**The People's Vaccine: Intellectual Property,
Access to Essential Medicines, and the Coronavirus COVID-19**
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Abstract

This paper explores intellectual property and access to essential medicines in the context of the coronavirus COVID-19 public health crisis. It considers policy solutions to counteract vaccine nationalism and profiteering

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by pharmaceutical companies and vaccine developers. This paper considers the campaign for the development of a People's Vaccine led by the People's Vaccine Alliance, UNAIDS, Oxfam and Public Citizen. The WHO has established the ACT Accelerator in order to boost research, development, and deployment of COVID-19 technologies. However, the operation of COVAX thus far has been falling short of its original ambitions. The Medicines Patent Pool has expanded its jurisdiction to include the sharing of intellectual property related to COVID-19. Meanwhile, Costa Rica has proposed a COVID-19 Technology Access Pool – an idea for a new institutional structure which has been taken up by the WHO. In the context of the coronavirus public health crisis, there has also been discussion of the use of compulsory licensing and crown use to counteract profiteering and anti-competitive behavior. There has been a push by Universities Allied for Essential Medicines (UAEM) and others for the public licensing of COVID-19 technologies developed with government funding. The Open COVID Pledge has been taken by a number of intellectual property owners. In response to the assertion of proprietary rights in respect of COVID-19 technologies, the open movement has championed the development of Open Science models of science. India and South Africa have put forward a waiver proposal in the TRIPS Council to enable countries to take action in respect of COVID-19 without fear of retribution under trade laws. While the United States has been willing to support a TRIPS Waiver for vaccines, there remain a number of opponents to a TRIPS Waiver – including the European Union, Germany, Japan, and Switzerland. This paper makes the case that international intellectual property law should accommodate a People's Vaccine.

Keywords

Intellectual Property, Patent Law, Access to Essential Medicines, Compulsory Licensing, ACT Accelerator, Patent Pool, Medicines Patent Pool, C-TAP. Public Sector Licensing, Patent Pledges, Open Licensing, Open Innovation, Coronavirus, COVID-19, World Trade Organization, TRIPS Agreement 1994, Doha Declaration 2001, WTO General Council 2003, TRIPS Waiver.

I. Introduction

The current controversy over intellectual property and access to vaccines during the coronavirus crisis in 2020-2021 has its origins in a long history of international legal conflict over patent law and public health.

Legal systems have long had to deal with the emergency circumstances of public health epidemics.¹ In the past, there has been concern about patent races in respect of medicines during

¹ David Waltner-Toews, *On Pandemics: Deadly Diseases from Bubonic Plague to Coronavirus*, Melbourne: Black Inc., 2007, new edition 2020; Jonathan Quick with Bronwyn Fryer, *The End of Epidemics: How to Stop Viruses and Save Humanity Now*, Melbourne: Scribe, 2018, new edition 2020; Peter S. Doherty, *Pandemics: What Everyone Needs to Know*, Oxford: Oxford University Press, 2013; and John Fabian Witt,

public health epidemics.² In the 1980's, there was a debilitating patent race in respect of diagnostics for HIV/AIDS – which was eventually resolved through an agreement between the governments of France and the United States.³ The *TRIPS Agreement* 1994 laid down a framework for the protection of intellectual property rights, with due recognition of public interest objectives, such as the protection of public health.⁴ In the 1990's, there were dramatic conflicts between South Africa and large pharmaceutical companies over access to medicines sourced from India.⁵ In the end, the resolution of this conflict led to the recognition of the *Doha Declaration* 2001 – which recognized that nation states could make use of flexibilities to

American Contagions: Epidemics and the Law From Smallpox to COVID-19, New Haven and London: Yale University Press, 2020.

² Peter Drahos and Ruth Mayne (ed.), *Global Intellectual Property Rights: Knowledge, Access, and Development*, New York: Palgrave Macmillan, 2003; Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010; Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, Oxford: Oxford University Press, 2011; Burcu Kilic, *Boosting Pharmaceutical Innovation in the Post-TRIPS Era: Real-Life Lessons for the Developing World*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2014; Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, Diemen (Netherlands): AMB Publishers, 2016; Srividhya Ragavan and Amaka Vanni (ed.), *Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health and Pharmaceuticals*, Abingdon (Ox) and New York: Routledge, 2021; and Carlos Correa and Reto Hilty (ed.) *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law*, Cham: Springer, 2021.

³ Michael Kirby, 'Foreword' in Matthew Rimmer, *Intellectual Property and Biotechnology: Biological Inventions*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2008.

⁴ *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995); and *TRIPS Agreement* 1994 1869 UNTS 299; 33 ILM 1197 (1994)

⁵ Mark Heywood, 'South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health' (2009) 1 (1) *Journal of Human Rights Practice* 14-36; Amy Kapczynski and Jonathan Michael Berger, 'The Story of the TAC Case: the Potential and Limits of Socio-economic Rights Litigation in South Africa', in Deena Hurwitz and Margaret Satterthwaite (ed.), *Human Rights Advocacy Stories*, New York: Thomson/ Foundation Press, 2009, 43-79; Nathan Geffen, *Debunking Delusions: The Inside of the Treatment Action Campaign*, Auckland Park (South Africa): Jacana Media (Pty) Ltd, 2010; and Dylan Mohan Gray (director), *Fire in the Blood: Medicine Monopoly Malice*, Sparkwater Productions (producer), 2012, <https://www.imdb.com/title/tt1787067/>

address public health epidemics.⁶ There has nonetheless been controversy when developing nations have made use of domestic compulsory licensing provisions – with pharmaceutical companies making procedural and substantive complaints about such measures.⁷ The *WTO General Council Decision* 2003 was intended to assist the export of pharmaceutical drugs to developing nations and least developed nations – and has been encoded into the *TRIPS Agreement* 1994 in Article 31bis. But in practice, this export mechanism has proven difficult to use.

There has been major litigation over patent law and access to medicines in India – particularly because it has been seen as a ‘pharmacy of the developing world’.⁸ There have been patent disputes about medicines related to infectious diseases – as well as drugs associated with non-communicable diseases, such as cancer. Patent opposition by government entities and civil society organisations has become particularly important in India.⁹ There has been much debate accordingly about the use of intellectual property flexibilities in India to address public health

⁶ *Ministerial Declaration: Adopted on 14 November 2001*, WTO Doc WT/MIN(01)/DEC/1 [3] (2001) (*Doha Declaration*). For commentary, see Ellen ‘t Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*, Diemen (Netherlands): AMB Publishers, 2009.

⁷ *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (2003) (Decision of the General Council of 30 August 2003) (*WTO General Council Decision of 30 August 2003*). For commentary, see Frederick Abbott, and Rudolf Van Puymbroeck, *Compulsory Licensing for Public Health A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, Washington DC: World Bank, 2012.

⁸ *Novartis v. Union of India & Others* (1 April 2012) Civil Appeal No. 2706-2716 of 2013. See Hafiz Aziz ur Rehman, *The Pharmacy of the Developing World: India, Patent Law and Access to Essential Medicines*, PhD, ANU, 2007-2011. <https://openresearch-repository.anu.edu.au/handle/1885/110380>; and Ravinder Gabbie and Jillian Clare Kohler, ‘To Patent or Not To Patent? The Case of Novartis’ Cancer Drug Glivec in India’, (2014) 10 (3) *Globalization and Health* <https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-3>

⁹ Muhammad Zaheer Abbas, *Community-Based Patent Opposition In India: Access to Essential Medicines, Right to Health, and Sustainable Development*, PhD, 2015-2020, <https://eprints.qut.edu.au/180843/>

epidemics.¹⁰ There has been complex politics in respect of disease outbreaks in South-East Asia.¹¹

There have also been concerns about research and development in respect of neglected diseases – as well as emerging diseases. Especially given the global scale of the public health burden of malaria, there has been much concern about a lack of new treatments in respect of malaria.¹² There has been an under-investment by pharmaceutical drug companies in relation to tuberculosis.¹³ As MSF have noted, ‘Obsolete treatments, the lack of an effective vaccine, and the lack of suitable diagnostic tools make it difficult to control the global TB epidemic.’¹⁴ The emergence of new strains of influenza – such as avian influenza¹⁵ and porcine influenza¹⁶ – have also tested the intellectual property regime.¹⁷ There was a patent race in respect of genetic

¹⁰ Janice Mueller, ‘The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation’ (2007) 68 *University of Pittsburgh Law Review* 491-642; Hans Löfgren, *The Politics of the Pharmaceutical Industry and Access to Medicines: World Pharmacy and India*, Abingdon (Ox): Routledge, 2018; and Murphy Halliburton, *India and the Patent Wars: Pharmaceuticals in the New Intellectual Property Regime*, Ithaca: ILR Press, 2018.

¹¹ Sara E. Davies, *Containing Contagion: The Politics of Disease Outbreaks in Southeast Asia*, Baltimore: John Hopkins University Press, 2019.

¹² MSF, ‘Malaria’, <https://www.msf.org/malaria> and Sonia Shah, *How Malaria Has Ruled Humankind for 500,000 Years*, New York: Sarah Crichton Books, 2010.

¹³ Jisnu Das et al., ‘Use of Standardised Patients to Assess Quality of Tuberculosis Care: A Pilot, Cross-Sectional Study’ (2015) 15 (11) *The Lancet Infectious Diseases* 1305-1313; Madhukar Pai et al, ‘Tuberculosis’, (2016) *Nature Reviews Disease Primers* 1-23; Madhukar Pai, Natasha Correa, Nerges Mistry, and Prabhat Jha, ‘Reducing Global Tuberculosis Deaths - Time for India to Step Up (2017) 389 (10075) *The Lancet* 1174–1176.

¹⁴ MSF, ‘Tuberculosis’, <https://www.msf.org/tuberculosis>

¹⁵ Andrew Torrance, ‘Patents to the Rescue – Disasters and Patent Law’ (2007) 10 (3) *DePaul Journal of Health Care Law* 309-358; Dennis Crouch, ‘Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic’, (2009) 39 *Seton Hall Law Review* 1125-1136; Eileen Kane, ‘Achieving Clinical Equality in an Influenza Pandemic: Patent Realities’ (2009) 39 *Seton Hall Law Review* 1137-1172; and Samuel Oddi, ‘Plagues, Pandemics, and Patents: Legality and Morality’ (2011) 51 (1) *IDEA: The Intellectual Property Law Review* 1-46.

¹⁶ Dawn Dziuba, ‘TRIPS Article 31Bis and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection’ (2010) 20 (2) *Indiana International and Comparative Law Review* 195-212.

¹⁷ World Health Organization, ‘Patent Landscape for the H5 Virus: Interim Report’, 17 November 2007, https://www.who.int/influenza/resources/documents/avian_flu_landscape.pdf?ua=1 and World Intellectual Property Organization, ‘WIPO Patent Search Report on Pandemic Influenza Preparedness (PIP)-Related Patents and Patent Applications’, Geneva: World Intellectual Property Organization, 1 April 2011, https://www.who.int/influenza/resources/Influenza_FullReport_01Apr2011.pdf

sequencing the SARS virus – and discussion as to whether a patent pool would be appropriate to share key technologies.¹⁸ There has also been controversy over patents being granted in respect of the Middle East respiratory syndrome (MERS).¹⁹ There was also complicated geopolitics in terms of patent filings in respect of diagnostics and medicines developed in relation to the Ebola outbreak.²⁰ There has also been intellectual property raised in relation to the Zika outbreak.²¹ There is a need to learn from past history of unruly competition and rent-seeking in the field of medicine, and ensure a co-operative and collaborative approach to the development of COVID-19 technologies. Unfortunately, though, there has often been a historical amnesia – in which the lessons of past public health epidemics are forgotten by present day legislators and policy-makers. The Independent Panel for Pandemic Preparedness and Response has lamented: ‘As soon as a health threat or deadly outbreak fades from memory, complacency takes over in what has been dubbed a cycle of panic and neglect’.²²

The United Nations Secretary-General Ban Ki-Moon convened a special high-level committee to investigate ways and means of overcoming conflicts and deadlocks over intellectual property

¹⁸ E. Richard Gold, ‘SARS Genome Patent: Symptom or Disease?’ (2003) 361 (9374) *The Lancet* P2002-2003 (14 June); Matthew Rimmer, ‘The Race To Patent The SARS Virus: The TRIPS Agreement And Access To Essential Medicines’ (2004) 5 (2) *Melbourne Journal of International Law* 335-374; and James Simon, Eric Claassen, Carmen Correa, and Albert Osterhaus, ‘Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: the Possible Role of Patent Pooling’, (2005) 83 (9) *Bulletin of the World Health Organization* 707-710.

¹⁹ Carsten Richter, ‘European Patent Office Grants Controversial Patent Protecting Virus: Lessons from the Middle East Respiratory Syndrome Coronavirus Outbreak’ (2021) 39 *Nature Biotechnology* 287-290.

²⁰ Amir Attaran, and Jason Nickerson, ‘Is Canada Patent Deal obstructing Ebola Vaccine Development?’, (2014) 384 (9958) *The Lancet* PE61; Matthew Herder, Janice Graham, and E. Richard Gold, ‘From Discovery to Delivery: Public Sector Development of the rVSV-ZEBOV Ebola Vaccine’ (2020) 7 (1) *Journal of Law and the Biosciences* lsz019, <https://academic.oup.com/jlb/article/7/1/lsz019/5706941> and Paul Farmer, *Fevers, Feuds, and Diamonds: Ebola and the Ravages of History*, New York: Farrar, Straus and Giroux, 2020.

²¹ Knowledge Ecology International, ‘An Exclusive License to Patents on a New Zika Vaccine to Sanofi is Contrary to the Provisions of 35 U.S.C. 209(a)(1)’, 12 January 2017, <https://www.keionline.org/wp-content/uploads/Zika-12Jan2016-KEI-AFSCME-PFAM-UAEM-BAKER-35USC209a1.pdf> and Ana Santos Rutschman, ‘Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine’ (2017-2018) 127 *The Yale Law Journal* 651-666.

²² The Independent Panel for Pandemic Preparedness and Response, *COVID-19: Make It The Last Pandemic*, Main Report, 2021, 4 https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

and access to medicines.²³ The report by Ruth Dreifuss and others made a number of recommendations – such as suggesting that countries make use of intellectual property flexibilities to address public health epidemics.²⁴ Nonetheless, there was resistance to the implementation of the report from a number of developed nations – most notably the United States – as well as a range of pharmaceutical drug companies, biotechnology developers, and medical device manufacturers. If the recommendations of the high level report had been implemented, the international legal system may well have been better prepared for the issues around intellectual property and access to medicines arising in the context of the coronavirus.

In the midst of the coronavirus crisis, there has been a growing concern about the problem of vaccine nationalism. Wealthy nations have especially showed a proclivity for buying up and hoarding the vast majority of vaccine supplies. Jason Nickerson from the University of Ottawa and Matthew Herder from Dalhousie University contend: ‘If nationalizing vaccine production is to help realize a globally accessible COVID19 vaccine, then it cannot devolve into vaccine nationalism’.²⁵ Colum Lynch warns: ‘As the world races to develop a vaccine to end the still-raging coronavirus pandemic, “vaccine nationalism” threatens both the near-term fight against COVID-19 and the longer-term prospects of multilateral cooperation.’²⁶ Brook Baker cautions: ‘This unbridled nationalism, interlinked with a broken, profit-driven pharmaceutical system risks obstructing access to life-saving medicines worldwide.’²⁷ Richard Hass is fearful of the approach of vaccine nationalism:

²³ United Nations, ‘Ban Establishes Eminent Panel to Help Broaden Access to Quality Medicines at Affordable Costs’, United Nations News, 20 November 2015, <https://news.un.org/en/story/2015/11/516102-ban-establishes-eminent-panel-help-broaden-access-quality-medicines-affordable>

²⁴ Ruth Dreifuss, and others, *Report of the United Nations Secretary-General’s High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, September 2016, <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>

²⁵ Jason Nickerson and Matthew Herder, ‘COVID-19 Vaccines as Global Public Goods’ in Colleen Flood, Vanessa MacDonnell, Jane Philpott, Sophie Theriault, and Sridhar Venkatapuram (ed.), *Vulnerable: The Law, Policy and Ethics of COVID-19*, Ottawa: the University of Ottawa, 2020, 591-600.

²⁶ Colum Lynch, ‘America First’ vs. ‘The People’s Vaccine’, *Forbes Policy*, 6 July 2020, <https://foreignpolicy.com/2020/07/06/coronavirus-vaccine-nationalism-america-first-covax/>

²⁷ Brook Baker, ‘US-, China- and EU-First Nationalism and COVID-19 Technology Hoarding Push the Rest of the World to the End of the Line’, *InfoJustice*, 8 June 2020, <http://infojustice.org/archives/42383>

Continuing this national-level approach to a vaccine is a recipe for disaster. Only a handful of countries will be able to produce viable vaccines. The approach must be global. The reasons are not just ethical and humanitarian, but also economic and strategic, as global recovery requires collective improvement.²⁸

Hass warns: ‘Vaccine nationalism is almost certain to win out over vaccine multilateralism.’²⁹ Dr Tedros Adhanom Ghebreyesus, the director-general of WHO, has said: ‘Vaccine nationalism hurts us all and is self-defeating’.³⁰ He observed: ‘But on the flipside, vaccinating equitably saves lives, stabilises health systems and would lead to a truly global economic recovery that stimulates job creation.’³¹ Fatima Bhutto has questioned the morality of vaccine hoarding by wealthy nations.³² There have been concerns that vaccine nationalism will prolong the pandemic.³³ Equally, there has been a worry about entrusting the vaccine rollout to the capitalist marketplace – given the proclivities of intellectual property to engage in price hiking and profiteering in the past.

