

Chapter 11

Accessing and Benefit Sharing Avian Influenza Viruses Through the World Health Organization: a CBD and TRIPS Compromise Thanks to Indonesia's Sovereignty Claim?

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I. Introduction

The potential of avian influenza to infect humans on a pandemic scale with high mortality has created a new challenge for the United Nations' *Convention on Biological Diversity* ('CBD')¹ and the World Trade Organization's (*WTO's*) *Agreement on Trade-Related Aspects of Intellectual Property Rights* ('TRIPS' or 'TRIPS Agreement').² The challenge arises in the context of the legal arrangements for access and sharing of the influenza virus and the likely benefits resulting from that sharing. It is encapsulated in the following:

A deal is being negotiated that could see Indonesia end its policy of withholding samples from human cases of avian flu. Until now, Indonesia has refused to share its samples with the World Health Organization (WHO), saying it is unfair that ownership of the samples passes to the WHO collaborating centres, and that it does not benefit from any resulting papers or patents.

¹ *Convention on Biological Diversity* Opened for signature 5 June 1992, [1993] ATS 32 (entered into force 29 December 1993) ('*CBD*').

² *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3, annex 1C (*Agreement on Trade-Related Aspects of Intellectual Property Rights*) (entered into force 1 January 1995) ('*TRIPS Agreement*').

Indonesia says it will share samples under a material transfer agreement that allows research use, but gives Indonesia sovereign ownership of the samples. The country also wants access to vaccines developed using its samples. An international meeting [in November 2007] ended without agreement. But a statement, still being thrashed out by negotiators, is expected to open the way to concessions.³

There is a broadly accepted potential that vaccines can play a key role in limiting the impact of an avian influenza pandemic although the most efficient and effective response requires access to the virus to make the appropriate vaccines.⁴ As a consequence the existing legal frameworks, including the CBD and TRIPS, and the 'concession' made to Indonesia in making the H5N1 virus available to the World Health Organization's ('WHO's') Global Influenza Surveillance Network ('GISN'), comprising the National Influenza Centres, WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories,⁵ provides an unorthodox case study of the interaction between the CBD and TRIPS.

³ Nature News, 'Indonesia Edges Closer to Sharing Bird-flu Samples' (2007) 450 *Nature* 598. See also Endang Sedyaningsih, Siti Isfandari, Triono Soendoro and Siti Fadilah Supari, 'Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia' (2008) 37 *Annals Academy of Medicine Singapore* 482.

⁴ See, eg, *Avian and Pandemic Influenza: Best Practice for Sharing Influenza Viruses and Sequence Data*, 60th World Health Assembly, WHO Doc A60/INF.DOC./1 (2007) (Report by the Secretariat); Scientific Advisory Group on Pandemic Influenza (UK), *Pre-Pandemic and Pandemic Influenza Vaccines: Scientific Evidence Base* (2008) <ttp://www.dh.gov.uk> at 6 March 2009; World Health Organization, *Global Pandemic Influenza Action Plan to Increase Vaccine Supply*, WHO Doc WHO/IVB/06.13, WHO/CDS/EPR/GIP/2006.1 (2006).

⁵ See also World Health Organization, *A Summary of Tracking Avian Influenza A(H5N1) Specimens and Viruses Shared with WHO from 2003 to 2007* (2008)

This chapter addresses the legal framework applying to the sharing of genetic resources (in this case the avian influenza virus) and the ability of this framework to function efficiently and effectively. In short, a case study of access and benefit sharing. It outlines the ongoing 'conflict' between the CBD and TRIPS, then provides an overview of the CBD's access and benefit sharing framework. It then addresses the WHO's arrangements in place for accessing viruses and the development of vaccines to respond to potential pandemics (and other lesser outbreaks), then sets out the compromise arrangement between Indonesia and the Member States of the WHO so far. The chapter concludes with a discussion about the consequences of this compromise for the future implementation of the CBD and TRIPS arrangements, and the proposition that failure to negotiate a deal with Indonesia opens up the debate about the paramountcy of intellectual property and TRIPS, and the potential for other policy imperatives to override respect for intellectual property and TRIPS.

II. Influenza As a CBD 'Genetic Resource'

The CBD was signed at the conclusion of the United Nations Conference on Environment and Development⁶ with the objective of 'fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies,

<http://www.who.int/csr/disease/avian_influenza/TrackingHistoryH5N1_20080131.pdf> at 6 March 2009.

⁶ See Michael Grubb, Matthias Koch, Koy Thomson, Abby Munson and Francis Sullivan, *The Earth Summit Agreements: A Guide and Assessment* (1993).

taking into account all rights over those resources and to technologies, and by appropriate funding'.⁷ This objective of benefit sharing the uses of genetic resources marked a fundamental shift in binding international measures to conserve biodiversity:⁸ first, recognising that genetic resources are subject to a nation state's sovereign rights;⁹ second, by linking access to those resources with the outcomes of scientific research and commercial uses, and access to technology on more favourable and non-commercial terms, including the products and technologies of the private sector derived from those genetic resources;¹⁰ and third, by introducing intellectual property into the economic and policy debates about conserving genetic resources that might benefit future technological, economic and social development.¹¹

The term 'genetic resources' was broadly defined in the CBD to mean 'genetic material of actual or potential value', where 'genetic material' means 'any material of plant, animal, microbial or other origin containing functional units of heredity'.¹² This broad definition was an attempt by the international community to establish principles for the uses of genetic resources from *all* sources recognising that 'biological

⁷ CBD, art 1.

⁸ See, eg, David Tilford, 'Saving the Blueprints: The International Legal Regime for Plant Resources' (1998) 30 *Case Western Reserve Journal of International Law* 373, 387-418; Keith Aoki, 'Weeds, Seeds & Deeds: Recent Skirmishes in the Seed Wars' (2003) 11 *Cardozo Journal of International and Comparative Law* 247, 305-13.

⁹ CBD, art 15(1).

¹⁰ CBD, arts 15, 16, 19.

¹¹ CBD, preamble, arts 3, 10, 11, 15, 16, 19, 22. See also Organisation for Economic Co-operation and Development, *Harnessing Markets for Biodiversity: Towards Conservation and Sustainable Use* (2003) 18-19, 109; Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (2002) 57-72.

¹² CBD, art 2.

materials containing genetic resources have significant value for applications such as pharmaceuticals, biotechnological processes, mining, fisheries and forestry'.¹³ The term 'biological resources' includes 'genetic resources, organisms or parts thereof, populations, or any biotic component of ecosystems with actual or potential use or value to humanity'.¹⁴

The meaning of the term 'genetic resources' as defined in the CBD is not entirely clear, other than that the genetic resources over which access is being controlled are either from the state of origin of the resource or acquired by a party in accordance with the CBD.¹⁵ While the meaning of this term is essential to developing effective measures to implement an access regime and to share the ensuing benefits fairly and equitably,¹⁶ the parties to the CBD intended to cover a broader range of materials than the earlier United Nations Food and Agriculture Organization's *International Undertaking on Plant Genetic Resources*, and certainly included genetic materials from animals, plants and micro-organisms, whether terrestrial or marine.¹⁷ The Conference of the Parties ('COP') noted that, in practice, the CBD definition had

¹³ *Access to Genetic Resources and Benefit Sharing: Legislation, Administrative and Policy Information*, Conference of the Parties to the Convention on Biological Diversity 2nd mtg, [4], UN Doc No UNEP/CBD/COP/2/13 (1995) (Report by the Secretariat).

¹⁴ *CBD*, art 2.

¹⁵ *CBD*, art 15(3).

¹⁶ See Conference of the Parties to the CBD, *Access to Genetic Resources*, Conference of the Parties to the Convention on Biological Diversity 3rd mtg, [32], UN Doc UNEP/CBD/COP/3/20 (1996) (Note by the Executive Secretary).

