] the sovereign right of States over their biological resources’,³⁴ and that calcified as the framing for all future discussions on pathogen sharing at the WHO, challenging the previously held notion that pathogen samples were shared with the international scientific community as global public goods.³⁵ The PIP Framework was essentially an instrument that superimposed the ABS idea from the CBD on a system of virus sharing that was already underway through the GISN, turning it into a *quid pro quo*.

B. The Pandemic Influenza Preparedness Framework: Multilateral ABS for Some Influenza Viruses

The PIP Framework was adopted as a WHA Resolution in May 2011³⁶ and outlines multilateral ABS arrangements for the subset of influenza viruses that have human pandemic potential.³⁷ It does not apply to seasonal influenza viruses.³⁸ Furthermore, the PIP Framework does not attach benefit sharing obligations to the use of genetic sequence data derived from influenza viruses within its scope,³⁹ instead requiring parties to share genetic sequence data ‘in a rapid, timely and systematic manner’ with other WHO laboratories.⁴⁰ The

³¹ See discussion of different interpretations of the IHR in J Cook Lucas *et al.*, ‘Donating Human Samples: Who Benefits? Cases from Iceland, Kenya and Indonesia’ in D Schroeder and J Cook Lucas (eds), *Benefit Sharing* (Springer 2013).

³² R Irwin, ‘Indonesia, H5N1, and Global Health Diplomacy’ (2010) III Global Health Governance 21.

³³ The CBD (n 10) does not explicitly refer to pathogens, but rather, it applies to ‘genetic resources’. The CBD defines ‘genetic resources’ as ‘genetic material of actual or potential value’. The term ‘genetic material’ is defined as ‘any material of plant, animal, microbial or other origin containing functional units of heredity’. The Nagoya Protocol uses the same definitions for these terms as provided for in art 2 of the CBD. In terms of the language used by the CBD, when the pathogen is inside the host, we could consider the pathogen an *in situ* genetic resource. When the pathogen is isolated from the host, taken from its environment and stored in a plastic vial, we might then consider the pathogen an *ex situ* genetic resource. The language of ‘genetic resources’ from the CBD applies equally to both scenarios, without distinction.

³⁴ WHO, ‘Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework)’ (24 May 2011) UN Doc A64/VR/10, Preamble.

³⁵ J Youde, *Globalization and Health* (Rowman & Littlefield 2019) 115.

³⁶ PIP Framework (n 34).

³⁷ *ibid* art 3(1).

³⁸ *ibid* 3(2).

³⁹ See C Lawson, F Humphries and M Rourke, ‘The Future of Information under the CBD, Nagoya Protocol, Plant Treaty, and PIP Framework’ (2019) 22 *The Journal of World Intellectual Property* 103.

⁴⁰ PIP Framework (n 34) art 5.2.1.

WHO deferred the issue of how open access to genetic sequence data can undermine benefit sharing when potential users opt to access data instead of physical samples for some research and development applications.⁴¹

The PIP Framework provides for recommendations in two areas: the timely sharing of influenza samples with human pandemic potential between Member States and the WHO via the newly renamed Global Influenza Surveillance and Response System (GISRS);⁴² and the sharing of virus samples with third-party entities that operate outside of the GISRS, such as pharmaceutical companies and vaccine manufacturers.⁴³ In return, these external third-party entities share benefits with the WHO for distribution to Member States in the event of an influenza pandemic, including, and most notably vaccines.⁴⁴ To this end, the PIP Framework sets up a series of transactions wherein the WHO acts as an agent, or a middle man between providers and users of pandemic influenza virus samples, setting and negotiating the terms of two (variable) 'Standard Material Transfer Agreements' (SMTAs, essentially model contracts), and determining how vaccines and other benefits garnered through the system are distributed to Member States.

Under the PIP Framework, the first SMTA outlines the terms under which Member States (as National Influenza Centres) provide selected influenza viruses to the WHO (as the various GISRS laboratories),⁴⁵ and the second SMTA details the terms under which third-party recipients of certain virus samples (eg vaccine manufacturers) use those samples, including the sharing of benefits.⁴⁶ The sharing of benefits is not standard, rather, it is agreed between the WHO and third-party recipients according to their capacity and abilities. For vaccine manufacturers the benefit sharing options include the donation of 'at least 10 per cent of real time pandemic vaccine production to WHO' or to '[r]eserve at least 10 per cent of real time pandemic vaccine production at affordable prices to WHO'.⁴⁷ In the event of an influenza pandemic, the stockpile of donated vaccines will be distributed by the WHO to Member States 'according to public health risk and need'.⁴⁸ Of the use of SMTAs, Morten Walløe Tvedt and Tomme Young have noted that:

One aspect of the creation of a model agreement [in a multilateral system] is the need to get all parties to agree in advance to use it. In effect, this constitutes a pre-negotiation of at least part of all future ABS contracts. However, if adopted in

⁴¹ *ibid* art 5.2.4. The CBD and other UN fora are currently discussing how to handle digital sequence information (DSI) within the ABS transaction. See Lawson, Humphries and Rourke (n 39). ⁴² PIP Framework (n 34) art 5(1). ⁴³ *ibid* Annex 2. ⁴⁴ *ibid* art 6(11).

⁴⁵ *ibid* art 5.4.1 and Annex 1.

⁴⁶ *ibid* art 5.4.2 and Annex 2.

⁴⁷ *ibid* SMTA 2, art 4.1.1, Annex 2. It is worth noting that the stockpile is a 'virtual' one. Influenza vaccine manufacturers commit via an ABS agreement to supply a proportion of their real-time vaccine production to the WHO, and in the event of an influenza pandemic, vaccine manufacturers supply x per cent of their real-time production to the WHO, and the WHO will then transfer from the stockpile to recipient States. ⁴⁸ *ibid* art 6.9.2.

international negotiation, the agreement would *bind* only the source [provider] countries – who constitute less than half of the future parties to ABS contracts.⁴⁹

This is the case with the PIP Framework where Member States contribute their sovereign virus samples in accordance with the terms of the SMTA1, while the external user parties like vaccine manufacturers are able to negotiate variable (and apparently quite favourable) terms with the WHO.⁵⁰ While this is a multilateral ABS agreement,⁵¹ it can also be understood as a series of transactions with the WHO acting at the centre of a constellation of ABS contractual arrangements, acting as something of a Clearing House for pandemic influenza virus samples and associated vaccines.⁵²

That the WHO has conceded that pathogen samples are not public goods but sovereign genetic resources, but then created a multilateral ABS arrangement for just a tiny subset of sovereign pathogens under the PIP Framework, has fostered a great deal of confusion as to how to deal with all other human pathogens. All other pathogens were left within the remit of domestic legislation implemented under the CBD and/or the Nagoya Protocol; transferred through bilateral ABS agreements between providers and users. However, informal sharing of non-influenza pathogens remained at the heart of cooperative public health research and the WHO continued to encourage this.⁵³

C. MERS: Sovereign or Public Resources?

The tension between the WHO wanting pathogen samples to be shared as global public goods on the one hand and having recognised them as sovereign genetic resources within an ABS transaction on the other did not take long to cause problems.⁵⁴ In June 2012, one year after the adoption of the PIP Framework, a clinical specimen was taken from a patient in Saudi Arabia with a severe respiratory infection, later found to be caused by the novel Middle East

⁴⁹ Tvedt and Young (n 9) 125 (emphasis in original).

⁵⁰ See M Rourke, 'Access by Design, Benefits if Convenient: A Closer Look at the Pandemic Influenza Preparedness Framework's Standard Material Transfer Agreements' (2019) 97 *The Milbank Quarterly* 91.

⁵¹ While it is not clear whether the PIP Framework would qualify as a 'Specialised International [ABS] Instrument' in the sense of Article 4 of the Nagoya Protocol, it certainly outlines arrangements for accessing certain influenza virus samples and the sharing of benefits associated with their use and will therefore be referred to as an ABS instrument throughout this article.

⁵² While the term Clearing House originates in the banking sector, it is has more recently been used to describe a mechanism whereby generators of goods, services and/or information are matched with potential users, see G Van Overwalle *et al.*, 'Models for Facilitating Access to Patents on Genetic Inventions' (2005) 7 *Nature Reviews Genetics* 143; E van Zimmeren *et al.*, 'A clearing house for diagnostic testing: The solution to ensure access to and use of patented genetic inventions?' (2006) 84 *Bulletin of the World Health Organization* 352.

⁵³ M Rourke, 'The History of Accessing and Sharing Human Pathogens for Public Health Research' in SF Halabi and R Katz (eds), *Viral Sovereignty and Technology Transfer* (1st edn, Cambridge University Press 2020).

