
Who shall live when not all can live? Intellectual property in accessing and benefit-sharing influenza viruses through the World Health Organisation

Charles Lawson*

This article addresses the development of the World Health Organisation's (WHO) arrangements for accessing viruses and the development of vaccines to respond to potential pandemics (and other lesser outbreaks). It examines the ongoing "conflict" between the United Nations' Convention on Biological Diversity (CBD) and the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in the context of the debates about the paramountcy of intellectual property, and the potential for other (equity and development) imperatives to over-ride respect for intellectual property and TRIPS. The article concludes that the same intellectual property fault lines are evident in the WHO forum as those apparent at the CBD and the WTO fora, and an ongoing failure to properly address questions of equity and development. This poses a challenge for the Australian Government in guaranteeing a satisfactory pandemic influenza preparation and response.

INTRODUCTION

There is a broadly accepted potential that vaccines can and will play a key role in limiting the impact of an influenza pandemic with the most efficient and effective response requiring access to the virus to make the appropriate vaccines.¹ Under existing arrangements in Australia, the Australian Government participates in the World Health Organisation's (WHO) Global Influenza Surveillance Network (GISN) that comprises the National Influenza Centres (NICs) and the WHO Collaborating Centres (WHO CCs).² The NICs collect virus samples from patients with influenza-like-illness in countries around the world, and then the WHO CCs receive representative virus isolates from the NICs and subject them to antigenic and genetic analyses: (1) to make recommendations for the subsequent year's influenza vaccine preparations, and (2) as a global alert mechanism for emerging influenza

* BSc(Hons), LLB, PhD, LLM, Associate Professor, Australian Centre for Intellectual Property in Agriculture, Griffith Law School, Griffith University, Gold Coast, Queensland. This research was funded by an ARC Linkage-International Fellowship – LX0881935.

Correspondence to: c.lawson@griffith.edu.au.

¹ Department of Health and Ageing, *Australian Health Management Plan for Pandemic Influenza* (Department of Health and Ageing, 2008) p 22 ("CONTROL AUS 6c"); Ferguson N, Cummings D, Fraser C, Cajka J, Cooley P and Burke D, "Strategies for Mitigating an Influenza Pandemic" (2006) 442 *Nature* 448. See also Sixtieth World Health Assembly, *Avian and Pandemic Influenza: Best Practice for Sharing Influenza Viruses and Sequence Data, Report by the Secretariat*, A60/INF.DOC.1 (World Health Organisation, 2007); Scientific Advisory Group on Pandemic Influenza (UK), *Pre-Pandemic and Pandemic Influenza Vaccines: Scientific Evidence Base* (Scientific Advisory Group, 2008); World Health Organisation, *Global Pandemic Influenza Action Plan to Increase Vaccine Supply*, WHO/IVB/06.13 (World Health Organisation, 2006). Notably, "[s]ince the beginning of the [H1N1] pandemic on 19 April 2009 to 22nd May 2010, cumulatively 155 countries [NICs] shared a total of 25,733 specimens (19,709 clinical and 6024 isolates) with WHO CCs for further characterization": World Health Organisation, *Pandemic (H1N1) 2009 – Update 102: Weekly Virological Surveillance Update 28 May 2010* (World Health Organisation, 2010), http://www.who.int/csr/disease/swineflu/laboratory28_05_2010/en/index.html viewed 10 June 2010.

² See Department of Health and Ageing, *Annual Report 2008-09* (Paragon Printers, Australasia, 2009) p 221; Department of Health and Ageing, *Portfolio Budget Statements 2008-09, Budget Related Paper No 1.10* (Department of Finance and Deregulation, 2008) p 202. See also Department of Health and Ageing, *Portfolio Budget Statements 2010-11, Budget Related Paper No 1.11* (Department of Finance and Deregulation, 2009) p 363; Department of Health and Ageing, *Portfolio Budget Statements 2009-10, Budget Related Paper No 1.10* (Department of Finance and Deregulation, 2009) pp 341-342.

viruses with pandemic potential.³ The WHO CCs also make virus samples available for the manufacture of vaccines as a part of influenza pandemic preparedness and response.⁴

A problem arises because of the different perspectives about the role and place of intellectual property in the legal arrangements for accessing and benefit-sharing from the influenza virus provided by the NICs and made available by the WHO CCs.⁵ The dimensions of the problem are part of an ongoing equity and development argument between the predominantly poor and technologically deprived countries (the developing South countries) and the predominantly rich and technologically advanced countries (the developed North countries).⁶ This time the equity and development argument is in the context of sharing the benefits from accessed viruses for influenza pandemic preparedness and response:

Many developing countries are rightly concerned that due to the limits on how fast pandemic vaccines can be produced after a pandemic outbreak, there will be an acute shortage globally. Developed countries are already forking out hundreds of millions of dollars to place advance orders for vaccines. Developing countries cannot afford that, and fear they will be left with grossly inadequate supplies or none to inoculate their populations, as every country scrambles madly to get whatever quantities they can ... the developing countries have been asked to donate samples of viruses as new human cases of avian influenza occur, so that scientific work can be done to characterize the viruses and track the development of the influenza ... evidence is emerging that the viruses contributed by developing countries are already being extensively used for commercial activities ... This raises the issue of who gains and who is losing in this imbalanced state of affairs.⁷

As a consequence of the existing standards set by the United Nations' *Convention on Biological Diversity* (CBD)⁸ and the World Trade Organisation's (WTO) *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS),⁹ the WHO has sought to negotiate its own consistent legal arrangements for access to virus strains as the raw material for vaccine manufacture. The purpose of this article is to address the ongoing negotiation of the access agreements within a broader public health response to pandemic influenza (and other lesser outbreaks). In particular, the article addresses the place of intellectual property in those agreements and their potential to help or hinder a broader public health response. The article demonstrates that the debates continue about the paramountcy of intellectual property, and the potential for other policy imperatives to over-ride respect for intellectual property.

³ See generally WHO Global Influenza Virus Surveillance website, <http://www.who.int/csr/disease/influenza/influenzanetwork/en/index.html> viewed 10 June 2010.

⁴ See World Health Organisation, *Core Terms of Reference for WHO Collaborating Centres for Reference and Research on Influenza* (World Health Organisation, 2006), <http://www.who.int/csr/disease/influenza/whocccoretor2006.pdf> viewed 10 June 2010.

⁵ See Chan C-K, "Equitable Access to Pandemic Flu Vaccines" (2007) *TWN Info Service on Intellectual Property Issues* (31 March 2010), http://www.twinside.org.sg/title2/intellectual_property/info.service/2010/ipr.info.100311.htm viewed 10 June 2010; Rimmer M, "The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines" (2004) 5 *Melbourne Journal of International Law* 335 at 368-372. See also Gostin L and Berkman B, "Pandemic Influenza: Ethics, Law, and the Public's Health" (2007) 59 *Administrative Law Review* 121 at 133-134. See also Kane E, "Preparing for Pandemic Influenza: Achieving Clinical Equality in an Influenza Pandemic: Patent Realities" (2009) 39 *Seton Hall Law Review* 1137 at 1152-1162 (addressing the patent issues likely to arise); Crouch D, "Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic" (2009) 39 *Seton Hall Law Review* 1125 at 1126-1132 (patent enforcement during a pandemic).

⁶ For a broad overview in the context of biotechnology: see eg Acharya T, Daar A and Singer P, "Biotechnology and the UN's Millennium Development Goals" (2003) 21 *Nature Biotechnology* 1434. See also Smith R, Correa C and Oh C, "Trade, TRIPS, and Pharmaceuticals" (2009) 373 *The Lancet* 684; Stiglitz R, "Trade Agreements and Health in Developing Countries" (2009) 373 *The Lancet* 363; MacDonald R and Horton R, "Trade and Health: Time for the Health Sector to Get Involved" (2009) 373 *The Lancet* 273; Messerlin P, "Trade, Drugs, and Health-care Services" (2005) 365 *The Lancet* 1198.

⁷ Shashikant S, "Winners and Losers in the Sharing of Avian Flu Viruses" (2007) *TWN Info Service on Intellectual Property Issues* (SUNS #6249, 10 May 2007), http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.050705.htm viewed 10 June 2010.

⁸ [1993] ATS 32 (CBD).

⁹ [1995] ATS 38 being *Marrakesh Agreement Establishing the World Trade Organisation* [1995] ATS 8, Annex 1C (TRIPS).

The article begins by outlining the TRIPS and CBD frameworks, followed by a detailed analysis of the CBD's evolution which shows that equity and development were and remain a key concern of the negotiating parties and that have crystallised in the debates about intellectual property. It then traces the evolution of the WHO's response to accessing and benefit-sharing viruses in the context of the CBD and TRIPS; and addresses the WHO's other negotiations about intellectual property. The article concludes that the Australia Government needs to find a resolution to the ongoing debates in the context of accessing and sharing viruses, as without that access Australia's influenza pandemic preparedness and response is likely to become less certain. A resolution, however, is unlikely unless the North countries like Australia make concessions about the role and place of intellectual property.

TRIPS FRAMEWORK

TRIPS was an annexure to the Final Act of the 1986-1994 Uruguay Round of Multilateral Trade Negotiations which created the WTO. TRIPS essentially established the minimum intellectual property standards that must be applied by all WTO member states.¹⁰ 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 field of technology and whether products are imported or locally produced.¹¹

The terms "inventive step" and "capable of industrial application" are synonymous with the concepts of "non-obviousness" and "usefulness" respectively. The "exclusive rights" of a patent 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.¹²

The only direct exceptions permitted from this general scheme are inventions that are "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 their law", "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" and "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".¹³ Other indirect exceptions are a three-limbed and cumulative exception:

- there must be a "limited exception";
- the exception must not "unreasonably conflict with normal exploitation of the patent"; and
- the exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties";¹⁴

and that a patent holder's exclusive rights may be diminished by an authorising law after judicial or administrative process have determined the patent to be anti-competitive, although each authorisation must be considered on its individual merits.¹⁵

TRIPS has been embroiled in contentious debates 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",¹⁶ and the potential of patents to

¹⁰ TRIPS, Art 1. There are presently 153 members and 30 observer governments: see World Trade Organisation, *Members and Observers* (World Trade Organisation, 2008), http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm viewed 10 June 2010.

