

Biodiversity, Pathogen Sharing and International Law

Stephanie Switzer, Elisa Morgera, Elsa Tsioumani and Gian Luca Burci

1. Introduction

The sharing of pathogens is fundamental to global health and has the capacity to contribute, *inter alia*, to enhancing disease surveillance activities necessary for global health security, building and bolstering diagnostic capacity, assisting in risk assessment, as well as the development of vaccines and treatments such as antivirals.¹ In order for an effective infectious disease response to be realised, however, pathogen sharing on its own is not enough. Instead, ‘fair and equitable access to diagnostics, vaccines and treatments’² is also required.

Sharing of pathogens occurs in a number of ways; ‘ad hoc, bilaterally, as the need arises, or through existing networks of institutions and researchers.’³ The World Health Organisation (WHO) is often involved in pathogen sharing, performing a coordination or support role.⁴ The Global Polio Laboratory Network (GPLN), coordinated by the WHO, is an example of an existing network through which collaborating laboratories share samples of poliomyelitis virus.⁵ The GPLN complements the work of the Global Polio Eradication Initiative (GPEI) launched in 1988, which aims to ‘complete the eradication and containment of all wild, vaccine-related and Sabin polioviruses.’⁶ The global incidence of polio has decreased by 99.9% since the inception of the GPEI programme.⁷ The public health context is similar in respect of influenza, for which ‘monitoring the evolution and spread of viruses, and responding to outbreaks, is a continuous process, requiring constant access to samples of circulating influenza viruses.’⁸ Accordingly, thousands of

¹ WHO, ‘Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications – Study by the Secretariat’ available at <www.who.int/un-collaboration/partners/Nagoya_Full_Study_English.pdf> 6.

² *ibid.*

³ *ibid.* 5.

⁴ *ibid.* 19-20.

⁵ *ibid.* 6.

⁶ Polio Global Eradication Initiative ‘Our Mission’ <<http://polioeradication.org/who-we-are/our-mission/>> accessed 15 January 2019.

⁷ *ibid.*

⁸ WHO (n 1) 5.

samples are shared each year among collaborating laboratories of the Global Influenza Surveillance and Response System (GISRS), allowing for timely risk assessment as well as the development of measures of risk management such as vaccines.⁹

While the sharing of pathogens is clearly important to global health, it is not an area without controversy. Recently, particular concern has arisen in respect of the sharing of influenza viruses with human pandemic potential and of their benefits, including vaccines.¹⁰ This prompted the World Health Assembly to adopt in 2011 resolution WHA64.5 establishing the Pandemic Influenza Preparedness (PIP) Framework. The aim of this Framework is to promote the ‘objective of a fair, transparent, equitable, efficient, and 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, such as diagnostics and antivirals.’¹¹ Accordingly, under the PIP Framework, the sharing of influenza viruses of human pandemic potential is balanced with access to vaccines and the sharing of other benefits.

Shortly before the passing of resolution WHA64.5, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (hereinafter the Protocol) was adopted as a supplementary protocol to the UN Convention on Biological Diversity (CBD).¹² The Protocol expands upon the existing provisions of the CBD on access and benefit-sharing (ABS) with its objective being to promote the ‘fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.’¹³ While the Nagoya Protocol is silent on whether genetic resources within its scope include those with pathogenic potential, pathogens are considered by at least some commentators to fall within the scope of the Protocol.¹⁴ However, the particularities of pathogens are recognized within the Protocol, as Parties are required to ‘pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health.’¹⁵

⁹ *ibid.*

¹⁰ See discussion in section two, below.

¹¹ World Health Organization (WHO), Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, WHA64.5, 24 May 2011, <http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf> (hereinafter PIP Framework).

¹² Convention on Biological Diversity (CBD) 1992, 1760 UNTS 79.

¹³ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization 2014, CBD Decision X/1 (2010) (hereinafter Nagoya Protocol), art. 1.

¹⁴ See discussion in Marie Wilke, ‘A Healthy Look at the Nagoya Protocol - Implications for Global Health Governance’ in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective* (Martinus Nijhoff 2013) 132.

¹⁵ Nagoya Protocol, art. 8(b). See also preambular para 17.

The WHO PIP Framework is an ABS instrument that aims to put the sharing of influenza viruses of human pandemic potential on a par with access to benefits such as vaccines. Negotiated at broadly the same time, the ‘negotiation dynamics’ between the Nagoya Protocol and the PIP were ‘highly interlinked.’¹⁶ Despite these dynamics, however, a recent study by the WHO noted the existence, *inter alia*, of concerns that implementation of the Protocol could result in complexity, high transaction costs and potentially limit pathogen sharing.¹⁷ While the WHO study noted that the Protocol and the PIP were potentially complementary, it found a lack of legal clarity in respect of the relationship of the PIP Framework’s ABS provisions with that of the Protocol, with a consequent potential impact upon public health.¹⁸

Against the above background, this chapter focuses on the relationship between the PIP Framework and the Protocol to illustrate the legal issues arising from the interaction of different ABS systems. The chapter will also focus on concerns about fragmentation of international law, as well as the defensive approach adopted by States to prevent the establishment of normative hierarchy, particularly in the area of pathogen sharing. While there has been some discussion in the literature about the relationship between the Nagoya Protocol and the PIP Framework, much of this has sought to determine which instrument should apply in a particular situation. Our approach in this chapter is different: we seek to emphasise the potential of the principle of mutual supportiveness in international law as a tool to facilitate fruitful interactions between overlapping regimes. The legal and conceptual space, as well as the practical need, for such mutual supportiveness to guide interaction(s) between the two regimes at issue stems from the fact that the Nagoya Protocol, to borrow from the work of Cass Sunstein, is constructed as an ‘incompletely theorised agreement’ which offers opportunities for learning and experimentation with other regimes. Onto this conceptual foundation, we construct a framework for analysis of the PIP Framework and Nagoya Protocol focused on 1) opportunities for mutual learning and 2) experimentation across different international regimes and instruments.