¹⁷ *Access to Genetic Resources and Benefit Sharing: Legislation, Administrative and Policy Information*, Conference of the Parties to the Convention on Biological Diversity 2nd mtg, [49]-[50], UN Doc UNEP/CBD/COP/2/13 (1995) (Report by the Secretariat).

difficulties of under- and over-inclusion. Troublingly, the definition included human genetic materials,¹⁸ left out biochemicals¹⁹ and *ex-situ* holdings acquired before 29 December 1993²⁰ and applied only to some marine resources:²¹ '[t]he concern here was that, as these resources represent important and valuable manifestations of genetic diversity, leaving them outside the [CBD] would undermine the extent to which the [CBD] would be able to ensure the distribution of the full benefits of utilisation; a fundamental requirement of the equitable sharing of benefits'.²² Unfortunately neither the COP nor the CBD's Secretariat have provided a definitive explanation of what the term 'genetic resource' might mean, noting that in practice a number of Contracting Parties have adopted access regimes with broader scope than the CBD's definition, including 'genetic resources and derivatives'.²³ The ongoing elaboration and negotiation of an international regime on access and benefit-sharing shows the content of the CBD's term 'genetic resource' remains broad, flexible and contentious.²⁴

¹⁸ Ibid [64]-[65].

¹⁹ Ibid [51].

²⁰ Ibid [54].

²¹ Ibid [61]-[63].

²² *Access to Genetic Resources*, Conference of the Parties to the Convention on Biological Diversity 3rd mtg, [33], UN Doc UNEP/CBD/COP/3/20 (1996) (Note by the Executive Secretary).

²³ Ibid [34]; Conference of the Parties to the CBD, *Review of National, Regional and Sectoral Measures and Guidelines for Implementation of Article 15*, Conference of the Parties to the Convention on Biological Diversity 4th mtg, [30]-[34], UN Doc UNEP/CBD/COP/4/23 (1998).

²⁴ See Conference of the Parties to the CBD, *Report of the Conference of the Parties to the Convention on Biological Diversity on the Work of its Ninth Meeting*, Conference of the

The COP's discussions about avian influenza have focussed on the potential impact on wildlife.²⁵ However, the WHO appears to conceive of avian influenza as something to which the CBD might apply, '[r]ecognizing the sovereign right of States over their biological resources',²⁶ and this also appears to be the position of Indonesia.²⁷ Thus, for avian influenza viruses found within the sovereign jurisdiction of Indonesia there appears to be a strong argument that they could be 'genetic resources' for the purposes of the CBD²⁸ – this is arguably strengthened by the broad interpretation of this term to

Parties to the Convention on Biological Diversity 9th mtg, [194]-[195], UN Doc UNEP/CBD/COP/9/29 (2008).

²⁵ See, eg, Conference of the Parties to the CBD, *Report of the Eighth Meeting of the Parties to the Convention on Biological Diversity*, Conference of the Parties to the Convention on Biological Diversity 8th mtg, [70]-[75], UNEP/CBD/COP/8/31 (2006).

²⁶ Sixtieth World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, Res WHA60.28, World Health Assembly 60th mtg, preamble (2007).

²⁷ See Intergovernmental Meeting on Pandemic Influenza Preparedness, *Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness*, WHO Doc A/PIP/IGM/5 (2007), annex (Fundamental Principles and Elements for the Development of A New System for Virus Access and Fair And Equitable Benefit Sharing Arising from the Use of the Virus for the Pandemic Influenza Preparedness), [1] (Proposal by Indonesia).

²⁸ Albeit some countries maintain viruses are not natural resources covered by the CBD and object to the use of CBD language by the WHO: see Sangeeta Shashikant, *Key Issues Unresolved at WHO Meeting on Influenza Virus Sharing* (2008) Third World Network <<http://www.twinside.org.sg/title2/health.info/2008/twnhealthinfo20081201.htm>> at 6 March 2009.

include derivatives in putting the CBD into effect and accepted in the language of the WHO's ongoing discussions and negotiations about avian influenza virus sharing.²⁹

III. The CBD and TRIPS Context

At the time the CBD was being negotiated, there was almost universal consensus that the predominantly poor countries with the majority of the Earth's useful biological diversity (the South) should benefit from the exploitation of that diversity by the predominantly rich and technologically advanced countries (the North).³⁰ However, the content of the benefits to be shared from exploiting that accessed diversity and the issue of access to and transfer of technology to exploit those genetic resources remained contentious.³¹ A central contention was the developed North's view that intellectual property should be maintained and respected,³² the South contended that

²⁹ For example, the 'principles' addressed by the WHO in negotiating access and benefit sharing of viruses '[r]ecognize[s] the sovereign right of States over their biological resources': Intergovernmental Meeting on Pandemic Influenza Preparedness: *Sharing of Influenza Viruses and Access to Vaccines and other Benefits Open-Ended Working Group, Chair's Text – Draft – Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, WHO Doc A/PIP/IGM/WG/6 (2008) [1.1].

³⁰ See, eg, United Nations Development Program, *Conserving Indigenous Knowledge: Integrating New Systems of Integration* (1994). The developed countries of the North, though, are not a homogeneous, cohesive or coordinated block: see Rane Panjabi, *The Earth Summit at Rio: Politics, Economics and the Environment* (1997) 263-4.

³¹ See Alexander Gillespie, 'Common Property, Private Property and Equity: Clash of Values and the Quest to Preserve Biodiversity' (1995) 12 *Environmental and Planning Law Journal* 388, 389-92 and accompanying footnotes.

³² See generally, Panjabi, above n 30.

its genetic resources had value and exploiting that value was an opportunity to address poverty alleviation and technological development requiring more favourable and non-commercial terms of access to useful technology.³³ The contentions over the CBD might be reduced to: '[t]he South wants the technology and the North wants the South to have it. But while the South sees itself as a potential partner, the North looks South and sees only paying customers'.³⁴

The outcome of these contentions in the final text of the CBD was to postpone the resolution through agreeable diplomatic language effecting a compromise: 'that patents and other intellectual property rights may have an influence on the implementation of this [CBD]' with an obligation to 'cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives'.³⁵ The diplomatic language allowed the technology-rich countries of the North (principally the United States, European Union and Japan) to agree to preferential and concessional access to and transfer of technology using undefined terms that would not undermine the concern of the North to maintain their existing intellectual property arrangements.³⁶ The outcome

³³ See, eg, United Nations Environment Program, *Report of the Ad Hoc Working Group on the Work of the Second Session in Preparation for a Legal Instrument on Biological Diversity*, 7, UN Doc UNEP/BioDiv2/3 (1990).

³⁴ Tilford, above n 8, 419.

³⁵ *CBD*, art 16(5). See also Patricia Lucia and Cantuária Marin, *Providing Protection for Plant Genetic Resources: Patents, Sui Generis Systems, and Biopartnerships* (2002) 92.

³⁶ See, eg, Grubb et al, above n 6, 29.

was, at best, an in-principle agreement to exchange genetic resources for benefits that might include access to and transfer of technology.³⁷

This compromise also partly reflected the unresolved tensions between intellectual property negotiations in the areas of international trade and the environment being concurrently negotiated in different forums. The environmental CBD was negotiated under the auspices of the United Nations Environment Programme, the international trade TRIPS Agreement was being negotiated under the auspices of the General Agreement on Tariffs and Trade ('GATT').³⁸ The CBD attempted to set a balance by encouraging biodiversity rich countries to maintain their resources so that they might be sustainably used by countries with highly developed technology, with the benefits accruing to both biodiversity-rich and poor countries.³⁹ In contrast, TRIPS attempted to establish new rules and disciplines moving intellectual property into the realm of international trade laws so as to reduce distortions and impediments to international trade while encouraging new invention relying on the formula 'patents = free trade + investment = economic growth'.⁴⁰ According to the generalised South-North divide,⁴¹

³⁷ See, eg, Secretariat of the Convention on Biological Diversity, *Handbook of the Convention on Biological Diversity* (2nd edition, 2003) 310.

³⁸ See, eg, Secretariat of the World Trade Organization, *Trade and Environment at the WTO* (Secretariat of the World Trade Organization, 2004) <http://www.wto.org/english/res_e/booksp_e/trade_env_e.pdf> at 6 March 2009.

³⁹ See Organisation for Economic Co-operation and Development, above n 11, 18-19, 109.