¹¹ TRIPS, Art 27(1).

¹² TRIPS, Art 28.

¹³ TRIPS, Art 27(2) and (3).

¹⁴ TRIPS, Art 30.

¹⁵ TRIPS, Art 31.

¹⁶ Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (World Trade Organisation, 2001) at [1].

exacerbate those public health crises.¹⁷ These issues were first formally identified in the Doha Ministerial Declaration¹⁸ and agreement set out in the *Declaration on the TRIPS Agreement and Public Health*.¹⁹ Subsequent work by the TRIPS Council and WTO General Council extended the pharmaceutical product patent obligations until 2016,²⁰ and formulated a resolution to importing pharmaceuticals under a compulsory licence to members without the necessary manufacturing capability.²¹ A proposal to amend TRIPS was agreed upon²² with a waiver in place until that amendment took effect,²³ and this may have provided a solution to making patented pharmaceuticals available in public health programs.²⁴ The significance of these developments was also to confirm that “TRIPS does not and should not prevent members from taking measures to protect public health”,²⁵ 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”.²⁶ Importantly, however, Australia has committed not to taking advantage of these provisions.²⁷ So far the TRIPS amendment has not yet been adopted²⁸ and the waiver only relied on once.²⁹ The developed countries assert these procedures are an effective measure,³⁰ noting that other means are also available³¹ and point for practical examples to the donation of vaccines in response to the H1N1 influenza pandemic.³² The developing countries, however, are not so certain.³³ The outcome has been to initiate informal

¹⁷ See eg Nielsen J and Nicol D, “Pharmaceutical Patents and Developing Countries: The Conundrum of Access and Incentive” (2002) 13 AIPJ 21 at 21-24.

¹⁸ Ministerial Conference, *Ministerial Declaration*, WT/MIN(01)/DEC/1 (World Trade Organisation, 2001) at [17].

¹⁹ WT/MIN(01)/DEC/2, n 16 at [4]-[7].

²⁰ See *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 (World Trade Organisation, 2002); General Council, *Least-Developed Country Members – Obligations under Art 70(9) of the TRIPS Agreement with Respect to Pharmaceutical Products*, WT/L/478 (World Trade Organisation, 2002).

²¹ See General Council, *Implementation of Para 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (World Trade Organisation, 2003).

²² See Ministerial Conference, *Ministerial Declaration: Doha Work Programme*, WT/MIN(05)/DEC (World Trade Organisation, 2005) at [40].

²³ See WT/L/540, n 21; General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* WT/L/540/Corr.1 (World Trade Organisation, 2005).

²⁴ Whether this will be effective remains unresolved: see eg Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, IP/C/M/61 (World Trade Organisation, 2010) at [104]-[135]. See also Vandoren P and Eeckhaute J, “The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” (2005) 6 *Journal of World Intellectual Property* 779.

²⁵ WT/MIN(01)/DEC/2, n 16 at [4]. See also Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits, *Interdisciplinary Working Group on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits, Proposal of the Republic of Indonesia*, A/PIP/IGM/5 (World Trade Organisation, 2007) Annex.

²⁶ WT/MIN(01)/DEC/2, n 16 at [6]. See also A/PIP/IGM/5, n 25 at Annex.

²⁷ See WT/L/540, n 21, p 2 (fn 3).

²⁸ See Council for Trade-Related Aspects of Intellectual Property Rights, *Protocol Amending the TRIPS Agreement – Status of Acceptances*, IP/C/W/490/Rev.6 (World Trade Organisation, 2010).

²⁹ See IP/C/M/61, n 24 at [106].

³⁰ See eg IP/C/M/61, n 24 at [106] (Canada), at [115] and [129] (United States), at [120] (Australia).

³¹ See eg IP/C/M/61, n 24 at [115] (United States), at [120] (Australia).

³² See eg IP/C/M/61, n 24 at [115] (United States), at [120] (Australia).

³³ See IP/C/M/61, n 24 at [103] (Egypt, speaking on behalf of the African Group), at [110] (Tanzania, speaking on behalf of the LDC Group), at [113] (India), at [116] (Ecuador), at [118] (Pakistan), at [121] (Brazil), at [122] (China), at [123] (Venezuela), at [125] (Angola).

consultations about the operation of the scheme³⁴ and to leave open the question of whether TRIPS is an impediment to measures taken to protect public health.

The result of all these debates and the *Declaration on the TRIPS Agreement and Public Health* has been to recognise there are “flexibilities” in TRIPS, but few developing countries have been willing to actually take advantage of those “flexibilities”.³⁵ In short, there remains a marked difference in the preferred approaches to intellectual property between the predominantly poor and technologically deprived South countries and the predominantly rich and technologically developed North countries.³⁶ As an example of a developed North country, Australia has been at the vanguard of TRIPS (and TRIPS-plus), championing its implementation though a rapid adoption of its minimum standards,³⁷ ensuring TRIPS measures are passed through to other international and regional agreements,³⁸ and most recently, accepting further TRIPS-plus measures in the negotiated *Australia–United States Free Trade Agreement*.³⁹ Australia has been reluctant to contemplate limiting intellectual property once granted according to the existing standards⁴⁰ and has signalled its willingness to maintain the paramountcy of intellectual property over other competing policy objectives.⁴¹

CBD FRAMEWORK

At the time the CBD was being negotiated, there was almost universal consensus that the predominantly poor South countries with the majority of the Earth’s useful biological diversity should benefit from the exploitation of that diversity by the predominantly rich and technologically advanced North countries.⁴² 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.⁴³ The now-familiar central contention was the developed North’s view that

³⁴ IP/C/M/61, n 24 at [135]-[136].

³⁵ See eg Chaves G and Oliviera M, “A Proposal for Measuring the Degree of Public Health-Sensitivity of Patent Legislation in the Context of the WTO TRIPS Agreement” (2007) 85 *Bulletin of the World Health Organisation* 49; Oliviera M, Bermudez J, Chaves G and Velásquez G, “Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation that Favours Public Health?” (2004) 82 *Bulletin of the World Health Organisation* 815. See generally Outterson K, “Should Access to Medicines and TRIPS Flexibilities be Limited to Specific Diseases?” (2008) 34 *American Journal of Law and Medicine* 279; Oh C, “Compulsory Licences: Recent Experiences in Developing Countries” (2006) 1 *International Journal of Intellectual Property Management* 22; Nielsen and Nicol, n 17. Notably, free trade agreements may further limit any “flexibilities”: see Roffe P and Spennemann C, “The Impact of FTAs on Public Health Policies and TRIPS Flexibilities” (2006) 1 *International Journal of Intellectual Property Management* 75.

³⁶ See eg New W, “Rich and Poor Countries Divided over Patent Treaty” (2006) 84 *Bulletin of the World Health Organisation* 344.

³⁷ See eg the rapid implementation of TRIPS standards in Australia: *Patents (World Trade Organisation) Amendment Act 1994* (Cth). Notably, Australia has also been a keen promoter of the benefits of TRIPS through technical cooperation and capacity building: see eg IP/C/M/61, n 24 at [207].

³⁸ See eg *Singapore–Australia Free Trade Agreement* [2003] Australian Treaty Series 16, Ch 13, Art 2(1).

³⁹ *Australia–United States Free Trade Agreement* [2005] Australian Treaty Series 1, Ch 17 Art 9.

⁴⁰ Intellectual property, and particularly patents, remains a key policy measure to promote innovation, foreign investment and economic advancement: see Commonwealth of Australia, *Powering Ideas: An Innovation Agenda for the 21st Century* (Department of Innovation, Industry, Science and Research, 2009) pp 53, 56-57. See also Review of the National Innovation System, *Venturous Australia: Building Strength in Innovation* (Cutler & Co Ltd, 2008) pp 83-87.

⁴¹ This is particularly evident in balancing innovation and biodiversity conservation objectives (and the balancing between the CBD and TRIPS): see eg Lawson C, “Regulating Access to Biological Resources: The Market Failure for Biodiversity Conservation” (2006) 24 *Law in Context* 137.

⁴² See eg United Nations Development Program, *Conserving Indigenous Knowledge: Integrating New Systems of Integration* (United Nations Development Program, 1994). Although the developed countries of the North were not a homogeneous, cohesive or coordinated block: see Panjabi R, *The Earth Summit at Rio: Politics, Economics and the Environment* (Northeastern University Press, 1997) pp 263-264.

⁴³ See Gillespie A, “Common Property, Private Property and Equity: Clash of Values and the Quest to Preserve Biodiversity” (1995) 12 *EPLJ* 388 at 389-392 and the references therein.

intellectual property should be maintained and respected.⁴⁴ Meanwhile, the South contended that 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 (now familiar equity and development arguments).⁴⁵ In essence, 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.”⁴⁶

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”.⁴⁷ The diplomatic language allowed the technology-rich North countries (principally the United States, the 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 countries to maintain their existing intellectual property arrangements.⁴⁸ The outcome was, at best, just an in-principle agreement to exchange genetic resources for benefits that might include access to and transfer of technology.⁴⁹

The CBD was signed at the conclusion of the United Nations Conference on Environment and Development⁵⁰ with an objective of “the 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, taking into account all rights over those resources and to technologies, and by appropriate funding”.⁵¹ This objective of benefit-sharing the uses of genetic resources marked a fundamental shift in binding international measures to conserve biodiversity:⁵² first, by recognising that genetic resources are subject to a nation state’s sovereign rights;⁵³ secondly, 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;⁵⁴ and thirdly, by introducing intellectual property into the economic and policy debates about conserving genetic resources that might benefit future technological, economic and social development.⁵⁵

⁴⁴ See generally Panjabi, n 42.