In section two, we will delve further into the legal issues surrounding the relationship between the PIP Framework and the Nagoya Protocol with a view to discerning at a more granular level the legal issues arising from the interaction of these different ABS systems. In section three, we seek to position the current debate regarding the interaction of different ABS systems as one ultimately engaging the more fundamental question of how to facilitate effective interactions between regimes with overlapping scope. In this section, we draw from a range of literature, including from the realm of political science, as well as from the principle of mutual

¹⁶ Wilke (n 14) 125.

¹⁷ WHO (n 1) 7.

¹⁸ See generally *ibid* 18.

supportiveness in international law. In section four, we identify specific opportunities for mutual learning and experimentation under the Protocol and the PIP Framework, drawing on the concept of the incompletely theorised agreement to elucidate how uncertainties in the interaction between regimes may in fact produce positive externalities for ABS regimes that both allow for – but also require – further development for their effective operationalization. In section five, we conclude by reflecting on the opportunities for mutual learning across these two regimes premised on a proactive approach to experimentation in international law, rather than an exclusively defensive focus aimed at preventing normative hierarchy by clarifying the applicability of different regimes.

While our focus is on the relationship between the Protocol and the PIP Framework, our findings are nevertheless relevant for devising ways to manage constructively the interplay between the Nagoya Protocol with other pathogen-sharing schemes beyond influenza with pandemic human potential. As we confront a widening array of new and emerging infectious diseases whose control requires international collaboration such as MERS-CoV, Zika and new strains of influenza with pandemic potential, the world requires maximizing opportunities for collaboratively learning how to best address these global issues.¹⁹

2. Section Two – Legal Background

In this section, we begin by elucidating upon the legal background to the development of both the Nagoya Protocol and the PIP Framework. In so doing, we seek to articulate the flexibilities envisaged in the implementation of the Nagoya Protocol, highlighting its multi-level structure and the opportunities provided for experimentation by its non-hierarchical construction. Such flexibility could, however, be seen as detrimental to legal certainty, a concern which finds expression in recent discussions within the WHO on the (potential) implications for public health of the ABS system established by the Protocol. We then go on to provide some necessary additional background to the legal structure and underpinning dynamics of the PIP Framework. In the last strand of this section, we turn our attention to key aspects of the international debate on the interactions between the Protocol and the PIP Framework.

¹⁹ See generally WHO Executive Board, 140th Session, Report of the 2016 PIP Framework Review Group EB140/16 (2016) Annex 1, 14 <http://apps.who.int/gb/eb-wha/pdf_files/EB140/B140_16-en.pdf>.

2.1. *The Nagoya Protocol*

The Nagoya Protocol is a significant expansion on the existing provisions of the CBD on access and benefit-sharing²⁰ in respect of genetic resources and traditional knowledge associated with such resources.²¹ It aims to put into effect the 3rd objective of the CBD²² by detailing how to operationalise the provisions of CBD Article 15 with the aim of further supporting the effective implementation of the ABS provisions of the Convention.²³ CBD Article 15 established in general terms that sovereignty over natural resources extended to a right to regulate access to genetic resources: it stipulated that such access should be on mutually agreed terms (MAT) and with prior informed consent (PIC) (unless otherwise specified by the country concerned), implying a bilateral ABS system between providers and users of genetic resources. These provisions are expanded upon in the Protocol and importantly, they are coupled by specific, innovative obligations to support compliance with the domestic legislation of the Party providing genetic resources, and contractual obligations reflected in MAT. The Protocol sets down in Article 6, for example, baseline procedural requirements for PIC, as well as minimum specifications for MAT.²⁴ In the same vein, Article 5 of the Protocol gives further flesh to the meaning of fair and equitable benefit-sharing, clarifying that such benefits may be both monetary as well as non-monetary with States directed under Article 5 (5) to introduce ‘legislative, administrative or policy measures, as appropriate’ to ensure the sharing of benefits upon MAT.

Article 5 of the Protocol is illustrative of the particular reliance placed on national legislation to operationalise the Protocol’s “primary mandates”,²⁵ with Young, for example, articulating how the Protocol does not actually *create* an ABS regime, but rather calls for its creation through myriad paths of “implementation”

²⁰ Indeed, art. 1 of the CBD sets out that it is aimed, among other things, at the achievement of, ‘the fair and equitable sharing of benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.’ See also art. 8 (j) and art. 15 CBD.

²¹ See Elisa Morgera, Matthias Buck and Elsa Tsioumani, ‘Introduction’ in Morgera, Buck and Tsioumani (n 14) 1-17.

²² Nagoya Protocol, 2nd preambular recital, which reiterates the relevant wording of CBD, art. 1.

²³ Nagoya Protocol, 4th and 12th preambular recital.

²⁴ See discussion in Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unravelling The Nagoya Protocol: A Commentary on Access and Benefit-sharing to the Convention on Biological Diversity* (Brill 2014) 139-169.

²⁵ Tomme Rosanne Young, ‘An International Cooperation Perspective on the Implementation of the Nagoya Protocol’ in Morgera, Buck and Tsioumani (n 14) 451, 462. That is not to say that there are not, to use the terminology of Young, ‘international ABS implementation tools’ with, for example, the ABS clearing house provided for in art. 14 Nagoya Protocol one such international tool; at 469.

and “regime development”.²⁶ In this regard, Young has opined that the creation of a functional ABS regime under the Protocol calls for coordination across different levels and functional areas of law.²⁷ This extends to a requirement for coordination across different legal orders and among different actors involved in ABS.²⁸ In this sense, the Protocol’s approach to governance is *multi-level* rather than hierarchical, with possibilities existing for flexibility and learning through implementation domestically and internationally.²⁹ Such flexibility arguably provides room for *experimentation* with a number of provisions, such as that on model contract clauses,³⁰ allowing a range of actors to contribute to building legal understandings as to their operation as well as to their implementation. However, an acknowledged ‘by-product’ of flexibility is the challenge(s) this can pose to Parties involved in the Protocol’s implementation.³¹ We can discern, at least in part, the challenges regarding the flexibility in the Protocol’s operation in respect of the relationship between the Nagoya Protocol and the PIP Framework. The 2016 Review of the PIP Framework noted, for example, that significant overlap existed with respect to the operation of the PIP Framework and the Protocol. The PIP Framework Review further noted that there was uncertainty as to whether both instruments would potentially apply to sharing of influenza virus of human pandemic potential.³² This could result in duplication and potentially slow down virus sharing, with a consequent impact upon pandemic preparedness and response.³³ We turn to these challenges in due course but before doing so, we delineate in more detail the legal structure and defining features of the PIP Framework.