⁴⁰ Susan Sell and Aseem Prakash, 'Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights' (2004) 48 *International Studies Quarterly* 143, 154. See also Peter Drahos, 'Global Property Rights in Information: The Story of TRIPS at the GATT' (1995) 13 *Prometheus* 6, 7.

the CBD imposes obligations on the biodiversity-rich South to provide access to its genetic resources;⁴² in return the technology-rich North facilitates access and transfer of technology, know-how, financial support and incentives⁴³ that promote economic growth, directly addressing the development agenda to alleviate poverty.⁴⁴

The expressed objection of the leading technology-rich North state, the United States, to the CBD's agreed text was that the treatment of finances, intellectual property, technology transfer and biotechnology were inadequate.⁴⁵ Of particular concern, the language dealing with intellectual property was 'a constraint to the transfer of technology rather than ... a prerequisite'⁴⁶ reflecting the United States' biotechnology industry's perspective that the CBD opened the way for countries to reduce the level of intellectual property protection and introduce compulsory licensing

⁴¹ For a contemporaneous commentary see: Geoffrey Palmer, 'The Earth Summit: What Went Wrong at Rio?' (1992) 70 *Washington University Law Quarterly* 1005.

⁴² *CBD*, arts 6-15.

⁴³ *CBD*, arts 16-21.

⁴⁴ See, eg, *Report of the United Nations Conference on the Environment and Development*, annex 1 (*Rio Declaration on Environment and Development*), UN Doc A/CONF 151/26 (Vol I) (1992).

⁴⁵ Secretariat of the Convention on Biological Diversity, above n 37, 311. See also 'United States: Declaration Made at the United Nations Environment Programme Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity' (1992) 31 *International Legal Materials* 848.

⁴⁶ United States Department of State, 'Convention on Biological Diversity' (1992) 3 *US Department of State Dispatches* 423.

arrangements.⁴⁷ However, the United States, following a change of administration, signed the CBD, subject to the following telling proviso:

The United States declares its understanding that access to and transfer of technology subject to intellectual property rights under this [CBD] require the recognition of, and consistency with, the adequate and effective protection of intellectual property rights, and thus does not provide a basis for the use of compulsory licensing laws to compel private companies to transfer technology under this agreement ... The United States declares its understanding of Art 16(2) that the phrase 'fair and favourable terms' means terms that are determined by a free market without trade restrictions and government coercion ... *The United States declares its understanding that fair and equitable sharing of the benefits arising out of the utilisation of genetic resources requires members of this [CBD] to respect the rights of other member countries and of private parties to the technology that arise out of such utilisation of genetic resources* ... For this reason the United States believes that the extension of adequate and effective intellectual property protection for the technology derived from the use of genetic resources is an essential prerequisite to the success of the [CBD].⁴⁸

Following entry into force of the CBD on 29 December 1993, minimum intellectual property standards have been established and codified in TRIPS for WTO member states (from 1 January 1995). The interaction between the CBD and TRIPS remains contentious. The internationally contested inherent conflicts are that TRIPS requires genetic materials be protected by patents or a *sui generis* plant variety that privately appropriates genetic resources over which a country has sovereign rights under the CBD. Further, these privileges do not also require the additional measures set out in

⁴⁷ United States Patent and Trademark Office, 'Biotech Group Explain Objection to Earth Summit's Biodiversity Treaty' (1992) 44 *Patent, Trademark and Copyright Journal* 120.

⁴⁸ Gillespie, above n 31, 394 (emphasis added). See also Kal Raustiala, 'Domestic Institutions and International Regulatory Cooperation: Comparative Responses to the Convention on Biological Diversity' (1997) 49 *World Politics* 482, 492-4.

the CBD, such as prior informed consent, mutually agreed terms and benefit sharing.⁴⁹

IV. CBD's Framework for Access and Benefit Sharing

Having articulated the general objective for the fair and equitable sharing of the benefits arising from using genetic resources, the CBD imposes a framework for its implementation. Thus, access to genetic resources is according to the authority of countries '[r]ecognising the sovereign rights of States over their natural resources'⁵⁰ with an obligation to facilitate access for 'environmental sound uses' without imposing restrictions that are counter to the CBD's objectives.⁵¹ Further, access must be from countries of origin or countries that have acquired the genetic resources according to the CBD,⁵² on mutually agreed terms,⁵³ with prior informed consent,⁵⁴ and most importantly, taking:

⁴⁹ See Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made*, UN Doc IP/C/W/368/Rev.1/Corr.1 (2006) (Note by the Secretariat, Corrigendum); Conference of the Parties to the CBD, *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity – Summary of Issues Raised and Points Made – Submission by the WTO Secretariat*, Conference of the Parties to the Convention on Biological Diversity 8th mtg, UN Doc UNEP/CBD/COP/8/INF/37 (2006).

⁵⁰ *CBD*, art 15(1). See also art 3.

⁵¹ *CBD*, art 15(2).

⁵² *CBD*, art 15(3).

⁵³ *CBD*, art 15(4).

⁵⁴ *CBD*, art 15(5).

legislative, administrative or policy measures, as appropriate, and in accordance with arts 16 [access to and transfer of technology] and 19 [handling of biotechnology and distribution of its benefits] and where necessary through the financial mechanism established by arts 20 [financial resources] and 21 [financial mechanism] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources.⁵⁵

In dealing with the access to and transfer of technology, the CBD text provides:

Each Contracting Party, recognising that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this [CBD], undertakes subject to the provisions of this art [16] to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.⁵⁶

Where access to and transfer of technology is made and the technology is 'subject to patents and other intellectual property rights', then 'access and transfer shall be provided on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights'.⁵⁷ Significantly, the CBD expressly provides that access to and transfer of technology to developing countries (and presumably this also includes the 'developing and least developed countries' as distinguished by TRIPS)⁵⁸ 'shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and where

⁵⁵ *CBD*, art 15(7).

⁵⁶ *CBD*, art 16(1).

⁵⁷ *CBD*, art 16(2).

⁵⁸ See *TRIPS Agreement*, art 66.

necessary in accordance with the financial mechanism'.⁵⁹ For all countries, the access to and transfer of technology 'protected by patents and other intellectual property rights' must be on 'mutually agreed terms' and 'in accordance with international law',⁶⁰ and:

The Contracting Parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this [CBD], shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.⁶¹

A key element in the access to and transfer of technology in exchange for access to genetic resources contemplated by the CBD text is that contracting states take 'legislative, administrative or policy measures' to require the private sector to facilitate 'access to, joint development and transfer of technology' for the benefit of 'both governmental institutions and the private sector of developing countries'.⁶² In respect of biotechnology, measures include the 'effective participation in biotechnological research activities'⁶³ and 'the results and benefits arising from biotechnologies based upon genetic resources'.⁶⁴ Other measures deal with the exchange of information⁶⁵ and technical and scientific cooperation.⁶⁶

⁵⁹ *CBD*, art 16(2)

⁶⁰ *CBD*, art 16(3).

⁶¹ *CBD*, art 16(5).

⁶² *CBD*, art 16(4).

⁶³ *CBD*, art 19(1).

⁶⁴ *CBD*, art 19(2).

⁶⁵ *CBD*, art 17.

⁶⁶ *CBD*, art 18.

A further requirement is that, 'as far as possible and as appropriate', each contracting party should '[a]dopt measures relating to the use of biological resources to avoid or minimise adverse impacts on biological diversity'.⁶⁷ The CBD text also recognises the special place of traditional and community knowledge, practices and innovations, requiring contracting parties, 'as far as possible and as appropriate', to:

[R]espect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.⁶⁸

Of particular significance to intellectual property, the CBD text also provides that contracting parties 'shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity'.⁶⁹ The CBD is not intended to affect 'existing' rights and obligations of contracting parties 'except where the exercise of those rights and obligations would cause serious damage or a threat to biological diversity'.⁷⁰

The voluntary Bonn Guidelines⁷¹ proposed the establishment of a 'competent national authority',⁷² identified the responsibilities of contracting parties that are the origin of

⁶⁷ CBD, art 10(b)

⁶⁸ CBD, art 8(j).

⁶⁹ CBD, art 11.

⁷⁰ CBD, art 22(1).