⁴⁵ 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*, UNEP/BioDiv2/3 (United Nations Environment Program, 1990) p 7.

⁴⁶ Tilford D, “Saving the Blueprints: The International Legal Regime for Plant Resources” (1998) 30 *Case Western Reserve Journal of International Law* 373 at 419.

⁴⁷ CBD, Art 16(5). See also Lucia P and Marin C, *Providing Protection for Plant Genetic Resources: Patents, Sui Generis Systems, and Biopartnerships* (Kluwer Law International, 2002) p 92.

⁴⁸ See eg Grubb M, Koch M, Thomson K, Munson A and Sullivan F, *The “Earth Summit” Agreements: A Guide and Assessment* (Brookings Institution Press, 1993) p 29.

⁴⁹ See eg Secretariat of the Convention on Biological Diversity, *Handbook of the Convention on Biological Diversity* (2nd ed, Secretariat of the Convention on Biological Diversity, 2003) p 310.

⁵⁰ See Grubb at al, n 48.

⁵¹ CBD, Art 1.

⁵² See eg Tilford, n 46 at 387-418; Aoki K, “Weeds, Seeds & Deeds: Recent Skirmishes in the Seed Wars” (2003) 11 *Cardozo Journal of International and Comparative Law* 247 at 305-313.

⁵³ CBD, Art 15(1).

⁵⁴ CBD, Arts 15, 16 and 19.

⁵⁵ CBD, Preamble and Arts 3, 10, 11, 15, 16, 19 and 22. See also Organisation for Economic Co-operation and Development, *Harnessing Markets for Biodiversity: Towards Conservation and Sustainable Use* (Organisation for Economic Co-operation and Development, 2003) pp 18-19 and 109; Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (Commission on Intellectual Property Rights, 2002) pp 57-72.

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”⁵⁶ with an obligation to facilitate access for “environmental sound uses” without imposing restrictions that are counter to the CBD’s objectives.⁵⁷ Further, access must be from countries of origin or countries that have acquired the genetic resources according to the CBD,⁵⁸ on mutually agreed terms,⁵⁹ with prior informed consent,⁶⁰ and most importantly, taking legislative, administrative or policy measures to fairly and equitably share the benefits following research and development and commercialisation,⁶¹ and providing or facilitating access to and transfer of technology.⁶² 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)⁶³ “shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and where necessary in accordance with the financial mechanism”.⁶⁴ 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”,⁶⁵ 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 (Art 16(5)).

A key element in the access to and transfer of technology in exchange for access to genetic resources contemplated by the text of the CBD 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”.⁶⁶ In respect of biotechnology, the measures include the “effective participation in biotechnological research activities”⁶⁷ and “the results and benefits arising from biotechnologies based upon genetic resources”.⁶⁸ Other measures deal with the exchange of information⁶⁹ and technical and scientific cooperation.⁷⁰ 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”.⁷¹ Further, the CBD was not

⁵⁶ CBD, Art 15(1). See also Art 3.

⁵⁷ CBD, Art 15(2).

⁵⁸ CBD, Art 15(3).

⁵⁹ CBD, Art 15(4).

⁶⁰ CBD, Art 15(5).

⁶¹ CBD, Art 15(7).

⁶² CBD, Art 16(2).

⁶³ See TRIPS, Art 66. See also Committee for Development Policy, *Handbook on the Least Developed Country Category: Inclusion, Graduation and Special Support Measures* (Committee for Development Policy, 2008) pp 1-14.

⁶⁴ CBD, Art 16(2).

⁶⁵ CBD, Art 16(3).

⁶⁶ CBD, Art 16(4).

⁶⁷ CBD, Art 19(1).

⁶⁸ CBD, Art 19(2).

⁶⁹ CBD, Art 17.

⁷⁰ CBD, Art 18.

⁷¹ CBD, Art 11.

intended to affect the “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”.⁷²

The fourth Conference of the Parties (COP) decided to convene a Panel of Experts on Access and Benefit-sharing (the Panel)⁷³ and an Inter-Sessional Meeting on the Operations of the Convention (ISOC) as “a preparatory discussion” on access to genetic resources.⁷⁴ The ISOC began assessing the relationship between intellectual property and the relevant provisions of the TRIPs and the CBD,⁷⁵ ex situ collections made before 29 December 1993,⁷⁶ and a number of other matters that the Panel should consider.⁷⁷ The fifth COP took note of the Panel’s report⁷⁸ and the ISOC report,⁷⁹ and then decided, in dealing with access to genetic resources, to establish an Ad Hoc Open-Ended Working Group on Access and Benefit-sharing with the mandate to develop guidelines and other approaches to access and benefit-sharing.⁸⁰ The outcome of this decision was the Ad Hoc Open-Ended Working Group’s report that recommended the adoption of the *Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation*,⁸¹ although key terms remained to be defined, including “access to genetic resources”, “benefit-sharing”, “commercialisation”, “derivatives”, “provider”, “user”, “stakeholder”, “ex situ collection” and “voluntary nature”.⁸² The key objective of the guidelines was “to assist Parties in developing an overall access and benefit-sharing strategy ... and in identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits”.⁸³ In addressing the role of intellectual property in implementing access and benefit-sharing arrangements the Ad Hoc Open-Ended Working Group recommended that the COP “invite” countries to disclose the country of origin of genetic resources in applications for intellectual property “as a possible contribution to tracking compliance” with the obligations under the CBD of prior informed consent and the mutually agreed terms to access genetic resources.⁸⁴ Further information-gathering about intellectual property and access and benefit-sharing was also recommended and a role envisioned for WIPO in developing model intellectual property clauses for negotiation of mutually agreed terms in contractual agreements.⁸⁵

As “merely the first step on a long and complex process to secure access and benefit-sharing”⁸⁶ under the CBD, the sixth COP adopted the *Bonn Guidelines on Access to Genetic Resources and Fair*

⁷² CBD, Art 22(1).

⁷³ Conference of the Parties to the Convention on Biological Diversity, *Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, UNEP/CBD/COP/4/27 (United Nations Environment Program, 1998) p 109.

⁷⁴ UNEP/CBD/COP/4/27, n 73, p 132.

⁷⁵ Conference of the Parties to the Convention on Biological Diversity, *Report of the Inter-Sessional Meeting on the Operations of the Convention*, UNEP/CBD/COP/5/4 (United Nations Environment Program, 1999) pp 30-31.

⁷⁶ UNEP/CBD/COP/5/4, n 75, pp 31-32.

⁷⁷ UNEP/CBD/COP/5/4, n 75, pp 28-30.

⁷⁸ Conference of the Parties to the Convention on Biological Diversity, *Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, UNEP/CBD/COP/5/23 (United Nations Environment Program, 1998) p 25.

⁷⁹ UNEP/CBD/COP/5/23, n 78, p 21.

⁸⁰ UNEP/CBD/COP/5/23, n 78, pp 197-198.

⁸¹ Conference of the Parties to the Convention on Biological Diversity, *Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing*, UNEP/CBD/COP/6/6 (United Nations Environment Program, 2001) p 14.

⁸² UNEP/CBD/COP/6/6, n 81, pp 14 and 15.

⁸³ UNEP/CBD/COP/6/6, n 81, p 16.

⁸⁴ UNEP/CBD/COP/6/6, n 81, p 36.

⁸⁵ UNEP/CBD/COP/6/6, n 81, pp 36-38.

⁸⁶ Conference of the Parties to the Convention on Biological Diversity, *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, UNEP/CBD/COP/6/20 (United Nations Environment Program, 2002) p 19.

and Equitable Sharing of the Benefits Arising out of their Utilisation (Bonn Guidelines)⁸⁷ as voluntary guidelines that apply to all genetic resources covered by the CBD (except human genetic resources),⁸⁸ in a manner that is “coherent and mutually supportive of the work of relevant international agreements and institutions” and “without prejudice” to the *International Treaty on Plant Genetic Resources for Food and Agriculture*.⁸⁹ The sixth COP “invited” countries “when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit-sharing” to comply with the Bonn Guidelines.⁹⁰

The Bonn Guidelines proposed the establishment of a “competent national authority”,⁹¹ identified the responsibilities of contracting parties that are the origin of genetic resources and the implementation of mutually agreed terms,⁹² and set out the steps in the access and benefit-sharing process.⁹³ 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.⁹⁴ 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.⁹⁵

Significantly, however, the sixth COP clearly identified the Bonn Guidelines as merely a step in the evolution of the CBD’s objectives,⁹⁶ and initiated further work in developing other approaches to access and benefit-sharing and capacity-building,⁹⁷ other measures to implement prior informed consent,⁹⁸ and documented the experience from countries implementing the Bonn Guidelines.⁹⁹

The sixth COP also decided to reconvene the Ad Hoc Open-Ended Working Group on Access and Benefit-sharing to advise the COP “recognising” that “a package of measures may be necessary to address the different needs of Parties and stakeholders in the implementation of access and benefit-sharing arrangements”.¹⁰⁰ Importantly, some COP members asserted that the Bonn Guidelines should “be used through a negotiation process to develop an international legally binding instrument on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilisation”.¹⁰¹ The development of an international regime is underway through an Ad Hoc Open-ended Working Group on Access and Benefit-sharing and distinct groups of technical and legal experts that are presently establishing and negotiating the text of an agreement.¹⁰² Recent meetings of

⁸⁷ See UNEP/CBD/COP/6/20, n 86, pp 60-62, 253-269 (Bonn Guidelines).

⁸⁸ Bonn Guidelines, n 87, cl 9.

⁸⁹ Bonn Guidelines, n 87, cl 10.

⁹⁰ UNEP/CBD/COP/6/20, n 86, p 253.

⁹¹ Bonn Guidelines, n 87, cl 12.

⁹² Bonn Guidelines, n 87, cl 14.

⁹³ Bonn Guidelines, n 87, cl 20-48.

⁹⁴ See UNEP/CBD/COP/6/20, n 86, pp 263, 274-275.