2.2. The Pandemic Influenza Preparedness Framework

The origins of the PIP Framework are traceable to the avian influenza (H5N1) outbreak in 2006, with a growing fear that the virus could successfully transmit among humans and start a highly lethal pandemic.³⁴ Indonesia had shared human samples with the network of WHO-coordinated laboratories for risk assessment and risk management purposes³⁵ but in 2007 refused to continue doing so upon discovering

²⁶ *ibid* 457.

²⁷ *ibid* 462 - 463

²⁸ See Morgera, Buck and Tsioumani, ‘Introduction’ (n 21) 10.

²⁹ *ibid*.

³⁰ Nagoya Protocol, art. 19.

³¹ See Morgera, Buck and Tsioumani, ‘Introduction’ (n 21) 11.

³² WHO (n 19) 96.

³³ *ibid*.

³⁴ See generally Wilke (n 14) 124.

³⁵ See generally David Fidler, ‘Influenza Virus Samples, International Law, and Global Health

that an Australian pharmaceutical firm had developed a vaccine from one of the shared samples.³⁶ Indonesia also based its refusal to share samples upon the principle of sovereignty over genetic resources enshrined in the CBD; in essence, ‘it had never consented to the sharing of samples with private companies or to the commercial application of the samples ... now limiting Indonesia’s access to said vaccines ... in violation of the principle of sovereignty over genetic resources.’³⁷ The WHO subsequently confirmed that H5N1 samples shared through its Global Influenza Surveillance Network (GISN, later renamed GISRS) were modified and patents applied for in respect of genetic sequences of these modified samples without Indonesia’s consent.³⁸ This led to a situation which, in the words of Fidler, meant that ‘(d)eveloping countries provided information and virus samples to the WHO-operated system; pharmaceutical companies in industrialized countries then obtained free access to such samples, exploited them, and patented the resulting products, which the developing countries could not afford.’³⁹

Following the controversy, the World Health Assembly in 2007 passed Resolution WHA60.28 which urged Member States, ‘to continue to support, strengthen and improve the WHO Global Influenza Surveillance Network and its procedures through the timely sharing of viruses or specimens with WHO Collaborating Centres, as a foundation of public health, to ensure critical risk assessment and response, and to aim to ensure and promote transparent, fair and equitable sharing of benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies.’⁴⁰ The WHO Director General was further mandated, ‘to identify and propose, in close consultation with Member States, frameworks and mechanisms that aim to ensure fair and equitable sharing of benefits, in support of public health, among all Member States, taking strongly into consideration the specific needs of developing countries.’⁴¹ Four years of arduous negotiations resulted in the adoption in 2011 of World Health Assembly resolution WHA64.5 and the creation of the PIP Framework. As a World Health Assembly Resolution, it is not an international agreement in the ‘traditional’ international law sense⁴² though it clearly has legal effects.

As articulated in the introduction to this piece, the aim of the Framework is to ensure the sharing of biological material (BM) of influenza viruses with human

Diplomacy’ (2008) 14 *Emerging Infectious Diseases* 88.

³⁶ *ibid.*

³⁷ Wilke (n 14) 124.

³⁸ Fidler (n 35) 88.

³⁹ *ibid.*

⁴⁰ WHA60.28, 1(1).

⁴¹ *ibid* 2(1).

⁴² On the legal effects of WHA Resolutions, see Gian Luca Burci and Claude-Henry Vignes, *World Health Organization* (Kluwer Law International 2004).

pandemic potential (IVPP) on an ‘equal footing’ with access to the benefits arising from such sharing. Only IVPP falls within the PIP Framework system to the exclusion of seasonal influenza viruses though there have been discussions on whether to expand PIP Framework’s scope accordingly.⁴³ Under the PIP Framework, Member States should share IVPP BM through the GISRS.⁴⁴ GISRS functions under WHO terms of reference with transfers of PIP BM between GISRS collaborating institutions conducted through standard material transfer agreements (SMTA1).⁴⁵ BM of IVPP transferred to recipients outside the system are again regulated by standard material transfer agreements negotiated and concluded by the WHO (SMTA2). Each SMTA, once executed, constitutes a binding contract. The PIP Framework also introduced an Influenza Virus Tracking Mechanism (IVTM) as a confidence-building measure, to track transfers of BM within the system.

Transfers taking place under SMTA1 do not attract benefit-sharing obligations, nor can recipients apply for intellectual property rights over materials exchanged under the SMTA1.⁴⁶ There is no such exclusion for intellectual property rights in respect of recipients of PIP BM under SMTA2. However, recipients under an SMTA2 must engage in benefit-sharing activities according to a range of options annexed to the Agreement and to be agreed upon case-by-case. This can include a commitment to provide vaccines and antivirals during an outbreak of pandemic influenza.⁴⁷ Benefits are not shared on a bilateral basis between provider and recipient, but rather multilaterally through WHO with particular regard to the needs of developing countries. As a contract, the terms of SMTA2, including agreed benefit-sharing arrangements, are binding upon the relevant parties. Accordingly, while the PIP Framework is itself a soft law instrument, its central innovation from a global health perspective⁴⁸ is its reliance upon *private* law contractual instruments (SMTAs) to facilitate a central goal of global *public* health goal in the guise of

⁴³ For a note of discussion to bring seasonal influenza under the PIP see WHO (n19), s. 3.2.1. Samples of seasonal influenza are shared through the GISRS, which predates (as GISN) the formation of the PIP Framework. GISRS is coordinated by the Global Influenza Programme (GIP) although there is now close collaboration with the Secretariat of the PIP Framework; see generally Alan J Hay and John W McAuley, ‘The WHO Global Influenza Surveillance and Response System (GISRS)-A Future Perspective’ (2018) 12 *Influenza and Other Respiratory Viruses* 551.