⁷¹ See Conference of the Parties to the CBD, *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Conference of the Parties to the

genetic resources and the implementation of mutually agreed terms,⁷³ and set out the steps in the access and benefit sharing process.⁷⁴ While the Bonn Guidelines do not appear to favour a specific approach to intellectual property rights, they contemplate private contracts addressing intellectual property rights and other matters between the resource holder and the exploiter dealing with the access and benefit sharing arrangements.⁷⁵ However, the Bonn Guidelines do deal at some length with the various methods by which benefits might be shared, identifying those involved in the resource management, scientific and commercial process and the various kinds of monetary and non-monetary benefits.⁷⁶

The development of an international regime is underway through the Ad Hoc Open-ended Working Group on Access and Benefit-sharing and distinct groups of technical and legal experts which are presently establishing and negotiating the text of an agreement.⁷⁷ It seems unlikely at this stage that the proposed international regime will notably restrict or limit existing TRIPS obligations, although the potential remains.⁷⁸

Convention on Biological Diversity 6th mtg, annex 1 (Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Sixth Meeting), VI/24(A) (Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization), UN Doc UNEP/CBD/COP/6/20 (2002) ('Bonn Guidelines').

⁷² Ibid [14].

⁷³ Ibid [16].

⁷⁴ Ibid [22]-[50].

⁷⁵ Ibid [45]-[50], annex, C.

⁷⁶ Ibid [45]-[50], appendix II,.

⁷⁷ See Conference of the Parties to the CBD, *Report of the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity*, Conference of the Parties to the Convention on Biological Diversity 7th mtg, UNEP/CBD/COP/7/21 (2004) 298-313; *Report of the Eighth Meeting of the Parties to the Convention on Biological Diversity*, above n 25, 128-

V. TRIPS Framework's Affect on Access and Benefit Sharing

TRIPS was an annexure to the Final Act of the 1986-1994 Uruguay Round of Multilateral Trade Negotiations which created the WTO. TRIPS essentially establishes the minimum intellectual property standards that must be applied by all WTO member states.⁷⁹ In respect of access and benefit sharing the CBD's genetic resources patents are the major form of intellectual property that will apply.⁸⁰ TRIPS provides, in part, that 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application ... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the

38; *Report of the Conference of the Parties to the Convention on Biological Diversity on the Work of its Ninth Meeting*, above n 24, 110-22.

⁷⁸ See Charles Lawson and Jay Sanderson, 'The Evolution of the CBD's Development Agenda that may Influence the Interpretation and Development of 'TRIPS' in Justin Malbon and Charles Lawson (eds), *Interpreting and Implementing the WTO Trade Related Agreement on Intellectual Property Rights: Is TRIPS Fair?* (2008) 131, 150-1.

⁷⁹ *TRIPS Agreement*, art 1.

⁸⁰ See Life Sciences Program, World Intellectual Property Organization, *Patent Issues Related to Influenza Viruses and Their Genes: An Overview* (2007) <http://www.who.int/csr/disease/avian_influenza/WIPO_IP_%20paper19_10_2007.pdf> at 8 March 2009; and Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits, *Patent Issues Related to Influenza Viruses and Their Genes*, WHO Doc A/PIP/IGM/3 (2007) (Report by the Director-General).

field of technology and whether products are imported or locally produced'.⁸¹ The terms 'inventive step' and 'capable of industrial application' are synonymous with the concepts of 'non-obviousness' and 'usefulness', respectively. For patenting genetic materials these words have been interpreted in many countries, including Australia, in such a way that the composition of genetic materials (such as a virus isolated from a bodily fluid sample) can be claimed as an 'invention' once removed from 'nature' with an industrial 'use'.⁸² The 'exclusive rights' of a patent owner are 'to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes' the patented product, process and product of the process.⁸³ The only direct exceptions permitted from this general scheme are: (i) inventions 'necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by ... law'; (ii) 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'; and (iii) 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes'.⁸⁴ There is also a cumulative three-limbed indirect exception. Firstly, the exception must only be a 'limited exception'. Secondly, the exception must not 'unreasonably conflict with normal exploitation of the patent'. And finally, the exception must not 'unreasonably prejudice

⁸¹ *TRIPS Agreement*, art 27(1).

⁸² See Charles Lawson and Catherine Pickering, 'Patenting Genetic Materials – Failing to Reflect the Value of Variation in DNA, RNA and Amino Acids' (2000) 11 *Australian Intellectual Property Journal* 69, 71-9.

⁸³ *TRIPS Agreement*, art 28.

⁸⁴ *TRIPS Agreement*, art 27(2)-(3).

the legitimate interests of the patent owner, taking account of the legitimate interests of third parties',⁸⁵ and that a patent holder's exclusive rights may be diminished by an authorising law after judicial or administrative processes have determined the patent to be anti-competitive, although each authorisation must be considered on its individual merits.⁸⁶

At least in theory, the property value established in the genetic resources by controlling access under the CBD can be distinguished from the value of the potential intellectual property from using that genetic resource, so that some of the value of the intellectual property can contribute to the compensation and incentive for biological diversity conservation.⁸⁷ At its most simple, the property rights over the accessed genetic resources under the CBD deal *only* with the tangible 'genetic resources'. TRIPS patents, meanwhile, relate *only* to the intangible innovation and creativity in products and processes that result from using the biological resource. Thus a patent deals with an 'invention' that is novel, non-obvious, and industrially useful and described in a way that can be followed by others, and establishes property (or 'exclusive rights' to certain dealings with the 'invention'). These are different economy commodities, one the tangible genetic resource and the other the intangible application of that genetic resource for an innovative or creative and useful purpose.⁸⁸

⁸⁵ *TRIPS Agreement*, art 30.

⁸⁶ *TRIPS Agreement*, art 31.

⁸⁷ For an overview of the issues see, eg, Timothy Swanson and Timo Goeschl, 'Property Rights Issues Involving Plant Genetic Resources: Implications of Ownership for Economic Efficiency' (2000) 32 *Ecological Economics* 75, 79-85.

⁸⁸ See Life Sciences Program, World Intellectual Property Organization, above n 80, 14-16. See also *Patent Issues Related to Influenza Viruses and Their Genes*, above n 80; Initiative for

This distinction may not, however, be so elegant in practice as a patent confounds the right to deal with the genetic resource as it is embodied in a tangible form (such as a purified and isolated virus sequence, or a composition *per se*) with the right to prevent others from using the genetic resource in other embodiments (such as the virus sequence in a diagnostic device or the preparation of a vaccine).⁸⁹ In short, the uncertainty arises because past claims (and disclosures in the public domain) to compositions *per se* may limit the value of future uses of the same or similar compositions, even where those uses are entirely different, because the patent's 'exclusive rights' are attached to the composition *per se* (according to its definition and description) rather than its many and varied useful application(s). As a consequence, the problem posed by patents is the potential to undermine the value of the accessed genetic resource and other *in situ* genetic resources by creating uncertain proprietary and use rights in the tangible accessed materials, and the uses of that material in innovative or creative and useful embodiments.⁹⁰ In the context of avian

Vaccine Research, World Health Organization, *Mapping of Intellectual Property Related to the Production of Pandemic Influenza Vaccines* (2007).

⁸⁹ See, eg, Lawson and Pickering, above n 82; Charles Lawson, 'Patenting Genetic Diversity – Old Rules May be Restricting the Exploitation of a New Technology' (1999) 6 *Journal of Law and Medicine* 373. See also Life Sciences Program, World Intellectual Property Organization, above n 80, 27-33; Ad Hoc Open-Ended Working Group on Access and Benefit-sharing, *Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology*, Ad Hoc Open-ended Working Group on Access and Benefit-sharing 3rd mtg, 32-52, UN Doc UNEP/CBD/WG-ABS/3/INF/4 (2005) (Submission by the European Community).