⁹⁵ See UNEP/CBD/COP/6/20, n 86, pp 264-265, 267-269. To date, Australia has implemented the Bonn Guidelines arrangements through the *Environment Protection and Biodiversity Conservation Act 1999* (Cth), the *Biodiscovery Act 2004* (Qld) and the *Biological Resources Act 2006* (NT).

⁹⁶ See UNEP/CBD/COP/6/20, n 86, pp 253, 255.

⁹⁷ UNEP/CBD/COP/6/20, n 86, pp 253, 270-273; see also Conference of the Parties to the Convention on Biological Diversity, *Report of the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity*, UNEP/CBD/COP/7/21 (United Nations Environment Program, 2004) p 298.

⁹⁸ UNEP/CBD/COP/6/20, n 86, p 253.

⁹⁹ UNEP/CBD/COP/6/20, n 86, p 253. See also UNEP/CBD/COP/7/21, n 97, pp 297-298.

¹⁰⁰ UNEP/CBD/COP/6/20, n 86, p 271.

¹⁰¹ UNEP/CBD/COP/6/20, n 86, p 62.

¹⁰² See Conference of Parties to the Convention on Biological Diversity, *Report of the Conference of the Parties to the Convention on Biological Diversity on the Work of its Ninth Meeting*, UNEP/CBD/COP/9/29 (United Nations Environment

the Ad Hoc Open-ended Working Group have a negotiating text, albeit there appears to be very little consensus about the role and place of intellectual property in the scope of the proposed agreement.¹⁰³ It seems very unlikely at this stage that the proposed international regime will in any way restrict or limit existing TRIPS obligations, although the potential remains.¹⁰⁴ Again, the key disagreements are about intellectual property and benefit-sharing.¹⁰⁵

WHO AND INFLUENZA

The WHO has a broad concern to address pandemic influenza preparedness.¹⁰⁶ Under this broad remit the WHO's *International Health Regulations 2005* established a framework (from 15 June 2007) for preventing, controlling and responding to the international spread of diseases such as influenza.¹⁰⁷ As part of detailing obligations "to prevent, protect against, control and provide a public health response to the international spread of disease",¹⁰⁸ there is also an 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,¹¹¹ the WHO convened a consultation with national immunisation programs, national regulatory authorities, vaccine manufacturers and the research community to draw up the *Global Pandemic*

Program, 2008) pp 110-122; Conference of Parties to the Convention on Biological Diversity, *Report of the Eighth Meeting of the Parties to the Convention on Biological Diversity*, UNEP/CBD/COP/8/31 (United Nations Environment Program, 2006) pp 128-138; UNEP/CBD/COP/7/21, n 97, pp 298-313.

¹⁰³ See eg the highly bracketed text (indicating lack of consensus) being negotiated: Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, *Report of the Seventh Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing*, UNEP/CBD/WG-ABS/7/8 (United Nations Environment Program, 2009) pp 21-22.

¹⁰⁴ See Lawson C and Sanderson J, "The Evolution of the CBD's Development Agenda that may Influence the Interpretation and Development of TRIPS" in Malbon J and Lawson C (eds), *Interpreting and Implementing the WTO Trade Related Agreement on Intellectual Property Rights: Is TRIPS Fair?* (Edward Elgar, 2008) pp 150-151.

¹⁰⁵ See by way of example the treatment of intellectual property in the highly bracketed text (indicating lack of consensus) of the proposed agreement: UNEP/CBD/WG-ABS/7/8, n 103, pp 21-56. Notably one commentator stated: "'The [developed North] want easy access to genetic resources in other countries,' she said. 'If they have their way, the protocol will at most require compliance with existing legislation in the developing countries. On the other hand the biodiversity-rich developing [South] want to assert national sovereignty over biological resources, and to ensure that the protocol binds industrialised countries to sharing any benefits'": Fog L, "Tensions Remain over Biological Access Protocol" (2010) *Science and Development Network* (2 April 2010), <http://www.scidev.net/en/news/tensions-remain-over-biological-access-protocol.html> viewed 10 June 2010.

¹⁰⁶ See resolutions: Sixty-Third World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHA63.1 (World Health Organisation, 2010); Sixty-Second World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHA62.10 (World Health Organisation, 2009); Sixtieth World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHA60.28 (World Health Organisation, 2007); Fifty-Ninth World Health Assembly, *Application of the International Health Regulations (2005)*, WHA59.2 (World Health Organisation, 2006); Fifty-Eighth World Health Assembly, *Strengthening Pandemic-Influenza Preparedness and Response*, WHA58.5 (World Health Organisation, 2005); Fifty-Sixth World Health Assembly, *Prevention and Control of Influenza Pandemics and Annual Epidemics*, WHA56.19 (World Health Organisation, 2003).

¹⁰⁷ Fifty-Eighth World Health Assembly, *Revision of the International Health Regulations*, WHA58.3 (World Health Organisation, 2005) (*International Health Regulations 2005*). See also WHA59.2, n 106.

¹⁰⁸ *International Health Regulations 2005*, Art 2.

¹⁰⁹ *International Health Regulations 2005*, Art 46.

¹¹⁰ WHA59.2, n 106 at [4(4)].

¹¹¹ See Fifty-Eighth World Health Assembly, *Strengthening Pandemic Influenza Preparedness and Response*, Report by the Secretariat, A58/13 (World Health Organisation, 2005) at [4]-[19].

Influenza Action Plan to Increase Vaccine Supply to identify and prioritise practical solutions for reducing the anticipated gaps in vaccine supply.¹¹² Subsequently, and after considering the developments, responses and follow-ups to avian and pandemic influenza,¹¹³ members reaffirmed their obligations under the *International Health Regulations 2005*, recognising “the sovereign right of States over their biological resources”, and recognising that “intellectual property rights do not and should not prevent Member States from taking measures to protect public health”.¹¹⁴ Members also requested the Director-General of the WHO to undertake work directed at resolving the apparent conflicts between access and benefit-sharing the virus.¹¹⁵ Importantly, the request specifically addressed the access and benefit-sharing of viruses from which vaccines could be made to deal with avian and other pandemic influenzas.¹¹⁶ This request involved both an interdisciplinary working group¹¹⁷ and an intergovernmental meeting.¹¹⁸

In response, the Director-General convened an interdisciplinary working group

to revise the terms of reference of WHO Collaborating Centres, H5 Reference Laboratories, and national influenza centres, devise oversight mechanisms, formulate draft standard terms and conditions for sharing viruses between originating countries and WHO Collaborating Centres, between the latter and Third Parties, and to review all relevant documents for sharing viruses and sequencing data, based on mutual trust, transparency, and overriding principles exemplified in the text of [2(5)].¹¹⁹

The interdisciplinary working group then addressed these matters, in part, in the context of “sharing of viruses and information, and subsequent benefits” and “development of standard terms and conditions and terms of reference for the transfer of influenza viruses”.¹²⁰ 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, whose availability would be a top priority in the event of a pandemic.¹²¹

The interdisciplinary working group also reported that the terms and conditions applying should be that “[n]o party ... receiving, handling and using [the virus specimens] shall claim ownership rights over [the virus specimens]”.¹²² Further, any “patent protection or other intellectual property rights” claims were required to “disclose in the patent application, the country from where [the virus specimens] were collected”, and, if there were to be any “financial gain”, to make a contribution to the “WHO’s Coordinated International Sharing of Influenza Viruses & Benefits” agreement.¹²³ This latter agreement setting out a range of benefit-sharing options including cash, access to technology, transfer

¹¹² See WHO/IVB/06.13, n 1. See also WHA59.2, n 106; WHA58.5, n 106.

¹¹³ See WHO/IVB/06.13, n 1.

¹¹⁴ WHA60.28, n 106, [Preamble]. See also Sixtieth World Health Assembly, *Avian and Pandemic Influenza: Developments, Response and Follow-up, Report by the Secretariat*, A60/7 (World Health Organisation, 2007).

¹¹⁵ WHA60.28, n 106 at [2].

¹¹⁶ WHA60.28, n 106 at [2(5)].

¹¹⁷ WHA60.28, n 106 at [2(5)].

¹¹⁸ WHA60.28, n 106 at [2(7)].

¹¹⁹ Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits, *Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness, Report by the Director-General*, A/PIP/IGM/4 (World Health Organisation, 2007) Annex at [1].

¹²⁰ A/PIP/IGM/4, n 119, Annex at [4].

¹²¹ A/PIP/IGM/4, n 119, Annex at [11].

¹²² A/PIP/IGM/4, n 119, Annex, Appendix 3 at [30].

¹²³ A/PIP/IGM/4, n 119, Annex, Appendix 3 at [31]-[32].

of technology and know-how, provision of vaccines and their developmental components.¹²⁴ The outcomes of the interdisciplinary working group then contributed to the subsequent intergovernmental meeting.¹²⁵

The Director-General 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”.¹²⁶ The outcome of this intergovernmental meeting was to identify and reaffirm the relevant “guiding principles” for “the sharing of, and access to, benefits that result from the sharing of influenza viruses”:¹²⁷

- (a) timely sharing of viruses within the Global Influenza Surveillance Network;
- (b) application of the same standard terms and conditions to all transactions, as appropriate;
- (c) timely consultation and sharing of information with originating countries, especially on use outside the Network;
- (d) for any use of influenza viruses outside the scope of the terms of reference of WHO Collaborating Centres, H5 Reference Laboratories, and national influenza centres submission of a request directly to the relevant national influenza centre or other originating laboratory of the country where the virus was collected and require appropriate response from the national influenza centre; such requests would be bilateral activities not requiring the intervention of WHO;
- (e) recognition and respect of the crucial and fundamental role and contribution of countries in providing viruses for the Global Influenza Surveillance Network;
- (f) increased involvement, participation and recognition of contribution of scientists from originating country in research related to viruses and specimens;
- (g) attribution of the work and increased co-authorship of scientists from originating countries in scientific publications;
- (h) due consideration of relevant national and international laws.¹²⁸

And:

- Member States should designate and adequately support a national influenza centre in order to participate actively in the WHO Global Influenza Surveillance Network.
- All Member States with a national influenza centre laboratory conducting surveillance should share nationally representative samples of seasonal influenza viruses on a regular and timely basis and all novel influenza viruses on an urgent basis by sending the viruses to a WHO Global Influenza Surveillance Network Collaborating Centre or H5 Reference Laboratory of the Member State’s choosing.
- The genetic sequence data and any other information of urgent public health importance derived from the analysis of influenza viruses collected through the WHO Global Influenza Surveillance Network should be made available to all Member States in an open and timely manner.
- The influenza viruses collected through the WHO Global Influenza Surveillance Network should be shared routinely among the Network’s Collaborating Centres and H5 Reference Laboratories in order to facilitate global monitoring of influenza, risk assessment and vaccine development and production, taking all appropriate biosecurity concerns into consideration.
- The individual research efforts of Member States should not be adversely affected by their participation in the WHO Global Influenza Surveillance Network.
- Global surveillance of influenza should be a cooperative, voluntary public health activity of Member States in order to strengthen global health security and is not a profit-making activity.