The coronavirus COVID-19 has tested the strengths, limits and flexibilities of patent law, policy, and practice. Patent law provides exclusive rights in respect of inventions, which are novel, inventive, and useful. Patent law also provides for mechanisms to allow for public access to inventions to enable technology transfer, promote public health, and support competition. Patent law, policy, and practice will play a key role in the research, development, and deployment of COVID-19 technologies. This project will look at what patent flexibilities could be used in the United States and elsewhere to ensure the fair and equitable distribution of

²⁸ Richard Hass, ‘The Politics of a COVID-19 Vaccine’, *Project Syndicate*, 14 July 2020, <https://prosyn.org/WCaVyfd>

²⁹ Ibid.

³⁰ Tedros Adhanom Ghebreyesus, ‘WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 – 8 January 2021’, World Health Organization, 8 January 2021, <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-8-january-2021>

³¹ Ibid.

³² Fatima Bhutto, ‘The World's Richest Countries are Hoarding Vaccines. This is Morally Indefensible’, *The Guardian*, 17 March 2021, https://theguardian.com/commentisfree/2021/mar/17/rich-countries-hoarding-vaccines-us-eu-africa?CMP=share_btn_tw

³³ Elizabeth Melimopoulos, ‘Why Hoarding COVID Vaccines Could Prolong Pandemic’, *Al Jazeera*, 19 February 2021, <https://aje.io/c9ccv>

COVID-19 technologies. It will also examine long-term law reform in respect of intellectual property, which will better prepare us for global challenges – such as the coronavirus COVID-19 public health pandemic.

In terms of its methodology, this paper also builds upon the work of Duncan Matthews, which was focused upon the role of civil society organisations and social movements in pushing for access to essential medicines, human rights, and sustainable development.³⁴ Taking its cue from such research, this paper focuses in particular upon the People's Vaccine campaign – which has evolved into the broad-based People's Vaccine Alliance. The People's Vaccine Alliance is an umbrella movement – 'a coalition of organisations and activists united under a common aim of campaigning for a "people's vaccine" for COVID-19.'³⁵ The group observes that in order to achieve a 'People's Vaccine' it will be necessary to 'Break the shackles of intellectual property on vaccines and COVID-19 knowledge.' The People's Vaccine Alliance elaborates:

This will allow every nation to produce or buy vaccine doses at affordable rates. All Government leaders must support the WTO proposal by India and South Africa to temporarily waive intellectual property on Covid-19 vaccines, treatments and related technologies. They must also force pharmaceutical companies to share their COVID-19-related technology and know-how through the World Health Organization's COVID-19 Technology Access Pool.³⁶

The members of the organization include Free the Vaccine, Global Justice Now, Public Citizen, the Yunus Centre, Frontline AIDS, Amnesty International, Oxfam, SumOfUs and UNAIDS. This paper considers the work of other key non-government organisations and civil society groups – such as the MSF Access Campaign, Universities Allied for Essential Medicines, and Human Rights Watch. This paper is also informed by the economic scholarship of Mariana Mazzucato.³⁷ Her work has been focused upon the reform of health innovation – particularly

³⁴ Duncan Matthews, *Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements*, Cheltenham (UK) and Northampton (MA): Edward Elgar, 2011.

³⁵ The People's Vaccine Alliance, 'What is the People's Vaccine Alliance?', <https://peoplesvaccine.org/faq/>

³⁶ The People's Vaccine Alliance, 'Our Demands', <https://peoplesvaccine.org/our-demands/>

³⁷ Mariana Mazzucato and Giovanni Dosi (ed.), *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, Cambridge and New York: Cambridge University Press, 2006; Mariana Mazzucato, *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*, London and New York: Anthem Press,

of late in respect of the coronavirus crisis. This paper also draws upon innovation policy in its understanding of the responses of governments and corporations to the coronavirus crisis.³⁸

Drawing upon past research in the field of access to essential medicines, this paper considers a number of options to address intellectual property and vaccines during the coronavirus COVID-19 public health crisis. By design, this paper is intended to be an overview and a survey the suite of various options which have been mooted in respect of intellectual property and access to essential medicines (rather than just a concentrated focus on a single public policy proposal). Part II considers the call for a People's Vaccine by the People's Vaccine Alliance, UNAIDS, Oxfam, Public Citizen, and various other leaders. Part III provides an early evaluation of the ACT Accelerator – which is designed to accelerate the research, development, and deployment of COVID-19 vaccines, diagnostics, and treatments. Part IV considers the expansion of the role of patent pools – considering the precedent of the Medicines Patent Pool, and the new proposal by Costa Rica for WHO to establish a Coronavirus Technology Access Pool (CTAP). Part V looks at the threat of compulsory licensing to ensure access to COVID-19 technologies – both for domestic purposes and for export. It also examines the adoption of Crown Use and Government Use measures. Part VI examines the debate over public sector licensing in relation to technologies designed to combat the coronavirus. Part VII explores open models of innovation. As well as outlining the Open COVID Pledge, it considers various proposals for a model of Open Science. Finally, in Part VIII, there is a discussion of the proposal from India and South Africa to put in place a waiver of the *TRIPS Agreement* 1994 to enable countries to combat the coronavirus – a TRIPS Waiver for short. While the United States has been willing to support a TRIPS Waiver for vaccines, there remain a number of countries – such as members of the European Union, Switzerland, Norway, the United Kingdom, and Japan – which have opposed the adoption of a TRIPS Waiver. In the conclusion, this paper makes the case that international intellectual property should accommodate a People's Vaccine.

2014; Mariana Mazzucato, *The Value of Everything: Making and Taking in the Global Economy*, London: Allen Lane, 2018; Joad Medeiros, 'This Economist Has a Plan to Fix Capitalism. It's Time We All Listened', *Wired*, 8 October 2019, <https://www.wired.co.uk/article/mariana-mazzucato>; Mariana Mazzucato, 'How Does Innovation Really Happen?', *Wired Smarter*, 21 February 2020, <https://www.youtube.com/watch?v=uXWhwereXYo>; and Mariana Mazzucato, *Mission Economy: A Moonshot Guide to Changing Capitalism*, New York: Harper Business, 2021.

³⁸ Joshua Gans, *The Pandemic Information Gap and the Brutal Economics of COVID-19: Design Thinking, Design Theory*, New York: Random House, 2020.

II. The People's Vaccine

A. The Origins of the People's Vaccine Alliance

In July 2020, UNAIDS and Oxfam called for the establishment of a People's Vaccine.³⁹ They have contended that 'Governments and international partners must unite around a global guarantee which ensures that, when a safe and effective vaccine is developed, it is produced rapidly at scale and made available for all people, in all countries, free of charge'.⁴⁰ They have also called for a similar approach to other treatments, diagnostics, and technologies related to COVID-19: 'The same applies for all treatments, diagnostics, and other technologies for COVID-19.'⁴¹

Having witnessed the tragedy of the HIV/AIDS epidemic in Uganda, Winnie Byanyima has long been a steadfast advocate for access to essential medicines.⁴² She was a panel member of the United Nations Secretary General's High Level Panel on Access to Medicines in her capacity as the Executive Director of Oxfam International.⁴³ Recalling the tragedy of the HIV/AIDS epidemic, Byanyima has called for a fair and equitable approach to access to essential medicines during the coronavirus crisis.⁴⁴ She has emphasized the need for a human-

³⁹ UNAIDS, 'COVID-19 Vaccine Open Letter', 14 July 2020, https://www.unaids.org/en/resources/presscentre/featurestories/2020/may/20200514_covid19-vaccine-open-letter

⁴⁰ Ibid.

⁴¹ Ibid.

⁴² Jon Cohen, "'I'm Known as An Activist.' New UNAIDS Leader Takes Charge", *Science*, 27 November 2019, <https://www.sciencemag.org/news/2019/11/i-m-known-activist-new-unaid-leader-takes-charge>

⁴³ Ruth Dreifuss, and others, *Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, United Nations, 2016, <http://static1.squarespace.com/static/562094dec4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>

⁴⁴ Winnie Byanyima and Matthew Kavanaugh, 'This World Aids Day: The Global Response to HIV Stands on a Precipice', *The Guardian*, 1 December 2020, https://www.theguardian.com/global-development/2020/dec/01/this-world-aids-day-the-global-response-to-hiv-stands-on-a-precipice?CMP=share_btn_tw

rights based approach to the COVID-19 response, ensuring that there is health for all, and freedom from discrimination and stigma.⁴⁵ As the Executive Director of UNAIDS, she has been a champion of the People's Vaccine:

With AIDS we saw that when treatments were found the wealthier people in wealthier countries got back to health, while millions of people in developing countries were left to die. We must not repeat the same mistake when a vaccine for COVID-19 is found. The right to health is a human right—it should not depend on the money in your pocket or the colour of your skin to be vaccinated against this deadly virus. A vaccine should be a global public good and free of charge for all.⁴⁶

She has sought to frame the question of the People's Vaccine in terms of human rights, the right to health, universal healthcare, sustainable development, equality, and justice. Winnie Byanyima observed: 'UNAIDS and other members of the People's Vaccine Alliance are calling for a new approach that puts public health first by sharing knowledge and maximizing supply to make sure that no one is left behind.'⁴⁷ She feared: 'Anything short of that will lead to more deaths and economic chaos, forcing millions into destitution.'⁴⁸

Winnie Byanyima has called upon Big Pharma to share intellectual property to achieve a People's Vaccine.⁴⁹

⁴⁵ Winnie Byanyima, 'Opening Remarks at the High-Level Meeting on AIDS', UNAIDS, 8 June 2021, https://www.unaids.org/en/resources/presscentre/featurestories/2021/june/20210608_opening-remarks-unaid-executive-director-hlm

⁴⁶ UNAIDS, 'Survivors of COVID-19 from 37 Countries are Among almost 1,000 people who have Signed an Open Letter to Pharmaceutical Industry Leaders Calling for a "People's Vaccine"', Press Release, 29 September 2020, https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/september/20200929_covid-19-survivors-write-to-pharmaceutical-bosses-to-demand-a-peoples-vaccine

⁴⁷ UNAIDS, 'President of Nigeria Unites Behind the Call for a People's Vaccine for COVID-19,' Press Release, 16 October 2020, https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201016_president-nigeria-unites-behind-call-for-peoples-vaccine-for-covid19

⁴⁸ Ibid.

⁴⁹ Winnie Byanyima, 'Letter: To Be a People's Vaccine, Big Pharma Must Share Intellectual Property', *Financial Times*, 26 November 2020, <https://www.ft.com/content/59393e03-20ac-466b-81d1-5773ddf86449>

Helen Clark, the former Prime Minister of New Zealand, and Winnie Byanyima, the head of UNAIDS, have expanded upon the case for a People’s Vaccine.⁵⁰ The pair maintained: ‘Granting one company exclusive rights to the science, know-how and intellectual property of a coronavirus vaccine will prevent us from getting the billions of doses that the world needs.’⁵¹ They argued: ‘This extraordinary moment calls for a better approach than our current regime of monopoly rights.’⁵² They suggest: ‘Aside from insisting on the sharing of knowledge and intellectual property, rich countries should be urgently financing the rapid expansion of safe manufacturing capacity in developing countries.’⁵³ Clark has added:

Faced with this crisis, we cannot carry on business as usual. The health of each of us depends on the health of all of us. The COVID-19 vaccine must not belong to anyone and must be free for everyone. Diplomatic platitudes are not enough—we need legal guarantees, and we need them now.⁵⁴

Helen Clark expanded upon such concerns about access to medicines as part of her Independent Panel report into the global response to COVID-19.⁵⁵

Winnie Byanyima has been distressed by the lack of progress on vaccine equity in 2021.⁵⁶ She said that the current situation was inequitable: ‘Today we are witness to a vaccine apartheid that is only serving the interests of powerful and profitable pharmaceutical corporations while costing us the quickest and least harmful route out of this crisis.’⁵⁷ Byanyima feared:

⁵⁰ Helen Clark and Winnie Byanyima, ‘The World Needs A “People’s Vaccine” for Coronavirus, Not a Big-Pharma Monopoly’, *The Guardian*, 23 July 2020, https://www.theguardian.com/commentisfree/2020/jul/23/world-needs-coronavirus-vaccine-big-pharma-monopoly-astrazeneca-patent-pandemic?CMP=share_btn_tw

⁵¹ Ibid.

⁵² Ibid.

⁵³ Ibid.

⁵⁴ Oxfam, ‘World Leaders Unite in Call for a People’s Vaccine Against COVID-19’, Press Release, 14 May 2020, <https://www.oxfam.org/en/press-releases/world-leaders-unite-call-peoples-vaccine-against-covid-19>

⁵⁵ The Independent Panel for Pandemic Preparedness and Response, *COVID-19: Make It The Last Pandemic*, Main Report, 2021, https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

⁵⁶ Winnie Byanyima, ‘We Are Seeing a Global Vaccine Apartheid. People’s Lives Must Come Before Profit’, *The Guardian*, 29 January 2021, <https://theguardian.com/global-development/2021/jan/29/a-global-vaccine-apartheid-is-unfolding-peoples-lives-must-come-before-profit>

⁵⁷ Ibid.

‘Unjustifiably high prices block access and threaten to push more countries into an ever-deeper debt crisis’.⁵⁸ In her view, ‘If we continue to pursue the vaccine model we have, we will fail to get this pandemic under control for years to come.’⁵⁹

Byanyima has warned: ‘Failure to change course will come at the cost of millions of lives and livelihoods around the world; to our progress on tackling poverty; to businesses...; and to our collective public health and economic security.’⁶⁰ She cautioned that ‘the costs of vaccine inequality will not be confined to those living in the poorest countries.’⁶¹ Byanyima observed: ‘The longer the virus is allowed to continue in a context of patchy immunity, the greater the chance of mutations that could render the vaccines we have and the vaccines some people in rich countries have already received, less effective or ineffective.’⁶²

B. Endorsements of the People’s Vaccine Campaign

The Washington DC based civil society organization Public Citizen have also supported this initiative for a People’s Vaccine.⁶³

Cyril Ramaphosa – the President of South Africa – has supported the call for a People’s Vaccine – has stressed: ‘Billions of people today await a vaccine that is our best hope of ending this pandemic’.⁶⁴ He observed: ‘As the countries of Africa, we are resolute that the COVID-19 vaccine must be patent free, rapidly made and distributed, and free for all.’⁶⁵ Ramaphosa observed: ‘All the science must be shared between governments.’⁶⁶ In his view, ‘Nobody should be pushed to the back of the vaccine queue because of where they live or what they

⁵⁸ Ibid.

⁵⁹ Ibid.

⁶⁰ Ibid.

⁶¹ Ibid.

⁶² Ibid.

⁶³ Zain Rivzi, ‘The People’s Vaccine’, June 2020 (last updated), <https://www.citizen.org/article/the-peoples-vaccine/>

⁶⁴ Oxfam, ‘World Leaders Unite in Call for a People’s Vaccine Against COVID-19’, Press Release, 14 May 2020, <https://www.oxfam.org/en/press-releases/world-leaders-unite-call-peoples-vaccine-against-covid-19>

⁶⁵ Ibid.

⁶⁶ Ibid.

earn.’⁶⁷ The Government of South Africa has sponsored the TRIPS Waiver – alongside India - in order to realise this ambition of a People’s Vaccine.⁶⁸

Muhammadu Buhari – the President of the Federal Republic of Nigeria – has endorsed the proposal: ‘Only a People’s Vaccine with equality and solidarity at its core can protect all of humanity and get our societies safely running again.’⁶⁹ He noted that ‘a bold international agreement cannot wait.’⁷⁰

Imran Khan, the Prime Minister of Pakistan commented:

We must work together to beat this virus. We must pool all the knowledge, experience and resources at our disposal for the good of all humanity. No leader can rest easy until every individual in every nation is able to rapidly access a vaccine free of charge.⁷¹

Former President of Liberia, Ellen Johnson Sirleaf said: ‘Learning the lessons from the fight against Ebola, governments must remove all the barriers to the development and rapid roll out of vaccines and treatments.’⁷² In her view, ‘No interest is more important than the universal need to save lives’.⁷³

⁶⁷ Ibid.

⁶⁸ The Governments of India and South Africa, ‘Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19’, IP/C/W/669, 2 October 2020, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> and <https://www.keionline.org/34061>

⁶⁹ UNAIDS, ‘President of Nigeria Unites Behind the call for a People’s Vaccine for COVID-19,’ Press Release, 16 October 2020, https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201016_president-nigeria-unites-behind-call-for-peoples-vaccine-for-covid19

⁷⁰ Ibid.

⁷¹ Oxfam, ‘World Leaders Unite in Call for a People’s Vaccine Against COVID-19’, Press Release, 14 May 2020, <https://www.oxfam.org/en/press-releases/world-leaders-unite-call-peoples-vaccine-against-covid-19>

⁷² Ibid.

⁷³ Ibid.

Nelson Barbosa, former Finance Minister of Brazil, noted: ‘Market solutions are not optimal to fight a pandemic.’⁷⁴ He commented: ‘A public health care system, including free vaccination and treatment when that becomes available, is essential to deal with the problem, as shown by the Brazilian experience with compulsory licensing of antiretroviral drugs in the case of HIV.’⁷⁵ Traditionally, the Government of Brazil has been a supporter of the use of TRIPS flexibilities to support access to essential medicines. However, strangely, the Bolsonaro Government has been an opponent of the TRIPS Waiver.⁷⁶ The Brazilian Senate, though, has voted to suspend patent protection on COVID-19 vaccines.⁷⁷

The call for a People’s Vaccine has also been supported by a range of eminent citizens, leaders, and elders. World leaders (past and present) join notable economists, health advocates and others, from the Chair of the Elders and the former President of Ireland, Mary Robinson, to the Nobel Laureate, Joseph Stiglitz, the Director of African Centres for Disease Control and Prevention, Dr John Nkengasong and Dainius Puras, the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

Survivors of the coronavirus COVID-19 from 37 countries have also lent their support to a letter, which supports a People’s Vaccine.⁷⁸ The signatories to the letter include 242 COVID-19 survivors from South Africa to Finland and New Zealand to Brazil. The signatories also included 190 people in 46 countries who have lost relatives to the virus, and 572 signatories with underlying health conditions, which made them vulnerable to COVID-19. The letter said:

⁷⁴ Oxfam, ‘World Leaders Unite in Call for a People’s Vaccine Against COVID-19’, Press Release, 14 May 2020, <https://www.oxfam.org/en/press-releases/world-leaders-unite-call-peoples-vaccine-against-covid-19>

⁷⁵ Ibid.