⁹⁰ For overly broad patent claims to biological materials see Lawson and Pickering, above n 82. For uncertain definitions and descriptions see Charles Lawson, 'Depositing Seeds to Comply with the *Patents Act 1990* (Cth) – The Adequacy of Definition and Description?' (2004) 23

influenza the consequence is potentially even starker: existing patents claiming a virus, or part of a virus composition *per se*, or a step in the development of a vaccine using a virus, or part of a virus composition *per se*, may prevent the use of that composition or require consent of with the patent holder to exercise the patented product, process or product of the process. The real potential for these kinds of results is readily apparent from an analysis of the existing avian influenza and vaccine patents⁹¹ and goes to the core of Indonesia's concern that an Indonesian provided H5N1 virus sample provided to the WHO's Global Influenza Surveillance Network ('GISN') was given to an Australian vaccine manufacturer that intended to patent (in some respect) the vaccine that Indonesia would then need to purchase.⁹²

Notably, TRIPS was embroiled in contentions between its members about 'the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics'⁹³ and the potential of patents to exacerbate those public health crises.⁹⁴

This arose in the context of whether TRIPS might be ameliorated by taking advantage

University of Tasmania Law Review 68. See also Life Sciences Program, World Intellectual Property Organization , above n 80.

⁹¹ See *Patent Issues Related to Influenza Viruses and Their Genes*, above n 80; Life Sciences Program, World Intellectual Property Organization, above n 80; Initiative for Vaccine Research, World Health Organization, above n 88.

⁹² See Sedyaningsih et al, above n 3, 486.

⁹³ *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (2001) [1].

⁹⁴ See, eg, Jane Nielsen and Dianne Nicol, 'Pharmaceutical Patents and Developing Countries: The Conundrum of Access and Incentive' (2002) 13 *Australian Intellectual Property Journal* 21, 21-4.

of one of its 'principles': 'Members may ... adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development ...'.⁹⁵ These issues were first formally identified in the Doha Declaration,⁹⁶ and then in the Declaration on the TRIPS Agreement and Public Health that provided, in part: 'we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'.⁹⁷

Subsequent work by the TRIPS Council and General Council extended the pharmaceutical product patent obligations until 2016 (para 7),⁹⁸ and formulated a resolution for importing pharmaceuticals under compulsory license to members without the necessary manufacturing capability to produce their own essential

⁹⁵ *TRIPS Agreement*, art 8(1).

⁹⁶ *Ministerial Declaration: Adopted on 14 November 2001*, WTO Doc WT/MIN(01)/DEC/1 (2001) [17] ('Doha Declaration').

⁹⁷ *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (2001) [4]-[7].

⁹⁸ See *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc IP/C/25 (2005) (Decision by the Council for TRIPS of 27 June 2002); Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Art 66(1) of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (2002); *Least-Developed Country Members – Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products*, WTO Doc WT/L/478 (2002) (Decision of the General Council of 8 July 2002)

medicines.⁹⁹ By the time of the Hong Kong Ministerial Conference the issue had further advanced,¹⁰⁰ so that through the amendment of TRIPS (specifically, the addition of art 31*bis*) there may be a solution to making patented pharmaceuticals available in public health programmes.¹⁰¹ The significance of these developments has been to confirm that 'TRIPS does not and should not prevent members from taking measures to protect public health',¹⁰² and that a solution exists for the making of vaccines through compulsory licensing where 'WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS'.¹⁰³

Despite all these developments, the threshold TRIPS obligations to respect patent rights remain subject only to the limited exceptions allowed by the 'flexibility' in TRIPS, and the possibility of compulsory licensing in the absence of necessary manufacturing capability. In addressing avian influenza and the likely resultant

⁹⁹ See *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (2003) (Decision of the General Council of 30 August 2003).

¹⁰⁰ *Doha Work Programme*, Ministerial Conference 6th sess, WTO Doc WT/MIN(05)/DEC (2005) [40] (Ministerial Declaration).

¹⁰¹ See Council for Trade-Related Aspects of Intellectual Property Rights, *Protocol Amending the TRIPS Agreement – Status of Acceptances*, WTO Doc IP/C/W/490/Rev.1 (2007) (Note from the Secretariat – Revision).

¹⁰² *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (2001) [4]. See also *Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness*, above n 27, annex.

¹⁰³ *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (2001) [6]. See also *Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness*, above n 27.

pandemic the response will require both improvements to domestic production capacity and efficacy of pandemic influenza vaccines targeted to the specific influenza variants.¹⁰⁴ The concern for countries of the South is that existing patents claiming a virus, or part of a virus composition *per se*, or a step in the development of a vaccine using a virus, or part of a virus composition *per se*, may prevent the use of that composition or require agreement with the patent holder to exercise the patented product, process or product of the process.¹⁰⁵ And while some of these patents may not be applicable in the particular jurisdiction, the technology necessary to develop efficient and effective vaccines needs to be accessed from patent holders in the countries of the North together with the related know-how and regulatory submissions data.¹⁰⁶ In short, intellectual property is a central concern in developing effective responses to avian influenza and the likely resultant pandemic.

VII. WHO and Avian Influenza

The WHO's International Health Regulations (2005) established a framework (effective from 15 June 2007) for preventing, controlling and responding to the international spread of diseases such as avian influenza.¹⁰⁷ As part of the general

¹⁰⁴ See Kelley Lee and David Fidler, 'Avian and Pandemic Influenza: Progress and Problems with Global Health Governance' (2007) 2 *Global Public Health* 215, 218-24. See also *Global Pandemic Influenza Action Plan to Increase Vaccine Supply*, above n 4.

¹⁰⁵ See *Patent Issues Related to Influenza Viruses and Their Genes*, above n 80; Life Sciences Program, World Intellectual Property Organization, above n 80; and Initiative for Vaccine Research, World Health Organization, above n 88.

¹⁰⁶ See, eg, Initiative for Vaccine Research, World Health Organization, above n 88, 1-2.

¹⁰⁷ *Revision of the International Health Regulations*, Res WHA58.3, World Health Assembly 58th mtg (2005) (*International Health Regulations (2005)*); See also Fifty-Ninth World Health

obligation on States 'to prevent, protect against, control and provide a public health response to the international spread of disease',¹⁰⁸ there is a more specific obligation to deal with 'biological substances':

States Parties shall, subject to national law and taking into account relevant international guidelines, facilitate the transport, entry, exit, processing and disposal of biological substances and diagnostic specimens, reagents and other diagnostic materials for verification and public health response purposes under these Regulations.¹⁰⁹

In implementing the International Health Regulations (2005), however, members were 'urged' to 'disseminate to WHO collaborating centres information and relevant biological materials related to highly pathogenic avian influenza and other novel influenza strains in a timely and consistent manner'.¹¹⁰ In addition to these measures, and expressly in response to the H5N1 avian influenza, the WHO convened a consultation with national immunisation programmes, national regulatory authorities, vaccine manufacturers and the research community to draw up the Global Pandemic Influenza Action Plan to Increase Vaccine Supply to identify and prioritise practical

Assembly, *Application of the International Health Regulations (2005)*, Res WHA59.2, World Health Assembly 59th mtg (2006); Fifty-Eighth World Health Assembly, *Strengthening Pandemic-Influenza Preparedness and Response*, Res WHA58.5, World Health Assembly 58th mtg (2005).

¹⁰⁸ *International Health Regulations (2005)*, art 2

¹⁰⁹ *Ibid* art 46.

¹¹⁰ *Application of the International Health Regulations (2005)*, Res WHA59.2, World Health Assembly 59th mtg (2006), [4(4)].

solutions for reducing the anticipated gaps in vaccine supply.¹¹¹ Subsequently, and after considering the developments, responses and follow-ups to avian and pandemic influenza,¹¹² members reaffirmed their obligations under the International Health Regulations (2005), recognising 'the sovereign right of States over their biological resources', and recognizing that 'intellectual property rights do not and should not prevent Member States from taking measures to protect public health'.¹¹³ Members also requested the Director-General of the WHO to undertake work directed at resolving the apparent conflicts between access to and benefit sharing of the virus.¹¹⁴ Importantly, the request specifically addressed the access to and benefit sharing of viruses from which vaccines could be made to deal with avian and other pandemic influenzas.¹¹⁵ This request involved both an interdisciplinary working group¹¹⁶ and an intergovernmental meeting.¹¹⁷

In response, the Director-General convened an interdisciplinary working group¹¹⁸ that addressed access and benefit sharing, in part, in the context of 'sharing of viruses and

¹¹¹ See World Health Organization, *Global Pandemic Influenza Action Plan to Increase Vaccine Supply*, above n 4. See also *ibid*; *Strengthening Pandemic-Influenza Preparedness and Response*, Res WHA58.5, World Health Assembly 58th mtg (2005).