¹²⁴ A/PIP/IGM/4, n 119, Annex, Appendix 3 at [annex].

¹²⁵ See A/PIP/IGM/4, n 119.

¹²⁶ Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits, *Reports by the Director-General: Summary Progress Reports*, A/PIP/IGM/2 Rev.1 (World Health Organisation, 2007) at [1].

¹²⁷ A/PIP/IGM/2 Rev.1, n 126 at [2].

¹²⁸ WHA60.28, n 106 at [2(5)].

- The technological benefits of participation in the WHO Global Influenza Surveillance Network, including improved access to vaccines, should be available to all countries.¹²⁹

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:

Acknowledging the urgent need for fair, transparent, equitable and effective international mechanisms aimed at ensuring access to H5N1 vaccine and fair and equitable sharing of benefits, in support of public health amongst Member States taking into consideration the needs of developing countries (resolution WHA60.28);

...

Acknowledging that the current system does not deliver the desired level of fairness, transparency and equity.¹³⁰

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 “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).¹³¹ 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”.¹³² The interim traceability measures included that “each A (H5N1) virus so submitted [be] assigned a unique identifier and data on it are stored in an electronic database” so that “[d]ata 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”.¹³³ There was also agreement to convene an open-ended working group to further advance the work of developing a traceability mechanism and an advisory mechanism¹³⁴ before suspending proceedings.¹³⁵ 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.¹³⁶ What essentially remained to be resolved was the text of the access and benefit-sharing “arrangements”, there remaining some contention about whether these concerned the definitions and scope for the sharing of viruses or a “standard Material Transfer Agreement”.¹³⁷

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

¹²⁹ World Health Organisation Executive Board, *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, Report by the Secretariat*, EB120/INF.DOC./3 (World Health Organisation, 2007) at [7].

¹³⁰ World Health Organisation Executive Board, *Interim Statement of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits*, EB122/5 (World Health Organisation, 2008) Annex 5 [Preamble]. See also Intergovernmental Meeting on Pandemic Influenza Preparedness, *Sharing of Influenza Viruses and Access to Vaccines and other Benefits Open-Ended Working Group, Benefit-sharing, A/PIP/IGM/WG/4* (World Health Organisation, 2008).

¹³¹ EB122/5, n 130, Annex 5 at [1] and [2]. See also A/PIP/IGM/WG/4, n 130.

¹³² EB122/5, n 130, Annex 5 at [3]. See also A/PIP/IGM/WG/4, n 130.

¹³³ Sixty-First World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Report by the Secretariat*, A61/4 (World Health Organisation, 2008) at [4].

¹³⁴ EB122/5, n 130, Annex 5 at [4]. See also A/PIP/IGM/WG/4, n 130.

¹³⁵ See A61/4, n 133 at [3].

¹³⁶ See EB122/5, n 130 at [6] and Annex 6. See also A/PIP/IGM/WG/4, n 130.

¹³⁷ EB122/5, n 130, Annex 6. See also A/PIP/IGM/WG/4, n 130.

consensus”.¹³⁸ A “Chair’s text” was to be prepared for a future meeting and “benefit-sharing” was “crucial” and “the issue will be discussed” at that future meeting.¹³⁹ The “Chair’s text” was subsequently prepared and considered by the resumed open-ended working group and then an intergovernmental meeting.¹⁴⁰

The intergovernmental meeting finally negotiated a *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*¹⁴¹ that was originally developed as the “Chair’s text” considered by an open-ended working group and the intergovernmental meeting.¹⁴² The agreed (consensus) parts of the framework included:

- *Scope* – that the framework “applies to the sharing of H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits” but *not* “seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in [shared] clinical specimens”.¹⁴³
- “*Influenza virus with human pandemic potential*” – “designates any wild-type influenza virus that has been found to infect humans and that has a haemagglutinin antigen that is distinct from those in seasonal influenza viruses so as to indicate that the virus has potential to be associated with pandemic spread within human populations with reference to the *International Health Regulations 2005* for defining characteristics”.¹⁴⁴
- “*Influenza vaccine, diagnostic and pharmaceutical manufacturers*” – means “public or private entities including academic institutions, government owned or government subsidized entities, non-profit organizations or commercial entities that develop and/or produce human influenza vaccines and other products derived from or using H5N1 or other influenza viruses of human pandemic potential”.¹⁴⁵
- *Sharing* – “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: (i) to the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory of the originating Member State’s choice.”¹⁴⁶ The subsequent transfer of materials remains contentious.¹⁴⁷
- *Benefit-sharing* – “Member States should, working with the WHO Secretariat, contribute to a pandemic influenza benefit-sharing system and call upon relevant institutions, organizations, and entities, influenza vaccines, diagnostics and pharmaceutical manufacturers and public health researchers to also make appropriate contribution to this system.”¹⁴⁸ A comprehensive series of

¹³⁸ 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*, A/PIP/IGM/WG/5 (World Health Organisation, 2008) at [9].

¹³⁹ A/PIP/IGM/WG/5, n 138 at [10]; World Health Organisation Executive Board, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Report by the Secretariat*, EB124/4 (World Health Organisation, 2008) at [3].

¹⁴⁰ See 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*, A/PIP/IGM/WG/6 (World Health Organisation, 2008).

¹⁴¹ See Sixty-Second World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Outcome of the Resumed Intergovernmental Meeting – Report by the Director-General*, A62/5 Add.1 (World Health Organisation, 2009) Annex at [8]. See also A/PIP/IGM/WG/4, n 130.

¹⁴² See A/PIP/IGM/WG/6, n 140.

¹⁴³ A62/5 Add.1, n 141, Annex (Appendix at [3.1]-[3.2]).

¹⁴⁴ A62/5 Add.1, n 141, Annex (Appendix at [4.1]).

¹⁴⁵ A62/5 Add.1, n 141, Annex (Appendix at [4.2]).

¹⁴⁶ A62/5 Add.1, n 141, Annex (Appendix at [5.1.1]).

¹⁴⁷ See A62/5 Add.1, n 141, Annex (Appendix at [5.1]-[5.4]).

¹⁴⁸ A62/5 Add.1, n 141, Annex (Appendix at [6.1.1]).

likely benefits were identified, including information, capacity-building, stockpiles, tiered pricing, technology transfer, innovative financing, and so on, all subject to the proviso that influenza vaccine manufacturers are “urged” to contribute.¹⁴⁹

The outcome of the intergovernmental meeting was to consider a traceability mechanism (Virus Traceability Mechanism within the WHO),¹⁵⁰ an advisory mechanism (Advisory Group; Terms of Reference for four categories of laboratories within the WHO Global Influenza Surveillance Network),¹⁵¹ and update virus sample sharing negotiations (including the outcomes of the working groups).¹⁵² The intergovernmental meeting was eventually suspended with there remaining disagreement about the form and content of the benefit-sharing arrangements and obligations.¹⁵³ In suspending the intergovernmental meeting, the following was agreed:

The Intergovernmental Meeting decided to ...

- (b) acknowledge the need to have informal consultations among interested Member States and relevant regional economic integration organizations in the inter-sessional period, using all possible forums, in order to find ways of resolving the remaining issues; ...
- (d) request the Director-General to undertake, taking into account the Intergovernmental Meeting’s revised text, and if necessary with the advice of the Advisory Group, the following preparatory work:
 - (i) further development of the traceability mechanism;
 - (ii) preparation of the detailed terms of reference of WHO Collaborating Centres on Influenza, the WHO H5 Reference Laboratories, essential regulatory laboratories, and the National Influenza Centres, following the guiding principles included in the Intergovernmental Meeting text;
 - (iii) preparation of a revised version of the technical part of the Standard Material Transfer Agreement, following the agreed principles of the Intergovernmental Meeting text;
 - (iv) preparation of a report identifying the needs and priorities for each of the benefits listed in s 6 of the Intergovernmental Meeting text, in particular concerning the vaccine stockpile, as well as options for their financing.¹⁵⁴

The outcome of access and benefit-sharing at this stage was the consensus principle:¹⁵⁵ “Member States to share, on an equal footing, influenza viruses with pandemic potential and benefits, considering these as equally important parts of the collective action for global public health.”¹⁵⁶

¹⁴⁹ See A62/5 Add.1, n 141, Annex (Appendix at [6.4.2], [6.6.1], [6.9.3], [6.10.1.1] and so on).

¹⁵⁰ EB124/4, n 139, at [12] and Annex 1 (Appendix 1). See also 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*, A/PIP/IGM/9 (World Health Organisation, 2008).

¹⁵¹ EB124/4, n 139 at [12] and Annex 1 (Appendix 2). See also Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines, *Reports of the Director-General: Establishment of the Advisory Mechanism*, A/PIP/IGM/8 (World Health Organisation, 2008).