⁷⁶ Human Rights Watch, ‘Brazil: Support Wider Vaccine Production at WTO Waiving Some Intellectual Property Rules is Crucial for Faster, More Equitable Access’, Human Rights Watch, 9 March 2021, <https://www.hrw.org/node/378133/printable/print>

⁷⁷ Ricardo Brito, ‘Brazil Senate Votes to Suspend Patent Protection on COVID-19 Vaccines’, *Reuters*, 30 April 2021, <https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-senate-votes-suspend-patent-protection-covid-19-vaccines-2021-04-30/>

⁷⁸ UNAIDS, ‘Survivors of COVID-19 from 37 Countries are Among Almost 1,000 people who have Signed an Open Letter to Pharmaceutical Industry Leaders calling for a ‘People’s Vaccine’’, Press Release, 29 September 2020, https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/september/20200929_covid-19-survivors-write-to-pharmaceutical-bosses-to-demand-a-peoples-vaccine

Some of us have lost loved ones to this killer disease. Some of us have come close to death ourselves. Some of us are continuing to live in fear that contracting this disease would be fatal for us. We see no justification why your profit or monopolies should mean anyone else should go through this.⁷⁹

The letter describes pharmaceutical corporations as ‘carrying on with business as usual - defending monopolies while refusing to share research and know-how’ and calls on industry leaders to ‘ensure COVID-19 vaccines and treatments reach everyone who needs them by preventing monopolies, ramping up production and sharing knowledge.’⁸⁰

One of the signatories, Dilafruz Gafurova, 43, from Tajikistan, discussed the difficulties that her family faced during the coronavirus outbreak:

Me and my husband got sick with this disease. We could only rely on ourselves as hospitals were full ... It was really difficult to get the right medicines. I am a mother of four children ... I was afraid to leave them alone in this world if something bad could happen with me ... The reason I am signing this letter is to help others to get [a] vaccine. Not all the people around the world can get this vaccine, as they simply cannot afford it. They hardly [have enough to meet] their daily needs.⁸¹

The letter was organised by the People's Vaccine Alliance, a global coalition of organisations and activists united under a common aim of campaigning for a people’s vaccine for COVID-19 that is based on shared knowledge and is freely available to everyone everywhere.

Heidi Chow from Global Justice Now, a member of the People’s Vaccine Alliance said: ‘Pharmaceutical companies need to pay attention to the demands of people from around the world who have experienced the fear and devastation of COVID-19.’⁸² She commented: ‘The industry cannot block its ears to these voices but should respond immediately by ending their monopolies and commit to sharing manufacturing know-how.’⁸³ She maintained: ‘These

⁷⁹ Ibid.

⁸⁰ Ibid.

⁸¹ Ibid.

⁸² Ibid.

⁸³ Ibid.

actions are crucial to expand vaccine supplies so that all countries can affordably access effective vaccines.’⁸⁴

The economist Professor Mariana Mazzucato has learnt her support to the People’s Vaccine Campaign. She has written a piece with Els Torreele and Henry Lish on the challenges and proposals for delivering the People’s Vaccine.⁸⁵ Torreele, Mazzucato and Lishi Li conclude: ‘Delivering a People’s Vaccine is only a first test; the public sector must finally rise to the challenge to reset its relationship with the private sector and prepare societies for even greater challenges.’⁸⁶ Mazzucato has called for a mission-focused approach to biomedical innovation.⁸⁷ She observed: ‘The mission here was to develop and produce a COVID-19 vaccine that was affordable and globally accessible – and left no one behind.’⁸⁸

Sanjay Reddy and Arnab Acharya have articulated the economic case for a People’s Vaccine.⁸⁹ They commented that ‘the current challenge provides a stark demonstration of what is needed for research and development to serve the broader public interest.’⁹⁰ Reddy and Acharya have warned: ‘Failing to do what both sound economics and morality require may keep a life-saving product out of the hands of many of the world’s people, unnecessarily prolonging a global calamity.’⁹¹

⁸⁴ Ibid.

⁸⁵ Els Torreele, Mariana Mazzucato and Henry Lish Li, ‘Delivering the People’s Vaccine: Challenges and Proposals for the Biopharmaceutical Innovation System’ UCL Institute for Innovation and Public Purpose, Policy Brief series (IIPP PB 12), 25 January 2021, <https://www.ucl.ac.uk/bartlett/public-purpose/publications/2021/jan/delivering-peoples-vaccine>

⁸⁶ Ibid.

⁸⁷ Mariana Mazzucato, *Mission Economy: A Moonshot Guide to Changing Capitalism*, New York: Harper Business, 2021.

⁸⁸ Ibid., 83 (ebook version).

⁸⁹ Sanjay Reddy and Arnab Acharya, ‘The Economic Case for a People’s Vaccine’, *Boston Review*, 15 September 2020, <http://bostonreview.net/science-nature/sanjay-g-reddy-arnab-acharya-economic-case-peoples-vaccine#.X492ccXLblc.twitter>

⁹⁰ Ibid.

⁹¹ Ibid.

In order to achieve its goals, the People’s Vaccine Alliance has supported a number of public policy initiatives – including patent pools, compulsory licensing, government use or crown use, public sector licensing, patent pledges, open licensing, and open innovation.

C. Opposition to the People’s Vaccine Campaign

Ellen ‘t Hoen laments that there has been little support for the rhetoric about the People’s Vaccine amongst wealthy nations.⁹² She noted: ‘Unfortunately, despite the lofty promises of the vaccine as a global public good, wealthy nations are not making such demands.’⁹³ Achal Prabhala, Benny Kuruvilla, Burcu Kilic and Dana Brown have been concerned that the WTO may seek to stymie the proposal for a ‘People’s Vaccine’.⁹⁴ They have advocated: ‘As the Covid-19 pandemic aggressively advances, the WTO has the opportunity to sway the planet away from monopoly medicine, and towards a new planetary health system.’⁹⁵ They present the debate as a choice between ‘People or profit; a people’s vaccine or a debilitating vaccine apartheid.’⁹⁶

III. The ACT Accelerator

In April 2020, the World Health Organization (WHO) and its partners launched the Access to COVID-19 Tools (ACT Accelerator).⁹⁷ This initiative was designed to promote research, development, and deployment of vaccines, treatments, diagnostics, and other health equipment designed to address the COVID-19 crisis.

⁹² Ellen ‘t Hoen, ‘COVID-19 Crisis and WTO: Why India and South Africa’s Proposal on Intellectual Property is Important’, *The Wire*, 12 October 2020, <https://thewire.in/law/covid-19-crisis-wto-intellectual-property-vaccine-public-health>

⁹³ Ibid.

⁹⁴ Achal Prabhala, Benny Kuruvilla, Burcu Kilic and Dana Brown, ‘We can’t let the WTO get in the way of a “People’s Vaccine”’, *The Guardian*, 15 October 2020, http://www.theguardian.com/commentisfree/2020/oct/15/peoples-vaccine-coronavirus-covid-wto?CMP=share_btn_tw

⁹⁵ Ibid.

⁹⁶ Ibid.

⁹⁷ World Health Organization, ‘The Access to COVID-19 Tools (ACT) Accelerator’, <https://www.who.int/initiatives/act-accelerator>

A. The Establishment of the ACT Accelerator

For its part, the World Health Organization (WHO) has set up the ACT Accelerator – a global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines.⁹⁸ This new institution was launched at the end of April 2020. According to WHO, ‘The goal of the ACT-A is to end the COVID-19 pandemic as quickly as possible by reducing COVID-19 mortality and severe disease through the accelerated development, equitable allocation, and scaled-up delivery of vaccines, therapeutics and diagnostics to reduce mortality and severe disease, restoring full societal and economic activity globally in the near term, and facilitating high-level control of COVID-19 disease in the medium term.’⁹⁹ WHO emphasizes: ‘A key principle underpinning the ACT-Accelerator is the need for equitable distribution of COVID-19 tools to those most in need’.¹⁰⁰ WHO comments: ‘Whether a person can access tests, treatment and a vaccine for COVID-19 should not be determined by where they live.’¹⁰¹

A number of nation states, philanthropists, and civil society organisations have endorsed this initiative. The governments of Austria, Belgium, Canada, France, Germany, Italy, Mexico, Morocco, New Zealand, Norway, Saudi Arabia, South Africa, Spain, and the United Kingdom, and the European Commission have supported the ACT-Accelerator. The participating global health organizations include The Bill and Melinda Gates Foundation; Coalition for Epidemic Preparedness Innovations (CEPI), the Global Alliance for Vaccines and Immunizations (GAVI), Global Fund to fight AIDS Tuberculosis and Malaria (GFATM), UNITAID, The Foundation for Innovative New Diagnostics (FIND), The Wellcome Trust, the World Bank Group and the World Health Organization (WHO).

The ACT-Accelerator comprises four pillars – including diagnostics, therapeutics, vaccines, and the strengthening of the health system. CEPI and GAVI will manage the vaccines program – which is known as COVAX. Unitaid and the Wellcome Trust will look after therapeutics.

⁹⁸ World Health Organization, ‘Access to COVID-19 Tools – ACT Accelerator’, [https://www.who.int/publications/m/item/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator)

⁹⁹ World Health Organization, ‘ACT-Accelerator – Frequently Asked Questions’, <https://www.who.int/initiatives/act-accelerator/faq>

¹⁰⁰ Ibid.

¹⁰¹ Ibid.

FIND and the Global Fund will be in charge of diagnostics. There have been costed plans for the work of the ACT-Accelerator. Overall, \$US 31.3 billion has been sought for the ACT-Accelerator.¹⁰²

Germany's Chancellor Angela Merkel has said: 'We will only be able to overcome the pandemic if we achieve a truly global solution to the COVID-19 crisis. This is a test of our generation's human kindness.'¹⁰³

Australia's Prime Minister Scott Morrison has called for the development of 'a safe vaccine, available to all, affordable to all.'¹⁰⁴ Likewise New Zealand's Prime Minister Jacinda Ardern has said: 'We will advocate for universal access for any treatments and vaccines.'¹⁰⁵ Australia and New Zealand have been playing a productive diplomatic role in encouraging co-operative efforts in respect of research upon the coronavirus COVID-19.

Canada's Prime Minister Justin Trudeau and a number of other world leaders wrote a letter to the *Washington Post*, emphasizing that 'where you live should not determine whether you live.'¹⁰⁶ The letter emphasized that 'we must urgently ensure that vaccines will be distributed according to a set of transparent, equitable and scientifically sound principles.'¹⁰⁷

B. The Operation of the ACT Accelerator

¹⁰² World Health Organization, 'ACT-Accelerator Investment Case', 26 June 2020, <https://www.who.int/publications/m/item/act-accelerator-investment-case>

¹⁰³ European Commission, 'Coronavirus Global Response: Kick Off Of New Campaign with Support of Global Citizen', 28 May 2020, https://ec.europa.eu/commission/presscorner/detail/en/ip_20_952

¹⁰⁴ Scott Morrison, 'Coronavirus Global Response International Pledging Event', Prime Minister of Australia, 5 May 2020, <https://www.pm.gov.au/media/coronavirus-global-response-international-pledging-event>

¹⁰⁵ Global Citizen, 'Statements of Support for the 'Global Goal: Unite For Our Future' Campaign', 22 June 2020, <https://www.globalcitizen.org/en/enquiries/press/global-citizen-and-european-commission-announce-global-goal-unit/statements-of-support/>

¹⁰⁶ Justin Trudeau, and others, 'The International Community Must Guarantee Equal Global Access to a COVID-19 Vaccine', *The Washington Post*, 16 July 2020, <https://www.washingtonpost.com/opinions/2020/07/15/international-community-must-guarantee-equal-global-access-covid-19-vaccine/>

¹⁰⁷ Ibid.

There has been a range of academic work, which has considered and evaluated the operation of the ACT-Accelerator and the COVAX scheme in particular.

Mark Eccleston-Turner and Harry Upton comment that ‘the prevalence of vaccine nationalism threatens to limit the ability of the facility to meet both its funding targets and its ambitious goals for vaccine procurement.’¹⁰⁸ They observe that ‘a failure to adequately address the underlying lack of infrastructure in developing countries threatens to further limit the success of the COVAX Facility.’¹⁰⁹ Lisa Herzog and her colleagues maintain that COVAX must go beyond a proportional allocation of COVID vaccines to ensure fair and equitable access.¹¹⁰ *The Lancet* editorialized that there was a need to go beyond the institution of COVAX: ‘An authoritative voice with moral credentials is needed to support global access to vaccines, to intervene when that goal is under threat, and to call out unfair practices.’¹¹¹

In practice, though, there has been difficulties with the COVAX scheme, struggling to obtain sufficient supplies in the face of vaccine nationalism and shortages.¹¹² In April 2021, the WHO published its priorities, strategies, and budget for the ACT-Accelerator for 2021.¹¹³ In its report, the WHO highlighted the multitude of challenges posed by the COVID-19 crisis:

The world continues to deal with an unprecedented threat which extends far beyond a global health crisis. We are facing an economic, humanitarian, security, and human rights crisis. Dire challenges have been unfolding and countries have spent trillions to address the ramifications of COVID-19. As of early March, COVID-19 has tragically claimed more than 2.6 million lives and infected over 117

¹⁰⁸ Mark Eccleston-Turner and Harry Upton, ‘International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility’ (2021) 99 (2) *The Milbank Quarterly* 426-449.

¹⁰⁹ Ibid.

¹¹⁰ Lisa Herzog, Ole Notheim, Ezekiel Emanuel, and Matthew McCoy, ‘COVAX must go beyond Proportional Allocation of Covid Vaccines to ensure Fair and Equitable Access’ (2021) 372 *The British Medical Journal* m4853 doi:10.1136/bmj.m4853

¹¹¹ Editorial, ‘Access to COVID-19 Vaccines: Looking Beyond COVAX’ (2021) 397 (10278) *The Lancet* 941.

¹¹² Donato Paolo Mancini, and Michael Peel, “‘Vaccine Nationalism’ delays WHO’s Struggling COVAX Scheme”, *Financial Times*, 2 September 2020, <https://www.ft.com/content/502df709-25ac-48f6-aee1-aec7ac03c759?sharetype=blocked>

¹¹³ World Health Organization, ‘ACT-A Prioritized Strategy and Budget for 2021’, Geneva: World Health Organization, 2021, <https://www.who.int/publications/m/item/act-a-prioritized-strategy-and-budget-for-2021>

million people worldwide. Many countries are experiencing a resurgence in cases, often more extreme than previous waves, putting immense strain on health systems. New and more transmissible variants of the virus are taking hold in many countries. Evidence is also growing of the long-term health effects of COVID-19 or ‘Long COVID’, amplifying the burden on health systems and economies, and increasing the importance of disease prevention.¹¹⁴

The document highlighted the key achievements of the institution. The document also emphasized its priorities for 2021. The ACT-Accelerator has four key priorities – ‘1. Rapidly scale up the delivery of at least 2 billion doses of vaccines; 2. Bolster R&D, evaluations & regulatory pathways to optimize products and address variants; 3. Stimulate rapid and effective uptake and use of COVID-19 tests, treatments and PPE; 4. Ensure a robust pipeline of essential tests, treatments and PPE.’¹¹⁵ The document discussed the ways and means that the ACT-Accelerator could maximise its impact.

The April 2021 document also highlights a significant funding gap. Delivering on the ACT-Accelerator’s promises requires an additional \$US22.1 billion in 2021. The document discusses the issues around financing COVAX. The April 2021 document also makes an economic case for investing in the ACT-Accelerator. The report noted: ‘In January 2021, a study commissioned by the International Chamber of Commerce demonstrated that even with strong COVID-19 vaccine coverage in high-income countries, inequitable access to COVID-19 tools elsewhere would cost high income economies an additional US\$ 2.4 trillion in 2021 alone.’¹¹⁶ The report observed: ‘Investing in ACT-Accelerator dwarfs the potential multiplier benefits of domestic fiscal support investments’.¹¹⁷ The report cautioned: ‘If COVID-19 transmission is uncontrolled anywhere in the world, it remains a threat to everyone everywhere in the world.’¹¹⁸

In a resolution, the European Parliament pointed out that ‘11 billion doses are needed to vaccinate 70 % of the world’s population and that only a fraction of that amount has been

¹¹⁴ Ibid., 4.

¹¹⁵ Ibid., 12.

¹¹⁶ Ibid., 3.

¹¹⁷ Ibid., 3.