¹¹² See *Global Pandemic Influenza Action Plan to Increase Vaccine Supply*, above n 4.

¹¹³ *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, Res WHA60.28, World Health Assembly 60th mtg, preamble (2007).

¹¹⁴ *Ibid* [2].

¹¹⁵ *Ibid* [2(5)].

¹¹⁶ *Ibid* [2(5)].

¹¹⁷ *Ibid* [2(7)].

¹¹⁸ Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits, *Sharing of Influenza Viruses and Access to*

information, and subsequent benefits' and 'development of standard terms and conditions and terms of reference for the transfer of influenza viruses'.¹¹⁹ While failing to provide a comprehensive consensus view, the interdisciplinary working group reported that the 'overriding concern expressed by most members ... was that neither intellectual property rights nor prior informed-consent requirements, if any, should stand in the way of developing and producing a pandemic influenza vaccine'.¹²⁰ The interdisciplinary working group also reported on the content of the proposed terms and conditions. The group considered that no party receiving, handling or using virus specimens should claim ownership,¹²¹ intellectual property claims needed to disclose the specimen's country of origin, and any 'financial gain' from an intellectual property should require an equivalent financial contribution to the WHO.¹²² This latter agreement set out a range of benefit sharing options including: cash, access to technology, transfer of technology and know-how, and provision of vaccines and their developmental components.¹²³ The outcomes of the

Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness, WHO Doc A/PIP/IGM/4 (2007) annex [1] (Report by the Director-General).

¹¹⁹ Ibid annex [4].

¹²⁰ Ibid annex [11].

¹²¹ Ibid annex, appendix 3 (Standard Terms and Conditions for the Transfer and Use of Influenza Biological Materials) [30].

¹²² Ibid annex, appendix 3 (Standard Terms and Conditions for the Transfer and Use of Influenza Biological Materials) [31]-[32].

¹²³ Ibid annex, appendix 3 (Standard Terms and Conditions for the Transfer and Use of Influenza Biological Materials) (Contribution Agreement to WHO's Coordinated International Sharing of Influenza Viruses & Benefits By and between WHO and [COMPANY NAME]).

interdisciplinary working group then contributed to the subsequent intergovernmental meeting.¹²⁴

The Director-General also convened an intergovernmental meeting 'to identify and propose, in close consultation with Member States, frameworks and mechanisms that aimed to ensure fair and equitable sharing of benefits'.¹²⁵ The outcome of this intergovernmental meeting was to identify and re-affirm the relevant 'guiding principles' for 'the sharing of, and access to, benefits that result from the sharing of influenza viruses'.¹²⁶ There was also an 'interim statement' from the intergovernmental meeting that appeared to accept that the existing domestic and international legal frameworks were not appropriate.¹²⁷

¹²⁴ See *ibid.*

¹²⁵ *Reports by the Director-General: Summary Progress Reports*, WHO Doc A/PIP/IGM/2 Rev.1 (2007) [1].

¹²⁶ *Ibid* [2]. See also *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, Res WHA60.28, World Health Assembly 60th mtg (2007) [2(5)]; *Avian and Pandemic Influenza: Developments, Response and Follow-up, and Application of the International Health Regulations (2005): Best Practice for Sharing Influenza Viruses and Sequence Data*, Executive Board 120th sess, WHO Doc EB120/INF.DOC./3 (2007) [7] (Report by the Secretariat).

¹²⁷ World Health Organisation Executive Board, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits – Intergovernmental Meeting: Report of Progress to Date*, Executive Board 122nd sess, WHO Doc EB122/5 (2008) annex 5 (Interim Statement of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits) preamble ('*Pandemic Influenza – Annex 5 – Interim Statement*'). See also Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits Open-Ended Working Group *Pandemic Influenza Preparedness: Sharing of*

The outcome of this intergovernmental meeting was to 'establish a technical and feasible system as soon as possible within WHO to track all shared H5N1 and other potentially pandemic human viruses and the parts thereof' (a traceability mechanism) and to 'establish an advisory mechanism to monitor, provide guidance to strengthen the functioning of the system and undertake necessary assessment of the trust-based system needed to protect public health' (an advisory mechanism).¹²⁸ In the interim however, 'viruses and samples are to be shared within the WHO system, consistent with national laws and regulations, while the detailed framework for virus sharing and benefit sharing continues to be developed'.¹²⁹ The interim traceability measures required that 'each A (H5N1) virus so submitted [be] assigned a unique identifier and data on it [be] stored in an electronic database'. The data to be stored in this was to 'include the location of each virus, information on analyses that have been done on the virus, further use of the virus in the development of H5N1 vaccine viruses, and recipients of the vaccine viruses and other viruses'.¹³⁰ The meeting also agreed to convene an open-ended working group to further advance the work of developing a

Influenza Viruses and Access to Vaccines and Other Benefits – Intergovernmental Meeting: Report of Progress to Date, Executive Board 122nd sess, WHO Doc EB122/5 (2008) annex 6 (Consolidated Outcome Text: Index) [2]-[2.5] (*Pandemic Influenza – Annex 6 – Consolidated Outcome Text: Index*),

¹²⁸ *Pandemic Influenza – Annex 5 – Interim Statement*, above n 127, [1]-[2]. See also *Pandemic Influenza – Annex 6 – Consolidated Outcome Text: Index*, above n 127.

¹²⁹ *Pandemic Influenza – Annex 5 – Interim Statement*, above n 127, [3]. See also *Pandemic Influenza – Annex 6 – Consolidated Outcome Text: Index*, above n 127.

¹³⁰ *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, World Health Assembly 61st mtg, WHO Doc, A61/4 (2008) [4] (Report by the Secretariat).

traceability mechanism and an advisory mechanism¹³¹ before suspending proceedings.¹³² While there remained considerable work to be done before reaching a comprehensive agreement about the sharing of viruses, it was apparent at this stage that the core requirements of the CBD for sovereign rights over biological resources, prior informed consent and access and benefit sharing according to agreement would form part of the resolution.¹³³ What essentially remained to be resolved was the text of the access and benefit sharing 'arrangements', some contention remaining about whether these were the definition and scope for the sharing of viruses or a 'Standard Material Transfer Agreement'.¹³⁴ Notably, Indonesia prefers the latter.¹³⁵ The significance of the terminology reflected the likely sources of influence on the 'arrangements' with the phrase 'Standard Material Transfer Agreement' having resonance for the CBD and other similar genetic resource sharing legal frameworks, such as the Food and Agriculture Organisation of the United Nations' *International Treaty on Plant Genetic Resources for Food and Agriculture*.¹³⁶

¹³¹ *Pandemic Influenza – Annex 5 – Interim Statement*, above n 127, [4]. See also *Pandemic Influenza – Annex 6 – Consolidated Outcome Text: Index*, above n 127.

¹³² *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, above n 130, [3].

¹³³ See *Pandemic Influenza – Annex 5 – Interim Statement*, above n 127, [6]. See also *Pandemic Influenza – Annex 6 – Consolidated Outcome Text: Index*, above n 127.

¹³⁴ *Pandemic Influenza – Annex 6 – Consolidated Outcome Text: Index*, above n 127.

¹³⁵ *Ibid.*

¹³⁶ See Charles Lawson, 'Patents and the CGIAR System of International Agricultural Research Centres' Germplasm Collections under the *International Treaty on Plant Genetic Resources for Food and Agriculture*' (2004) 55 *Australian Journal of Agricultural Research* 307.