¹⁵² World Health Organisation Executive Board, Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits – Resumed Intergovernmental Meeting, *Report by the Director-General*, EB124/4 Add.1 (World Health Organisation, 2009) at [15] and Annex 2.

¹⁵³ See EB124/4 Add.1, n 152, at [14] and [15] and Annex 2.

¹⁵⁴ EB124/4 Add.1, n 152, Annex 1 at [14]. See also WHA62.10, n 106; 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 Influenza Viruses and Access to Vaccines and Other Benefits*, *Report by the Director-General*, A/PIP/IGM/13 (World Health Organisation, 2009) at [2].

¹⁵⁵ See WHA62.10, n 106; A62/5 Add.1, n 141, Annex.

¹⁵⁶ Sixty-Third World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Outcome of the Process to Finalize Remaining Elements under the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, *Report by the Secretariat*, A63/4 (World Health Organisation, 2010) at [3]. See also EB124/4 Add.1, n 152 at [14]; A62/5 Add.1, n 141.

Subsequent discussions¹⁵⁷ refined the contentious issues to the Standard Material Transfer Agreement, benefit-sharing and intellectual property.¹⁵⁸ More specifically, the unresolved issues were about

- the Standard Material Transfer Agreement and its use with vaccine manufacturers;
- the role and place of intellectual property in the use of accessed viruses; and
- various other matters including the role and place of the CBD.¹⁵⁹

These issues remain to be resolved, with discussion identifying apparent divergent approaches and possible resolutions:

- *Standard Material Transfer Agreement and relations with influenza vaccine manufacturers* – “one perspective espoused a binding, all-encompassing agreement, covering both virus and benefit-sharing, while the other perspective supported an agreement limited to virus sharing” with the proposed resolution being two separate agreements, one a generally applicable Standard Material Transfer Agreement and the other an individual agreement with influenza vaccine manufacturers according to the *Guiding Principles for the Development of Benefit-sharing Arrangements with Influenza Vaccine Manufacturers*;¹⁶⁰ and
- *Intellectual property* – “one [perspective] supporting no restriction on the right of parties handling [accessed virus samples] to seek intellectual property rights with respect to inventions developed with these materials, and the other seeking to limit or restrict pursuit of intellectual property rights” with the proposed resolution being to allow intellectual property to be claimed while “urging” granting the WHO “a non-exclusive, royalty-free, sub-licensable licence with respect to such rights, to the extent that this is not prohibited by law, regulation or third-party obligation”.¹⁶¹

And more recently, an “open-ended working group” was convened¹⁶² which has prepared and collected suggested text for the Standard Material Transfer Agreement.¹⁶³ The advance has been to suggest two forms of the Standard Material Transfer Agreement: one for use by “entities inside the WHO network” and another for “entities outside the WHO network”.¹⁶⁴ While the work of the “open-ended working group” will continue,¹⁶⁵ the negotiations are balanced with a negotiating text with some parts attracting consensus and remaining parts subject to further negotiation.¹⁶⁶ Significantly, the intellectual property provisions remain contested. The intellectual property provisions for use by “entities inside the WHO network” are more clearly articulated with text being proposed:¹⁶⁷

[If intellectual property rights are obtained on inventions derived from the use of Materials, the holder/[provider] of such rights should grant to WHO a non-exclusive, royalty-free license, which WHO will sub-license to interested developing countries, for the purpose of maximizing availability of critical benefits on a non-profit basis, such as vaccines and anti-virals, for pandemic influenza preparedness purposes.]

¹⁵⁷ See WHA63.1, n 106; WHA62.10, n 106. See also Sixty-Third World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Outcome of the Process to Finalize Remaining Elements under the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, Report by the Secretariat*, A63/6 (World Health Organisation, 2010).

¹⁵⁸ A63/4, n 156 at [7].

¹⁵⁹ See A63/4, n 156, Annex at [5]-[11].

¹⁶⁰ A63/4, n 156, Annex (at [5]-[6] and Appendixes 1 and 2).

¹⁶¹ A63/4, n 156, Annex (at [7]-[10] and Appendix 3).

¹⁶² WHA63.1, n 106. See also Sixty-Third World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Outcome of the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, Report by the Director-General*, A63/48 (World Health Organisation, 2010) Annex.

¹⁶³ A63/48, n 162, Annex (Appendix).

¹⁶⁴ A63/48, n 162, Annex at [5].

¹⁶⁵ See WHA63.1, n 106.

¹⁶⁶ See A63/48, n 162, Annex (Appendix 2, White Paper 1).

¹⁶⁷ See also A63/48, n 162, Annex (Appendix 2, White Paper 1 and at [4.1.3], [4.1.5] and [4.3]).

Or

[The provider shall not seek to obtain any intellectual property rights in connection with such materials.]¹⁶⁸

Or

[If the provider is a national government laboratory, it shall not seek to obtain a patent on PIP biological materials transferred pursuant to this SMTA.

The provider and the recipient acknowledge that any intellectual property rights associated with the materials or their use will not be disturbed by this SMTA.]

Or

[Delete].¹⁶⁹

Meanwhile, for “entities outside the WHO network”, the Standard Material Transfer Agreement is only at the stage of considering the various alternatives.¹⁷⁰ The various alternatives are poorly articulated although they appear to accept that the WHO should have a non-exclusive, royalty-free licence on any intellectual property from derived materials with the potential to sub-license for the purposes of pandemic influenza preparedness.¹⁷¹ The unresolved intellectual property matters in the various agreements are essentially about whether intellectual property can be claimed, and if it is, whether it can be disregarded in some circumstances (such as pandemic influenza preparedness purposes). The other unresolved matter is the form and quantum of benefits.¹⁷²

WHO AND INTELLECTUAL PROPERTY

At the same time as debates have been 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 Health¹⁷³ and an intergovernmental working group¹⁷⁴ 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 against diseases that disproportionately affect developing countries”.¹⁷⁵ The outcome was 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 2008-2015.¹⁷⁶ The aim was stated as follows:

The global strategy on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines, ... provide a medium-term framework for securing an enhanced

¹⁶⁸ Notably, the proposal from Brazil, India and Indonesia suggests: “The Recipient shall not seek to obtain any intellectual property rights in connection with such Materials”: A63/48, n 162, Annex (Appendix 2, White Paper 2 and at [4.3]).

¹⁶⁹ A63/48, n 162, Annex (Appendix 2, White Paper 1 and at [3.1.3]).

¹⁷⁰ See A63/48, n 162, Annex (Appendix 2, White Paper 1 (Annex), White Papers 2 and 3 (Proposal from Brazil, India and Indonesia) and White Paper 4 (WHO EURO Region Proposal)).

¹⁷¹ See A63/48, n 162, Annex (Appendix 2, White Paper 1 (Annex, [2]) and White Paper 3 and at [4.1]).

¹⁷² A63/48, n 162, Annex (Appendix 2, White Paper 1 (Annex at [2]), White Paper 3 (at [4.1]) and White Paper 4 (at [2] and Annex)).

¹⁷³ See Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission* (World Health Organisation, 2006).

¹⁷⁴ Sixty-First World Health Assembly, *Report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property*, A61/9 (World Health Organization, 2008); Sixtieth World Health Assembly, *Public Health, Innovation and Intellectual Property: Progress made by the Intergovernmental Working Group, Report by the Secretariat*, A60/27 (World Health Organisation, 2007).

¹⁷⁵ Fifty-Ninth World Health Assembly, *Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action*, WHA59.24 (World Health Organization, 2006) at [3(1)]; Fifty-Sixth World Health Assembly, *Intellectual Property Rights, Innovation and Public Health*, WHA56.27 (World Health Organisation, 2003) at [2(2)].

¹⁷⁶ A63/6, n 157; A61/9, n 174.

and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area.¹⁷⁷

The “global strategy”¹⁷⁸ and the “agreed parts of the plan of action”¹⁷⁹ 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.¹⁸⁰ So, eg, unaccepted text included:

- removing the provision “[t]he right to health takes precedence over commercial interests”;¹⁸¹
- 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 production of health products in developing countries through investment and capacity building”;¹⁸²
- removing 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”;¹⁸³

and so on. 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*” (emphasis added),¹⁸⁴ and so on.¹⁸⁵ The effective outcome of the WHO’s considerations of intellectual property, innovation and public health is to use acceptable diplomatic language that maintains the intellectual property status quo and formally recognises the “problem”:¹⁸⁶

Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.¹⁸⁷

Thus, the role and place of intellectual property in implementing the WHO’s concerns about intellectual property, innovation and public health has been to focus on “capacity building and training” in collaboration with the World Intellectual Property Organisation and the World Trade

¹⁷⁷ Sixty-First World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21 (World Health Organization, 2008) Annex at [13].

¹⁷⁸ See WHA61.21, n 177, Annex 1 (Global Strategy).

¹⁷⁹ See WHA61.21, n 177, Annex 1 Appendix (Plan of Action).

¹⁸⁰ Compare WHA61.21, n 177, Annex (final text) with A61/9, n 174, Annex 1 (negotiation text).

¹⁸¹ A61/9, n 174 at [18].

¹⁸² A61/9, n 174 at [34].

¹⁸³ A61/9, n 174 at [36].

¹⁸⁴ WHA61.21, n 177, Annex at [39].

¹⁸⁵ See also Lerner J, “Intellectual Property and Development at WHO and WIPO” (2008) 34 *American Journal of Law and Medicine* 257 at 260-269.

¹⁸⁶ Perhaps unsurprisingly, there remains no consensus about “Element 5”: see Sixty-Second World Health Assembly, *Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action, Open Paragraphs on Stakeholders*, A62/16 Add.3 (World Health Organisation, 2009) Annex; Sixty-Second World Health Assembly, *Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action, Report by the Secretariat*, A62/16 (World Health Organisation, 2009) at [12]; A61/9, n 174, Annex at [35]-[36]. See also Expert Working Group on Research and Development Financing, *Report of the World Health Organization Expert Working Group on Research and Development Financing* (World Health Organisation, 2010) pp 2-9; Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, *Review of Recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health*, A/PHI/IGWG/1/2 (World Health Organisation, 2006) at [2].