⁴⁴ PIP Framework, 5.1.1; ‘Member States, through their National Influenza Centres and Other authorized laboratories, should in a rapid, systematic and timely manner provide PIP biological materials from all cases of H5N1 and other influenza viruses with human pandemic potential, as feasible, to the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory of the originating Member State’s choice.’

⁴⁵ PIP Framework, Annex 1.

⁴⁶ *ibid.*

⁴⁷ *ibid* Annex 2.

⁴⁸ Lawrence Gostin, *Global Health Law* (Harvard University Press 2014) 376.

pandemic preparedness and response. The goal of global health security is ultimately enshrined in the International Health Regulations, IHR (2005).⁴⁹ Not only do SMTAs assist in enrolling the private sector into a normative commitment to global health preparedness and response,⁵⁰ but they are also an important element in achieving the equity envisaged during the negotiations of the PIP Framework.⁵¹

An additional and indeed innovative form of benefit-sharing established under the PIP Framework is the ‘partnership contribution.’⁵² This is unique in the international ABS landscape and consists of financial contributions from vaccine, diagnostic and pharmaceutical manufacturers who use GISRS. The partnership contribution funds pandemic preparedness and response. The sum due is equivalent to 50% of the running costs of the GISRS which at present is approximately \$28 million.⁵³ As articulated by Gostin, international instruments in the sphere of global health seldom address private actors, so the approach of the PIP Framework is a ‘governance innovation’⁵⁴ that has contributed significantly to bolstering preparedness.⁵⁵

2.3. The Relationship between the PIP Framework and the Nagoya Protocol

In terms of the relationship between the PIP Framework and the Protocol,⁵⁶ while a number of proposals were made during the negotiation of the PIP Framework and Health Assembly resolution WHA64.5 which, if accepted, would have put the Framework either outside the scope of the Nagoya Protocol or have recognised it as hierarchically ‘superior’, these were not adopted and hence do not find expression within the final text of the Framework.⁵⁷ However, the regimes are linked both

⁴⁹ World Health Assembly, Revision of the International Health Regulations, WHA58.3, 23 May 2005, (hereinafter IHR (2005)).

⁵⁰ On the enrolment of the private sector into the normative underpinnings of the IHR, see Gearóid Ó Cuinn and Stephanie Switzer, ‘Ebola and the Airplane – Securing Mobility through Regime Interactions and Legal Adaptation’ (2019) 32 *Leiden Journal of International Law* 71.

⁵¹ Gostin (n 48).

⁵² PIP Framework, 6.14.3

⁵³ See at <www.healthpolicy-watch.org/who-report-shows-global-progress-on-influenza-preparedness-response/>.

⁵⁴ Gostin (n 48).

⁵⁵ See generally <www.healthpolicy-watch.org/who-report-shows-global-progress-on-influenza-preparedness-response/>

⁵⁶ See discussion in Wilke (n 14) 141.

⁵⁷ See *ibid* 143.

textually and normatively. Public health is, for example, accorded particular recognition in the preamble to the Protocol which directs Parties to be, '[m]indful of the International Health Regulations (2005) of the World Health Organisation and the importance of ensuring access to human pathogens for public health preparedness and response purposes.' As discussed further below, there are further references to health in the Protocol, specifically, 'present or imminent emergencies that threaten or damage human, animal or plant health' within the text of Article 8 (b) though the meaning of such an emergency is not defined. Conversely, the PIP Framework recognizes as one of its principles 'the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks'⁵⁸

As noted above, in 2016 the WHO Secretariat undertook a study on the implications of implementation of the Nagoya Protocol for public health.⁵⁹ While noting positive aspects of the Protocol from its capacity to promote 'greater trust and more equitable sharing of benefits', the study nevertheless found that there was a lack of clarity in respect to the application of the Nagoya Protocol to the sharing of influenza samples – both seasonal and pandemic.⁶⁰ The study also noted concerns that, depending upon the national legislation adopted by States to implement the Protocol, the procedures for bilateral PIC and MAT could prove overwhelming to the GISRS system that shares thousands of samples annually.⁶¹ A 2016 PIP Framework Review Group made similar findings, articulating that while the PIP Framework was the result of international negotiations aimed at balancing access with benefit-sharing, the Protocol could pose a threat to the PIP Framework. This, in the view of the Review Group, was due to the fact that, 'the implementation of the Nagoya Protocol may introduce uncertainty in relation to the sharing of influenza viruses, since numerous bilateral transactions could be required to be negotiated, which could delay the access to viruses.'⁶²

As a 'path' to deal with such uncertainty, the WHO 2016 study proposed three ways forward. The first would be to recognize the PIP Framework as a 'specialized international access and benefit-sharing instrument' within the meaning of Nagoya Protocol Article 4 (4). Under this provision, where such an instrument 'is consistent with and does not run counter to the objectives of the CBD and the Nagoya Protocol, the Nagoya Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resources covered by and for the purpose of the specialized instrument.'⁶³ In essence, recognition of the PIP Framework as a specialised international ABS instrument would exclude the applicability of

⁵⁸ PIP Framework, 1 (11).

⁵⁹ WHO (n 1).

⁶⁰ *ibid* 18.

⁶¹ *ibid*.

⁶² WHO (n 19) finding 71.

⁶³ WHO (n 1) 24.

the provisions of the Protocol to IVPP BM shared under the PIP Framework system. The 2016 WHO study also recommended that flexibilities in national implementing legislation such as those provided for under Article 8 (b) be availed of. Finally, the study suggested that use could be made of the space provided in Article 19 of the Protocol to develop standard templates for PIC and MAT in respect of pathogen sharing. The study suggested that this could be accompanied by codes of conduct for access to pathogens and benefit-sharing, as provided for in Article 20 of the Protocol.