¹¹⁸ Ibid., 3.

produced’.¹¹⁹ The European Parliament observed ‘that an approach based on pledges of excess doses is insufficient.’¹²⁰ The European Parliament noted that ‘COVAX is facing a shortfall of 190 million doses due to the current COVID-19 situation in India and will not meet its supply objectives for the foreseeable future.’¹²¹ In its resolution, the European Parliament ‘underlines the need to prioritise supplying COVAX’ and ‘regrets moves by the UK and the US in developing a secondary re-sale market to sell surplus vaccines to other industrialised countries.’¹²²

The Independent Panel for Pandemic Preparedness and Response – co-chaired by Helen Clark and Ellen Sirleaf – considered the operation of COVAX as part of its inquiry.¹²³ In its summary, the Panel acknowledged: ‘The uneven access to vaccination is one of today’s pre-eminent global challenges.’¹²⁴ The Panel was deeply concerned about the international inequities in the distribution of vaccines. The Panel commented: ‘The COVID-19 Vaccines Global Access Facility (COVAX Facility), rapidly established with the intention of ensuring global, equitable access, is making good progress but has been hampered in that goal by a lack of sufficient funds and by vaccine nationalism, and now, vaccine diplomacy.’¹²⁵

The Panel considered the high hopes and expectations for the international institution of COVAX:

A core mechanism to address global vaccine availability is COVAX, launched by WHO and partners in April 2020 as the vaccines pillar of its Access to COVID-19 Tools Accelerator (ACT-A). Its initial aim expressed in September 2020 was to purchase 2 billion COVID-19 vaccine doses by the end of

¹¹⁹ European Parliament, *Meeting the Global COVID-19 Challenge: Effects of Waiver of the WTO TRIPS Agreement on Covid-19 Vaccines, Treatment, Equipment and Increasing Production and Manufacturing capacity in Developing Countries*. 10 June 2021, 2021/2692 (RSP), P9_TA(2021)0283, https://www.europarl.europa.eu/doceo/document/TA-9-2021-0283_EN.html

¹²⁰ Ibid.

¹²¹ Ibid.

¹²² Ibid.

¹²³ The Independent Panel for Pandemic Preparedness and Response, *COVID-19: Make It The Last Pandemic*, Main Report, 2021, https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

¹²⁴ Ibid., 12.

¹²⁵ Ibid., 12.

2021 and deliver them to people in 190 countries. By mid-March 2021, COVAX had shipped 30 million doses to at least 54 countries (53, 54). At that time COVAX expected approximately 1.8 billion doses to be available to 92 low- and middle-income countries before the end of 2021, covering 27% of their populations.¹²⁶

The Panel observed soberly that ‘these expectations must contend with uncertainties of manufacturing capacity, regulation, funding availability, final contract terms and the readiness of countries to deliver their national COVID-19 vaccination programmes’.¹²⁷ The Panel reflected: ‘Had COVAX had sufficient and readily available early funding it would have been better able to secure enough immediate supply to meet its aims’.¹²⁸

The Independent Panel recommended: ‘High income countries with a vaccine pipeline for adequate coverage should, alongside their scale up, commit to provide to the 92 low and middle income countries of the Gavi COVAX Advance Market Commitment, at least one billion vaccine doses no later than 1 September 2021 and more than two billion doses by mid-2022, to be made available through COVAX and other coordinated mechanisms.’¹²⁹

There has been controversy that developed nations, such as Canada and Australia, have purchased medicines and vaccines from COVAX.¹³⁰ On the 6th June 2021, the Health Minister Greg Hunt announced that Australia paid \$123 million to buy the option to purchase 24 million doses from COVAX.¹³¹ The Australian Council for International Development chief executive,

¹²⁶ Ibid., 41.

¹²⁷ Ibid., 41.

¹²⁸ Ibid., 41.

¹²⁹ Ibid., 14 and 63.

¹³⁰ Anthony Galloway, ‘Australia Dipped into COVAX Pfizer Stockpile Intended for Poor Nations’, *The Sydney Morning Herald*, 17 August 2021, <https://www.smh.com.au/politics/federal/australia-dipped-into-covax-pfizer-stockpile-intended-for-poor-nations-20210816-p58j2j.html>; Paul Karp, ‘Australia’s Pfizer Purchase from Vaccine-Sharing COVAX Stockpile Under Fire’, *The Guardian*, 17 August 2021, <https://www.theguardian.com/australia-news/2021/aug/17/australia-pfizer-purchase-from-vaccine-sharing-covax-stockpile-under-fire>; and Chris Barrett and Karuni Rompies, ‘Australia Should Return COVAX Vaccines, Says Ex-Indonesian Minister’, *The Sydney Morning Herald*, 18 August 2021, <https://www.smh.com.au/world/asia/australia-should-return-covax-vaccines-says-ex-indonesian-minister-20210817-p58jkm.html>

¹³¹ The Hon. Greg Hunt, ‘Transcript – COVID-19 Vaccine Rollout’, Minister for Health and Aged Care, Australian Parliament, 6 June 2021,

Marc Purcell, said that the Australian Government had shown ‘desperation to get the preferable vaccine, Pfizer, from any sources into Australia’.¹³²

He emphasized: ‘But we can’t forget that our fortunes are tied up with reducing and eradicating Covid in the developing countries that surround Australia.’¹³³ Purcell noted: ‘The COVAX facility is open to countries in genuine need, but clearly countries like Indonesia, Philippines and Malaysia should be a priority for donors like Australia.’¹³⁴ The Shadow Foreign Affairs Minister Penny Wong commented: ‘If Mr Morrison has had to resort to accessing vaccines intended for developing countries, he should be upfront about that.’¹³⁵

C. Reform of COVAX

Stakeholders have proposed a strategic review of the ACT Accelerator to inform decision-making on enhancing its current functioning and its potential role beyond the 1st quarter of 2022. The strategic review will consider the ACT Accelerator achievements, best practices, challenges, and gaps as a basis for recommendations to enhance its future work.

The People’s Vaccine Alliance has been critical of COVAX as a knowledge-sharing initiative, noting: ‘While it is encouraging that at least 170 countries have agreed to work together, rich countries continue to cut bilateral supply deals with pharmaceutical companies which undermine this global effort and limit supply to poorer nations.’¹³⁶ The People’s Vaccine Alliance has been disappointed by the opaque nature of the organization: ‘So far COVAX has not been transparent about the deals it is making with pharmaceutical companies and remains

https://parlinfo.aph.gov.au/parlInfo/download/media/pressrel/8000210/upload_binary/8000210.pdf;fileType=application%2Fpdf#search=%22hunt%20covax%20%20minister%20for%20health%20and%20aged%20care%22

¹³² Anthony Galloway, ‘Australia Dipped into COVAX Pfizer Stockpile Intended for Poor Nations’, *The Sydney Morning Herald*, 17 August 2021, <https://www.smh.com.au/politics/federal/australia-dipped-into-covax-pfizer-stockpile-intended-for-poor-nations-20210816-p58j2j.html>

¹³³ Ibid.

¹³⁴ Ibid.

¹³⁵ Paul Karp, ‘Australia’s Pfizer Purchase from Vaccine-Sharing COVAX Stockpile Under Fire’, *The Guardian*, 17 August 2021, <https://www.theguardian.com/australia-news/2021/aug/17/australia-pfizer-purchase-from-vaccine-sharing-covax-stockpile-under-fire>

¹³⁶ The People’s Vaccine Alliance, ‘FAQ’, <https://peoplesvaccine.org/faq/>

silent on how it will tackle monopolies'.¹³⁷ The People's Vaccine Alliance also laments the lack of democratic input into the organization, observing 'COVAX lacks transparency on decision-making and developing countries have not been involved in strategic decisions' and 'Civil society has also been excluded from decision-making processes.'¹³⁸

The People's Vaccine Alliance is also critical that 'COVAX does not use its purchasing power to push corporations to share the science, knowledge and technology behind their vaccines, which could lead to scaled up production.'¹³⁹ The People's Vaccine Alliance also observes: 'We are also deeply concerned that Covax is considering a tiered pricing model that would mean many middle-income countries, already facing economic turmoil and with under-resourced health systems, may not be able to afford the vaccine or would be forced deeper into debt.'¹⁴⁰ The People's Vaccine Alliance has called for a reformation of COVAX.¹⁴¹

IV. Patent Pools

Patent pools have been used to address access issues – particularly where there are patent thickets. Joseph Stiglitz and his collaborators comment that 'patent pools... are part of a broader agenda to reform how life-saving drugs are developed and made available.'¹⁴² The People's Vaccine Alliance has been a supporter of patent pools during the coronavirus crisis.¹⁴³

A. The Medicines Patent Pool

In 2006, the MSF Access Campaign and Knowledge Ecology International mooted the establishment of a patent pool to help provide access to HIV medicines.¹⁴⁴ The Medicines

¹³⁷ Ibid.

¹³⁸ Ibid.

¹³⁹ Ibid.

¹⁴⁰ Ibid.

¹⁴¹ Ibid.

¹⁴² Joseph Stiglitz, Arjun Jayadev and Acal Prabhala, 'Patents vs. the Pandemic', *Project Syndicate*, 23 April 2020, <https://www8.gsb.columbia.edu/articles/chazen-global-insights/patents-vs-pandemic>

¹⁴³ The People's Vaccine Alliance, 'FAQ', <https://peoplesvaccine.org/faq/>

¹⁴⁴ Michelle Childs, 'Towards a Patent Pool for HIV Medicines: The Background' (2010) 4 *The Open AIDS Journal* 33–36.

Patent Pool was established as an independent public health entity in 2010 – with the support of UNITAID. According to the Medicines Patent Pool, ‘Our mission is to increase access to, and facilitate the development of, life-saving medicines for low- and middle income countries (LMICs).’¹⁴⁵ The Medicines Patent Pool discusses its strategies: ‘We do this through an innovative approach to voluntary licensing and patent pooling.’¹⁴⁶ The Medicines Patent Pool emphasizes that it takes a collaborative approach: ‘We work with a range of partners — civil society, international organisations, industry, patient groups and governments — to prioritise and license novel and existing medicines and health technologies for people in these countries.’¹⁴⁷

The mandate of the Medicines Patent Pool is to ‘accelerate access to affordable quality treatments for people living with HIV, hepatitis C and tuberculosis, as well as HIV-associated co-morbidities.’¹⁴⁸ The role of the Medicines Patent Pool has evolved over the years: ‘Since 2018, MPP has expanded its mandate to other patented essential medicines on the World Health Organization (WHO)’s Model List of Essential Medicines (EML) as well as medicines with strong potential for future inclusion on the EML.’¹⁴⁹

In 2020, the Medicines Patent Pool has temporarily expanded its mandate to include COVID-19 related technologies.¹⁵⁰ Marie-Paule Kieny and Charlie Gore from the Medicines Patent Pool have argued that there needs to be a master plan to address the licensing of COVID-19 patents.¹⁵¹ They have offered their institutional expertise:

The Medicines Patent Pool has made it clear that we stand ready to help. We have already started gathering patent information for products being tested in clinical trials, like the antiviral remdesivir and the biologic tocilizumab. We’re making it available via our online database, MedsPaL. This repository

¹⁴⁵ Medicines Patent Pool, ‘Who We Are’, <https://medicinespatentpool.org/who-we-are/about-us/>

¹⁴⁶ Ibid.

¹⁴⁷ Ibid.

¹⁴⁸ Ibid.

¹⁴⁹ Ibid.

¹⁵⁰ Medicines Patent Pool, ‘COVID-19’, <https://medicinespatentpool.org/what-we-do/disease-areas/#pills-COVID-19>

¹⁵¹ Marie-Paule Kieny and Charles Gore, ‘The World Needs a Master Plan for COVID-19 Patents. We’re Creating One’, *Barrons*, 10 April 2020, <https://barrons.com/articles/the-world-needs-a-master-plan-for-covid-19-patents-were-building-one-51586524940>

of patent intelligence was established to allow countries and procurement agencies to identify patents that could hinder access to new medical innovations.¹⁵²

Kieny and Gore observed: ‘We are already in discussions with the WHO about how MPP could support the intellectual property pool and tap into our relationships with governments, industry, and key public health organizations to seek licensing agreements that could speed access to Covid-19 drugs, diagnostics, and vaccines.’¹⁵³

The chair of the Unitaid Executive Board Marisol Touraine has also offered her support for the initiative: ‘Unitaid is fully engaged in the global response to COVID-19 and supports the call by the President of Costa Rica for voluntary pooling of intellectual property rights for medicines and diagnostics to promote the global fight against COVID-19.’¹⁵⁴ She added: ‘The Medicines Patent Pool, set up and funded by Unitaid a decade ago, has a proven track record and is immediately available to the WHO to begin this urgent work.’¹⁵⁵

Charles Gore of the Medicines Patent Pool has discussed the difficulties of engaging with intellectual property holders: ‘Unfortunately what we’ve seen is too little of, ‘Let’s do this all together as a world’, and a little too much of me-first.’”¹⁵⁶ He also noted that vaccine nationalism was also distorting the operation of the marketplace: ‘If countries are saying the most important thing is, “I want you to do a deal now with me”, the companies can’t say, “We’ll come back to you later, we’re trying to do a deal for global access”.’¹⁵⁷

In a background paper for the Independent Panel, Ellen ‘t Hoen and her colleagues support the involvement of the Medicines Patent Pool: ‘The Medicine Patent Pool’s expertise in licensing

¹⁵² Ibid.

¹⁵³ Ibid.

¹⁵⁴ Medicines Patent Pool, ‘The Medicines Patent Pool and Unitaid Respond to Access Efforts for COVID-19 Treatments and Technologies’, Press Release, 31 March 2020, <https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies/>

¹⁵⁵ Ibid.

¹⁵⁶ Michael Safi, ‘WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began’, *The Guardian*, 22 January 2021, <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began>

¹⁵⁷ Ibid.

IP to maximise access together with a COVID-19 vaccine technology transfer hub engaging manufacturers and potential manufacturers should be an integral part of this initiative'.¹⁵⁸

In July 2021, the Medicines Patent Pool announced that it was joining a new consortium to boost vaccine capacity in South Africa and Sub-Saharan Africa.¹⁵⁹ Dr. Soumya Swaminathan, Chief Scientist of WHO, noted: 'Inequitable manufacturing and distribution of vaccines is behind the wave of death, which is now sweeping across many low- and middle-income countries that have been starved of vaccine supply.'¹⁶⁰ She stressed: 'Building vaccine manufacturing capacity in South Africa is the first step in a broader effort to boost local production to address health emergencies and strengthen regional health security.'¹⁶¹ Charles Gore, Executive Director of the Medicines Patent Pool, commented: 'Within the consortium, MPP will provide appropriate intellectual property analysis, define and negotiate terms and conditions of the agreements, provide alliance management and make use of our established robust selection process to allow further technology recipients to benefit.'¹⁶² Other partners of the consortium include biotechnology company Afrigen; vaccine company Biovac; the South African Medical Research Council; and the Africa Centres for Disease Control and Prevention (Africa CDC).

This initiative is designed to improve regional biomanufacturing capacity – which has been a significant shortfall during the coronavirus public health crisis.

The Independent Panel recommended that 'the World Trade Organization and WHO to convene major vaccine-producing countries and manufacturers to get agreement on voluntary

¹⁵⁸ Ellen 't Hoen, Ellen, Christopher Garrison, Pascale Boulet, Kaitlin Mara and Katrina Perehudoff, *Scaling-Up Vaccine Production Capacity: Legal Challenges and Recommendations*, Background Paper 6, Commissioned by the Independent Panel for Pandemic Preparedness and Response, May 2021, <https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccinationlegal-aspects.pdf>

¹⁵⁹ Medicines Patent Pool, 'New Consortium Working to Boost Vaccine Production in South Africa', Press Release, 30 July 2021, <https://medicinespatentpool.org/news-publications-post/south-africa-tech-transfer-hub-loi-press-release/>

¹⁶⁰ Ibid.

¹⁶¹ Ibid.

¹⁶² Ibid.

licensing and technology transfer arrangements for COVID-19 vaccines (including through the Medicines Patent Pool).’¹⁶³ The Independent Panel suggested: ‘If actions do not occur within three months, a waiver of intellectual property rights under the Agreement on Trade-Related Aspects of Intellectual Property Rights should come into force immediately.’¹⁶⁴

B. C-TAP

The Government of Costa Rica has been a policy entrepreneur during the global public health crisis, and has put forward the diplomatic proposal of establishing a COVID-19 Technology Access Pool (C-TAP for short).¹⁶⁵

Taking up the proposal, the WHO issued a Solidarity Call to Action in May 2020.¹⁶⁶ WHO emphasized: ‘The COVID-19 pandemic has revealed the fallibility of traditional ways of working when it comes to equitable access to essential health technologies.’¹⁶⁷ WHO stressed: ‘This initiative sets out an alternative, in line with WHO’s efforts to promote global public health goods, based on equity, strong science, open collaboration and global solidarity.’¹⁶⁸ WHO called on all stakeholders to ‘place, in the WHO COVID-19 Technology Access Pool or its implementing partner platforms, references to shared information and/or commitments to all relevant technologies, knowledge, intellectual property, and data on terms that facilitate their use in research, development and innovation and manufacturing and that would permit effective technology transfer and early access to key technologies for the detection, prevention, treatment and response of COVID-19’.¹⁶⁹

¹⁶³ The Independent Panel for Pandemic Preparedness and Response, *COVID-19: Make It The Last Pandemic*, Main Report, 2021, 14 and 63 https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

¹⁶⁴ Ibid., 14 and 63.

¹⁶⁵ President Carlos Alvarado Quesada, ‘C-TAP Solidarity Call to Action Launch’, YouTube 29 May 2020, <https://www.youtube.com/watch?v=GQLjsDx1I5s> and Medicines Patent Pool, ‘Launch of the COVID-19 Technology Access Pool (C-TAP)’, 29 May 2020, <https://medicinespatentpool.org/news-publications-post/launch-of-the-covid-19-technology-access-pool-c-tap/>

¹⁶⁶ World Health Organization, ‘Solidarity Call to Action’, 29 May 2020, <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>

¹⁶⁷ Ibid.

¹⁶⁸ Ibid.

¹⁶⁹ Ibid.