⁵⁴ See Rourke, 'Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of "Viral Sovereignty" and the Mark It Left on the World' (n 12).

respiratory syndrome coronavirus (MERS-CoV).⁵⁵ The patient sample had been sent from Saudi Arabia to Erasmus Medical Centre (EMC) in the Netherlands for analysis, and the announcement of the novel coronavirus was made on ProMED-mail on 20 September 2012.⁵⁶

After it was found that the EMC had submitted a patent application (in part) for the ‘nucleic acid and/or amino acid sequences of the MERS-CoV genome’, and that they were providing isolates of the virus to other researchers around the world under their institutional material transfer agreement (MTA), the Saudi government made it clear that they felt their sovereign rights over the sample had been violated.⁵⁷ Under the CBD, they had ‘the sovereign right to exploit their own [biological] resources pursuant to their own environmental policies’,⁵⁸ and as has been discussed, this includes any pathogenic genetic resources. This was a right that was recognised by the WHO with the adoption of the PIP Framework, which explicitly ‘recognize[s] the sovereign right of States over their *biological resources*’ (emphasis added), not just those of influenza viruses of pandemic potential. During the standoff between the Saudi government and EMC, the WHO Director-General at the time, Dr Margaret Chan, urged WHO Member States to share MERS-CoV ‘viruses and specimens with WHO collaborating centres ... not in a bilateral manner’.⁵⁹

There was no multilateral ABS agreement in place to share such samples with the WHO collaborating centres and the samples continued to be shared by EMC without regard for any sovereign interest the Saudi government had in those samples and, therefore, any related benefits generated using those samples in research and development. The physician that sent the sample from Saudi Arabia to the EMC in the Netherlands noted that ‘[u]ltimately, there is a need for a global agreement about ownership and sharing of virus samples’.⁶⁰ Yet the tension over the new recognition of sovereign rights over pathogens and the global research commons (the way things had always been done before the introduction of the PIP Framework) continued into yet another infectious disease emergency: Ebola.

⁵⁵ A Zaki *et al.*, ‘Isolation of a Novel Coronavirus from a Man with Pneumonia in Saudi Arabia’ (2012) 367 NEJM 1814.

⁵⁶ AM Zaki, ‘PRO/EDR> Novel coronavirus – Saudi Arabia: human isolate: Archive Number: 20120920.1302733’ (*ProMED*, 20 September 2012) <<https://promedmail.org/promed-post/?id=1302733>>.

⁵⁷ See M Rourke, ‘The History of Accessing and Sharing Human Pathogens for Public Health Research’ in S Halabi and R Katz (eds), *Viral Sovereignty and Technology Transfer* (1st edn, Cambridge University Press 2020).

⁵⁸ CBD (n 10) art 3.
⁵⁹ Quote from Margaret Chan reported in ‘WHO urges information sharing over novel coronavirus’ (*BBC News*, 23 May 2013) <<https://www.bbc.com/news/health-22649922>>. See also L Garrett, ‘Why a Saudi Virus Is Spreading Alarm’ (*Council on Foreign Relations*, 29 May 2013) <<https://www.cfr.org/expert-brief/why-saudi-virus-spreading-alarm>>.

⁶⁰ D Butler, ‘Tensions Linger over Discovery of Coronavirus’ [2013] *Nature* <www.nature.com/articles/nature.2012.12108>. For a discussion about the tension between intellectual property rights and sovereign rights over MER-CoV, see Rourke, ‘Access by Design, Benefits If Convenient: A Closer Look at the Pandemic Influenza Preparedness Framework’s Standard Material Transfer Agreements’ (n 50).

D. Ebola: West African Sovereignty Ignored

The WHO's substandard response to the West African Ebola crisis of 2014–16 left a public health leadership vacuum that ultimately led to intervention by the UN Security Council.⁶¹ The emergency response involving in-country diagnostic laboratories from multiple US government and international agencies⁶² 'resulted in Ebola virus samples from West Africa being distributed around the world with little attention paid to the sharing of benefits from research and development on the samples'.⁶³ Many countries contributed mobile diagnostic laboratories to aid in the response, and at the conclusion of their efforts, many Ebola samples were 'export[ed] out of the affected country without an agreement' with the host nation.⁶⁴ Furthermore, these samples were provided to academic and commercial researchers for research and development.⁶⁵ At the conclusion of the emergency response 'there [were] a multitude of Ebola samples that [were] unaccounted for'.⁶⁶

Unlike MERS-CoV, the Ebola emergency occurred after the WHO had plenty of time to reckon with the potential consequences of recognising pathogen samples as sovereign resources and therefore the subject of ABS regulations.⁶⁷ Despite the clear recognition of sovereign rights over pathogen samples in the PIP Framework,⁶⁸ and acknowledgement that any pathogenic genetic resources not within the scope of the PIP Framework are by default within the remit of the CBD and Nagoya Protocol, West African nations were denied the ability to exercise their sovereign rights over the Ebola virus samples that were collected from their nationals and in their territories.⁶⁹

Many of these samples were taken without the prior informed consent of the national governments, and the terms for their use in any future research and development were never mutually agreed upon.⁷⁰ Some attempts have been made by these nations to retroactively exercise their sovereign authority over the samples that were taken without their prior informed consent, but while their sovereign rights to those resources may technically endure, exercising those rights is made particularly difficult when samples are outside of their territories and therefore outside their functional control.⁷¹ When users and the WHO ignore the sovereign rights of provider States, providers miss out on opportunities to capture some of the benefits of research and development for their own populations through the ABS transaction.

⁶¹ UNSC Res 2177 (18th September 2014) UN Doc/S/Res/2177.

⁶² A Abayomi *et al.*, 'Managing Dangerous Pathogens: Challenges in the Wake of the Recent West African Ebola Outbreak' (2016) 1 *Global Security: Health, Science and Policy* 51, 51–2.

⁶³ D Fidler, 'Africa, COVID-19, and International Law: From Hegemonic Priority to the Geopolitical Periphery?' (2020) *Ethiopian Yearbook of International Law* 2019 31, 36.

⁶⁴ Abayomi *et al.* (n 62).

⁶⁵ *ibid* 52.

⁶⁶ *ibid.*

⁶⁷ Rourke, 'Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of "Viral Sovereignty" and the Mark It Left on the World' (n 12).

⁶⁸ PIP Framework (n 34) art 1(11).

⁶⁹ See section 'Ebola: West African Sovereignty Ignored' above.

⁷⁰ See *ibid.*

⁷¹ See *ibid.*

III. AGAINST TRANSACTIONAL APPROACHES

As the above section demonstrated there is a clear lack of legal certainty in respect of pathogen ABS, which is made even more confusing by the WHO's wavering stance on whether to treat pathogen samples, associated information and medical countermeasures as public or private goods during global health emergencies.⁷² During the COVID-19 pandemic, in December 2020, the WHO announced plans 'to establish a Bio Bank – a globally agreed system for sharing pathogen materials and clinical samples to facilitate the rapid development of safe and effective vaccines and medicines'.⁷³ In his address to the UN General Assembly on 4 December 2020, WHO Director-General Dr Tedros Adhanom Ghebreyesus stated:

The [COVID-19] pandemic has also shown that there is an urgent need for a globally agreed system for sharing pathogen materials and clinical samples, to facilitate the rapid development of medical countermeasures as global public goods. Switzerland has generously offered the use of a high-security laboratory at which WHO would manage a new 'biobank', and we are now developing the framework under which samples would be provided and shared.⁷⁴

This was the full extent of the information offered on the planned biobank, noticeably devoid of any mention of benefit sharing, and the announcement was seen as undermining future discussions on pathogen ABS by WHO Member States.⁷⁵ Was this a rejection of the buyer–seller paradigm for pathogen samples; an attempt to strengthen the old, pre-PIP Framework norms of free and open sharing of pathogen samples? The Director-General's statement is further confused by the reference to medical countermeasures as being global public goods; it is unclear if WHO's position is that the development of medical countermeasures, or global equitable access to the products of such development is actually the global public good.

The language of the WHO is confusing when it comes to talk of pathogen samples, associated information and medical countermeasures like vaccines and antivirals, all of which the WHO has variably referred to as sovereign

⁷² Rourke, 'Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of "Viral Sovereignty" and the Mark It Left on the World' (n 12).

⁷³ '10 Global Health Issues to Track in 2021' (*WHO*, 24 December 2020) <<https://www.who.int/news-room/spotlight/10-global-health-issues-to-track-in-2021>>.

⁷⁴ T Adhanom Ghebreyesus, 'WHO Director-General's Opening Remarks at the United Nations General Assembly Special Session – 4 December 2020' (*WHO*, 4 December 2020) <<https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-united-nations-general-assembly-special-session---4-december-2020>>.

⁷⁵ E Hammond, 'Questions swirl about proposed WHO pathogen collection: Effort to "shortcut" the Nagoya Protocol raises fairness and equity and other issues' (Third World Network (TWN) Briefing Paper, January 2021) <https://twon.my/title2/briefing_papers/twn/Questions%20about%20proposed%20WHO%20pathogen%20collection%20Jan2021%20Hammond.pdf>.

resources, private goods, or as global public goods. Meanwhile, the PIP Framework, the only pathogen sharing instrument adopted by WHO Member States, recognises the sovereign rights of nations over their pathogen samples and treats medical countermeasures as private goods donated to the WHO by private pharmaceutical companies.

A. ABS Conceptual Complexities

Despite still not clarifying their stance on whether the subjects of an ABS transaction are sovereign resources or global public goods, a consensus appears to be building at the WHO that a multilateral ABS instrument would be a suitable approach to pathogen sharing.⁷⁶ However, there are fundamental and complex questions of scope and application that should be addressed before any further multilateral pathogen ABS instruments are created. The issue of how traditional knowledge associated with pathogenic genetic resources is one such complexity that the WHO is yet to consider, yet traditional knowledge of Indigenous peoples and local communities is a vital component of the ABS transaction under the Nagoya Protocol.⁷⁷

After nearly three decades of ABS policies, the CBD is still trying to resolve definitional and scoping ambiguities. Some of the definitional issues that might apply for a multilateral pathogen ABS instrument are: what is the country of origin for a virus?⁷⁸ Is it the nation where the virus was isolated as the PIP Framework contends or would the country of evolutionary origin, the place a virus species has developed its ‘distinctive properties’ have a superior sovereignty claim?⁷⁹ Do sovereign rights over a virus extend throughout time and use to any of its derivatives? That is, when are sovereign rights extinguished, if ever? Are pathogen genetic sequence data considered genetic resources, or a derivative of a genetic resource?⁸⁰ These are the sorts of complexities that the WHO would need to address before adopting any future multilateral pathogen ABS instruments. Indeed, these issues should have been addressed prior to the adoption of the PIP Framework, but all remain unresolved at the time of writing.