In 2016, the second meeting of the Conference of the Parties serving as the Meeting of the Parties (COP/MOP 2) to the Nagoya Protocol discussed the WHO study with some expressing concern over the initiative taken outside of the Protocol to clarify its relationship with the PIP Framework. As a result, Parties requested the CBD Secretariat to liaise with WHO, share information on implementation of Article 8(b) of the Protocol, and carry out a study on the criteria and process to identify a specialised international ABS instrument within the meaning of Article 4(4) of the Protocol.⁶⁴ In 2018, COP/MOP 3 considered possible criteria for identifying specialized international ABS instruments and requested more time to take a decision.⁶⁵ Arguably, what these decisions reveal is a concern among States regarding the creation of hierarchy in international law and a propensity to address unclear relationships among different international instruments in a defensive way by avoiding the creation of hierarchies and focusing on concerns about which fora and/or which conditions determine priority among regimes. Some developing countries in particular were concerned about missing opportunities to promote fair and equitable benefit-sharing in the context of implementation of the Nagoya Protocol, due to developments happening in other fora, where they may be in a weaker negotiating position.

What is usually not considered in these intergovernmental discussions, however, is the opportunity for different regimes to share learning and support experimentation that can be mutually beneficial in their respective development and implementation. This is particularly important in the context of international regimes where the key concept, in this case, benefit-sharing, gives rise to unsettled questions about the achievement of its objectives, notably fairness and equity, as well as effectiveness.

An additional element of complexity in the implementation of each regime, as well as in their relationship, consists in the unexpectedly rapid development of biotechnology, in particular the increasing ability of laboratories to completely sequence the genomic structure of living organisms and turn them into digital files

⁶⁴ CBD/NP/MOP/DEC/2/5 (16 December 2016). See generally Earth Negotiations Bulletin, 'Summary of the UN Biodiversity Conference – 2-17 December 2016' (20 December 2016) <<http://enb.iisd.org/download/pdf/enb09678e.pdf>>, 27-28.

⁶⁵ CBD/NP/MOP/DEC/3/14 (30 November 2018).

that can be stored and accessed via databanks. Such a technology is referred to as ‘Genetic Sequence Data’ (GSD) by WHO and ‘Digital Sequence Information’ (DSI) in the environmental context: it enables laboratories to reconstruct a pathogen using a digital file as a source. This development creates challenges both for the implementation of each individual regime, as well as for their interactions, since both the PIP Framework and the CBD/Nagoya Protocol are explicitly premised on access to biological materials rather than information. Increasing reliance by research institutions and pharmaceutical companies on GSD/DSI to produce vaccines and other medical technologies risks side-lining, both legally and politically, the bargain achieved by the instruments under consideration. Both WHO and the Meeting of the Parties to the Nagoya Protocol are currently discussing the implications of GSD/DSI, in the former case with a view to expanding the PIP Framework’s scope to GSD and in the latter to consider whether information can be plausibly subsumed within the scope of the Protocol.⁶⁶ While this development is of the highest importance for the future of ABS and pathogen-sharing, the current transitional phase and uncertainty over both legal nature as well as practical consequence have led us in this chapter to focus on the sharing of biological materials *stricto sensu*.

3. Section Three

In this section, we present the current debate regarding the interaction of different ABS systems as one ultimately engaging the more fundamental question of how to facilitate effective interactions between regimes with overlapping scope.⁶⁷ We do so by exploring the complementary perspectives of regime interaction from international relations and the principle of mutual supportiveness from general international law.

As articulated above, the Nagoya Protocol establishes the framework for building an ABS regime but it does not build the regime as such.⁶⁸ Further regime development through multi-level implementation is required and more broadly, the structural foundation of the Protocol mandates coordination across different spheres, levels and actors within the Nagoya legal space.⁶⁹ In the words of Young, ‘completion and implementation of any sub-component of a regime, without the

⁶⁶ WHO, ‘Approaches to Seasonal Influenza and Genetic Sequence Data Under the PIP Framework’ (December 2018) <www.who.int/influenza/pip/WHA70108b_Analysis.pdf>.

⁶⁷ Please note section three and four both draw heavily on the work of Elisa Morgera, Stephanie Switzer and Elsa Tsioumani, ‘Study into Criteria to Identify a Specialized International Access and Benefit-Sharing Instrument, and a Possible Process for Its Recognition’ (2018) (CBD/SBI/2/INF/17).

⁶⁸ Young (n 25) 456.

⁶⁹ See discussion in section two, above.

rest of the overall regime may not, in itself, achieve any ABS objective.’ Rather, what is required is consideration of how these different elements ‘will interact (to) avoid gaps, overlaps, loopholes and other obstacles to effectiveness.’⁷⁰

Building the Nagoya Protocol regime clearly *also* implies consideration of how it will interact with other (related) regimes in practice, with active efforts required to navigate overlaps and governance gaps. Consideration of the interaction between the Protocol and the PIP Framework is only one part of the overall jigsaw. Conceptualised in this way, we begin to see the overlap and interaction between the Protocol and the PIP Framework not only as a legal issue, but rather as one requiring *management* of the inevitable – and indeed ongoing – regime interactions within the broader ABS space.⁷¹ These interactions could amount to a ‘regime complex’ – a network of ‘partially overlapping and non-hierarchical institutions governing a particular issue-area,’⁷² ‘exhibiting overlapping membership, and generat[ing] substantive, normative or operative interactions recognized as potentially problematic, whether or not they are managed effectively.’⁷³ Clearly, the governance of ABS may be conceptualised as a complex consisting of the Protocol, the CBD and approximately a dozen international institutions and processes including, *inter alia*, the WHO, as well as the Food and Agricultural Organization of the UN (FAO) with its International Treaty on Plant Genetic Resources for Food and Agriculture.⁷⁴ The CBD and the Protocol are undoubtedly at the centre of this institutional complex,⁷⁵ but within the ABS institutional complex are various sub-complexes that each have different dynamics and approaches to interaction.⁷⁶

Navigating these ABS sub-complexes, and indeed, working out proactive tools to manage the interactions between them, is a key task within the ABS institutional complex. *Managing* interactions among these sub-complexes requires an approach that is by necessity *legal*, but also goes beyond the law. This is because interaction

⁷⁰ Young (n 25) 457.

⁷¹ From the IR domain, one of the more commonly used definitions of a regime is ‘a set of implicit or explicit principles, norms, rules, and decision-making procedures around which actors’ expectations converge in a given area of international relations’: Stephen D Krasner, ‘Structural Causes and Regime Consequences’ (1982) 36 *International Organization* 185, 186.