The leader of Costa Rica Carlos Alvarado Quesada and the director-general of WHO, Tedros Adhanom Ghebreyesus contended: ‘When a COVID-19 does become available, it should be treated as a global public good’.¹⁷⁰ The pair called on ‘all governments to ensure that the outcomes of publicly funded COVID-19 research are affordable, available, and accessible to everyone around the world’.¹⁷¹ Costa Rica and the World Health Organization have established a plan for a COVID-19 Technology Access Pool: ‘The COVID-19 Technology Access Pool (C-TAP) will compile, in one place, pledges of commitment made under the Solidarity Call to Action to voluntarily share COVID-19 health technology related knowledge, intellectual property and data.’¹⁷² The new institution is designed to complement existing mechanisms: ‘The Pool will draw on relevant data from existing mechanisms, such as the Medicines Patent Pool and the UN Technology Bank-hosted Technology Access Partnership.’¹⁷³

The People’s Vaccine Alliance emphasized that there was a need to ‘ensure maximum production of vaccine doses by pushing pharmaceutical companies and research institutions to share the science, technology and know-how behind their vaccines with the WHO COVID-19 Technology Access Pool (C-TAP)’.¹⁷⁴

However, some pharmaceutical companies and biotechnology developers have been unwilling to join this voluntary initiative thus far. Ellen ‘t Hoen reflects that ‘the success of C-TAP will depend on the political support it will receive.’¹⁷⁵ She notes: ‘So far, 40 countries have endorsed the initiative’.¹⁷⁶ Ellen ‘t Hoen comments that ‘persuasion will need to come from governments

¹⁷⁰ Carlos Alvarado Quesada and Tedros Adhanom Ghebreyesus, ‘Globalizing the Fight against the Pandemic’, *Project Syndicate*, 29 May 2020, <https://www.project-syndicate.org/commentary/covid19-access-pool-vaccine-data-ip-sharing-by-carlos-alvarado-quesada-and-tedros-adhanom-ghebreyesus-2020-05>

¹⁷¹ Ibid.

¹⁷² World Health Organization, ‘COVID-19 Technology Access Pool’, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool>

¹⁷³ Ibid.

¹⁷⁴ The People’s Vaccine Alliance, ‘FAQ’, <https://peoplesvaccine.org/faq/>

¹⁷⁵ Ellen ‘t Hoen, ‘COVID-19 Crisis and WTO: Why India and South Africa’s Proposal on Intellectual Property is Important’, *The Wire*, 12 October 2020, <https://thewire.in/law/covid-19-crisis-wto-intellectual-property-vaccine-public-health>

¹⁷⁶ Ibid.

and institutions that spend public resources on the development of new drugs and vaccines by demanding from their recipients that they share the IP and know-how they create with the funds with the WHO C-TAP.’¹⁷⁷

Access to medicines scholar and civil society activist Brook Baker has maintained that there is a strong rationale for Costa Rica’s proposal for an emergency COVID-19 technology intellectual property pool.¹⁷⁸

Dr Muhammad Zaheer Abbas has argued that Costa Rica’s proposal for the creation of a global pooling mechanism deserves serious consideration.¹⁷⁹ He contends: ‘The COVID-19 pooling mechanism has the potential to accelerate scientific discovery by acting as a clearinghouse for fast-track and equitable licensing of rights for collaborative follow-on innovation of priority health technologies.’¹⁸⁰ Dr Abbas also observes: ‘This pooling mechanism also has the potential to facilitate equitable and affordable access to potential health technologies by mobilizing the maximum available global manufacturing capacity as it will enable the interested and qualified developers, producers, or manufacturers of priority health technologies to license rights in a non-exclusive manner on royalty-free basis or on equitable terms.’¹⁸¹

In January 2021, a coalition of public-health and humanitarian groups including the People’s Vaccine Alliance sent a letter to the WHO raising their concerns about the management of C-TAP and calling for public clarification of the programme.¹⁸² The civil society organizations Knowledge Ecology Action and Health Action International expressed concern about the WHO’s leadership of C-TAP. Knowledge Ecological International exhorted the WHO to ‘to

¹⁷⁷ Ibid.

¹⁷⁸ Brook Baker, ‘Rationale for Supporting Costa Rica’s Proposal for Emergency COVID-19 Technology IP Pool for All Countries’, *InfoJustice*, 25 March 2020, <http://infojustice.org/archives/42137>

¹⁷⁹ Muhammad Zaheer Abbas, ‘Treatment of the novel COVID19: Why Costa Rica’s Proposal for the Creation of a Global Pooling Mechanism deserves Serious Consideration?’, (2020) 7 (1) *Journal of Law and the Biosciences*, <https://academic.oup.com/jlb/article/7/1/lsaa049/5862546>

¹⁸⁰ Ibid.

¹⁸¹ Ibid.

¹⁸² Michael Safi, ‘WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began’, *The Guardian*, 22 January 2021, <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began>

exert greater leadership in measures to scale production, increase competition, and speed the delivery of vaccines, therapeutics and other technologies and other technologies in the COVID-19 response.¹⁸³ HAI said that the Director-General's report on the COVID-19 response should 'acknowledge the Covid-19 Technologies Pool (C-TAP), a platform which, by gathering and channeling IP, know-how and other relevant data could play critical role in transferring technology and scaling up production of vaccines, diagnostics and other health goods necessary to vanquish this pandemic.'¹⁸⁴ The People's Vaccine Campaign added: 'We have been advocating that governments, manufacturers and research institutions support the pool and will continue to do that, but the WHO needs to be more transparent about its activities and proactive as regards its leadership of and advocacy for C-TAP if it is to succeed.'¹⁸⁵

In February 2021, the Director-General of the World Health Organization called on vaccine developers to do more to share their data and technology: 'Having received substantial public funding, we encourage all manufacturers to share their data and technology to ensure global, equitable access to vaccines and we call on companies to share their dossiers with WHO faster and more fully than they have been doing so we can review them for emergency use listing.'¹⁸⁶ This statement seems to be a renewed effort to get intellectual property holders to re-engage with C-TAP.

In correspondence with *Nature* in March 2021, Etienne Billette de Villemeur, Vianney Dequiedt and Bruno Versaavel despaired: 'The WHO's COVID-19 Technology Access Pool has so far received no contributions from industry.'¹⁸⁷ They observed: 'The practice of pooling

¹⁸³ Knowledge Ecology International, 'EB 148 – WHO's COVID-19 Technology Access Pool (C-TAP) Comes Under Scrutiny', 20 January 2021, <https://www.keionline.org/35064>

¹⁸⁴ Ibid.

¹⁸⁵ Gabriela Bucher, 'Letter to the Director-General of the World Health Organization from Oxfam on Behalf of the People's Vaccine Alliance, and Health Action International', 21 January 2021, <https://www.keionline.org/wp-content/uploads/HE-Dr-Tedros-Letter-from-Peoples-Vaccine-Alliance-and-Health-Action-International.pdf>

¹⁸⁶ ABC News, 'World Health Organization Chief Says Drug Companies Should Share Vaccine-making Capacity', *ABC News*, 7 February 2021, <http://abc.net.au/news/2021-02-07/who-says-drug-firms-should-share-covid-vaccine-making-capacity/13129922>

¹⁸⁷ Etienne Billette de Villemeur, Vianney Dequiedt and Bruno Versaavel, 'Pool Patents to get COVID Vaccines and Drugs to All', *Nature*, Correspondence, 19 March 2021, <https://www.nature.com/articles/d41586-021-00759-9>

patented technologies for the production of medicines already occurs for HIV, hepatitis C and tuberculosis treatments.’¹⁸⁸ The researchers emphasized that ‘Fees are typically lower when licences are negotiated as a bundle with generics producers, implying increased volume.’¹⁸⁹ They observed: ‘Yet firms can anticipate extra revenue from participation in a voluntary pool, and thus be more willing to maintain innovation and share know-how than with compulsory licensing.’¹⁹⁰

In May 2021, Spain formally joined the C-TAP initiative. The President of the Government of Spain Pedro Sanchez said: ‘We invite governments and especially the pharmaceutical industry to join us so that the initiative can achieve tangible results.’¹⁹¹ Spain is collaborating with the C-TAP initiative to openly licence a serological test for COVID-19 developed by CSIC researchers.¹⁹² Sanchez stressed that ‘Only by leading by example will we be effective in preaching solidarity’ and ‘only through solidarity can this crisis be overcome and the wounds of our societies healed’.¹⁹³

In the United Kingdom Parliament, Liberal Democrat Layla Moran has chided the United Kingdom Government for its lack of co-operation with C-TAP.¹⁹⁴ She posed the question: Why did we not endorse the WHO COVID technology access protocol?’¹⁹⁵ She noted: ‘That global initiative is meant to prevent monopolies from blocking global access to coronavirus vaccines, and I do not understand how we in this House can say that we believe in global access to these

¹⁸⁸ Ibid.

¹⁸⁹ Ibid.

¹⁹⁰ Ibid.

¹⁹¹ World Health Organization, ‘Spain Has Formally Joined The C-TAP Initiative’, Twitter, 25 May 2021, <https://twitter.com/who/status/1397138437120090114?lang=en>

¹⁹² Government of Spain, ‘Sánchez announces that Spain will donate an additional 15 million vaccines to fight COVID-19’, 2 June 2021, <https://www.lamoncloa.gob.es/lang/en/presidente/news/Paginas/2021/20210602gavicovax-summit.aspx>

¹⁹³ Ibid.

¹⁹⁴ The Hon. Layla Moran, ‘The Role of the United Kingdom Government in Ensuring Innovation and Equitable Access to Treatment within the international COVID-19 Response’, Hansard, United Kingdom Parliament, 5 November 2020, <https://hansard.parliament.uk/Commons/2020-11-05/debates/78F58139-2878-4CC8-A220-1980A0025D6A/InternationalCovid-19ResponseInnovationAndAccessToTreatment#contribution-CD682B35-CCC2-4A90-8677-81A6DF6DA6DB>

¹⁹⁵ Ibid.

vaccines, yet not back that protocol.’¹⁹⁶ Dr Philippa Whitford MP of the Scottish National Party has also asked the Prime Minister Boris Johnson to ‘make a public statement in support of the proposal from the President and Minister of Health of Costa Rica for the WHO to create a global pooling mechanism for rights in COVID19 related technologies for the detection, prevention, control and treatment of the COVID-19 pandemic.’¹⁹⁷

Likewise, in Ireland, there has been a debate about the role of C-TAP. Dr Aisling McMahon told legislators: ‘The C-TAP model is needed because production capacity for vaccines, medicines and diagnostics for COVID can be increased globally but, in order to do this, more companies must license and share intellectual property rights, know-how and technologies to enable others to produce them.’¹⁹⁸ She stressed: ‘Access to Medicines Ireland encourages the Government to endorse formally the global solidarity call to action and the Covid-19 Technology Access Pool as soon as possible and to take action at an EU level to encourage greater support for the C-TAP.’¹⁹⁹ In response, a number of legislators have called for the Government of Ireland to support C-TAP.²⁰⁰ The Joint Committee on Foreign Affairs and Defence recommended: ‘Formal endorsement of C-TAP by the Government’; ‘Government advocating for C-TAP and other mechanisms at international level, particularly at the EU and at the UN Security Council’ ‘Government assistance to encourage more pharmaceutical

¹⁹⁶ Ibid.

¹⁹⁷ The Hon. Philippa Whitford MP, ‘Equitable Access to COVID-19 Diagnostics, Vaccines and Treatments’, the All-Parliamentary Group for Vaccines for All, House of Commons, April 2020, <https://stopaids.org.uk/wp-content/uploads/2020/04/Equitable-access-to-COVID-19-diagnostics-vaccines-and-treatments-1-1.pdf>

¹⁹⁸ Aisling McMahon, ‘Distribution of COVID-19 Vaccines to Developing Countries’, Joint Committee on Foreign Affairs and Defence Debate, Houses of the Oireachtas, Ireland, 9 February 2021, https://www.oireachtas.ie/en/debates/debate/joint_committee_on_foreign_affairs_and_defence/2021-02-09/2/

¹⁹⁹ Ibid.

²⁰⁰ Houses of the Oireachtas, ‘Foreign Affairs Committee launches Report on the Distribution of COVID-19 Vaccines to Developing Countries’, Press Release, 11 March 2021, <https://www.oireachtas.ie/en/press-centre/press-releases/20210311-foreign-affairs-committee-launches-report-on-the-distribution-of-covid-19-vaccines-to-developing-countries/> and Joint Committee on Foreign Affairs and Defence, Report on the Distribution of COVID-19 Vaccines to Developing Countries’, Houses of the Oireachtas, Ireland, March 2021, https://data.oireachtas.ie/ie/oireachtas/committee/dail/33/joint_committee_on_foreign_affairs_and_defence/reports/2021/2021-03-05_report-on-the-distribution-of-covid-19-vaccines-to-developing-countries_en.pdf

companies to join CTAP’ and an increase of ‘financial support for the World Health Organisation’s ACT Accelerator.’²⁰¹

The President of Ireland Michael Higgins has provided vocal support for C-TAP.²⁰² He has called for global solidarity: ‘The possibility of safe, effective and affordable diagnostics, therapeutics and vaccines provides vital hope of overcoming COVID-19, but unless such medical tools are fully accessible to all on an equitable basis the world remains at risk.’²⁰³ He cautioned: ‘Unequal responses to the pandemic will widen inequalities already exacerbated by the impact of COVID-19.’²⁰⁴ Higgins emphasized: ‘The only effective, enduring, sustainable approach to healthcare provision is one founded on real multilateralism and solidarity that enables us all to be ethical partners in the necessary structural change that can deliver universal access to COVID health discoveries.’²⁰⁵ The President of Ireland underlined that access to essential medicines raised fundamental questions about global social justice: ‘For those of us who believe in global social justice, we place so much collective hope on its advancement.’²⁰⁶ He concluded: ‘Solidarity among nations is key if we are to optimise the world’s management and eventual exit from this pandemic.’²⁰⁷

²⁰¹ Joint Committee on Foreign Affairs and Defence, Report on the Distribution of COVID-19 Vaccines to Developing Countries’, Houses of the Oireachtas, Ireland, March 2021, 12, https://data.oireachtas.ie/ie/oireachtas/committee/dail/33/joint_committee_on_foreign_affairs_and_defence/reports/2021/2021-03-05_report-on-the-distribution-of-covid-19-vaccines-to-developing-countries_en.pdf

²⁰² Costa Rica, UNAIDS and World Health Organization, ‘High Level Event – The Challenge of a Lifetime: Ensuring Universal Access to COVID-19 Health Technologies – with the President of Costa Rica Carlos Alvarado Queada, the President of Ireland Michael Higgins, the Executive Director of UNAIDS Winnie Byanyima, and the Director-General of the World Health Organization, Tedros Adhanom Ghebreyesus’, 25 September 2020, https://www.facebook.com/watch/live/?v=3321649844589012&ref=watch_permalink

²⁰³ Michael Higgins, ‘The Challenge of a Lifetime: Ensuring Universal Access to COVID-19 Health Technologies’, High-Level Virtual Event at the 75th Session of the United Nations General Assembly, Friday, 25th September 2020, <https://president.ie/en/diary/details/president-addresses-un-meeting-on-universal-access-to-covid-19-health-technologies/speeches>

²⁰⁴ Ibid.

²⁰⁵ Ibid.

²⁰⁶ Ibid.

²⁰⁷ Ibid.

The European Parliament has lent its support for the WHO effort to create a COVID-19 Technology Access Pool.²⁰⁸ In a resolution, the European Parliament ‘reaffirms its support for the WHO COVID-19 C-TAP initiative and the mRNA vaccine technology transfer hub; regrets that so far pharmaceutical companies have decided not to engage in the C-TAP initiative; urges the Commission to incentivise pharmaceutical companies to share their technologies and know-how through C-TAP and include commitments on technology transfer partnerships with third parties, particularly developing countries, in the EU’s future advance purchase agreements’.²⁰⁹ However, the European Commission has shown less enthusiasm for sharing intellectual property as part of a pool.

In a background paper for the Independent Panel, Ellen ‘t Hoen and her colleagues conclude C-TAP could be an effective policy solution: ‘A more effective solution will therefore be the implementation of an initiative such as C-TAP that, in a predictable manner, assures access to all relevant Intellectual Property: patents, know-how, data, technology and materials.’²¹⁰

As of August 2021, C-TAP has assembled a number of implementing partners – including the Medicines Patent Pool, the Open COVID Pledge, and the Tech Access Partnership.²¹¹ The role of these collaborators will be further discussed in some of the subsequent parts of the paper.

C. Opposition to Patent Pools

²⁰⁸ Ed Silverman, ‘European Parliament Backs WHO Effort To Create A COVID-19 Technology Access Pool’, *STAT*, 13 July 2020, <https://www.statnews.com/pharmalot/2020/07/13/europe-who-covid19-patents-vaccine-pandemic/>

²⁰⁹ European Parliament, *Meeting the Global COVID-19 Challenge: Effects of Waiver of the WTO TRIPS Agreement on Covid-19 Vaccines, Treatment, Equipment and Increasing Production and Manufacturing capacity in Developing Countries*. 10 June 2021, 2021/2692 (RSP), P9_TA(2021)0283, https://www.europarl.europa.eu/doceo/document/TA-9-2021-0283_EN.html

²¹⁰ Ellen ‘t Hoen, Ellen, Christopher Garrison, Pascale Boulet, Kaitlin Mara and Katrina Perehudoff, *Scaling-Up Vaccine Production Capacity: Legal Challenges and Recommendations*, Background Paper 6, Commissioned by the Independent Panel for Pandemic Preparedness and Response, May 2021, <https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccinationlegal-aspects.pdf>

²¹¹ World Health Organization, ‘How WHO C-TAP Works?’, August 2021, <https://www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap>

There remains concern that wealthy nations – who are donors to the WHO – have been trying to sideline C-TAP.²¹² Moreover, leaders of pharmaceutical drug companies and vaccine developers have been unco-operative with sharing their data and technology with C-TAP.²¹³ Notably, the chief executive of Pfizer, Albert Bourla, has maintained that companies are ‘investing billions to find a solution and, keep in mind, if you have a discovery, we are going to take your (intellectual property), I think, is dangerous.’²¹⁴ Similarly, AstraZeneca chief executive Pascal Soriot argued at that, ‘if you don’t protect intellectual property, then essentially, there is no incentive for anybody to innovate’.²¹⁵ Thomas Cuni, the director of the International Federation of Pharmaceutical Manufacturers and Associations, a lobby group for the industry, maintained: ‘Circumventing IP rights will not solve perceived access challenges.’²¹⁶ The statement by the Pfizer and AstraZeneca leaders seems to suggest that private companies are wholly responsible for developing vaccines, treatments, and diagnostics for COVID-19 – when, of course, there has been massive public investment in such technologies.