⁷⁶ See Pt V, ‘The Push towards Multilateral Pathogen ABS’ below.

⁷⁷ M Rourke, ‘Who Are “Indigenous and Local Communities” and What Is “Traditional Knowledge” for Virus Access and Benefit-Sharing? A Textual Analysis of the Convention on Biological Diversity and Its Nagoya Protocol’ (2018) 25 *Journal of Law and Medicine* 707.

⁷⁸ F Humphries *et al.*, ‘COVID-19 Tests the Limits of Biodiversity Laws in a Health Crisis: Rethinking “Country of Origin” for Virus Access and Benefit-sharing’ (2021) 28 *Journal of Law and Medicine* 684. ⁷⁹ *ibid.*

⁸⁰ U Jakob, ‘Norm Conflicts in Global Health: The Case of Indonesia and Pandemic Influenza Preparedness’ (Peace Research Institute Frankfurt 2020) 14 <<https://www.hsfk.de/en/publications/publication-search/publication/norm-conflicts-in-global-health-the-case-of-indonesia-and-pandemic-influenza-preparedness/>>.

B. The Folly of Linking Pathogen Access with the Provision of Vaccines

Whether bilateral or multilateral, pathogen ABS is a transaction. To reiterate, the access part of the transaction refers to access to sovereign viruses and associated genetic sequence data by user parties, and the benefit sharing part refers to access to private goods, such as vaccines, antivirals and diagnostic kits for those same parties that provided the sovereign resources. This is a *quid pro quo*: something in exchange for something else. One key problem with this transactional model is that it pits each party against the other as buyer and seller. While the providers of pathogen samples (users of benefits) and the users of pathogen samples (providers of benefits) have some common interests, such as reducing transaction costs within the ABS model, there is a much stronger opposing interest: where each stakeholder is looking to maximise their gains and minimise their costs within the ABS transaction. That is, the providers of sovereign pathogen samples want to maximise benefit sharing and users of sovereign resources want to minimise benefit sharing.

The PIP Framework was supposed to ensure that these transactions were effectively brokered by the WHO. In a multilateral ABS transaction, with an intermediating party (in this case, the WHO), the system is most attractive for providers of sovereign genetic resources if they can maximise the likelihood that benefits will accumulate to them specifically. For users, the multilateral system is most attractive if all providers are using it, and nobody is prepared to provide similar genetic resources (or the more intangible alternative: genetic sequence data) outside the multilateral system and at a lower cost. Providers would prefer strong monitoring, compliance, and enforcement measures; users would likely prefer the opposite.⁸¹ The multilateral mechanism is a less direct transaction, but the opposing incentives and market dynamics are still at play. Joseph Vogel *et al.* have highlighted the fact that the incentives in the PIP Framework can only work in certain circumstances:

Although the *quid pro quo* of one access for another appears ‘consistent with [and not] counter to’ the objectives of CBD and [Nagoya Protocol], incentives among stakeholders become distorted. For countries with poor governance, health care workers have few incentives to expedite samples into the international stream of Research and Development (R&D). Even for those with good governance, the sharing of a benefit among countries for submission of the same genetically sequenced sample dilutes the incentive to be the first to submit.⁸²

⁸¹ ‘A regime with shallow benefit-sharing obligations and weak compliance mechanisms ... increases providers’ incentives to shirk their commitments’. F Rabitz, ‘Access without Benefit-Sharing: Design, Effectiveness and Reform of the FAO Seed Treaty’ (2017) 11 *International Journal of the Commons* 621, 625.

⁸² J Vogel *et al.*, ‘Human Pathogens as Capstone Application of the Economics of Information to Convention on Biological Diversity: The Receptivity of Research Scientists’ (2013) 5 *International Journal of Biology* 121, 122.

For the PIP Framework (or similar multilateral pathogen ABS scheme) to work there need to be rewards for Member States for providing their sovereign resources. Specific rewards for the act of submitting viruses to the common pool. The WHO cannot do this; it *must* distribute benefits on an as needs basis, according to whatever country has the greatest public health requirements.⁸³ Under the PIP Framework, the WHO facilitates an ABS transaction where access is provided in exchange for the *potential* to obtain benefits.⁸⁴ The link between the act of providing access to the sharing of benefits is therefore too weak to discourage free riders: those who do not submit samples to the GISRS but can still expect to receive benefits if their country exhibits the greatest need in the event of a pandemic. This destroys the incentives required to ensure that countries continue to provide samples to the multilateral system and that the system is not readily undermined by bilateral ABS agreements that cut the WHO out of the middle. But the WHO, as an apolitical public health organisation, cannot be seen to give vaccines and antivirals to countries on anything other than a public health basis.⁸⁵ Thus, having the WHO as the mediator of an ABS system connecting the provision of viruses to the provision of vaccines is a folly, a potentially very dangerous one.

The PIP Framework is not compulsory; it is a non-binding Resolution adopted by the WHA. Indeed, no multilateral pathogen ABS instrument adopted by the WHO will ever be compulsory for whatever stakeholders it attempts to include.⁸⁶ This is because countries are sovereign and must adopt such measures of their own accord. The ABS arrangements outlined in the PIP Framework are only binding on those stakeholders that *choose* to enter into SMTAs with the WHO. This means that it is still lawful to engage in bilateral ABS arrangements for influenza viruses with human pandemic potential; both Member States as providers and potential third-party users of such resources are well within their rights to work outside of the WHO's multilateral system. This possibility will always stand to threaten the multilateral arrangements; even during negotiations for the PIP Framework, there were 'suspicions that Indonesia and the United States were endeavouring to broker a bilateral deal on sample sharing and benefit

⁸³ PIP Framework (n 34) art 6.10.1(ii). Note that there is currently no clear definition of what is meant by public health needs during a pandemic. See V Jain and S Tweed, 'Consensus on Disease Control Objectives in the Context of COVID-19 Vaccines' (2021) 99 Bulletin of the World Health Organization 322.

⁸⁴ M Eccleston-Turner, 'The Pandemic Influenza Preparedness Framework: A Viable Procurement Option for Developing States?' (2017) 17 Medical Law International 227.

⁸⁵ PIP Framework (n 34) art 6(1) reads: 'As regards the benefits outlined in this Framework, WHO should pay particular attention to policies and practices that promote the fair, equitable and transparent allocation of scarce medical resources (including, but not limited to, vaccines, antivirals and diagnostic materials) during pandemics based on public health risk and needs, including the epidemiology of the pandemic.'

⁸⁶ See Rourke and Eccleston-Turner (n 15).

sharing that would leave others out'.⁸⁷ Indeed, there are free-rider opportunities built into multilateral transactions for users of sovereign genetic resources as well as the providers. Thus, the system must be appealing enough to attract and maintain willing participants.

The free-rider problem does not exist solely on the access side of the transaction. As stated, potential user parties have the option of engaging in bilateral ABS arrangements with providers of sovereign genetic resources, circumventing any multilateral arrangements. But as technologies advance, they also have the option of circumventing any ABS arrangements at all, bilateral or multilateral, by using openly accessible genetic sequence data to synthesise the required genetic material. The negotiators of the PIP Framework deferred on dealing with the issue of genetic sequence data,⁸⁸ and so sequence data for influenza viruses shared through the PIP Framework remain outside the scope of the ABS transaction. Through advances in genetic sequencing, physical biological samples can be dematerialised (ie converted to information by determining the genetic sequence of the virus's genome), the data easily transferred around the world, stored on openly accessible databases such as GenBank, and then rematerialised (ie returned to a physical state as a viable virus sample) without having to engage in benefit sharing.

This is not merely a hypothetical or future possibility, but, a real and present issue.⁸⁹ It is anticipated that the technological capability to dematerialise and rematerialise pathogens will only increase in efficiency and ease, and decrease in entry costs, leading to a proliferation of its availability.⁹⁰ Thus, companies can utilise genetic sequence data in place of the physical virus sample for some applications and avoid entering into an SMTA2 with the WHO, and thus avoid sharing any benefits while themselves benefiting from the genetic resources of the provider nation. The current debates in the international ABS space about 'digital sequence information' (DSI) acknowledge that this presents a loophole to both bilateral and multilateral ABS arrangements,⁹¹ but the States that wish to capture the benefits from the use of digital sequence information are pushing up against the professed

⁸⁷ JE Lange, 'Negotiating Issues Related to Pandemic Influenza Preparedness: The Sharing of Influenza Viruses and Access to Vaccines and Other Benefits' in E Roskam and I Kickbusch (eds), *Negotiating and Navigating Global Health: Case Studies in Global Health Diplomacy* (World Scientific Publishing 2012) 145.

⁸⁸ PIP Framework (n 34) art 5.2.4.
⁸⁹ In 2017, a Canadian research team rematerialised the horsepox virus using only its genetic sequence data from an open source database after determining that the physical sample of the virus was too difficult to obtain: R Noyce, S Lederman and DH Evans, 'Construction of an Infectious Horsepox Virus Vaccine from Chemically Synthesised DNA Fragments' (2018) 13 PLOS ONE e0188453; M Rourke, A Phelan and C Lawson, 'Access and Benefit-Sharing Following the Synthesis of Horsepox Virus' (2020) 38 Nature Biotechnology 537.