⁷² Kal Raustiala and David G Victor, ‘The Regime Complex for Plant Genetic Resources’ (2004) 58 *International Organization* 277, 279.

⁷³ Amandine Orsini, Jean-Frédéric Morin, and Oran Young, ‘Regime Complexes: A Buzz, a Boom or a Boost for Global Governance?’ (2013) 19 *Global Governance* 27, 29.

⁷⁴ Sebastian Oberthür and Justyna Pozarowska, ‘Managing Institutional Complexity and Fragmentation: The Nagoya Protocol and the Global Governance of Genetic Resources’ (2013) 13 *Global Environmental Politics* 100, 106.

⁷⁵ *ibid.*

⁷⁶ Indeed, Oberthür and Pozarowska identify ‘three such sub-complexes that display separate logics of interaction, different types of division of labor and varying dynamics’, *ibid.*

both originates from and is shaped by political decisions.⁷⁷ This is a point echoed in the International Law Commission's report on fragmentation, which noted that while international law offers the structure for coordination and cooperation, either between States or between regimes and institutions, it does not contain clear-cut rules through which a global society's problem would be resolved, so '[d]eveloping these is a political task.'⁷⁸ Hence, when dealing with overlapping regimes, thinking upon how to use law to promote cooperation while at the same time recognising the inherently political aspect of this task is vital. Our approach echoes that of recent literature on overlapping regimes that has sought to draw attention to the ways in which certain legal processes have, 'created a space for pluralism, and contestation, and for the politicization of international law and of the jurisgenerative processes.'⁷⁹

Interplay management is 'the *conscious* efforts by relevant actors or groups to address and improve institutional interaction and its effects, usually in pursuit of collective objectives as enshrined in the institutions in question.'⁸⁰ Interplay management can take a number of different forms. It can relate to 'processes of learning' between institutions and regimes.⁸¹ Interplay management may be *normative* in that the norms of one institution either support or contradict those of another.⁸² It can also be *utilitarian* in that interplay may 'alter the costs and benefits of options available in another institution.'⁸³ Furthermore, interplay management may be *regulatory* with regard to prohibiting or permitting certain behaviour across regimes, as well as *enabling* it, in that it aims to create knowledge and understanding and enhance capacities to achieve shared governance goals.⁸⁴

⁷⁷ *ibid* 102.

⁷⁸ International Law Commission, Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law, UN Doc A/CN.4/L.682, 2006 (thereafter ILC study) para 488.

⁷⁹ Anne Peters, 'The Refinement of International Law: From Fragmentation to Regime Interaction and Politicization' (2017) 15 International Journal of Constitutional Law 671, 672.

⁸⁰ Oberthür and Pozarowska (n 74) 103 (emphasis added). Indeed, '[a]s the international legal system becomes more and more complex, the need for interplay management increases'; see Mark Axelrod, 'Savings Clauses and the "Chilling Effect" - Regime Interplay as Constraints on International Governance' in Sebastian Oberthür and Olav Schram Stokke (eds), *Managing Institutional Complexity: Regime Interplay and Global Environmental Change* (MIT Press 2011) 87, 89.

⁸¹ Olav Schram Stokke, 'The Interplay of International Regimes: Putting Effectiveness Theory to Work' (2001) FNI Report 14/2001, <www.fni.no/getfile.php/132044/Filer/Publikasjoner/FNI-R1401.pdf>, 10.

⁸² *ibid*.

⁸³ Sebastian Oberthür and Thomas Gehring, 'Institutional Interaction - Ten Years of Scholarly Development' in Oberthür and Stokke (n 80) 36.

⁸⁴ Sebastian Oberthür, 'Interplay Management: Enhancing Environmental Policy Integration Among International Institutions' (2009) 9 International Environmental Agreements: Politics, Law and Economics 371, 377.

The tools used by institutions to facilitate regime interplay management range from high-level coordination between institutions via the creation of a new institution for managing interaction, to 'lower' forms of interplay management such as information sharing.⁸⁵ Softer tools such as the latter may help foster mutual relationships between regimes by helping to facilitate institutional cooperation,⁸⁶ focusing upon processes and procedures designed to bring about learning and deliberation by multiple stakeholders.⁸⁷ Even when the capacity of information exchange and enhanced communication to bring about effective interplay between overlapping international regimes may not be obvious, policy diffusion across regimes, by building upon and cross-referencing norms from other regimes, may bring potential benefits.⁸⁸

The literature on regime interactions discussed above is instructive for a number of reasons. First, it provides empirical support for the contention that overlaps between regimes may promote synergies, depending upon how such overlaps are managed.⁸⁹ Furthermore, the literature also points to the potential of softer tools⁹⁰ to promote synergistic and mutually supportive outcomes.⁹¹

These insights provide a significant complement to legal approaches: general international law privileges a pragmatic solution to harmonizing what may appear as a fragmented legal landscape, through the adoption of new rules or the coordination of existing ones, while relying on legal interpretation to help structure the debate in order to foster *increased cooperation*.⁹² Foremost among the rule of international legal interpretation is mutual supportiveness, which builds upon the idea of international law as a 'system' comprised of disparate international rules that should be understood and applied as supporting each other.⁹³ Mutual supportiveness calls on States to avoid or resolve tensions between competing international

⁸⁵ *ibid* 375-377. See also Stokke (n 81) 12. See also discussion in Morgera, Switzer and Tsioumani (n 67) from which this discussion draws.

⁸⁶ See for example Harro van Asselt, 'Managing the Fragmentation of International Environmental Law: Forests at the Intersection of the Climate and Biodiversity Regimes,' (2012) 44 *New York University Journal of International Law and Politics* 1205, 1258.

⁸⁷ Margaret A Young, 'Fragmentation or Interaction: the WTO, Fisheries Subsidies, and International Law' (2009) 8 *World Trade Review* 477, 479. Though see Oberthür (n 84) at 382.

⁸⁸ See generally Young, *ibid*. On the synergistic potential of cross-referencing to promote synergistic regime interactions, see generally Ó Cuinn and Switzer (n 50). See also Morgera, Switzer and Tsioumani (n 67).

⁸⁹ See generally Oberthür (n 84) 376.