Following this intergovernmental meeting the open-ended working group convened and decided 'to further the work on sharing influenza viruses and access to vaccines and other benefits by discussing, in an issue-based manner, aspects on which it was likely for the meeting to reach consensus'.¹³⁷ A 'Chair's text' was to be prepared for a future meeting and 'benefit sharing' was identified as 'crucial', with the minutes recording that 'the issue will be discussed' at that future meeting.¹³⁸ The 'Chair's text' was subsequently prepared and considered by the resumed open-ended working group and then an intergovernmental meeting.¹³⁹ The intergovernmental meeting considered a traceability mechanism,¹⁴⁰ an advisory mechanism,¹⁴¹ and updated virus sample sharing negotiations.¹⁴² The outcome was to entrench the bipolarity of views between South and North: the South, being the predominant providers of viruses, wanted to

¹³⁷ Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits Open-Ended Working Group, *Open-ended Working Group: Report on Progress to Date*, WHO Doc A/PIP/IGM/WG/5 (2008) [9].

¹³⁸ Ibid [10]; World Health Organization Executive Board, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, Executive Board 124th sess, WHO Doc EB124/4 (2008) [3] (Report by the Secretariat).

¹³⁹ See *Chair's Text – Draft – Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, above n 29.

¹⁴⁰ See Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines, *Reports by the Director-General: Summary Progress Reports – WHO Influenza Virus Traceability Mechanism*, WHO Doc A/PIP/IGM/9 (2008).

¹⁴¹ See Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines, *Reports of the Director-General: Establishment of the Advisory Mechanism*, WHO Doc A/PIP/IGM/8 (2008).

¹⁴² See *Chair's Text – Draft – Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, above n 29.

avoid development-stage intellectual property restrictions through benefit sharing arrangements; the North, hosting the laboratories and manufacturing capacity to produce vaccines and other medical products, wanted to allow intellectual property claims and avoid detailed (and potentially restrictive) benefit sharing arrangements.¹⁴³ The meeting was eventually suspended with disagreement remaining about the form and content of the benefit sharing arrangements and obligations.¹⁴⁴

VIII. WHO Compromise Arrangement

An early outcome of the WHO's action on avian influenza was an agreement to negotiate the terms of an instrument addressing issues relating to the sharing of viruses, including: sovereign rights, benefit sharing, capacity building, intellectual property, oversight mechanisms, technology transfer and transparency and accountability.¹⁴⁵ The content of the negotiating text falls within the obligations imposed by both the CBD and TRIPS and highlights the conflict between these obligations.¹⁴⁶

Significantly, at the same time that these debates were taking place about avian influenza and virus sharing, the WHO was also considering a policy formulated by the Commission on Intellectual Property Rights, Innovation and Public Health and an intergovernmental working group directed to 'an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products

¹⁴³ See Shashikant, above n 28.

¹⁴⁴ See *ibid.*

¹⁴⁵ *Pandemic Influenza – Annex 6 – Consolidated Outcome Text: Index*, above n 127.

¹⁴⁶ See, eg, *ibid.* arts 5.2-5.3, 7.1-7.2.

against diseases that disproportionately affect developing countries'.¹⁴⁷ The outcome was to the adoption of a 'global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property' for the period 2008-15.¹⁴⁸

The 'global strategy' and the 'agreed parts of the plan of action' do not displace the existing internationally contested provisions of the CBD or TRIPS. Essentially, the WHO's 'global strategy' position maintains the *status quo* for the CBD and TRIPS. This is important, as the negotiation of the 'global strategy' and the 'agreed parts of the plan of action' expressly excluded propositions that might have limited the application of the CBD or TRIPS.¹⁴⁹ So, for example, the statement that '[t]he right to health takes precedence over commercial interests'¹⁵⁰ was removed and the phrase 'promote transfer of technology and production of health products in developing countries through investment and capacity building, including by providing guidance on appropriate technologies' was reduced to 'promote transfer of technology and

¹⁴⁷ Fifty-Sixth World Health Assembly, *Intellectual Property Rights, Innovation and Public Health*, World Health Assembly 56th mtg, Res WHA56.27 (2003) [2(2)]; *Application of the International Health Regulations (2005)*, Res WHA59.2, World Health Assembly 59th mtg (2006) [3(1)].

¹⁴⁸ *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, World Health Assembly 61st mtg, Res WHA61.21 (2008) [1], annex (Global Strategy on Public Health, Innovation and Intellectual Property) [13].

¹⁴⁹ Compare the final text: Ibid annex (Global Strategy on Public Health, Innovation and Intellectual Property) with the negotiating text: Sixty-First World Health Assembly, *Report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property*, World Health Assembly 61st mtg, WHO Doc A61/9 (2008) annex 1.

¹⁵⁰ *Report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property*, above n 149, [18].

production of health products in developing countries through investment and capacity building'.¹⁵¹ Similarly, the phrase 'avoid the incorporation of TRIPS-plus measures in any trade agreements and in national legislation that may have negative impact on access to health products or treatments in developing countries' was removed.¹⁵² Notably, provisions were also included that expressly maintained the effect of existing international agreements, such as the phrase 'frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, *consistent with international agreements*',¹⁵³ and so on.

The 'Chair's text' considered by the open-ended working group and the intergovernmental meeting¹⁵⁴ reflected these tensions about intellectual property although there was acceptance by all parties that a resolution was necessary for global preparedness to deal with avian influenza and the likely resultant pandemic.¹⁵⁵ Thus, for example, the 'Chair's text' set out principles apparent in both the CBD and TRIPS: the sovereign right of states over their biological resources, the role of intellectual

¹⁵¹ Ibid [34].

¹⁵² Ibid [36].

¹⁵³ *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, World Health Assembly 61st mtg, Res WHA61.21 (2008) annex [39] (emphasis added).

¹⁵⁴ See *Chair's Text – Draft – Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, above n 29.

¹⁵⁵ See, eg, Ministers of Foreign Affairs of Brazil France, Indonesia, Norway, Senegal, South Africa, and Thailand, 'Oslo Ministerial Declaration – Global Health: A Pressing Foreign Policy Issue of Our Time' (2007) 369 *The Lancet* 1373.

property as an incentive, the development of new healthcare products, and the taking of measures to protect public health.¹⁵⁶

The 'Chair's text' envisions a 'Standard Materials Transfer Agreement' that 'will be standardized, universal and globally applicable to all transfers of PIP biological materials and not subject to further negotiation'.¹⁵⁷ The 'ownership' of transferred materials remains contested with the possibility that ownership is either not transferred or not asserted.¹⁵⁸ Further, the proposed intellectual property provision again reflects tensions apparent in both the CBD and TRIPS.¹⁵⁹

The outcome of the intergovernmental meeting in December 2008 failed to reach agreement and will resume during the May 2009 World Health Assembly.¹⁶⁰ The role and place of intellectual property and benefit sharing remain contentious with there being a polarising of interests between the South and North countries: essentially, the South countries asserting the significance of linkages between access and benefit sharing and the North countries asserting the contrary.¹⁶¹

¹⁵⁶ *Chair's Text – Draft – Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits*, above n 29, [1.1] (PP7-PP10).

¹⁵⁷ *Ibid* [5.3.2].

¹⁵⁸ *Ibid* annex 1 [11].

¹⁵⁹ *Ibid* annex 1 [12].

¹⁶⁰ See Shashikant, above n 28.

¹⁶¹ See *ibid*.

IX. Discussion

Generally, 'genetic resources' are understood to have value. However, it is frequently the case that a particularly valuable resource will be found together with large quantities of presently valueless materials with the potential of significant up-front expenditure to distinguish between the valuable and other useless materials.¹⁶² In those circumstances the negotiating power generally lies with those wanting to access the genetic resources (the bio-prospectors) and as a consequence the value of 'genetic resources' has generally been valued lowly – the value does not reflect the costs that would be reasonable, adequate and sufficient as an incentive for biological diversity conservation.¹⁶³ However, in the case of Indonesia's H5N1 viruses, Indonesia as the 'genetic resource' holder has the negotiating power and is in a position to dictate terms of use. The significance of the 'concession' made to Indonesia in making the H5N1 virus available to elements of the WHO's GISN is that it is one of the first instances where the provider of 'genetic resources' is in a position where they have a clearly identifiable material that others (bio-prospectors) want, and also have a driving imperative to obtain so as to mitigate their public health responses to pandemic influenza. Further, Indonesia is a country of the South, (with the interests of the predominantly poor countries with the majority of the Earth's useful biological diversity) hoping to benefit from the exploitation of its genetic diversity by the predominantly rich and technologically advanced countries of the North. In this context, Indonesia's H5N1 viruses provide an unorthodox case study of the interaction between the CBD and TRIPS.