⁹⁰ An issue that is of acute concern for biosecurity experts; see G Koblenz, 'The De Novo Synthesis of Horsepox Virus: Implications for Biosecurity and Recommendations for Preventing the Reemergence of Smallpox' (2017) 15 Health Security 620.

⁹¹ See eg Lawson, Rourke and Humphries (n 8).

norm of open access to genetic sequence data⁹² that has been the status quo since the Human Genome Project.⁹³

The WHO is framing the ABS transaction as a way of protecting developing countries from and responding to infectious diseases, but we can see that the bilateral ABS transaction can create a situation where only one country gets benefits that might be more effectively distributed elsewhere, or that bilateral ABS negotiations can be threatened by the open availability of DSI or the spread of the pathogen to the territories of other nations, diluting incentives to share benefits. On the other hand, multilateral pathogen ABS may be better equipped at pooling benefits to distribute to those nations most in need during an infectious disease emergency, but it is always vulnerable to nations acting outside of the multilateral arrangement to engage in bilateral ABS which may be more beneficial for the country in question, but not the world as a whole. Such are the dangers of pitting stakeholders against each other as buyers and sellers in an ABS transaction and creating a market environment where individualism and competition are valued over cooperation.

C. Market Logic and Market Failures

This brings us to the problem of power imbalances between contracting parties, and the consequences of applying market logic in an uneven, skewed marketplace. In her analysis of why ABS has fallen short under the CBD, Carmen Richerzhagen notes that:

The market structure has a strong impact on negotiations and their outcome. To reach fair and equitable benefit sharing, negotiations on ABS must be undertaken by equal partners. In case of changes [where] renegotiations must take place, contracting partners should be on par with each other. Due to market conditions, however, provider countries are in a weaker position.⁹⁴

The ABS transaction is often touted as being mutually beneficial, indeed, this concept is present throughout the CBD and Nagoya Protocol. However, as Richerzhagen points out, this is not possible if there are major power differentials between provider and user, seller, and buyer. Developing countries are not often able to turn down deals that are seemingly beneficial in the short term, but that may not be beneficial (and may even be detrimental) over the long term.

⁹² See eg Ad Hoc Technical Expert Working Group on Digital Sequence Information on Genetic resources, '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, Convention on Biological Diversity' (2020) CBD/DSI/AHTEG/2020/1/5 <<https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf>>.

⁹³ See S Hilgartner, *Reordering Life: Knowledge and Control in the Genomics Revolution* (MIT Press 2017) Ch 6.

⁹⁴ Richerzhagen (n 6) 251.

The power differential between developing States as providers of pathogen samples and pharmaceutical companies as users of pathogen samples is substantial. For starters, the stakes are much higher for developing countries. In a pandemic, if they cannot secure medical countermeasures, the lives of their citizens are at risk. If pharmaceutical companies cannot secure a sample, there are likely other options, including alternative (if not optimal) samples or genetic sequence data that can be found online. One potential benefit of the drive towards multilateral pathogen ABS agreements is that the WHO (as the natural home for such multilateral public health agreements) would be in a stronger negotiating position than developing States acting separately and alone and would therefore be able to secure enhanced access to medical countermeasures in negotiation with pharmaceutical manufacturers. The logic is that the WHO acting as something of a Clearing House for transactions between providers and users could help to rebalance the uneven market in favour of developing nations as pathogen providers. In the context of the PIP Framework, Marie Wilke has stated:

Unlike before the PIP Framework, when negotiations were conducted on a bilateral basis (often involving developing countries), it is the WHO that negotiates the final SMTA which introduces further checks and balances, thereby increasing the effectiveness, and more importantly, the equity.⁹⁵

Despite this purported advantage, the operation of the PIP Framework and its SMTA2s between third-party users suggests that it may not be able to significantly enhance effectiveness and equity. As previously stated, the SMTAs are (necessarily) not as standardised as the name suggests.⁹⁶ The relevant provisions on liability and indemnities, warranties, duration and termination of contracts, governing law, and dispute resolution in the SMTA2s are not standardised within the PIP Framework and remain simply 'to be agreed by the parties'.⁹⁷ If it is not possible to reach a consensus on *all* the terms, the negotiations will fail, and the SMTA2 will not enter into force, leading to fewer vaccines being available for the PIP vaccine stockpile. Moreover, as so much of the SMTA2 is flexible and subject to negotiation, it will likely provide the third-party user, in this example, a vaccine manufacturer with a stronger negotiating position than the WHO, as the manufacturer will be one of a very limited number of users that can potentially provide a product (vaccines) that will be in very high demand in the event these benefit sharing agreements are triggered, and the WHO will be one of a significant number of potential purchasers or recipients of such

⁹⁵ M Wilke, 'The World Health Organization's Pandemic Influenza Preparedness Framework as a Public Health Resource Pool' in E Kamau and G Winter (eds), *Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law* (1st edn, Routledge 2013).

⁹⁶ At least not for the SMTA2s between the WHO and third-party users. There is little scope for providing countries to negotiate terms in the SMTA1.

⁹⁷ PIP Framework (n 34) arts 5, 6 and 9–13, Annex 2, SMTA2.

products. If the WHO cannot reach agreeable terms with the manufacturer, they could simply take their product elsewhere to a purchaser more willing to agree favourable terms.

This has certainly been the case in the race for COVID-19 vaccines. In response to concerns about how developing States would be able to access COVID-19 vaccines, following their experience during 2009-H1N1,⁹⁸ the WHO formed the COVAX Facility in early 2020. This multilateral effort was intended to maximise the negotiating power on behalf of developing States, however, despite the multilateral efforts, bilateral advance purchase agreements have undermined the COVAX Facility by increasing competition for a limited supply of vaccines, thereby reducing the number of doses available for timely procurement and distribution by the multilateral COVAX Facility.⁹⁹ It is also apparent that developed countries were willing to offer highly favourable terms to vaccine manufacturers, in exchange for guaranteeing themselves priority access, particularly around price, immunity and liabilities.¹⁰⁰

D. Supply-Side Issues with Pathogen ABS

Unlike most other physical resources, in many respects, culturable pathogen samples can be non-exhaustive and their use non-exclusive. Some pathogens can be grown and replicated to the point where an infinite number of replicate samples exist.¹⁰¹ This means that anyone can ‘consume’ a pathogen sample during the research process, without diminishing the amount available for others.¹⁰² Therefore, in a marketplace, pathogens might be more appropriately dealt with as information rather than a physical resource.¹⁰³ Despite this, the current approach to pathogen ABS treats pathogens as tangible assets that a State can exercise sovereign rights over, something akin to property rights,¹⁰⁴ where the

⁹⁸ Turner (n 13).

⁹⁹ Eccleston-Turner and Upton, ‘The Procurement of a COVID-19 Vaccine in Developing Countries: Lessons from the 2009-H1N1 Pandemic’ (n 13); M Eccleston-Turner and H Upton, ‘International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility’ (2021) 99(2) *The Milbank Quarterly* 426.

¹⁰⁰ Eccleston-Turner and Upton, ‘International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility’ (n 99).

¹⁰¹ Limited because some pathogen samples are not culturable and they can change characteristics through the process of creating replicates (eg passaging in cell lines).

¹⁰² P Samuelson, ‘The Pure Theory of Public Expenditure’ (1954) 36 *The Review of Economics and Statistics* 387; P Samuelson, ‘Diagrammatic Exposition of a Theory of Public Expenditure’ (1955) 37 *The Review of Economics and Statistics* 350; A Samado, ‘Public Goods’ in J Eatwell, M Milgate and P Newman (eds), *The New Palgrave: A Dictionary of Economics Vol IV* (1st edn, Palgrave Macmillan 1987).

¹⁰³ J Vogel, ‘The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing’ (2011) 7 *Law, Environment and Development Journal* 52.

¹⁰⁴ ‘At the domestic level, the State is the repository of sovereign rights and their assertion is akin to a form of private property rights as the State acquires all the rights over a given resource when it

rights holder can exclude others from accessing and/or using those tangible resources without prior informed consent.¹⁰⁵

As is the case with a traditional market, market forces can determine the terms of access to pathogens in the ABS model, where rare and valuable viruses (eg smallpox)¹⁰⁶ are controlled and could therefore command higher market value.¹⁰⁷ In this marketplace, some pathogen samples will remain rare and valuable, for instance, a new virus variant with an unusual phenotype, or a virus sample from a previously unknown host species. However, the scarcity that can make a pathogen 'valuable' in ABS terms is predicated on the pathogen being contained, whether in terms of host range and prevalence or in terms of sample storage within the sovereign territory of one or a few nations.

In such instances, there are limited options for potential users (eg pharmaceutical researchers) to access the resource and they will therefore be required to negotiate with the nation (or nations)¹⁰⁸ that have the pathogen in *in situ* conditions.¹⁰⁹ At this point the nation *may* be able to negotiate very favourable terms through a bilateral ABS agreement, securing benefits for their populations, possibly for the supply of vaccines or medical countermeasures. However, it is a truism of public health that infectious diseases do not respect international boundaries, and the moment the pathogen crosses the territorial borders of that nation and begins to spread internationally the negotiation position of the originator State is significantly hampered or wholly eroded, as occurred recently with Zika.