⁹⁰ van Asselt (n 86) 1258. See also Oberthür (n 84). See further Young (n 87).

⁹¹ Oberthür (n 84) 383.

⁹² Erik Franckx, 'The Protection of Biodiversity and Fisheries Management: Issues Raised by the Relationship between CITES and LOSC' in David Freestone, Richard Barnes and David Ong (eds), *The Law of the Sea: Progress and Prospects* (OUP 2006) 210 231-232 (albeit focused on *lex posterior* rather than *lex specialis*).

⁹³ Riccardo Pavoni, 'Mutual Supportiveness as a Principle of Interpretation and Law-Making: A

regimes both through interpretation, as well as through law-making. In essence, the principle of mutual supportiveness calls upon States to pursue the negotiation in good faith of instruments that help to clarify the relationship between competing regimes, particularly when efforts to interpret such conflict away have been to no avail.⁹⁴ Mutual supportiveness is therefore a broader concept than the general rules of treaty interpretation, because it also addresses law-making and is not limited to treaties, but applies also to other international '*instruments*' (such as decisions taken under a treaty or otherwise inter-governmentally approved).⁹⁵ These decisions may represent 'different ways of dealing' with a common issue under different international regimes, but can still 'lead to mutually supportive outcomes,'⁹⁶ thereby paving the way for 'fruitful interactions' between the two regimes.⁹⁷

As we discuss in the next section, the legal structure of the Protocol provides space for particular forms of interplay management, with a focus on experimentation and mutual learning with other regimes. Accordingly, we aim to throw light on the use of law and legal techniques to promote cooperation, while recognising that interplay management is not simply a legal process but one that has a political dimension.

4. Section Four – Translations

In this section, we examine the opportunities for mutual learning and experimentation in respect of both the Protocol and the PIP Framework. We draw on the concept of the incompletely theorised agreement to elucidate how uncertainties in the interaction between regimes may in fact produce positive externalities in the sense of leaving space for proactive cross-regime conversations and mutual learning.

Approaches to managing regime interplay based upon mutual learning and experimentation are explicitly foreseen within the text of the Protocol. Article 4 (3) of the Protocol, for example, encourages 'due regard ... to useful and relevant on-

Watershed for the "WTO-and-Competing-Regimes" Debate?,' (2010) 21 *European Journal of International Law* 649, at 650.

⁹⁴ *ibid* 661-669.

⁹⁵ The term "instrument", which, for example, is used in art. 4 (4) of the Protocol is not a term of art in international law, but it can be argued that such a term can cover both binding and non-binding instruments of an intergovernmental nature. We are grateful to Prof. Robin Churchill for pointing this out; see discussion in Morgera, Switzer and Tsioumani (n 67).

⁹⁶ Harro van Asselt, Francesco Sindico and Michael Mehling, 'Global Climate Change and the Fragmentation of International Law', (2008) 30 *Law and Policy* 423, 430.

⁹⁷ Margaret A Young, 'Climate Change and Regime Interaction', (2011) 5 *Carbon and Climate Law Review* 147, at 147.

going work or practices under such international instruments and relevant international organizations, provided they are supportive of and do not run counter to the objectives of the Convention and this Protocol.’ The reference to ‘useful’ arguably conveys an understanding that such a process can provide opportunities for fruitful exchanges and mutual learning. Furthermore, the text of Article 4 (3) directs the Parties to implement the Protocol, ‘in a mutually supportive manner with other international instruments relevant to this Protocol.’ Accordingly, the text of the Protocol provides an explicit recognition that its ongoing operation – the building of the regime, to paraphrase Young⁹⁸ – is not based on ideas such as hierarchy but rather on the promotion of mutual supportiveness.

Another way in which mutual supportiveness between the PIP Framework and the Protocol could manifest in practical terms is through Article 4 (4) of the Protocol. This provision of the Protocol underlines that Nagoya functions as a residual regime for ABS,⁹⁹ and does not apply in the case of application of a specialized ABS instrument as long as Parties ensure *not only* that specialized ABS agreements do not undermine the CBD and Protocol objectives, but *also*, that they contribute to their realization.¹⁰⁰ Attention should also be given to thinking upon how *ongoing* interactions such as information exchange, learning and deliberation might be fostered and promoted so as to prevent the *legal* recognition of an ABS instrument as a specialized international instrument under Article 4 (4) from leading to a political disconnection between the instrument in question and the Nagoya Protocol.¹⁰¹ This point is supported by the text of Article 4 (3), which while mainly addressing ongoing work in other fora, would also be helpful after the recognition of an instrument as a specialized international ABS instrument pursuant to Article 4 (4).¹⁰²

Mutual supportiveness may also involve an element of experimentation at a number of levels; in essence, a process of determining ‘best practices’ across different scales to determine a solution best suited to achieving synergistic outcomes. This is the case of the Protocol provisions on model contractual clauses and on codes of conduct. Moreover, the provision under Article 10 of the Protocol for a global multilateral benefit-sharing mechanism for transboundary situations or

⁹⁸ See generally Young (n 25).

⁹⁹ The first sentence of art. 4(4) indicates that; ‘This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention.’ The phrasing of the second sentence in art. 4(4) indicates that the Nagoya Protocol does not subsume other ABS agreements, but rather functions as a *residual* regime operating in the absence of specialized ABS instruments that meet certain conditions. See discussion in Morgera, Switzer and Tsioumani (n 67).

¹⁰⁰ Art. 4(2) provides that Parties must ensure that these agreements, ‘are supportive of and do not run counter to the objectives of the Convention and of the Protocol.’ Indeed, Nagoya Protocol, Art. 4(2) explicitly points the negative and positive side – ‘supportive of and do not run counter to the objectives of the Convention and [the] Protocol’. See Riccardo Pavoni, ‘The Nagoya Protocol and WTO Law’ in Morgera, Buck and Tsioumani (n 14) 185, 207.

¹⁰¹ See discussion in Morgera, Switzer and Tsioumani (n 67).