¹⁸⁷ WHA61.21, n 177, Annex at [4].

Organisation¹⁸⁸ and engage in initiatives to strengthen, promote and support capacities to manage and apply intellectual property to innovation and promote public health.¹⁸⁹ Significantly, a contemporaneous Expert Working Group on Research and Development Financing¹⁹⁰ has accepted that “the integrity of intellectual property rights” was important as an incentive to stimulate research and development, but that the major focus should be on public support through grants, contributions, tax exemptions and other forms of financing,¹⁹¹ and further, the plan of action implementing intellectual property measures remains uncertain.¹⁹² In short, the WHO’s apparent interest in intellectual property, innovation and public health has not challenged the existing role and place of intellectual property, but rather entrenched the existing standards and practices. This position, however, has now been challenged¹⁹³ and the WHO has subsequently resolved to establish the Consultative Expert Working Group to address a number of matters, including de-linking R&D costs from product prices, thus directly challenging the role and place of intellectual property.¹⁹⁴

DISCUSSION

The analysis in this article so far shows that, in the context of the WHO’s arrangements for accessing viruses and the development of vaccines to respond to potential pandemics (and other lesser outbreaks), the role and place of intellectual property has so far eluded consensus. Despite this lack of consensus, however, negotiations have advanced to the stage of draft Standard Material Transfer Agreements that implement the CBD’s core standards of sovereign rights of states over their natural resources,¹⁹⁵ and access from countries of origin (or countries that have acquired the genetic resources according to the CBD)¹⁹⁶ on mutually agreed terms¹⁹⁷ and with prior informed consent.¹⁹⁸ This contractual approach is also consistent with that envisioned by the CBD’s Bonn Guidelines.¹⁹⁹ The negotiation of a Standard Material Transfer Agreement is a significant development because this undoubtedly accepts that the CBD sets out at least some of the relevant legal standards for

¹⁸⁸ See A63/6, n 157 at [9]. See also World Health Organisation Executive Board, *Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action, Report by the Secretariat*, EB126/6 (World Health Organisation, 2009) at [9]. See also A62/16, n 186 at [8] (“capacity building, information sharing, and technical and policy support”); Sixty-Second World Health Assembly, *Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action – Proposed Progress Indicators, Report by the Secretariat*, A62/16 Add.2 (World Health Organisation, 2009) at [8] (“Element 5”); Council for Trade-Related Aspects of Intellectual Property Rights, *Technical Cooperation Activities: Information from Other Intergovernmental Organisations – World Health Organisation (WHO)*, IP/C/W/516/Add.1 (World Trade Organisation, 2008).

¹⁸⁹ See A62/16 Add.2, n 188 at [8] (“Element 5”). See also A63/6, n 157 at [2]-[3].

¹⁹⁰ Sixty-Third World Health Assembly, *Public Health, Innovation and Intellectual Property: Report of the Expert Working Group on Research and Development Financing*, A63/6 Add.1 (World Health Organization, 2010). See also Expert Working Group on Research and Development Financing, n 186; WHA61.21, n 177 at [4(7)].

¹⁹¹ See generally A63/6 Add.1, n 190, Annex at [21]-[30]. See also Expert Working Group on Research and Development Financing, n 186, p 1.

¹⁹² See A62/16, n 186 at [12]; A62/16 Add.3, n 186 (“Element 5”). Notably the progress on this aspect of the plan of action was not address at the Sixty-Second World Health Assembly: see A63/6, n 157.

¹⁹³ See eg Sixty-Third World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Outcome of the Consultation on the Report of the Expert Working Group on Research and Development: Coordination and Financing, Report by the Director-General*, A63/6 Add.2 (World Health Organisation, 2010) Annex at [4]-[12].

¹⁹⁴ See Shashikant S, “WHA Agrees to Roadmap to Take Forward Work on R&D, Financing” (2010) *TWN Info Service on Intellectual Property Issues* SUNS #6931 (27 May 2010), http://www.twinside.org.sg/title2/intellectual_property/info.service/2010/ipr.info.100509.htm viewed 10 June 2010.

¹⁹⁵ CBD, Art 15(1).

¹⁹⁶ CBD, Art 15(3).

¹⁹⁷ CBD, Art 15(4).

¹⁹⁸ CBD, Art 15(5).

¹⁹⁹ See UNEP/CBD/COP/6/20, n 86, pp 60-62, 253-269 (Bonn Guidelines).

determining accessing and benefit-sharing viruses,²⁰⁰ and consequentially, that the countries of origin have something of value to trade.²⁰¹ More importantly, this signals access and benefit-sharing viruses as another front in the debates about the role and place of intellectual property in other fora, such as the CBD and the WTO, and the ongoing failure to properly address questions of equity and development.²⁰² Essentially, the debate remains between the developed North's view that intellectual property should be maintained and respected,²⁰³ and the developing South's contention that sharing valuable genetic resources is an opportunity to address poverty alleviation and technological development requiring more favourable and non-commercial terms of access to useful technology.²⁰⁴ The analysis here demonstrates that the attempts by the developing North countries at the WHO to maintain existing intellectual property standards through the *Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action* have been challenged,²⁰⁵ and attempts to distinguish virus sharing as something outside the realm the CBD framework have been thwarted.²⁰⁶ The failure of the developed North to agree to suitable intellectual property standards in these draft Standard Material Transfer Agreements effectively continues the ongoing debates. The recent experience, however, from the influenza A (H1N1) 2009 pandemic and the failure of the developed North to provide timely and suitable access to a vaccine has merely confirmed and entrenched the developing South's concerns about fairly sharing the benefits from accessed viruses.²⁰⁷

²⁰⁰ Albeit there remains a health exceptionalism perspective with complex roots in self-interest and domestic and international politics: see eg Feldbaum H and Michaud J, "Health Diplomacy and the Enduring Relevance of Foreign Policy Interests" (2010) 7(4) *Public Library of Science Medicine* 20 April 2010.

²⁰¹ See also Franklin N, "Sovereignty and International Politics in the Negotiation of the Avian Influenza Material Transfer Agreement" (2009) 17 JLM 355. Compare also the changing perspectives about sovereignty: see eg Fidler D, "Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1" (2010) 7(5) *Public Library of Science Medicine* (4 May 2010); Garrett L and Fidler D, "Sharing H5N1 Viruses to Stop a Global Influenza Pandemic" (2007) 4(11) *Public Library of Science Medicine* 1712.

²⁰² For a detailed analysis of the evolution of this debate at the CBD see eg Lawson C, "Implementing an Objective of the Convention on Biological Diversity – Intellectual Property, Access to Genetic Resources and Benefit-sharing in Australia" (2005) 22 EPLJ 130.

²⁰³ For example, the United States has recently stated: "At a fundamental level, she said that the most critical element in ensuring appropriate prior informed consent and access and benefit sharing was the development and strengthening of national regimes and legal frameworks designed specifically to accomplish these objectives. Bringing the patent system into the equation simply did not make sense, particularly in the absence of well functioning prior informed consent and access and benefit sharing regimes. She said that her delegation continued to puzzle over how new patent requirements including the possibility of denial of patents or revocation of patents in some circumstances would help accomplish the legitimate and important objectives that Members shared. The most effective way to ensure the effective sharing of benefits was to bring about the generation of benefits in the first place. Benefits would be generated when useful and good products were developed and commercialized. The existence of an incentive through the patent system was a critical element in encouraging such development and commercialization. When this happened and when meaningful national systems were in place, then Members could have confidence in the common objectives they had identified": IP/C/M/61, n 24 at [88]. For an overview of the developed North's justifications: see eg Mahoney R, Pablos-Mendez A and Ramachandran S, "The Introduction of New Vaccines into Developing Countries III. The Role of Intellectual Property" (2007) 22 *Vaccine* 786 at 788-789.

²⁰⁴ For example, India has recently stated: "Despite the fact that the CBD had been signed several years before the TRIPS Agreement had entered into force, the TRIPS Agreement was oblivious to the intellectual property provisions of the CBD so far. This contradiction obstructed the proper implementation of the CBD and caused an imbalance in the TRIPS Agreement. The steep rise in bioprospecting for natural remedies and other purposes and patent applications based on genetic resources and associated traditional knowledge could have undesirable consequences in the absence of internationally acceptable legal regulations. The issue therefore must be dealt with urgently and with priority": IP/C/M/61, n 24 at [67].

²⁰⁵ See A63/6 Add.2, n 193, Annex at [4]-[12] (*Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action*). See also Mara K and New W, "Developing Countries Blast WHO Report on IP, Demand 'Credible' Approach" (2010) *Intellectual Property Watch* (18 May 2010), <http://www.ip-watch.org/weblog/2010/05/18/developing-countries-blast-who-report-on-ip-demand-credible-approach> viewed 10 June 2010.

²⁰⁶ See Fidler D, "Influenza Virus Samples, International Law, and Global Health Diplomacy" (2008) 14 *Emerging Infectious Diseases* 88, 90-93; Garrett and Fidler, n 201.