Zika virus was discovered in Uganda in 1947, was known to cause mild disease in humans across Asia and Africa and caused a large outbreak of more severe disease in 2007 in the Pacific island of Yap.¹¹⁰ In 2015, reports from Brazil indicated that the Zika infection was associated with microcephaly and Guillain-Barré syndrome in newborns,¹¹¹ resulting in renewed research interest in the virus. European and US researchers were working mostly with samples from earlier outbreaks while efforts were made

asserts direct ownership of the same.' P Cullet, 'Property-Rights Regimes over Biological Resources' (2001) 19 *Environment and Planning C: Government and Policy* 651, 652.

¹⁰⁵ While Article 15(2) of the CBD (n 10) states that 'Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention', the ability to regulate access to genetic resources in order to provide prior informed consent for their use requires that access is restricted to some degree.

¹⁰⁶ MF Rourke, 'Never Mind the Science, Here's the Convention on Biological Diversity: Viral Sovereignty in the Smallpox Destruction Debate' (2018) 25 *Journal of Law and Medicine* 429.

¹⁰⁷ See section on genetic sequence data (Digital Sequence Information, or DSI)

¹⁰⁸ Or subnational jurisdiction, in some instances, like in India and Australia.

¹⁰⁹ Or is otherwise considered the authorised provider of the pathogen samples in accordance with the CBD. The CBD (n 10) distinguishes between the '[c]ountry of origin of genetic resources' and the '[c]ountry providing genetic resources' (art 2), where the providing party must 'have acquired the genetic resources in accordance with this Convention' (art 15(3)).

¹¹⁰ M Kindhauser *et al.*, 'Zika: The Origin and Spread of a Mosquito-Borne Virus' (2016) 94 *Bulletin of the World Health Organization* 675, 675.

¹¹¹ *ibid* 675.

to obtain new samples from Brazil.¹¹² Reportedly, the major reason for Brazil not sharing samples resided in their ABS legislation which had created ‘considerable confusion within the country and abroad about how and when samples could be exported and shared’.¹¹³ As Brazilian lawyers negotiated terms for the access and use of their virus samples¹¹⁴ with US government representatives, the Zika virus spread into Puerto Rico.¹¹⁵ As a US territory, the US Centres for Disease Control and Prevention (CDC) could readily obtain novel Zika virus samples from Puerto Rico and the negotiations with Brazil ended without the transfer of any Zika samples from Brazil.¹¹⁶

The Brazilian government found out the hard way that ‘the existence of identical [or near identical] genetic resources in neighbouring countries, offer alternatives for users and weaken the bargaining position of single providers’.¹¹⁷ Such are the dangers of pursuing bilateral ABS contracts during a public health emergency from the perspective of the provider, or the supply-side of the ABS transaction. The desire of provider governments to secure benefits to protect their populations by leveraging one of the few bargaining chips they have can backfire, leaving vulnerable populations even more vulnerable. The incentives to exercise any positive control over samples is therefore decreased, with the alternative being to submit samples to a global research commons and hope against the odds that some benefits will eventually make their way to *your* citizens in the event of a pandemic.

E. The Human Rights Case against the ABS Transaction for Pathogens

The human rights approach has been successful in improving access to medicines in developing States, particularly HIV/AIDS medicines.¹¹⁸ The right to health has been referenced in international agreements since the 1940s, having been first articulated in the Preamble to The Constitution of the World Health Organization,¹¹⁹ as well as at Article 25 of the United

¹¹² M Cheng, R Satter and J Goodman ‘Few Zika samples are being shared by Brazil, worrying international researchers’ (*STAT News*, 3 February 2016) <<https://www.statnews.com/2016/02/03/zika-samples-brazil/>>.

¹¹³ M Marinissen *et al.*, ‘Sharing of Biological Samples during Public Health Emergencies: Challenges and Opportunities for National and International Action’ in S Halabi and R Katz (eds), *Viral Sovereignty and Technology Transfer* (1st edn, Cambridge University Press 2020) 168–9.

¹¹⁴ As per their sovereign rights over genetic resources under ‘the Charter of the United Nations and the principles of international law’ (CBD (n 10) art 3) and reaffirmed by the CBD (CBD (n 10) Preamble and arts 3 and 15(1)).
¹¹⁵ Marinissen *et al.* (n 113) 170. ¹¹⁶ *ibid* 170–1.

¹¹⁷ Richerzhagen (n 6) 251.

¹¹⁸ D Matthews, ‘Right to Health and Patents’ in C Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2016).

¹¹⁹ ‘[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.’ Constitution of the World Health Organization (adopted 22 July 1946, entered into force 7 April 1948) 14 UNTS 185.

Nations Universal Declaration of Human Rights.¹²⁰ The right to health further finds reference in the Convention on the Elimination of All Forms of Racial Discrimination,¹²¹ the Convention on the Elimination of Discrimination Against Women,¹²² and the Convention on the Rights of Persons with Disabilities.¹²³ The clearest articulation of the right to health has come in The International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12(2) of which states, in part, that States Parties shall take the necessary steps in the ‘prevention, treatment and control of epidemic, endemic, occupational and other diseases’.¹²⁴

Clearly, access to pandemic vaccines falls within the purview of Article 12 (2). Access to medicine, as a component of the right to health, was elaborated upon in The Committee on Economic, Social and Cultural Rights (ESCR) General Comment No. 14: the Right to the Highest Attainable Standard of Health,¹²⁵ which states that States must ensure ‘provision of health care, including immunisation programmes against the major infectious diseases’¹²⁶ and ‘equal and timely access to basic preventive, curative, rehabilitative health services and ... the provision of essential drugs’.¹²⁷ In the context of access to medicines, the provision of ‘essential’ medicines is a core, non-derogable obligation, which States must fulfil as a minimum criterion to meet their obligations under the ICESCR.¹²⁸

The ICESCR does not provide an exhaustive list of which drugs constitute ‘essential’ medicines, and the world relies instead upon the WHO to define medicines as such in their Model List of Essential Drugs.¹²⁹ Pandemic influenza vaccine was listed as an ‘essential medicine’ on the 2009¹³⁰ and 2010 lists,¹³¹ when 2009-H1N1 was prevalent. It is likely that when the list is next updated, a vaccine for COVID-19 will be included within it. Clearly,

¹²⁰ [e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services’ Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III).

¹²¹ International Convention on the Elimination of All Forms of Racial Discrimination (adopted 7 March 1966, entered into force 4 January 1969) 660 UNTS 195, art 5(e)(iv).

¹²² Convention on the Elimination of All Forms of Discrimination Against Women (adopted 18 December 1979, entered into force 3 September 1981) 1249 UNTS 13, arts 11(1)(f) and 12.

¹²³ Convention on the Rights of Persons with Disabilities (adopted 13 December 2006, entered into force 3 May 2008) 2515 UNTS 3, art 25.

¹²⁴ International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 12(2)(c).

¹²⁵ UN Committee on Economic, Social and Cultural Rights, ‘General Comment No. 14 (2000): The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)’ (11 August 2000) UN Doc E/C.12/2000/4 (General Comment 14) <https://digitallibrary.un.org/record/425041/files/E_C.12_2000_4-EN.pdf>.

¹²⁶ *ibid* para 36.

¹²⁷ *ibid* para 17.

¹²⁸ *ibid* para 43(d).

¹²⁹ *ibid*.

¹³⁰ WHO, ‘WHO Model List of Essential Medicines: 16th list, March 2009’ (2009) <http://apps.who.int/iris/bitstream/10665/70642/1/a95055_eng.pdf>.

¹³¹ WHO, ‘WHO Model List of Essential Medicines: 16th list (updated), March 2010’ (2010) <http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf>.

access to pandemic vaccines falls within the purview of Article 12(2). Of equal relevance, but given less attention within the international legal system,¹³² is the Right to Enjoy the Benefits of Scientific Progress and its Applications, which is articulated in Article 27 of the Universal Declaration on Human Rights, and Article 15(1)(b) of the ICESCR. The right to science has received significantly less attention than the right to health,¹³³ and, as yet there is no General Comment from the ESCR Committee to act as an interpretative aid. However, the UN Special Rapporteur in the Field of Cultural Rights reported in 2012 that the Right to Enjoy the Benefits of Scientific Progress and Its Applications should be understood as including ‘access to all of the benefits of science by all, without discrimination’.¹³⁴

Of course, there is always a discrepancy between the articulation of human rights in international bodies and agreements, and the delivery of those same rights in real terms, particularly when those rights come up against real-world constraints. However, framing access to medicines as a ‘benefit’ that ought to be bought with the provision of pathogen samples (ie pathogen ABS) devalues the normative value of the human rights rhetoric that could provide developing countries a basis from which to claim vaccines and medicines as a right, not merely as a benefit flowing from their engagement with the ABS transaction.

The bilateral ABS approach applied to pathogens *may* be capable of enabling *some* developing countries to meet their human rights obligations in respect of their citizens, proving they are able to use the transactional approach to negotiate preferential access to vaccines, but it ignores the human rights (and needs) of those in neighbouring countries, or countries on the other side of the world, despite the explicit reliance by international human rights bodies on the normative authority of benefit sharing under the CBD.¹³⁵

¹³² It has been noted that the content of the right is not yet fully understood or articulated either at the national or international level, see W Schabas, ‘Study of the Right to Enjoy the Benefits of Scientific and Technological Progress and Its Applications’ in Y Donders and V Volodin (eds), *Human Rights in Education, Science and Culture: Legal Developments and Challenges* (Routledge 2007) 273; AR Chapman, ‘Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and Its Applications’ (2009) 8 *Journal of Human Rights* 1.