¹⁰² See discussion in *ibid* and above at section 2.3.

where it is not possible to obtain PIC provides further potential for experimentation.¹⁰³ In addition, and as elucidated upon above, ‘space’ for experimentation and mutual learning can be found under Nagoya Protocol Article 8 (b). A health emergency can certainly be a ‘public health emergency of international concern’ as determined by the WHO Director General using powers under the IHR (2005).¹⁰⁴ The broad formulation of Article 8 (b), however, does not exclude other international organizations working on pathogens, such as the International Plant Protection Convention¹⁰⁵ and accordingly foresees space for experimentation and mutual learning between countries with respect to cross-regime implementation at the domestic level.

The importance of experimentation can be motivated by the characterization of the Nagoya Protocol as an incompletely theorised agreement – that is, an agreement on which Parties could agree on ‘a highly abstract theory’ about benefit-sharing, but not necessarily on ‘what it entails in particular cases.’¹⁰⁶ While incompletely theorised agreements may represent a limited extent of consensus on a certain legal concept, they are not in themselves flawed. Such agreements may have societal benefits; we do not need to agree on everything to agree on something.¹⁰⁷ Article 4 (4) of the Protocol can be considered incompletely theorised because it encapsulates agreement on the ‘mid-level’ principle that certain ABS instruments can be specialized international instruments, but not agreement on how the principle plays out in particular circumstances – whether, for example, the PIP Framework is a specialized ABS instrument.¹⁰⁸ While the result of this may seem to be detrimental in that it produces uncertainty, it has arguably allowed space for processes of mutual learning between States, the WHO, the CBD, as well as the actors involved in this distinct space of ABS governance: for instance, on lessons learnt in the use of private contracts for the realization of fairness and equity,¹⁰⁹ or different methods to ensure the financial viability of international benefit-sharing mechanisms (such

¹⁰³ See further < www.cbd.int/doc/meetings/abs/abs-a10em-2016-01/official/abs-a10em-2016-01-02-en.pdf>.

¹⁰⁴ Wilke (n 14) 130.

¹⁰⁵ International Plant Protection Convention (Rome, 6 December 1951, in force 3 April 1952) 2367 UNTS 223.

¹⁰⁶ Cass R Sunstein, ‘Incompletely Theorized Agreements’ (2005) 108 *Harvard Law Review* 1733, 1739. See also Cass R Sunstein, ‘Incompletely Theorized Agreements in Constitutional Law’, John M. Olin Law and Economics Working Paper No. 322 (2 D Series).

¹⁰⁷ See generally *ibid*.

¹⁰⁸ For more on the different levels at which such agreements may be said to exist, see generally *ibid*.

¹⁰⁹ Elisa Morgera and Lorna Gillies, ‘Realizing the Objectives of Public International Environmental Law through Private Contracts: The Need for a Dialogue with Private International Law Scholars?’ in Duncan French, Verónica Ruiz Abou-Nigm and Kasey McCall Smith (eds), *Public and Private International Law: Strengthening Connections* (Hart 2018) 175-198.

as the partnership contribution in the PIP Framework discussed above).¹¹⁰ Indeed, the signing in 2015 of a memorandum of understanding between the CBD and the WHO¹¹¹ and ongoing cooperation on a range of issues linked to the relationship between biodiversity and human health point to a recognition of the importance of inter-regime learning.

Ever since the conclusion of the aforementioned MOU, the formal channel of communication between the two Secretariats has allowed for a regular exchange of information about developments, respective positions and needs, as well as areas of uncertainty. These, in turn, are taken into account in policy and normative developments. For example, the WHO Secretariat has been advocating for the recognition of the PIP Framework as a Specialized International Instrument under Article 4(4) of the Protocol and representing that position at subsequent meetings of the COP/MOP.¹¹² While the identification of criteria for the application of Article 4 (4) is still a work in progress as of January 2019, the Nagoya Protocol COP/MOP decided to include a standing item in the agenda of its subsequent sessions on cooperation with other international organizations ‘to take stock of developments in relevant international forums, including any information on specialized international access and benefit-sharing instruments recognized by another intergovernmental body and/or by a Party or group of Parties, with a view to enhancing mutual supportiveness between the Protocol and specialized international access and benefit-sharing instruments’.¹¹³ Similarly, WHO has impressed on the CBD Secretariat specific practical problems arising for the prompt sharing of seasonal influenza viruses from national implementation measures of the Nagoya Protocol.¹¹⁴

5. Section Five – Concluding Reflections

Amidst dominating concerns about fragmentation and potential hierarchies between the Nagoya Protocol and the WHO PIP Framework, this chapter calls attention to the need and opportunities for mutual learning across these two regimes premised both on the international law principle of mutual supportiveness and international relations studies on regime interactions. The chapter underscores how

¹¹⁰ Elisa Morgera, Study on Experiences Gained with the Development and Implementation of the Nagoya Protocol and Other Multilateral Mechanisms and the Potential Relevance of Ongoing Work Undertaken by Other Processes, Including Case Studies (2016) UN Doc UNEP/CBD/ABS/A10/EM/2016/1/2.

¹¹¹ See <www.cbd.int/doc/agreements/agmt-who-2015-07-23-mou-en.pdf>.

¹¹² WHO (n 66) 27.

¹¹³ *ibid.*

¹¹⁴ *ibid.* 29.

mutual learning can support a proactive approach to experimentation in international law that better suits the incompletely theorised nature of benefit-sharing under the Nagoya Protocol. This is particularly important where the key concept of benefit-sharing gives rise to unsettled questions about the achievement of its objectives as well as effectiveness. While the incompletely theorised nature of the Protocol may seem to be productive of uncertainty, our analysis has demonstrated it may also allow space for experimentation and processes of mutual learning to be engaged in between the WHO, the CBD, as well as the actors involved in this aspect of ABS governance. We therefore wish to emphasise the potential benefits of softer tools to help foster relationships between the relevant regimes by facilitating institutional cooperation and promoting learning and deliberation by multiple stakeholders.¹¹⁵ While our focus has been on the relationship between the Protocol and the PIP Framework, our findings are also relevant for thinking through and devising ways to manage the interplay between the Nagoya Protocol with other pathogen-sharing schemes beyond influenza with pandemic human potential, as well as other existing and emerging international instruments of relevance to ABS.

¹¹⁵ See also Young (n 87).