¹⁶² See, John Voumard, *Access to Biological Resources in Commonwealth Areas* (2000) 93-103.

¹⁶³ See Charles Lawson, 'Regulating Access to Biological Resources: The Market Failure for Biodiversity Conservation' (2006) 24 *Law in Context* 137, 146-151.

While the final details of the agreement for accessing Indonesia's H5N1 viruses has been generalised by the WHO processes to accessing all viruses, the development towards agreement has followed the contours of the CBD (and TRIPS) obligations.¹⁶⁴ That is, Indonesia has been specific in pressing its concerns about benefit sharing and tied these closely with the obligations established by the CBD. So, for example, the Indonesian proposal suggested the following 'fundamental elements' should be taken into account when developing any new system addressing access and benefit sharing:

The originating country providing access to virus: (1) retains sovereign rights over the virus and any virus material contained or incorporated in any substances or products created; (2) has the right to get immediately the results of the risk assessment; (3) has the right to timely receive seed virus and isolated virus at no cost; (4) has the right to participate in the execution of research and participate actively in publications; and (5) has the right to be adequately acknowledged.¹⁶⁵

Within these 'fundamental elements' is embedded the 'sovereign rights' of Indonesia to regulate access to all viruses within its sovereign jurisdiction. As a party to the CBD this also coincides with the obligation that access must be from countries of origin or countries that have acquired the genetic resources according to the CBD,¹⁶⁶ on mutually agreed terms,¹⁶⁷ with prior informed consent,¹⁶⁸ and the equitable sharing of benefits.¹⁶⁹

¹⁶⁴ See also Ministers of Foreign Affairs of Brazil France, Indonesia, Norway, Senegal, South Africa, and Thailand, above n 155.

¹⁶⁵ *Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness*, above n 27, annex [6].

¹⁶⁶ *CBD*, art 15(3).

¹⁶⁷ *CBD*, art 15(4).

Perhaps Indonesia's recourse to these obligations is to be expected, as a direct result of the GISN apparent breach of trust.¹⁷⁰ The publication of laboratory analyses based on Indonesian H5N1 viruses provided to GISN without timely involvement of Indonesian collaborators; the limited release of Indonesian H5N1 virus sequence data by GISN; and the use by private pharmaceutical companies of Indonesian H5N1 viruses (supplied by GISN) to manufacture vaccines without Indonesia's participation: resulted in Indonesia's drastic action to withhold Indonesian H5N1 viruses from the WHO's GISN.¹⁷¹ Before these events Indonesia's H5N1 viruses were collected and supplied without charge or obligation to elements of the GISN.¹⁷² However, in a broader context the international legal obligations established by the CBD and TRIPS have direct application.

The sting for the WHO's GISN accessing Indonesian H5N1 viruses, however, is that compliance with the CBD's obligations entails a contract-based access and benefit sharing arrangement, whereas compliance with the North country rhetoric about intellectual property: namely, that the terms and condition of intellectual property must be determined as a part of the access and benefit sharing contract, and that the existing intellectual property standards must be respected. Framing Indonesia's position within the context of the CBD and TRIPS obligations suggests Indonesia's

¹⁶⁸ CBD, art 15(5).

¹⁶⁹ CBD, art 15(7).

¹⁷⁰ See *Pandemic Influenza – Annex 5 – Interim Statement*, above n 127, preamble. See also *Pandemic Influenza – Annex 6 – Consolidated Outcome Text: Index*, above n 127.

¹⁷¹ See Sedyaningsih et al, above n 3, 485-6.

¹⁷² See *ibid* 485; World Health Organization, above n 5.

response is entirely reasonable (albeit eliciting moral outrage from some).¹⁷³ However, Indonesia's response also poses a specific dilemma for the North countries and their past actions in asserting the paramountcy of intellectual property in the debates about access to medicines that were eventually addressed, at least in part, in the *Declaration on the TRIPS Agreement and Public Health*.¹⁷⁴ Further, the North countries have consistently failed to negotiate a resolution to the South countries concerns about intellectual property claims over genetic resources (or 'bio-piracy') in the CBD's forums,¹⁷⁵ and those concerns have spilled over into the TRIPS forum (and other WTO forums) with the countries of the North maintaining the necessity for intellectual property over other policy objectives.¹⁷⁶ The result is that Indonesia's proposition that the WHO negotiate a contractual arrangement to access viruses found within Indonesia's sovereign territory and that the terms and conditions of access

¹⁷³ See, eg, The Lancet, 'International Health Regulations: The Challenges Ahead' (2007) 369 *The Lancet* 1763; European Centre for Disease Prevention and Control, *Interim ECDC Scientific and Public Health Briefing: Sharing influenza Virus Samples* (2008) 1-2 <http://ecdc.europa.eu/pdf/ECDC_influenza_briefing.pdf> at 9 March 2009. See also Laurie Garrett and David Fidler, 'Sharing H5N1 Viruses to Stop a Global Influenza Pandemic' (2007) 4(11) *Public Library of Science Medicine* 1712 <doi:10.1371/journal.pmed.0040330> at 9 March 2009.

¹⁷⁴ See *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (2001) [4]-[7]. See also Pedro Roffe, Christoph Spennemann and Johanna von Braun, 'From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health' in Pedro Roffe, Geoff Tansey and David Vivas-Eugui (eds), *Negotiating Health Intellectual Property and Access to Medicines* (2006) 9.

¹⁷⁵ These developing contentions are detailed in Lawson and Sanderson, above n 78, 135-43.

¹⁷⁶ See, eg, *ibid* 143-6.

reflect the agreement between the parties is, in effect, adopting exactly what has been agreed at the CBD.

The concern for countries of the South is that existing patents may prevent the use of a patented product, process or product of the process thereby tying up the technology necessary to develop efficient and effective vaccines.¹⁷⁷ Enhancing the production capacity and efficacy of pandemic influenza vaccines almost certainly depends on technology accessed from patent holders in countries of the North together with the related know-how and regulatory submissions data.¹⁷⁸ These concerns are specifically reflected in Indonesia's 'fundamental elements' that should be taken into account when developing any new system addressing access and benefit sharing:

[A f]ramework of benefit sharing is to be developed through agreed terms and conditions to ensure global stockpile of pre-pandemic and pandemic vaccines, accessibility of vaccine at an affordable price, access to and transfer of technology and know-how for production of vaccines, and empowerment and capacity building of vaccine manufacturing in developing countries.¹⁷⁹

¹⁷⁷ See *Patent Issues Related to Influenza Viruses and Their Genes*, above n 80; Life Sciences Program, World Intellectual Property Organization, above n 80; Initiative for Vaccine Research, World Health Organization, above n 88.

¹⁷⁸ See, eg, Initiative for Vaccine Research, World Health Organization, above n 88, 1-2, 19.

¹⁷⁹ *Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness*, above n 27, annex (Fundamental Principles and Elements for the Development of A New System for Virus Access and Fair And Equitable Benefit Sharing Arising from the Use of the Virus for the Pandemic Influenza Preparedness) [9].

The challenge for the North who want access to the Indonesian H5N1 viruses is that compliance with the CBD (and TRIPS) obligations is critical to mitigating their public health responses to pandemic influenza. This will require negotiation of a deal with Indonesia where Indonesia has the negotiating power and is in a position to dictate terms, including limiting the ownership of intellectual property, requiring the transfer of technology and know-how (probably establishing vaccine research and manufacturing facilities in Indonesia) and assistance in regulatory submissions data so that the vaccines are both safe and efficacious. The alternative will be to undermine the careful position which the countries of the North have engineered in establishing the paramountcy of TRIPS over the CBD and other policy objectives, and open the floodgates to the South's desire to limit the effect of TRIPS on the CBD and of TRIPS itself. In short, failure to negotiate a deal with Indonesia according to the terms and conditions agreeable to Indonesia opens up the debate about the paramountcy of intellectual property rights and TRIPS, and introduces the potential for other policy imperatives to override respect for intellectual property rights – in other words, if the North does not comply with its CBD and TRIPS rhetoric and commitments, why should the South?