¹³³ See A Phelan, ‘Human Rights Implications of Pathogen Sharing and Technology Transfer’ in S Halabi and R Katz (eds), *Viral Sovereignty and Technology Transfer* (Cambridge University Press 2020).

¹³⁴ UN Human Rights Council, ‘Report of the Special Rapporteur in the Field of Cultural Rights: The Right to Enjoy the Benefits of Scientific Progress and Its Applications’ (14 May 2012) UN Doc A/HRC/20/26.

¹³⁵ CBD (n 10) art 8(j); UNCHR, ‘Review of Developments Pertaining to the Promotion and Protection of Human Rights and Fundamental Freedoms of Indigenous Peoples’ (20 June 2001) UN Doc E/CN.4/Sub.2/AC.4/2001/2; *Akwé: Kon Guidelines* (Secretariat of the Convention on Biological Diversity 2004); as a precondition for benefit sharing by the Inter-American Court of Human Rights in *Case of the Saramaka People v Suriname* (Interpretation of the Judgment on Preliminary Objections, Merits, Reparations and Costs) Inter-American Court of Human Rights Series C No 185 (12 August 2008) Pt IV; UN Human Rights Council, ‘Report of the Expert Mechanism on the Rights of Indigenous Peoples’ (23 August 2010) UN Doc A/HRC/15/35.

Indeed, where regional human rights bodies have considered ABS issues, they have adopted the stance that ‘benefit sharing’ in the ABS context must be ‘equitable’,¹³⁶ although what precisely equitable means in the context of bilateral or multilateral pathogen ABS is yet to be defined. Equitable ABS transactions may be possible at the intra-State bilateral level where a benefit (typically monetary)¹³⁷ is provided to a defined people or group, however, this does not work at the inter-State level during a health emergency, nor does it work where the benefit in question is a finite physical resource that cannot be fairly or equitably divided between all those who need it. Ultimately, the framing of these issues in terms of ABS reduces equitable access to vaccines to something that can be traded (if you are fortunate enough to hold a pathogen of value), rather than viewing equitable access to vaccines as an innate right which all people have claim to, regardless of how much their government happens to have engaged in the bilateral or multilateral trading of pathogens.

IV. COVID-19—THE ABSURDITY OF ABS TRANSACTIONS IN A PANDEMIC

The ongoing COVID-19 pandemic provides us with an interesting example of these issues of the need to share pathogens and associated data and distribute scarce vaccines equitably during a global emergency.¹³⁸ As seen in the Zika example where Brazil had new and valuable variants of the virus, the logic underpinning ABS transactional approaches means that the provider country only has something of value (and therefore capable of enhancing a negotiation position) when it is rare. This logic can discourage sharing of the resource particularly in the early days of an outbreak, where rather than rapidly sharing the sample, the source country attempts to negotiate as beneficial an ABS agreement as possible. The early days of an outbreak are precisely when the world needs sample sharing to be occurring most efficiently.

Within the context of the COVID-19 pandemic, there was no meaningful discussion around providing access to COVID-19 vaccines linked to the provision of samples of SARS-CoV-2. This could be for any number of reasons, all of which point to the fact that the ABS transaction cannot work

¹³⁶ *Centre for Minority Rights Development (Kenya) and Minority Rights Group International on behalf of Endorois Welfare Council v Kenya* Comm No 276/2003 (African Commission on Human and Peoples’ Rights, 25 November 2009) para 274; *Case of the Saramaka People v Suriname* (Preliminary Objections, Merits, Reparations and Costs) Inter-American Court of Human Rights Series C No 172 (28 November 2007) para 138; Committee on the Elimination of Racial Discrimination, ‘Concluding Observations on Ecuador’ (2 June 2003) UN Doc CERD/C/62/CO/2, para 16; UN Permanent Forum on Indigenous Issues, ‘Report of the International Workshop on Methodologies Regarding Free, Prior Informed Consent and Indigenous Peoples’ (17 February 2005) UN Doc E/C.19/2005/3, para 46(i)(e).

¹³⁷ *Centre for Minority Rights Development (Kenya) and Minority Rights Group International on behalf of Endorois Welfare Council v Kenya* (n 136) para 274; *Case of the Saramaka People v Suriname* (n 136) para 138.

¹³⁸ Humphries *et al.* (n 78).

in a public health emergency. China released the genetic sequence of the novel coronavirus quickly and access to genetic and physical samples from other countries followed soon thereafter.¹³⁹ Therefore, by the time any source country had the chance to negotiate an ABS agreement in the early stages of the pandemic, in the hope of potentially securing fair and equitable access to vaccines for their population, the value of samples was minimal, if not completely negligible. Transactional approaches during a health emergency are unfair and inefficient. To be clear, this inefficiency is in *both* sides of the transaction that pathogen ABS seek to facilitate: ABS transactions slow down the rapid sharing of pathogens with the wider international research community, potentially hampering the response to an unfolding health emergency, and are not able to ensure equitable access to vaccines during a pandemic, either for the original host country where said pathogen emerged, or for the wider international community, especially developing countries. As discussed, a new mechanism was designed for the pooling and distribution of COVID-19 vaccines, the COVAX Facility, which was undermined by what has been termed ‘vaccine nationalism’, with developed countries securing vaccines before developing countries, even when those countries may be more in need and vaccinating rich countries first may not be the most efficient vaccination strategy if the end goal is ending the pandemic.

The circumstances of the COVID-19 pandemic necessarily split these issues in two: access to pathogen samples was not necessarily a problem, at least not after the virus had spread outside of China. It did not take long for this virus to become accessible for researchers that wished to use it.¹⁴⁰ The issue of vaccine access was therefore never linked to the provision of virus samples; this is even though the concept of ABS is starting to dominate the policy debates about pathogen sharing and vaccine delivery (see below). In this instance, there was no quid pro quo that could take place and is perhaps indicative of the problems of connecting these issues in the first place. Not all pathogens are like pandemic influenza and not all will have characteristics that conform as well to an ABS transaction. Arguably, even influenza does not conform well to the ABS transaction.¹⁴¹ Rather than being an anomaly, the COVID-19 pandemic might point to the fact that the ABS mechanism cannot be a solution to either

¹³⁹ On 10 January 2020, scientists in China publicly uploaded the first genetic sequence of severe acute respiratory syndrome–coronavirus 2 (SARS-CoV-2). Two days later, China officially shared the viral GSD with the World Health Organization (WHO). Since that time, thousands of SARS-CoV-2 sequences from around the globe have been uploaded to online databases such as GenBank and the Global Initiative on the Sharing of All Influenza Data (GISAID). However, physical samples of SARS-CoV-2 were not made available by China at all; physical samples were not available until researchers in Australia isolated the virus from a traveller from Wuhan on 29 January 2020 and sent the isolate to the WHO and other laboratories, see M Rourke *et al.*, ‘Policy Opportunities to Enhance Sharing for Pandemic Research’ (2020) 368 *Science* 716.

¹⁴⁰ Humphries *et al.* (n 78).

¹⁴¹ Despite always being touted as a success story, the PIP Framework has never been tested in an influenza pandemic and it is unclear whether it will be able to deliver the sorts of benefits promised during an influenza pandemic.

problem in a public health emergency.¹⁴² Indeed, the previous failings of the ABS regime in Zika, Ebola, and MERS indicates that a transaction of pathogen samples for medicines is not a fair or efficient approach for either rapid access to pathogen samples or fair and equitable access to vaccines resulting from sample utilisation.

V. THE PUSH TOWARDS MULTILATERAL PATHOGEN ABS

Despite the numerous problems with both bilateral and multilateral ABS that have been identified since the Indonesian virus sharing incident in 2006–07, the issue of pathogen ABS is an active field of investigation for the WHO, as part of a larger drive towards adopting multilateral approaches to pathogen ABS. In 2019, the WHO adopted decision WHA72(12) on the PIP Framework, which included a request for the Director-General ‘to collect, analyse, and present data on influenza virus sharing’ under the GISRS, including identifying ‘specific instances where influenza virus sharing has been hindered’;¹⁴³ and decision WHA72(13) on the public health implications of the Nagoya Protocol on current pathogen sharing practices.¹⁴⁴ These decisions have created an ongoing field of work for the WHO, attempting to understand current international pathogen sharing practices with a view to determining ‘options to provide additional transparency, equity, clarity and consistency in pathogen-sharing practices globally’.¹⁴⁵ This section will briefly outline some of the options that are currently being considered for pathogen sharing by various stakeholders. The following options are not necessarily mutually exclusive and could be used in combination, although as yet there is no indication of the WHO’s preferred option as their research into pathogen sharing continues.

The first option would be to reject the push towards including pathogens which infect humans within the definition of ‘genetic resources’ in the CBD and Nagoya Protocol. This option is based on the opinion that pathogens were never intended to be part of an ABS transaction under a series of international legal instruments that were originally designed for the regulation of bioprospecting.¹⁴⁶ While this may be true, this option ignores the fact that countries had sovereign authority over genetic resources prior to

¹⁴² Humphries *et al.* (n78).

¹⁴³ Seventy-second World Health Assembly, ‘Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits’ (n 2).

¹⁴⁴ Seventy-second World Health Assembly, ‘The public health implications of implementation of the Nagoya Protocol’ (n 2).