As the economist Mariana Mazzucato has noted, innovation has long been underpinned by public investment.²¹⁷ Mazzucato is the chair of a new WHO Council on the Economics of

²¹² Priti Patnaik, ‘WHO Donors seek a New Tech Transfer Hub under ACT-A, C-TAP Sidelined’, *Geneva Health Files*, 19 March 2021, <https://genevahealthfiles.substack.com/p/who-donors-seek-a-new-tech-transfer>

²¹³ Ed Silverman, ‘Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on COVID-19 Products’, *STAT*, 28 May 2020, <https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/>

²¹⁴ Ibid.

²¹⁵ Ibid.

²¹⁶ Michael Safi, ‘WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began’, *The Guardian*, 22 January 2021, <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began>

²¹⁷ Mariana Mazzucato and Giovanni Dosi (ed.), *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, Cambridge and New York: Cambridge University Press, 2006; Mariana Mazzucato, *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*, London and New York: Anthem Press, 2014; Mariana Mazzucato, *The Value of Everything: Making and Taking in the Global Economy*, London: Allen Lane, 2018; Joad Medeiros, ‘This Economist Has a Plan to Fix Capitalism. It’s Time We All Listened’, *Wired*, 8 October 2019, <https://www.wired.co.uk/article/mariana-mazzucato>; Mariana Mazzucato, ‘How Does Innovation Really Happen?’, *Wired Smarter*, 21 February 2020, <https://www.youtube.com/watch?v=uXWhwereXYo>; and Mariana Mazzucato, *Mission Economy: A Moonshot Guide to Changing Capitalism*, New York: Harper Business, 2021.

Health for All – which seeks to incorporate lessons learned during the COVID-19 pandemic.²¹⁸ The Council has suggested that there is a need to rethink for health innovation in light of the COVID-19 crisis.²¹⁹ The Council has highlighted problems in the pharmaceutical innovation ecosystem – including misaligned directionality and priority-setting; knowledge and access barriers; excessive financialization and de-industrialization; lack of resilience and limited spread of manufacturing infrastructure; and lack of public stewardship for access. The Council has called for purpose-driven innovation, and reshaping knowledge governance for the common good. The Council has also highlighted the need for the corporate governance – particularly ensuring that the principle of Health for All governs public-private partnerships. The Council calls for the building of resilient and diverse manufacturing capacity and infrastructure.

C-TAP will struggle to work, as intended, if it is unable to play a role in the facilitation of the transfer and dissemination of intellectual property. The Director-General of the WHO Dr Tedros maintains: ‘Manufacturers can do more: having received substantial public funding, we encourage all manufacturers to share their data and technology to ensure global equitable access to vaccines.’²²⁰ He was disappointed by the response of intellectual property holders to C-TAP.²²¹ He reflects:

We’re holding the door open for pharmaceutical companies that have become household names, although too few households have benefited from the lifesaving tools they have developed. They

²¹⁸ World Health Organization, ‘Global Experts of new WHO Council on the Economics of Health For All Announced’, 6 May 2021, <https://www.who.int/news/item/06-05-2021-global-experts-of-new-who-council-on-the-economics-of-health-for-all-announced>

²¹⁹ The WHO Council on the Economics of Health for All, ‘Governing Health Innovation for the Common Good’, Council Brief No. 1, 9 June 2021, <https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/councilbrief-no1.pdf>

²²⁰ World Health Organization, ‘WHO Director-General’s Opening Remarks at the Media Briefing on COVID-19’, 5 February 2021, <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-5-february-2021>

²²¹ Kerry Cullinan, ‘Indonesia and Bangladesh Reveal Massive Untapped Vaccine Production Capacity at C-TAP Anniversary’, *Health Policy Watch*, 28 May 2021, <https://healthpolicy-watch.news/indonesia-and-bangladesh-reveal-massive-untapped-vaccine-production-capacity-at-c-tap-anniversary/>

control the [intellectual property] that can save lives today, end this pandemic soon, and prevent future epidemics from spiralling out of control and undermining health economies and national security.²²²

The recalcitrance of technology developers to participate in such co-operative intellectual property sharing schemes may come back to haunt them. The refusal to license technology may lead to more dramatic options such as compulsory licensing and crown use being deployed to deal with the competition issue.

V. Compulsory Licensing and Crown Use/ Government Use

Under the *TRIPS Agreement* 1994, and the *Doha Declaration* 2001, nation states are entitled to use patent flexibilities such as compulsory licensing and crown use to address public health epidemics. The United Nations Secretary-General's High Level Panel on Access to Medicines expressed concern that nation states had not made the most of the patent flexibilities.²²³

In a briefing note, the World Trade Organization observes that 'the *TRIPS Agreement* allows compulsory licensing and government use of a patent without the authorization of its owner under a number of conditions aimed at protecting the legitimate interests of the patent holder.'²²⁴ The Secretariat comments: 'All WTO members may grant such licences and government-use orders for health technologies, such as medicines, vaccines and diagnostics, as well as any other product or technology needed to address COVID-19.'²²⁵

The People's Vaccine Alliance has supported the use of intellectual property flexibilities to provide access to essential medicines: 'We are saying that in these unprecedented times,

²²² Ibid.

²²³ Ruth Dreifuss, and others, *Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, United Nations, 2016, <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>

²²⁴ World Trade Organization, 'The TRIPS Agreement and COVID-19: Information Note', 15 October 2020, https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf

²²⁵ Ibid.

companies should share their knowledge and not enforce intellectual property rights in the interests of public health.’²²⁶

A. Compulsory Licensing for Domestic Purposes

A number of countries passed specific measures, indicating that they are willing to use compulsory licensing during the COVID-19 pandemic if need be. Bill C-13 amended Canada's Patent Act to empower the Commissioner of Patents, on the application of the Minister of Health, to authorize the Government of Canada or another specified person to supply a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern.²²⁷ Germany has passed amendments to an Act on the Prevention and Control of Infectious Diseases in Humans.²²⁸ The legislation authorizes the Ministry of Health to issue use orders in the context of an epidemic situation of national importance with respect to patented inventions related to medical products. Hungary's 2020 Government Decree 212/2020 (16 May) allowed for public health compulsory licensing for exploitation within Hungary based on Article 31 of the *TRIPS Agreement* 1994.²²⁹ In March 2020, Israel's Minister of Health issued a permit allowing the government to import generic versions of lopinavir/ritonavir from India for the purpose of exploring the possibility of treating COVID-

²²⁶ The People's Vaccine Alliance, 'FAQ' <https://peoplesvaccine.org/faq/>

²²⁷ Bill C-13 2020 (Canada) (also known by its short title of 'An Act respecting certain measures in response to COVID-19') <https://www.parl.ca/DocumentViewer/en/43-1/bill/C-13/royal-assent>; and Ed Silverman, 'A Canadian Bill would make it easier to issue Compulsory Licenses for Covid-19 Products', *STAT*, 25 March 2020, <https://www.statnews.com/pharmalot/2020/03/25/canada-compulsory-license-coronavirus-covid19/>

²²⁸ Sebastian Fuchs, 'COVID-19: New German Legislation to Fight Pandemic May Affect Granted German Patents', *Bird & Bird*, May 2020, <https://www.twobirds.com/en/news/articles/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents> and Liat Sanz Martinez, 'Compulsory Licensing Germany', *Kluwer Patent Blog*, 10 May 2021, <http://patentblog.kluweriplaw.com/2021/05/10/compulsory-licensing-germany/>

²²⁹ World Trade Organization, 'The TRIPS Agreement and COVID-19: Information Note', 15 October 2020, https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf

patients.²³⁰ The Parliament of Chile also supported compulsory licensing for coronavirus medicines and vaccines.²³¹ The Legislative Committee in Ecuador has approved a resolution on compulsory licensing of patents relating to the coronavirus.²³² A number of Latin American countries may well contemplate the use of compulsory licensing – given the aggressive, overbearing negotiating tactics of vaccine developers.²³³

In 2021, the Supreme Court of India considered the unprecedented humanitarian crisis in India, following the outbreak of the COVID-19 pandemic.²³⁴ It considered the supply of essential drugs; the method and manner of vaccination; the supply of oxygen; and the declaration of lockdown. The Supreme Court of India said that it sought to facilitate a dialogue between the stakeholders: ‘This bounded-deliberative approach is exercised so that the UOI and States can justify the rationale behind their policy approach which must be bound by the human rights framework which presently implicates the right to life under Article 21 and right to equality

²³⁰ Steven Scheer and Julie Steenhuisen, ‘Israel Approves Generic HIV Drug to Treat COVID-19 Despite Doubts’, *Reuters*, 19 March 2020, <https://www.reuters.com/article/us-health-coronavirus-israel-drug-idUSKBN216237>; Ed Silverman, ‘AbbVie Will allow Generic Copies of its HIV pill in Israel after the Government Approved a License’, *STAT*, 20 March 2020, <https://www.statnews.com/pharmalot/2020/03/20/abbvie-israel-hiv-kaletra-coronavirus-covid19/>; and Knowledge Ecology International, ‘Israel Issues Compulsory License to Allow the Government to Import Generic Versions of Kaletra’, 23 March 2020, <https://www.keionline.org/32503>

²³¹ Ed Silverman, ‘Chilean Lawmakers Support Compulsory Licensing for Coronavirus Medicines and Vaccines’, *STAT*, 18 March 2020, <https://www.statnews.com/pharmalot/2020/03/18/chile-compulsory-licensing-coronavirus-covid19-vaccines/>

²³² Knowledge Ecology International, ‘Legislative Committee in Ecuador Approves Resolution on Compulsory Licensing of Patents Relating to the Coronavirus’, Knowledge Ecology International, 20 March 2020, <https://www.keionline.org/32429> and Ed Silverman, ‘Ecuador Becomes The Latest Country to Eye Compulsory Licensing for COVID-19 Products’, *STAT*, 23 March 2020, <https://www.statnews.com/pharmalot/2020/03/23/ecuador-compulsory-licensing-covid19-coronavirus/>

²³³ Madlen Davies, Rosa Furneaux, Ivan Ruiz and Jill Langlois, “‘Held to Ransom’: Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal”, *The Bureau of Investigative Journalism*, 23 February 2021, <https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal>; and Al Jazeera, ‘Investigation: Drugmaker “Bullied” Latin American Nations’, *Al Jazeera*, 11 March 2021, <https://www.aljazeera.com/news/2021/3/11/investigation-pfizer-bullied-latin-american-nations>

²³⁴ *In Re: Distribution of Essential Supplies and Services During Pandemic* (2021) LL 2021 SC 2036, *Suo Moto Writ Petition (Civil) No. 3 of 2021* (Supreme Court of India).

under Article 14 of the Constitution.’²³⁵ The Supreme Court of India highlighted the importance of human rights – the right to life (including the right to health), and the right to equality – to questions of access to essential medicines and oxygen during the pandemic.

The Supreme Court of India discussed the potential for compulsory licensing in respect of vaccines and essential drugs covered by patents during the coronavirus crisis.²³⁶ The Supreme Court of India noted: ‘Several drugs that are at the core of the COVID treatment protocol are under patents in India including Remdesivir, Tocilizumab and Favipiravir.’²³⁷ The Supreme Court of India made reference to intellectual property flexibilities available under the *TRIPS Agreement* 1994, the *Doha Declaration* 2001, the *WTO General Council Decision* 2003, and the *TRIPS Waiver* (co-sponsored by India). The Supreme Court of India discussed the compulsory licensing powers available under the *Patents Act* 1970 (India). The Supreme Court of India noted: ‘In the context of the COVID-19 pandemic, we note that several countries such as Canada and Germany have relaxed the legal regimes governing the grant of compulsory licenses’.²³⁸ The Supreme Court of India also observed that there were patent provisions regarding government use; government acquisition; and patent revocation.

The Supreme Court of India urged the Modi Government to consider making use of intellectual property flexibilities to address the public health epidemic:

Whether and if so, the extent to which these provisions should be utilized is a policy decision for the Central Government. We have flagged the issue for its consideration. We have only outlined the legal framework within which the Central Government can possibly consider compulsory licensing and government acquisition of patents. The Central Government is free to choose any other course of action that it deems fit to tackle the issue of vaccine requirements in an equitable and expedient manner, which may involve negotiations with domestic and foreign producers of vaccines. We clarify that it is up to the

²³⁵ *In Re: Distribution of Essential Supplies and Services During Pandemic* (2021) LL 2021 SC 2036, *Suo Moto Writ Petition (Civil) No. 3 of 2021* (Supreme Court of India), [5].

²³⁶ *In Re: Distribution of Essential Supplies and Services During Pandemic* (2021) LL 2021 SC 2036, *Suo Moto Writ Petition (Civil) No. 3 of 2021* (Supreme Court of India).

²³⁷ *In Re: Distribution of Essential Supplies and Services During Pandemic* (2021) LL 2021 SC 2036, *Suo Moto Writ Petition (Civil) No. 3 of 2021* (Supreme Court of India) at [42].

²³⁸ *In Re: Distribution of Essential Supplies and Services During Pandemic* (2021) LL 2021 SC 2036, *Suo Moto Writ Petition (Civil) No. 3 of 2021* (Supreme Court of India) [45].

Central Government to choose the best possible measures it can undertake during the current crisis keeping in mind that public interest is of paramount importance.²³⁹

The Supreme Court of India concluded that the ‘Central Government can also consider using its powers under Sections 92, 100 or 102 of the Patents Act to increase production of essential drugs to ensure that it is commensurate to the demand.’²⁴⁰

There has been some disquiet that, while internationally the Government of India has been promoting the TRIPS Waiver in diplomatic negotiations, the Government of India has not fully utilized domestic patent flexibilities and exceptions during the coronavirus crisis.²⁴¹

The African Group has discussed the need to make use of flexibilities – such as compulsory licensing.²⁴² Canadian scholar Chidi Oguamanam has argued that ‘despite the current weakening of global institutional public health interventionist bodies and the tenuousness of international comity, Africa needs to strengthen its own regional health bodies as important pathways to scaling and dispersal of R&D efforts’.²⁴³ He suggests that: ‘A harmonization of regional and national institutional health capacities is necessary to prepare the continent to participate in the local production of a COVID19 vaccine under a global public good model’.²⁴⁴

²³⁹ *In Re: Distribution of Essential Supplies and Services During Pandemic* (2021) LL 2021 SC 2036, *Suo Moto Writ Petition (Civil) No. 3 of 2021* (Supreme Court of India) at [46].

²⁴⁰ *In Re: Distribution of Essential Supplies and Services During Pandemic* (2021) LL 2021 SC 2036, *Suo Moto Writ Petition (Civil) No. 3 of 2021* (Supreme Court of India) at [55].

²⁴¹ Priti Patnaik, ‘Where does India truly stand on the TRIPS Waiver: Q&A with Murali Neelakantan’, *Geneva Health Files*, 6 August 2021, <https://genevahealthfiles.substack.com/p/where-does-india-truly-stand-on-the?justPublished=true>

²⁴² Ed Silverman, ‘Africa Union urges Member Countries to remove Intellectual Property Barriers to Covid-19 vaccines’, *STAT*, 1 July 2020, <https://www.statnews.com/pharmalot/2020/07/01/africa-covid19-coronavirus-vaccines-patents-intellectual-property/> and Yousuf Vawda, ‘The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property’ (2021) *South Centre Policy Brief No. 99* <https://www.southcentre.int/wp-content/uploads/2021/08/PB-99.pdf>

²⁴³ Chidi Oguamanam, ‘COVID-19 and Africa: Does “One Size Fit All” in Public Health Intervention’, in Colleen Flood, Vanessa MacDonnell, Jane Philpott, Sophie Theriault, and Sridhar Venkatapuram (ed.), *Vulnerable: The Law, Policy and Ethics of COVID-19*, Ottawa: the University of Ottawa, 2020, 543-554 at 553.

²⁴⁴ *Ibid.*

The South Centre has provided guidance as to the use of compulsory licenses during the COVID-19 crisis.²⁴⁵

Hilary Wong of the University of California, Berkeley, has argued that there is a strong case for the use of compulsory licensing during the public health pandemic.²⁴⁶ She observes: ‘Compulsory licensing is a powerful public health tool – it can be instrumental for alleviating insufficient supplies of necessary pharmaceuticals as well as mitigating prohibitively expensive drug prices.’²⁴⁷ Wong notes: ‘While the rewards of patent protection are necessary to support continual innovation, the compulsory licensing exception exists for public health emergencies such as the current COVID-19 crisis.’²⁴⁸ Wong emphasizes that ‘Governments must do what is necessary to fight the present pandemic.’²⁴⁹ She also suggests that ‘International organizations can play a key role by providing the legal know-how as well as setting a supportive tone for using compulsory licensing.’²⁵⁰ Wong warns intellectual property owners against retaliation: ‘In the process, pharmaceutical companies and G20 countries should not deter or retaliate against developing countries pursuing such public health measures in the time of a pandemic.’²⁵¹

Ellen ‘t Hoen and her collaborators have noted the limitations of compulsory licensing - observing that ‘compulsory patent licences are granted product-by-product, and country-by-country and are time-limited.’²⁵² Moreover, ‘The Compulsory Licensing decision is subject to

²⁴⁵ South Centre, ‘Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic’, South Centre, March 2021, <https://www.southcentre.int/covid-19-compulsory-licenses-table-march-2021/> and Carlos Correa, ‘Expanding the Production of COVID-19 Vaccines to Reach Developing Countries: Lift the Barriers to Fight the Pandemic in the Global South’, South Centre, Policy Brief 92, April 2021, <https://www.southcentre.int/policy-brief-92-april-2021/>

²⁴⁶ Hilary Wong, ‘The Case for Compulsory Licensing During COVID-19’, (2020) 10 (1) *Journal of Global Health*, 010358. doi:10.7189/jogh.10.010358, <http://www.jogh.org/documents/issue202001/jogh-10-010358.pdf>

²⁴⁷ Ibid.