²⁰⁷ The various propositions from the developing South representatives illustrate these concerns: see Mara K, "New Intergovernmental Meeting at WHO Aims to Solve IP Rights and Influenza" (2010) *Intellectual Property Watch* (20 January

Pandemic influenza A (H1N1) 2009 was the most recent influenza outbreak addressed by the WHO under its legal regime:

In April 2009, the first cases of infection with pandemic influenza A (H1N1) 2009 virus, a new virus of swine origin not previously detected in humans, were reported from North America. On 25 April, in accordance with the provisions of the *International Health Regulations (2005)*, the Director-General, after consulting the IHR Emergency Committee, declared a Public Health Emergency of International Concern for the first time since the Regulations came into force. On 27 April, the level of pandemic alert was raised to WHO Pandemic Phase 4, to Phase 5 on 29 April, and to Phase 6 on 11 June.²⁰⁸

Virus samples were collected by the Mexico NICs from the epicentre of the H1N1 pandemic in Mexico and then provided to the WHO CCs.²⁰⁹ Candidate vaccine viruses were identified by the WHO CCs from these and other samples, and were then provided by the WHO CCs to the vaccine manufacturing industry worldwide.²¹⁰ The global manufacture of vaccines followed, with the developed countries essentially dominating the production output with a significant emphasis on meeting domestic needs ahead of any others.²¹¹ The Australian Government “made it clear to the Australian manufacturer CSL [Ltd] that it must fulfil the government’s domestic needs before exporting vaccine to the United States”.²¹² CSL Ltd was able to meet the Australian Government’s requirements.²¹³

While developed countries pledged and donated vaccines to developing countries, these amounts were insufficient and only eventuated *after* the developed countries’ domestic needs had been satisfied.²¹⁴ Perhaps significantly, the Mexican Health Secretary stated: “[W]e had to wait in the second line to buy the vaccine, because obviously the first shipments were for the countries that make the vaccine”.²¹⁵ A similar outcome was apparent for other developing countries:

As of early February 2010 however, only two of the 95 countries listed by WHO ... as having no independent means of obtaining flu vaccines – Azerbaijan and Mongolia – had received any. WHO had earlier planned to deliver vaccines to 14 of these countries by then, and even then shipments were

2010), <http://www.ip-watch.org/weblog/2010/01/20/new-intergovernmental-meeting-who-aims-to-solve-ip-rights-and-influenza> viewed 10 June 2010. See also Coleman C, “Allocating Vaccines and Antiviral Medications During an Influenza Pandemic” (2009) 39 *Seton Hall Law Review* 1111.

²⁰⁸ Sixty-Third World Health Assembly, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Update on the Pandemic Influenza A (H1N1) 2009 Virus, Report by the Secretariat*, A63/INF.DOC./1 (World Health Organisation, 2010) at [1].

²⁰⁹ See Chan, n 5. See also Mara, n 207 (“Mexico, where the 2009 pandemic of H1N1 (so-called swine flu) originated, said that ‘despite the good faith we showed in sharing the virus’ – which was credited by many at the meeting as the reason vaccines could be developed so rapidly – ‘we never received any benefits from that sharing’”).

²¹⁰ The Australian vaccine was developed from candidate vaccines A/California/4/2009(H1N1)swl and A/California/7/2009(H1N1)swl: World Health Organisation, *Status of Candidate Vaccine Virus Development for the Current Influenza A(H1N1) Virus* (World Health Organisation, 2009), http://www.who.int/csr/resources/publications/swineflu/vaccine_virus_development/en/index.html viewed 10 June 2010. See also A63/INF.DOC./1, n 208 at [14].

²¹¹ See Fidler, n 201. See also Kieny M and Fukuda K, “The Pandemic Influenza Challenge” (2008) 26(Supplement 4) *Vaccine* D3.

²¹² Fidler, n 201 citing McNeil D, “Nation is Facing Vaccine Shortage for Seasonal Flu”, *New York Times* (4 November 2009), <http://www.nytimes.com/2009/11/05/health/05flu.html> viewed 10 June 2010 (“The drawback of relying on foreign plants was made clear recently when the Australian government pressured CSL [Ltd] to keep its vaccine at home instead of fulfilling its contract for 36 million doses of swine flu vaccine for the United States”). See also Dayton L and Franklin M, “Nicola Roxon in Flu Vaccine Dilemma”, *The Australian* (7 January 2010), <http://www.theaustralian.com.au/news/nation/nicole-roxon-in-flu-vaccine-dilemma/story-e6f96nf-122581677813> viewed 10 June 2010 (“the minister confirmed the government was contractually bound to buy 21 million vaccine doses from pharmaceutical company CSL”); Knight E, “Swine Flu Vaccine is Least of CSL’s Concerns”, *Sydney Morning Herald* (29 May 2009), <http://www.smh.com.au/business/swine-flu-vaccine-is-least-of-csls-concerns-20090528-boyp.html> viewed 10 June 2010 (“But yesterday [the Australian Government] had no choice but to announce that it had given CSL the go-ahead to accelerate the development of a swine flu vaccine”).

²¹³ See Dayton and Franklin, n 212 (“we will be able to vaccinate anyone in the community who wants to be vaccinated”). Notably, public perceptions will be important as well as actually delivering vaccines: see Stephenson N and Jamieson M, “Securitising Health: Australian Newspaper Coverage of Pandemic Influenza” (2009) 31 *Sociology of Health and Illness* 525.

²¹⁴ See Fidler, n 201, and the references therein.

²¹⁵ Chan, n 5.

adequate to protect only 2 percent of the countries' populations. Pledges and exhortations aside, few were really surprised that when faced with perceived national emergencies, countries that could afford vaccines prioritized their own nationals first, and only when the worst had passed, transferred their leftovers to the poor using the WHO as a clearinghouse.²¹⁶

In short, the response of developed North confirmed that participation in the WHO's GISN (and its NICs and WHO CCs) was no guarantee that the developing South would obtain timely vaccines, and perhaps reinforced the South's perspectives about the inequities in the existing arrangements. The result has been to entrench the developing South's perspectives and raise the bar for the South's expectation in the ongoing negotiation of the Standard Material Transfer Agreements.²¹⁷

The concern for Australia is that access to future viruses for the manufacture of vaccines is likely to be more difficult and more expensive. This is a significant public health concern. In the context of accessing viruses to prepare and respond to potential pandemics (and other lesser outbreaks), the critical place of vaccines for preparation and response has been clearly stated by the Minister for Health and Ageing:

According to the World Health Organization, it is inevitable that the world will face another influenza pandemic. While there is no certainty about when the next one will occur, Australia must be prepared. An influenza pandemic could devastate a nation's health system and our health sector must be equipped to respond to minimise the impact on the health of all Australians and on the health system itself.²¹⁸

The ongoing difficulty is that Australia's preparation and response needs to be within a broader global response and some inherently difficult constraints:²¹⁹

To protect the global population, 6.2 billion doses of pandemic vaccine [in the context of developing H5N1 vaccines] will be needed, but under current manufacturing capacity the world can only produce 500 million doses. And, in a pandemic, it is industrialised countries that will have access to available vaccines, whereas developing countries – where a pandemic is likely to emerge – will be left wanting. In November, 2004, a WHO consultation reached the depressing conclusion that most developing countries would have no access to vaccine during the first wave of a pandemic and possibly throughout its duration.²²⁰

For Australia to access the relevant virus samples will necessitate finding acceptable terms and conditions for the exchange of a virus to the satisfaction of the provider of the initial virus sample.²²¹ While this might be achieved outside the WHO schemes,²²² the avenues already established through the WHO are likely to be valuable both in taking advantage of the existing global network of NICs and the WHO CCs, and in obtaining the optimal virus samples for manufacturing vaccines. This will inevitably require a conclusion of the negotiations over the draft Standard Material Transfer Agreements and resolving the existing intellectual property and benefit-sharing impasse. This is likely to be a significant hurdle, given that intellectual property debates echo other debates in other

²¹⁶ Chan, n 5.

²¹⁷ See eg Mara, n 207.

²¹⁸ Department of Health and Ageing, n 1, p ix. For an overview of the quantum of recent pandemics see eg WHO, *Pandemic (H1N1) 2009 – Update 102*, n 1. For a discussion of other relevant issues see eg Ly T, Selgelid M and Kerridge I, "Pandemic and Public Health Controls: Toward an Equitable Compensation System" (2007) 15 JLM 296; Davies T, "Non-voluntary Licensing of Antivirals under Patent: Options the Australian Government Should Consider in Light of a Potential Bird Flu Pandemic" (2006) 13 JLM 479.

²¹⁹ Although pre-vaccination using a cocktail of likely strains is favoured by the vaccine manufacturers: see Stöhr K, "Vaccinate Before the Next Pandemic?" (2010) 465 *Nature* 161.

²²⁰ Editorial, "Global Solidarity Needed in Preparing for Pandemic Influenza" (2007) 369 *The Lancet* 532. See also Kienny and Fukuda, n 211.

²²¹ See also Gostin L, "Global Goal for Swine Flu Vaccine Quest", *The Australian* (8 August 2009), <http://www.theaustralian.news.com.au/story/0,25197,25896462-23289,00.html> viewed 10 June 2010.

²²² See eg Sueker J, Blazes D, Johns M et al, "Influenza and Respiratory Disease Surveillance: The US Military's Global Laboratory-based Network" (2010) 4 *Influenza and Other Respiratory Viruses* 155.

forums²²³ and the prior unsatisfactory experience in dealing with virus-sharing and intellectual property.²²⁴ The outcome will undoubtedly involve some recognition that other (equity and development) imperatives over-ride respect for intellectual property and challenge the paramountcy of intellectual property as a policy objective by and of itself. As the analysis in the article demonstrates, the intellectual property provisions of the draft Standard Material Transfer Agreements need to be resolved and this will require concessions about intellectual property. The stakes are high as the alternative of no agreement raises the spectre of limiting pandemic preparedness and response and the prospect of the Australian Government deciding who shall live when not all can live.

²²³ See eg Lawson, n 202 at 131-134 (the conflict between the CBD and TRIPS). Notably, international regime complexes are inherently open to conflict and synergy: see eg Raustiala K and Victor D, "The Regime Complex for Plant Genetic Resources" (2004) 58 *International Organization* 277.

²²⁴ See also Rimmer, n 5 at 339-351 (Severe Acute Respiratory Syndrome virus or SARS virus); Hammond E, "Indonesia Fights to Change WHO Rules on Flu Vaccines" (2009) 20 *Seedling* 24 at 27-29 (H5N1 or "bird flu"); Sedyaningsih E, Isfandari S, Soendoro T and Supari S, "Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanisms: The Avian Influenza Case of Indonesia" (2008) 37 *Annals of the Academy of Medicine Singapore* 482 at 483-487 (H5N1 or "bird flu").