¹⁴⁵ WHO, ‘The public health implications of implementation of the Nagoya Protocol; Report by the Director-General’ (6 January 2021) EB148/21.

¹⁴⁶ D Fidler and L Gostin, ‘The WHO Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health’ (2011) 306 JAMA 200.

the adoption of the CBD,¹⁴⁷ that the CBD simply reaffirmed those rights, and that countries can and have already implemented ABS measures for pathogens within their domestic legislation.¹⁴⁸ Furthermore, it denies sovereign rights over pathogens which are now generally understood to be within the remit of the CBD and Nagoya Protocol.¹⁴⁹ In echoes of the arguments made against Indonesia's original claim of viral sovereignty in 2006–07, some stakeholders (namely the pharmaceutical industry) still see the inclusion of pathogens within the ABS transaction as a 'perversion of the original aims of the [CBD]' and therefore the Nagoya Protocol.¹⁵⁰ This is the basis for calls for the exemption of pathogens from the scope of the Nagoya Protocol.¹⁵¹

Secondly, the international community could create an obligation to provide pathogen access linked to the declaration of a Public Health Emergency of International Concern (PHEIC) under the International Health Regulations (2005). Within the IHR there already exists an obligation to share information¹⁵² (which may include genetic sequence data depending on how a Member State wishes to interpret the relevant provision) but no obligation to share pathogen samples with the WHO or other parties. This option would only apply in acute public health emergencies, and when a PHEIC declaration has been made by WHO (noting that not all acute emergencies which meet the criteria for a PHEIC are declared).¹⁵³ According to the Review Committee on the role of the IHR during the 2014–16 West Africa Ebola crisis, the:

¹⁴⁷ UNGA Res 1803 (XVII) 'Permanent Sovereignty over Natural Resources' (14 December 1962); UNGA Res 2158 (XXI) 'Permanent Sovereignty over Natural Resources' (22 November 1966); UNGA Res 3016 (XXVII) 'Permanent Sovereignty over Natural Resources of Developing Countries' (18 December 1972); UNGA Res 3171 (XVIII) 'Permanent Sovereignty over Natural Resources' (17 December 1973); UNGA Res 3281 (XXIX) 'Charter of Economic Rights and Duties of States' (12 December 1974) art 2(1); UNGA Res 3201 (S-VI) 'Declaration on the Establishment of a New International Economic Order' (1 May 1974).

¹⁴⁸ The WHO are currently exploring the implementation question, along with the impact this could have on ready access to pathogens during a health emergency; see WHO, 'Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications; Study by the Secretariat' (12 June 2018) <https://www.who.int/influenza/Nagoya_Full_Study_English.pdf>.

¹⁴⁹ WHO, 'The public health implications of implementation of the Nagoya Protocol; Report by the Director-General' (n 145) 2, para 5.

¹⁵⁰ 'As the Director-General of the International Federation of Pharmaceutical Manufacturers and Associations, a research-based biopharmaceutical industry body with official relations with the United Nations, I support the CBD, which has three laudable objectives: conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the use of genetic resources. But protecting the biodiversity of pathogens seems a perversion of the original aims of the convention.' T Cueni 'Novel coronavirus 2019-nCoV exposes a flaw in the Nagoya Protocol' (*STAT News*, 5 February 2021) <<https://www.statnews.com/2020/02/05/novel-coronavirus-exposes-nagoya-protocol-flaw/>>.

¹⁵¹ 'It is time to question the sense of retaining pathogens within the scope of the Nagoya Protocol and associated national legislation. It is surely in the overriding interest of global public health and epidemic and pandemic preparedness for the international community to work towards an effective and internationally coherent approach to exempt pathogens from the protocol.' Cueni, *ibid*.

¹⁵² International Health Regulations (2005) (adopted 23 May 2005, entered into force 15 June 2007) 2509 UNTS 79, arts 6 and 7.

¹⁵³ See M Eccleston-Turner and C Wenham, *Declaring a Public Health Emergency of International Concern: Between International Law and Politics* (Bristol University Press 2021).

WHO champions the open sharing of information on public health risks, and expands guidance on global norms for sharing data to biological samples and gene sequence data during public health emergencies.¹⁵⁴

So, samples and associated information, including genetic sequence data, could be shared with the WHO once a PHEIC has been declared under the authority of the IHR.¹⁵⁵ The extent to which the WHO would see this provision of samples and information as being part of an exchange akin to ABS is unclear. It is of course possible to share benefits associated with the use of pathogen samples during a PHEIC, but the requirements to enter into an ABS agreement prior to accessing and using those samples could potentially be waived. This may be in line with the special considerations for public health emergencies in the Nagoya Protocol which states that when developing and implementing their ABS measures, countries should:

Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal, or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries¹⁵⁶

However, this option leaves unresolved the issue of pathogen sample and data sharing when a PHEIC is not ongoing, or prior to its declaration. Given ongoing controversies about when and how a PHEIC is declared¹⁵⁷ this appears to be a considerable barrier.

Thirdly, there have been calls to expand the PIP Framework to include seasonal influenza samples¹⁵⁸ and genetic sequence data,¹⁵⁹ as well as

¹⁵⁴ WHO, '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) A69/21, 11, para 11. This paragraph is followed by '... WHO and States Parties should ensure that sharing of samples and sequence data is balanced with benefit-sharing on an equal footing' at 12.

¹⁵⁵ Rourke *et al.* (n 139).

¹⁵⁶ Nagoya Protocol (n 4) art 8(b).

¹⁵⁷ G Burci and M Eccleston-Turner, 'Preparing for the Next Pandemic: The International Health Regulations and World Health Organization during COVID-19' (2021) 2 Yearbook of International Disaster Law 259.

¹⁵⁸ See eg A Sloan, 'IP Neutrality and Benefit Sharing for Seasonal Flu: An Argument in Favor of WHO PIP Framework Expansion' (2018) 17 Chicago-Kent Journal of Intellectual Property 296. WHO, 'Review of the Pandemic Influenza Preparedness Framework – Report by the Director-General' (29 December 2016) EB140/16. The PIP Framework Review in 2016 noted that 'In reality, however, seasonal and pandemic influenza viruses exist as a continuum, involving humans, birds and other animals', and that '[t]he overwhelming majority of viruses shared through GISRS are seasonal viruses' (at 34). Therefore, the non-inclusion of seasonal influenza viruses in the PIP Framework is problematic.

¹⁵⁹ See eg L Gostin *et al.*, 'Virus Sharing, Genetic Sequencing, and Global Health Security' (2014) 345 Science 1295. WHO, 'Review of the Pandemic Influenza Preparedness Framework – Report by the Director-General' (n 158) 49 where the PIP Framework Review in 2016 noted that 'GSD is increasingly being used to develop several new types of vaccines without the need for physical virus' and that 'This dissonance, if not resolved soon, could threaten the relevance of

suggestions to expand the PIP Framework, or a create transactional mechanism very much like it, to all other pathogens.¹⁶⁰ The WHO's 2016 review of the PIP Framework stated 'an expansion of the PIP Framework itself to include other pathogens would be very challenging'¹⁶¹ because the specific characteristics of the PIP Framework have everything to do with the unique characteristics of influenza viruses and the GISN/GISRS structures that were already in place to deal with it.¹⁶² Furthermore, the WHO's mandate is human health, and it is not clear to what extent they would be in a position to regulate the sharing of animal pathogens that can also infect humans.

The WHO's 2016 review of the PIP Framework also stated that '[t]he PIP Framework is a foundational model of reciprocity for global public health that could be applied to other pathogens'¹⁶³ and others have sought to use the principles of the PIP Framework as a model for all pathogen ABS. Using the PIP Framework as a model for multilateral ABS could mean multiple things: replicating the negotiation process to achieve a new multilateral pathogen ABS mechanism through the WHO,¹⁶⁴ replicating the legal model of an overarching WHA resolution with the use of SMTAs to create apparently binding terms and conditions,¹⁶⁵ or replicating the overarching principles of the PIP Framework of 'equity, fairness, partnership, and transparency'.¹⁶⁶ The adoption of an agreement modelled too closely on the specifics of the PIP Framework would be unlikely as the PIP Framework was an agreement retrofitted to actual operations of the existing global influenza sample sharing system (GISN/GISRS). In the assessment of the WHO's 2016 review of the PIP Framework:

for most new and emerging pathogens, there is no established laboratory network that regularly shares samples and expertise with an associated established vaccine (or other product) production capacity. Thus, while the sharing of viruses and benefits on an equal footing could be applied to other pathogens, using the PIP Framework as a template is likely to present significant implementational and operational challenges.¹⁶⁷

the PIP Framework since the sharing of GSD largely operates outside the virus sharing and benefit sharing rules of the PIP Framework.'

¹⁶⁰ See eg E Hammond, 'Access and Benefit Sharing for Pathogens: An Overview of the Issues Facing the 2021 World Health Assembly and WHO Executive Board' (Third World Network Briefing Paper 2020) 4 <https://www.twn.my/title2/briefing_papers/twn/ABS%20pathogens%20TWNBP%20Dec2020%20Hammond.pdf>; National Academies of Sciences, 'The Development of the PIP Framework: Global Lessons on Equity and Fairness for Pandemic Preparedness' (National Academies Press (US) 2019) 97.

¹⁶¹ WHO, 'Review of the Pandemic Influenza Preparedness Framework – Report by the Director-General' (n 158).
¹⁶² *ibid* 37.
¹⁶³ *ibid* 13.