²⁴⁸ Ibid.

²⁴⁹ Ibid.

²⁵⁰ Ibid.

²⁵¹ Ibid.

²⁵² Ellen ‘t Hoen, Christopher Garrison, Pascale Boulet, Kaitlin Mara and Katrina Perekhodoff, *Scaling-Up Vaccine Production Capacity: Legal Challenges and Recommendations*, Background Paper 6, Commissioned by

judicial review which may suspend the execution of the Compulsory License.’²⁵³ ‘t Hoen and her team comment: It is not possible to grant blanket Compulsory Licenses for an entire field of technology or for an overarching purpose such as ‘combating a pandemic’.’²⁵⁴

B. Compulsory Licensing for the Export of Essential Medicines

There have been issues with the implementation of the *WTO General Council Decision 2003* – now codified as Article 31bis of the *TRIPS Agreement* 1994 - dealing with the export of pharmaceutical drugs.²⁵⁵ Nobel Laureate Professor Joseph Stiglitz has expressed his concern about the operation of the export mechanism under Article 31bis. He comments:

Life should always be put before profits, and never more so than in the midst of a pandemic. The WTO should not have rules that deliberately create barriers to importing needed drugs, whether it’s rich countries or poor; and especially so because those rules limit the ability of firms to achieve efficient economies of scale. The opt-out provision in Article 31bis is protectionism at its worst – where it is lives that may be lost as a result – and something clearly not in the interests of any country, large or small, importer or exporter, during the COVID-19 crisis.²⁵⁶

There needs be a reconsideration of the limited framework for compulsory licensing for the purposes of export – especially given the nature of the coronavirus public health epidemic. Stiglitz has called for substantive action for reform of the export system in the face of the coronavirus crisis.²⁵⁷

the Independent Panel for Pandemic Preparedness and Response, May 2021, <https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccinationlegal-aspects.pdf>

²⁵³ Ibid.

²⁵⁴ Ibid.

²⁵⁵ *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (2003) (Decision of the General Council of 30 August 2003) ('WTO General Council Decision of 30 August 2003'); and Article 31bis of the *TRIPS Agreement* 1994.

²⁵⁶ James Love, 'Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License in Another Country under 31bis of TRIPS Agreement', Knowledge Ecology International, 7 April 2020, <https://www.keionline.org/32707>

²⁵⁷ Amy Goodman, 'Joseph Stiglitz: Trump's "Trickle-Down" Economic Plans Are Not Enough to Meet Coronavirus Challenge', *Democracy Now!*, 19 March 2020, https://www.democracynow.org/2020/3/19/us_economy_coronavirus_stimulus_joseph_stiglitz

In the past, India has acted as a ‘Pharmacy of the Developing World’, and has provided generic medicines to other countries during public health epidemics.²⁵⁸ As India has needed to become TRIPS-compliant, there has been debate as to whether the compulsory export licence system is effective in India.²⁵⁹ However, during the coronavirus crisis, the Serum Institute of India has struggled with the demands of domestic supply – let alone the global demand for COVID-19 vaccines.²⁶⁰

There has been an effort to use the compulsory licensing scheme for the export of pharmaceutical drugs in Canada. As the author has written about previously, the export scheme has proven to be awkward and cumbersome in its operation.²⁶¹ In Canada, St. Catharines pharmaceutical company Biolyse Pharma has wanted to help with the global COVID-19 vaccine rollout.²⁶² The Government of Bolivia has expressed an interest in obtaining generic vaccines from Biolyse.²⁶³ Accordingly, Biolyse have made a license request to Johnson & Johnson, but that was denied by that company in March 2021.²⁶⁴ Biolyse has been critical on the obstacles that it has faced in its efforts to obtain compulsory licensing.²⁶⁵ John Fulton of

²⁵⁸ Hafiz Aziz ur Rehman, *The Pharmacy of the Developing World: India, Patent Law and Access to Essential Medicines*, PhD, ANU, 2007-2011. <https://openresearch-repository.anu.edu.au/handle/1885/110380>

²⁵⁹ Hafiz Aziz ur Rehman, 'WTO, Compulsory Export Licences and Indian Patent Law' (2011) 1 *Nordic Journal of Commercial Law* 1-32.

²⁶⁰ Laura Spinney, “‘We Took a Huge Risk’: The Indian Firm Making More Covid Jabs Than Anyone”, *The Guardian*, 14 February 2021, <https://www.theguardian.com/global-development/2021/feb/14/we-took-a-huge-risk-the-indian-firm-making-more-covid-jabs-than-anyone>

²⁶¹ Stephen Lewis, *Race Against Time: Searching for Hope in AIDS-Ravaged Africa*, Toronto: House of Anansi Press, 2006; Matthew Rimmer, 'The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid' (2005) 15 (7) *Expert Opinion on Therapeutic Patents* 889-909; and Matthew Rimmer, 'Race Against Time: The Export of Essential Medicines to Rwanda' (2008) 1 (2) *Public Health Ethics* 89-103.

²⁶² Shelby Knox, ‘St. Catharines Pharmaceutical Company Wants to Help with Global COVID-19 Vaccine Rollout’, *Newstalk 610 CKTB*, 11 March 2021, <https://iheartradio.ca/610cktb/news/st-catharines-pharmaceutical-company-wants-to-help-with-global-covid-19-vaccine-rollout-1.14749000>

²⁶³ Knowledge Ecology International, ‘Bolivia seeks to import COVID-19 Vaccines from Biolyse, if Canada Grants them a Compulsory License’, 11 May 2021, <https://www.keionline.org/36119>

²⁶⁴ Kerry Cullinan, ‘Company Pushes Canada to Grant Compulsory License for Johnson & Johnson COVID-19 Vaccine’, *Health Policy Watch*, 11 May 2021, <https://healthpolicy-watch.news/company-pushes-canada-to-grant-compulsory-license-for-johnson-johnson-covid-19-vaccine/>

²⁶⁵ Francesca Bruce, ‘Canadian Firm Scathing on Obstacles to Compulsory Licensing: Biolyse is Determined to Manufacture J&J’s COVID-19 Vaccine’, *Pink Sheet: Informa Pharma Intelligence*, 27 May 2021,

Biolyse observed: ‘CAMR is a big effort for a small company with a limited regulatory team.’²⁶⁶ He noted: I have spent the last 73 days trying to get an answer on how to trigger the process to begin’.²⁶⁷ Fulton observed: ‘If we can’t get a compulsory licensing mechanism like this from the *TRIPS agreement* to work right now, what’s the use?’²⁶⁸ Knowledge Ecology International noted: ‘Although Schedule 1 can be amended to include additional products, Canadian authorities have refused to tell KEI and Biolyse whether COVID-19 vaccines will be added to the list or what the estimated time frame is for that amendment to take place.’²⁶⁹ Knowledge Ecology International recommended law reform: ‘Canadian law should be amended, all the laws that restrict and prohibit companies from doing things like this should be amended, the two levels should be in play here.’²⁷⁰

In addition to Bolivia, Antigua and Barbuda have notified the WTO of their intent to import products using compulsory licences.²⁷¹ The Caribbean country has previously articulated its support for the TRIPS Waiver during the coronavirus crisis.

The Biolyse case highlights how the compulsory licensing system established by the *WTO General Council Decision* 2003 – and embedded in Article 31bis of the *TRIPS Agreement* 1994 – is broken. There needs to be a fundamental overhaul of the regime to facilitate the distribution and dissemination of essential medicines during pandemics – like in respect of the coronavirus.

<https://pink.pharmaintelligence.informa.com/PS144384/Canadian-Firm-Scathing-On-Obstacles-To-Compulsory-Licensing>

²⁶⁶ Ibid.

²⁶⁷ Ibid.

²⁶⁸ Ibid.

²⁶⁹ Kerry Cullinan, ‘Company Pushes Canada to Grant Compulsory License for Johnson & Johnson COVID-19 Vaccine’, *Health Policy Watch*, 11 May 2021, <https://healthpolicy-watch.news/company-pushes-canada-to-grant-compulsory-license-for-johnson-johnson-covid-19-vaccine/>

²⁷⁰ Francesca Bruce, ‘Canadian Firm Scathing on Obstacles to Compulsory Licensing: Biolyse is Determined to Manufacture J&J’s COVID-19 Vaccine’, *Pink Sheet: Informa Pharma Intelligence*, 27 May 2021, <https://pink.pharmaintelligence.informa.com/PS144384/Canadian-Firm-Scathing-On-Obstacles-To-Compulsory-Licensing>

²⁷¹ Knowledge Ecology International, ‘Antigua and Barbuda Notified the WTO Of Their Intent to Import Products Using Compulsory Licences’, 7 June 2021, <https://www.keionline.org/36241>

The European Union has opposed a proposal for a TRIPS Waiver. Instead, the European Union has instead proposed a ‘third way’ of simplifying and streamlining the use of compulsory licensing under the *TRIPS Agreement* 1994, the *Doha Declaration* 2001, and the *WTO General Council Decision* 2003.²⁷² The European Union noted: ‘The discussions in the Council for TRIPS since the start of the COVID-19 pandemic have identified aspects related to the use of compulsory licensing that, in the view of a number of WTO Members, limit the use of this tool.’²⁷³ The European Union suggested: ‘In order to address these aspects, provide more legal certainty and enhance the effectiveness of the system, the EU considers that all WTO Members should be ready to agree on the following: (a) The pandemic is a circumstance of national emergency and therefore the requirement to negotiate with the right holder may be waived; (b) To support manufacturers ready to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, on the basis of a compulsory licence, the remuneration for patent holders should reflect such affordable prices; and (c) The compulsory licence could cover any exports destined to countries that lack manufacturing capacity, including via the COVAX facility.’²⁷⁴ The European Union emphasized that it was ‘ready to engage on other points regarding the facilitation of the use of compulsory licensing as provided for in the *TRIPS Agreement* 1994.’²⁷⁵ Leaked documents have shown that the EU Council of Ministers defined its position on the TRIPS Waiver for vaccines in secret.²⁷⁶ There has been concern that Big Pharma have had an undue influence on the formation of the European Union position.

Human Rights Watch have questioned the justifications of the European Union for opposing the TRIPS Waiver.²⁷⁷ Human Rights Watch also observed that ‘there are significant barriers to

²⁷² European Union, ‘Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property’, Brussels, 4 June 2021, https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf For commentary, see Ed Silverman, ‘EU Pushes Rival Plan to COVID-19 IP Waiver, But Some Deride It As “Meaningless”’, *STAT*, 4 June 2021, <https://www.statnews.com/pharmalot/2021/06/04/covid19-vaccine-patents-europe-waiver/>

²⁷³ Ibid.

²⁷⁴ Ibid.

²⁷⁵ Ibid.

²⁷⁶ Corporate Europe Observatory, ‘Leaked Documents show EU Council of Ministers defined its position on TRIPS Waiver for Vaccines in Secret’, 4 July 2021, <https://corporateeurope.org/en/2021/06/leaked-documents-show-eu-council-ministers-defined-its-position-trips-waiver-vaccines>

²⁷⁷ Human Rights Watch, ‘Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver’, Human Rights Watch, 3 June 2021, <https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver>

making compulsory licenses a practical solution to the severe supply shortages the world is facing now.’²⁷⁸ A collection of scholars have suggested that ‘existing TRIPS flexibilities around compulsory licensing are incapable of addressing the present pandemic context adequately, both in terms of procedure and legal substance.’²⁷⁹ Jorge Contreras has considered the use of compulsory licensing, government use, and march-in rights during the coronavirus pandemic.²⁸⁰

C. Crown Use, Government Use, and Government Acquisition

In addition to compulsory licensing, there is also the option of crown use or government use of patented inventions. In the United Kingdom, the Hon. Philippa Whitford has called on the United Kingdom to utilize its crown use powers under patent law.²⁸¹ She commented: ‘Where patents, monopolies or exclusivities already exist on medical products that are potentially useful for tackling COVID-19, the UK government should issue crown use licenses where necessary to ensure scale up of production and ensure affordable access to these products.’²⁸² Whitford stressed: ‘COVID-19 is unprecedented as a public health emergency, and access to these medical products cannot be restricted by intellectual property rights.’²⁸³

There has been a parliamentary debate about this topic in Australia. During the coronavirus public health crisis, Shadow Minister the Hon. Brendan O’Connor suggested that the Australian Government should make use of the Crown Use provisions: ‘I also think the government will need to detail how Crown use of patents may be invoked, particularly for use

²⁷⁸ Ibid.

²⁷⁹ Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang, and Graham Dutfield, ‘The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic’, LSE Legal Studies Working Paper No. 06/2021, 24 May 2021, Available at SSRN: <https://ssrn.com/abstract=3851737> or <http://dx.doi.org/10.2139/ssrn.3851737>

²⁸⁰ Jorge Contreras, ‘Patents and Coronavirus – Compulsory Licensing, Government Use and March-In Rights’, *InfoJustice*, 28 March 2020, <http://infojustice.org/archives/42184>

²⁸¹ The Hon. Philippa Whitford MP, ‘Equitable Access to COVID-19 Diagnostics, Vaccines and Treatments’, the All-Parliamentary Group for Vaccines for All, House of Commons, April 2020, <https://stopaids.org.uk/wp-content/uploads/2020/04/Equitable-access-to-COVID-19-diagnostics-vaccines-and-treatments-1-1.pdf>

²⁸² Ibid.

²⁸³ Ibid.

for repurposed manufacturing businesses, to address shortages of essential goods impacted by disrupted supply chains.’²⁸⁴ He commented: ‘I have written to the Minister for Industry, Science and Technology inquiring as to whether the government had explored using this provision, particularly for urgent manufacturing of suppliers, such as facial masks or goods in short supply due to disrupted supply chains.’²⁸⁵ The Australian Government has warned that it will use its crown use powers if patent inventors engage in profiteering in respect of essential inventions.

As the United Nations Secretary General’s High-Level Panel on Access to Medicines made clear, there is a need for nation states to make better use of intellectual property flexibilities – such as compulsory licensing, crown use, and government acquisition.²⁸⁶

VI. Public Sector Licensing

Universities and public research organisations are playing a key role in the development of vaccines, diagnostics, and treatments to the coronavirus COVID-19.

There has been a growing corpus of literature on intellectual property, education, and technology transfer. Corynne McSherry – now legal director of the Electronic Frontier Foundation – wrote a classic book about the battle for the control of intellectual property in academia.²⁸⁷ In a series of works, Professor Jacob Rooksby – the Dean of Gonzaga Law School - has written about the growing pressures of commercialization of intellectual property generated by higher education institutions.²⁸⁸ Hans Radder has explored how the higher

²⁸⁴ The Hon. Brendan O’Connor, ‘Second Reading Speech on the *Coronavirus Economic Response Package Omnibus Bill* 2020 (Cth)’, Hansard, House of Representatives, Parliament of Australia, 23 March 2020, 2801.

²⁸⁵ Ibid.

²⁸⁶ Ruth Dreifuss, and others, *Report of the United Nations Secretary-General’s High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, United Nations, 2016, <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>

²⁸⁷ Corynne McSherry, *Who Owns Academic Work? Battling for Control of Intellectual Property*, Cambridge (MA): Harvard University Press, 2001.

²⁸⁸ Jacob Rooksby, *Universities that Litigate Patents*, University of Virginia, Thesis Dissertation, 2012; Jacob Rooksby, *Branding of the American Mind: How Universities, Capture, Manage, and Monetize Intellectual Property and Why It Matters*, Baltimore (Maryland): John Hopkins Press, 2016; Jacob Rooksby (ed.), *Research*

education system has been affected by commodification.²⁸⁹ Professor Joseph Stiglitz - the Nobel Laureate in Economics – has considered the relationship between intellectual property and learning, and has called for an expansion of the knowledge commons.²⁹⁰

There has been an array of legal conflicts over essential inventions developed by educational organisations and public research institutions in relation to biomedicine. There were conflicts between the University of California and Genentech in respect of patents and biotechnology – relating to human growth hormone and insulin.²⁹¹ Public researchers were involved in patent races with private biotechnology firms – like Myriad Genetics – in respect of genetic testing.²⁹² There has also been controversies over access to essential medicines in respect of HIV/AIDS, malaria, and tuberculosis, which had developed by public institutions.²⁹³ Amy Kapczynski and her colleagues called for an open licensing approach to university innovations in order to address global health inequities.²⁹⁴ There have been significant clashes in respect of patent

Handbook on Intellectual Property and Technology Transfer, Cheltenham and Northampton (Ma.): Edward Elgar Publishing Limited, 2020; and William Kaplin, Barbara Lee, Neal Hutchens and Jacob Rooksby, *The Law of Higher Education: Sixth Edition*, Hoboken (NJ): Jossey-Bass, 2020.