¹⁶⁴ See comments attributed to Makarim Wibisono in National Academies of Sciences (n 160) 97.
¹⁶⁵ See comments attributed to John Lange in *ibid* 97.

¹⁶⁶ See comments attributed to Anne Huvos in *ibid* 98.

¹⁶⁷ WHO, 'Review of the Pandemic Influenza Preparedness Framework – Report by the Director-General' (n 158) 37.

Whether the scope of the PIP Framework is somehow expanded to include other pathogens or is used as a model or template for pathogen ABS,¹⁶⁸ the adoption of another non-binding resolution for pathogen ABS would mean that any ABS provisions are still vulnerable to being undermined by bilateral ABS approaches as discussed in this article.

Lastly, there is the option to adopt a completely novel multilateral ABS agreement, not necessarily in the image of the PIP Framework, covering all human pathogens. This could take multiple forms as voluntary guidelines, a non-binding resolution, or a binding international treaty. The implementation of the Nagoya Protocol has been seen by some as ‘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, with the aim of having the agreement recognised as an Article 4.4 specialised instrument’.¹⁶⁹ Such an instrument would not necessarily use the same structure of the PIP Framework and would be designed in accordance with the principles of Article 15 of the CBD, and the Nagoya Protocol. Much has been made of the ability to have such an agreement recognised as a specialised international ABS instrument under Article 4(4) of the Nagoya Protocol, however this idea and its implications have not yet been thoroughly considered and there are still uncertainties around what international body or bodies can do the recognising (not all WHO Member States are parties to the Nagoya Protocol), and what effect recognition would actually have (recognition cannot, for instance, make non-binding ABS instruments compulsory).¹⁷⁰

Potential solutions to the problems identified in this article may need to be identified sooner, rather than later. On 30 March 2021 a joint statement signed by the WHO Director-General and 27 heads of State, which stated that ‘we believe that nations should work together towards a new international treaty for pandemic preparedness and response’ including in the field of equitable access to medical countermeasures during a pandemic. The signatories stated their commitment ‘to ensuring universal and equitable access to safe, efficacious and affordable vaccines, medicines and diagnostics for this and future pandemics’. They also boldly proclaimed that

¹⁶⁸ One recommendation of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response was that the WHO Secretariat and States Parties should ‘Consider using the PIP Framework or similar existing agreements as a template for creating new agreements for other infectious agents that have caused, or may potentially cause, PHEICs.’ WHO, ‘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’ (n 154) 11.

¹⁶⁹ WHO, ‘Implementation of the Nagoya Protocol on Pathogen Sharing: Public Health Implications; Study by the Secretariat’ (2017) 25 (for presentation at the 140th Executive Board) <https://www.who.int/influenza/Nagoya_Full_Study_English.pdf>.

¹⁷⁰ See CBD, ‘Study into Criteria to Identify a Specialized International Access and Benefit-Sharing Instrument, and a Possible Process for its Recognition: Note by The Executive Secretary’ (29 May 2018) CBD/SBI/2/INF/17 <<https://www.cbd.int/doc/c/9376/a644/1bed20a1837af8e3d1edc5f9/sbi-02-inf-17-en.pdf>> and Rourke and Eccleston-Turner (n 15).

'immunization is a global public good and we will need to be able to develop, manufacture and deploy vaccines as quickly as possible'.¹⁷¹ Strong words, which seemed to wholly ignore the fact that many of those same signatories were presently engaging in rampant vaccine nationalism during the COVID-19 pandemic, which was denying universal and equitable access to the world's poorest.¹⁷² Nevertheless, the proposed pandemic treaty does appear to be the most appropriate mechanism by which to resolve the conflict inherent within the current approach to pathogen ABS, namely, how can a pathogen be both a tradable sovereign genetic resource as well as a vital component of a pathogen research commons? As outlined above, at present the WHO is attempting to treat pathogens as both, with limited (to no) success.

This problem is further compounded by the fact that pathogens are seen by some developing countries as one of the few 'bargaining chips' they hold, and that the ABS transaction is a mechanism by which they could potentially secure much needed access to medicines.¹⁷³ To this end, the CBD and Nagoya can be seen as a mechanism to help rebalance the power divisions between developing and developed countries. Indeed, trading pathogens for access may be one of the few points of leverage developing countries do have in such circumstances. As efforts to ensure 'equitable' access to vaccines during COVID-19 demonstrates, developing countries continue to lack anything approaching fairness, equity, or justice, and without meaningful binding commitments regarding equitable access to medical countermeasures in a future pandemic treaty, expecting developing countries to give up the ability to trade their pathogens for access to countermeasures in an ABS transaction would be unjust. The point here is that developed countries are the ones who need to make the first move. They must ensure there is a fair system in place to deliver vaccines during the next pandemic *before* asking developing countries to forego their sovereign rights over their pathogens to contribute them to a research commons outside of any ABS arrangement.

VI. CONCLUSION—DELINKING ACCESS FROM BENEFIT SHARING

This article assesses the ability of the PIP Framework to achieve its stated objective of a 'fair, transparent, equitable, efficient, effective system' for accessing pandemic influenza samples and sharing the benefits associated with their use,¹⁷⁴ by analysing the ABS mechanism upon which it is based. As the final section has demonstrated, the ABS concept has taken over the

¹⁷¹ JV Bainimarama *et al.*, 'COVID-19 Shows Why United Action Is Needed for More Robust International Health Architecture' (*WHO*, 30 March 2021) <<https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture>>.

¹⁷² Eccleston-Turner and Upton, 'International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility' (n 99).

¹⁷³ Wilke (n 95).

¹⁷⁴ PIP Framework (n 34) art 2.

policy discussion on pathogen sharing at the WHO,¹⁷⁵ and there appears to be little scepticism of its ability to deliver vaccines and other medicines to countries when they are in need. Clearly, ready access to pathogen samples for epidemiological modelling as well as research and development is of vital importance, as is fair and equitable access to vaccines and medicines, especially for the most vulnerable populations in the world. However, it is not necessary to link these issues through anything that looks like an ABS transaction, whether bilateral or multilateral. Indeed, that ABS was never raised as a possible solution for either of these issues in relation to the COVID-19 pandemic indicates that it will not be suitable for future public health emergencies.

During the negotiations of the PIP Framework, there was some resistance to the linking of these issues through the ABS transaction.¹⁷⁶ Linking access to pathogens to the sharing of vaccines, whether through bilateral transactions or a series of transactions within a multilateral arrangement, turns pathogens into tradable commodities and introduces market dynamics into a relationship that could otherwise be mediated in a non-transactional way. Whether bilateral or multilateral, ABS creates (yet another) space in which providers and users are antagonists, buyers, and sellers, both of whom want to maximise their own gains. Despite this, 'there was and remains [...] a solid normative basis for the expectation that viruses, and other pathogens, for that matter, should be shared for the sake of global health'.¹⁷⁷ It is a norm that was, thankfully, upheld to some extent by China when they shared the genome sequence of SARS-CoV-2 quickly and freely in the very early days of the COVID-19 pandemic.¹⁷⁸ On the one hand, the world is relying on a norm to be able to respond to infectious disease emergencies, while on the other it is actively undermining this norm with the application of pathogen ABS policies.¹⁷⁹ This norm should be strengthened, and could be strengthened if developing countries were not made to feel that ABS policies were their only opportunity to get access to vaccines and antivirals during an infectious disease emergency. We should be looking to develop these issues in parallel. Linking the two issues, however, guarantees that neither access to pathogens nor the sharing of the benefits associated with their use will occur in a fair and equitable manner.

The stated goals of the CBD, Nagoya Protocol and PIP Framework are undoubtedly worthy, but the effectiveness of these instruments can and should

¹⁷⁵ S Laird *et al.*, 'Rethink the Expansion of Access and Benefit Sharing' (2020) 367 *Science* 1200.

¹⁷⁶ See Ambassador John Lange's comments in S Nebehay, 'Indonesia and U.S. Square off at Bird Flu Talks' (*Reuters Health E-line*, 20 November 2007) <<https://www.reuters.com/article/us-birdflu-who/indonesia-and-u-s-square-off-at-bird-flu-talks-idUSL2023534820071120>>.

¹⁷⁷ Jakob (n 80).

¹⁷⁸ See Rourke *et al.* (n 139) So early, in fact, that neither the virus nor the disease yet had these names.

¹⁷⁹ Jakob (n 80) 15.

be questioned so their weaknesses can be strengthened.¹⁸⁰ The rhetoric of equality and fairness makes ABS sound appealing, but its ability to actually deliver equity and fairness in the public health space is questionable, and our cynicism is supported by almost three decades of disappointing ABS outcomes in the environmental conservation space.¹⁸¹ These issues are better served when dealt with in parallel and incentives are matched, rather than being framed as a trade-off between parties with opposing incentives.

¹⁸⁰ We are certainly not arguing for the status quo ante: the inequalities that Indonesia raised in 2007 continue to be a problem. Prior informed consent for the use of sovereign genetic resources, recognition of the efforts of local scientists and the inclusion of local scientists in research using the genetic resources of their country should be seen as a basic scientific courtesy as opposed to a formal ABS requirement.

¹⁸¹ See eg K Divakaran Prathapan *et al.*, 'When the Cure Kills—CBD Limits Biodiversity Research' (2018) 360 *Science* 1405; D Neumann *et al.*, 'Global Biodiversity Research Tied up by Juridical Interpretations of Access and Benefit Sharing' (2018) 18 *Organisms Diversity & Evolution* 1. Lawson, Rourke and Humphries (n 8).