²⁸⁹ Hans Radder, *From Commodification to the Common Good: Reconstructing Science, Technology, and Society*, Pittsburgh: University of Pittsburgh Press, 2019.

²⁹⁰ Joseph Stiglitz and Bruce Greenwald, *Creating a Learning Society: A New Approach to Growth, Development, and Social Progress*, New York: Columbia University Press, 2014; and Dean Baker, Jayadev Arjun, and Joseph Stiglitz, *Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century*, AccessIBSA, 2017. Available online: <http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf>

²⁹¹ Matthew Rimmer, 'Genentech And The Stolen Gene: Patent Law and Pioneer Inventions' (2002/2003) 5 (6) *Bio-Science Law Review* 198-211; and Sally Smith Hughes, *Genentech: The Beginnings of Biotech*, Chicago: The University of Chicago Press, 2011.

²⁹² Jessica Lai, 'Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision', (2015) 5 *UC Irvine Law Review* 1041-1076; Matthew Rimmer, 'An Exorbitant Monopoly: The High Court of Australia, Myriad Genetics, and Gene Patents', in Duncan Matthews and Herbert Zech (ed.), *Research Handbook on Intellectual Property and the Life Sciences*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, June 2017, 56-103; and Shubha Ghosh, 'Myriad Post-Myriad', (2020) 47 (5) *Science and Public Policy* 638-646.

²⁹³ Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010.

²⁹⁴ Amy Kapczynski, Samantha Chaifetz, Zachary Katz, and Yochai Benkler, 'Addressing Global Health Inequities: An Open Licensing Approach for University Innovations' (2005) 20 (2) *Berkeley Technology Law Journal* 1031-114.

rights and stem cell research.²⁹⁵ More recently, there have been patent races between rival universities in respect of CRISPR – gene-editing technologies.²⁹⁶ There has also been emerging disputes over 3D printing and bioprinting developed by public research institutions.²⁹⁷ The USPTO has sought to encourage humanitarian innovation with its ‘Patents for Humanity’ programme – although that scheme has been marginal in dealing with access to medicines.²⁹⁸

Economist Mariana Mazzucato has highlighted that the pharmaceutical and biotechnology industries have benefitted enormously from publicly-funded blue sky research and state policies designed to facilitate commercialization.²⁹⁹ The People’s Vaccine Alliance have expressed concern that publicly-funded inventions are being exploited for private profit during the coronavirus crisis.³⁰⁰ Anna Marriott, Oxfam’s Health Policy Manager, commented: ‘These vaccines were funded by public money and should be first and foremost a global public good,

²⁹⁵ Matthew Rimmer, ‘The Attack Of The Clones: Patent Law And Stem Cell Research’ (2003) 10 (4) *Journal Of Law And Medicine* 488-505; and Matthew Rimmer, ‘The Last Taboo: Patenting Human Beings’ (2004) 14 (7) *Expert Opinion on Therapeutic Patents* 1061-1074.

²⁹⁶ Jacob Sherkow, ‘The CRISPR Patent Landscape: Past, Present, and Future’ (2018) 1 (1) *The CRISPR Journal* <https://www.liebertpub.com/doi/full/10.1089/crispr.2017.0013#.Wq8F65HDyKI.twitter>; Jennifer Doudna and Samuel Sternberg, *A Crack in Creation: Gene Editing and the Unthinkable Power to Control Evolution*, Boston and New York: Mariner Books/ Houghton Mifflin Harcourt Publishing Company, 2018; Henry Greely, *CRISPR People: The Science and Ethics of Editing Humans*, Cambridge (MA): MIT Press, 2021; and Walter Isaacson, *The Code Breaker: Jennifer Doudna, Gene Editing, and the Future of the Human Race*, New York: Simon & Schuster 2021.

²⁹⁷ Matthew Rimmer, ‘Make and Share: Intellectual Property, Higher Education, Technology Transfer, and 3D Printing in a Global Context’, in Jacob Rooksby (ed.), *Research Handbook on Intellectual Property and Technology Transfer*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2020, 447-479.

²⁹⁸ United States Patent and Trademark Office, ‘Patents for Humanity: COVID-19’, <https://www.uspto.gov/ip-policy/patent-policy/patents-humanity-covid-19>. For a critical evaluation of the scheme, see Matthew Rimmer, ‘Patents for Humanity’ (2012) 3 (2) *The World Intellectual Property Organization WIPO Journal* 196-221.

²⁹⁹ Mariana Mazzucato and Giovanni Dosi (ed.), *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, Cambridge and New York: Cambridge University Press, 2006; and Mariana Mazzucato, *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*, London and New York: Anthem Press, 2014,

³⁰⁰ Oxfam International, ‘COVID Vaccines Create 9 New Billionaires with Combined Wealth Greater than Cost of Vaccinating World’s Poorest Countries’, Press Release, 20 May 2021, <https://www.oxfam.org/en/press-releases/covid-vaccines-create-9-new-billionaires-combined-wealth-greater-cost-vaccinating>

not a private profit opportunity.’³⁰¹ She emphasized: ‘We need to urgently end these monopolies so that we can scale up vaccine production, drive down prices and vaccinate the world.’³⁰²

A. United States

The student-based group Universities Allied for Essential Medicines (UAEM) was established in 2001 in order to advocate flexible licensing in respect of publicly-funded humanitarian research.³⁰³ It helped convince Yale University and Bristol-Myers Squibb to permit generic production of a HIV-AIDS drug. Since this early victory, UAEM has grown into a worldwide student organization, which asks universities to promote global access to their inventions.

Given the public investment in respect of COVID-19 technologies, there has been much debate as to whether such research should be made publicly accessible and available. UAEM have been mapping public investment in COVID-19 technologies.³⁰⁴ The organization has called upon public research institutions to ‘free the vaccine.’³⁰⁵

Klara Lou – a member of UAEM from Vanderbilt University – wrote a stirring op-ed about the need for universities to commit to free the vaccine.³⁰⁶ She stressed: ‘As a student, I believe that our universities have the opportunity and great responsibility to increase universal access to crucial medicines such as the COVID-19 vaccine, especially since the research is done in our own labs.’³⁰⁷ Klara Lou argued: ‘To do this, universities have the power to influence pricing with their research choices, and we can reform the American research and development (R&D) pipeline from within our institutions.’³⁰⁸ She stressed: ‘We, the students, must speak up through

³⁰¹ Ibid.

³⁰² Ibid.

³⁰³ Universities Allied for Essential Medicines, <https://uaem.org/>

³⁰⁴ Universities Allied for Essential Medicines, ‘Tracking COVID-19 Investment,’ <https://www.publicmeds4covid.org/>

³⁰⁵ Ibid.

³⁰⁶ Klara Lou, ‘Dear Vanderbilt, Commit to A Free Vaccine’, *Vanderbilt Hustler*, 15 July 2020, <https://vanderbilthustler.com/33236/featured/guest-editorial-dear-vanderbilt-commit-to-a-free-vaccine/>

³⁰⁷ Ibid.

³⁰⁸ Ibid.

our actions for the #FreeTheVaccine movement.’³⁰⁹ She urged universities ‘to choose people over profits and make its intellectual property available for free in order to treat as many people and end the pandemic as quickly as possible.’³¹⁰

Navya Dasari, a 23-year-old student at the New York University School of Law and UAEM member, explained about the campaign: ‘We’re serious about the cause, we demand a seat at the table, and we have the knowledge and research to back our ideas up’.³¹¹ She said: ‘The lives of my loved ones abroad matter as much as the life of any American.’³¹² Dasari commented: ‘Although rich countries are getting vaccinated more quickly, the message of this pandemic remains true: None of us are safe until all of us are safe.’³¹³

UAEM have campaigned vigorously for universities and research institutions to better transfer their technologies to combat global public health challenges – like the coronavirus.³¹⁴

The University of California developed university licensing guidelines to support humanitarian efforts in respect of sustainable development goals in respect of public health, clean water, food security, and renewable energy.³¹⁵

Stanford University and a number of other universities have engaged in public sector licensing of intellectual property for the purpose of making products to prevent, diagnose, and treat

³⁰⁹ Ibid.

³¹⁰ Ibid.

³¹¹ Jacqui Germain, ‘Vaccine Nationalism: What Is It and How Is It Playing Out During COVID-19’, *Teen Vogue*, 6 May 2021, <https://www.teenvogue.com/story/vaccine-nationalism-what-is>

³¹² Ibid.

³¹³ Ibid.

³¹⁴ Ed Silverman, ‘Most U.S. Universities Get an “F” on Ensuring Access to Drugs They Discover’, *STAT*, 30 March 2021, <https://www.statnews.com/pharmalot/2021/03/30/universities-covid19-patents-drug-prices-clinical-trials/>

³¹⁵ Goldie Blumenstyk, ‘Graduate Students Press for “Humanitarian Licensing” Vow in U. of California Patent Policy’, *The Chronicle of Higher Education*, 14 December 2011, <https://www.chronicle.com/article/graduate-students-press-for-humanitarian-licensing-vow-in-u-of-california-patent-policy/> and University of California, ‘University Licensing Guidelines’, 2012, https://www.ucop.edu/research-policy-analysis-coordination/_files/licensing_guidelines_2012.pdf

COVID-19 during the pandemic.³¹⁶ The COVID-19 Technology Access Framework declares: ‘We are committed to implementing COVID-19 patenting and licensing strategies that are consistent with our goal of facilitating rapid global access’.³¹⁷ The COVID-19 Technology Access Framework explains: ‘For most types of technologies, this includes the use of rapidly executable non-exclusive royalty-free licenses to intellectual property rights that we have the right to license, for the purpose of making and distributing products to prevent, diagnose and treat COVID-19 infection during the pandemic and for a short period thereafter’.³¹⁸ The COVID-19 Technology Access Framework elaborates: ‘In return for these royalty-free licenses, we are asking the licensees for a commitment to distribute the resulting products as widely as possible and at a low cost that allows broad accessibility during the term of the license.’³¹⁹ The initial signatories included Stanford University, Harvard University, and the Massachusetts Institute of Technology. Additional signatories included the Broad Institute, Cornell University, Dartmouth University, Drexel University, Mississippi State University, Ohio State University, Oregon State University, Virginia Commonwealth University, Yale University, and a range of other universities.

In a letter to the United States Government, Knowledge Ecology International have argued that the United States Government should make use of its powers under the *Bayh-Dole Act* to ensure access to patents on coronavirus relevant inventions.³²⁰ The civil society organization has highlighted powers in respect march-in-rights on federally funded inventions; a global royalty free right in patents; the ability to retain title to contractor patents; and the capacity to assign rights in patents to the World Health Organization and other entities. The National Institutes of Health has responded to Knowledge Ecology International’s letter, observing: ‘The NIH will

³¹⁶ Stanford Office of Technology Licensing, ‘COVID-19 Technology Access Framework’, Stanford University, <https://otl.stanford.edu/covid-19-technology-access-framework>

³¹⁷ Ibid.

³¹⁸ Ibid.

³¹⁹ Ibid.

³²⁰ James Love, ‘Three Areas in Section 202 of the Bayh-Dole Act that Require Action to Ensure Sufficient Rights in Patents on Coronavirus Relevant Inventions’, Knowledge Ecology International, 14 March 2020, <https://www.keionline.org/32364>

consider the use of all its authorities, including the ones you identified, to hasten the goal of identifying safe and effective technologies to treat and prevent COVID-19 infections.’³²¹

Professor Jorge Contreras has observed that the United States Government has been reluctant to invoke its march-in-rights under the *Bayh-Dole Act*, and the provisions are limited in their scope: ‘Notwithstanding these drawbacks, march-in rights under the Bayh-Dole Act could be valuable tools to lift patent barriers that may currently impede the supply of goods and services needed to fight coronavirus.’³²² The economist Mariana Mazucatto has lamented: ‘And even though there are march-in rights under the *Bayh-Dole Act*, which allowed publicly financed research to be patented, unfortunately the NIH seems not to be interested in using them effectively.’³²³

Public Citizen have been concerned about the investment of the Trump administration into vaccines – without attaching conditions ensuring public access:

To varying degrees, the public has helped fund new ways of designing vaccines (“platform technologies”). These technologies are now being used to develop COVID-19 vaccines, with significant taxpayer support each step along the way. The public is paying for research, development, and manufacturing—with no strings attached. More funding is imminent. Yet unless the government requires these corporations to make these vaccines essentially public goods, a proven vaccine may not reach everyone who needs it.³²⁴

Public Citizen have conducted a number of case studies of companies which have received United States Government public funding for work on COVID-19 vaccines, treatments, and diagnostics.

³²¹ Mark Rohrbaugh, ‘Letter Concerning Section 202 of the Bayh-Dole Act and the Novel Coronavirus Pandemic’, National Institutes of Health, 6 April 2020, https://www.keionline.org/wp-content/uploads/NIH_Response_to_KEI_Azar_Bayh_Dole_Coronavirus_Letter_6April2020.pdf

³²² Jorge Contreras, ‘Patents and Coronavirus – Compulsory Licensing, Government Use and March-In Rights’, *InfoJustice*, 28 March 2020, <http://infojustice.org/archives/42184>

³²³ Mariana Mazzucato, *Mission Economy: A Moonshot Guide to Changing Capitalism*, New York: Harper Business, 2021, 83 (ebook).

³²⁴ Zain Rivzi, ‘The People’s Vaccine’, June 2020 (last updated), <https://www.citizen.org/article/the-peoples-vaccine/>

Some companies such as Moderna have given no guarantees that they will not seek to profit from vaccines.³²⁵ In particular, Public Citizen has highlighted that the Moderna vaccine was the result of public investment in the research of the National Institutes of Health (NIH).³²⁶ Peter Maybarduk, director of Public Citizen’s Access to Medicines program, observed:

This is the people’s vaccine. The NIH’s vaccine. It is not merely Moderna’s vaccine. Federal scientists helped invent it and taxpayers are funding its development. We all have played a role. It should belong to humanity.³²⁷

He argued that the United States Government should ‘make this vaccine a public good that is free and available to all and help scale up global manufacturing, in order to prevent medical rationing that could become a form of global vaccine apartheid.’³²⁸

Barney Graham, one of the US NIH scientists who invented a key piece of technology used in the Moderna and BioNTech/Pfizer vaccines, said that the government’s patent gave the Biden administration leverage over manufacturers.³²⁹ He observed: ‘Virtually everything that comes out of the government’s research labs is a non-exclusive licensing agreement so that it doesn’t get blocked by any particular company.’³³⁰ Graham noted: ‘That’s one of the reasons [I joined the NIH]: it’s to be able to use the leverage of the public funding to solve public health issues.’³³¹ It remains to be seen whether the Biden Administration will use this patent power to secure to better production and distribution of these key vaccines.

B. United Kingdom

³²⁵ Katherine J. Wu, ‘Some Vaccine Makers Say They Plan to Profit From Coronavirus Vaccine’, *The New York Times*, 21 July 2020, <https://www.nytimes.com/2020/07/21/health/covid-19-vaccine-coronavirus-moderna-pfizer.html>

³²⁶ Public Citizen, ‘Moderna Vaccine Belongs to the People’, Press Release, 16 November 2020, <https://citizen.org/news/statement-moderna-vaccine-belongs-to-the-people/>

³²⁷ Ibid.

³²⁸ Ibid.

³²⁹ Donato Paolo Mancini and Kiran Stacey, ‘Vaccine Patent Gives US “Leverage” Over Manufacturers’, *Financial Times*, 21 April 2001, <https://www.ft.com/content/d0c70cc2-0ffa-42dd-b0d0-0f76eeb273f0>

³³⁰ Ibid.

³³¹ Ibid.

In the United Kingdom, Oxford University played a key role in the development of what has become known as the Oxford AstraZeneca vaccine.³³² Oxford University vowed that ‘the default approach of the University and [Oxford University Innovation] ... will be to offer non-exclusive, royalty-free licences to support free of charge, at-cost or cost + limited margin supply as appropriate, and only for the duration of the pandemic, as defined by the WHO.’³³³ Nonetheless, urged on by the Bill & Gates Foundation, Oxford University entered into an exclusive vaccine deal with Astra Zeneca.³³⁴

There has been an anguished debate over the decision of Oxford University to develop its vaccine with AstraZeneca – given the implications that choice has had for the production and distribution of the COVID-19 vaccine. Christopher Garrison has provided a briefing note on the transformation of the Oxford COVID-19 vaccine into the AstraZeneca COVID-19 Vaccine.³³⁵ He reflects: ‘Rather than being a simple story of a non-profit academic research institute handing over its vaccine candidate to a ‘Big Pharma’ firm, ... there are a number of other non- and for-profit parties involved, including Vaccitech and OSI.’³³⁶ Garrison notes: ‘It is unsurprising that the lines between the Jenner Institute (Oxford University) and Vaccitech are blurred given that Sarah Gilbert and Adrian Hill are both leading investigators in the former as well as co-founders (and ~5% shareholders) of the latter.’³³⁷ Garrison suggests that ‘the operation of Consortium B during the pandemic may perhaps be a forerunner pointing to the development of new R&D coalitions and funding models that could serve humanity long beyond the Covid-19 pandemic.’³³⁸

³³² Sarah Gilbert and Catherine Green, *Vaxxers: The Inside Story of the Oxford AstraZeneca Vaccine and the Race against the Virus*, London: Hodder & Stoughton, 2021.

³³³ Oxford University Innovation, ‘Expedited Access for COVID-19 Related IP’, <https://innovation.ox.ac.uk/technologies-available/technology-licensing/expedited-access-covid-19-related-ip/>

³³⁴ Jay Hancock, ‘Oxford’s COVID vaccine deal with AstraZeneca raises concerns about access and pricing’, *Fortune*, 24 August 2020, <https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/>

³³⁵ Christopher Garrison, ‘How the “Oxford” COVID-19 Vaccine Became the “AstraZeneca” COVID-19 Vaccine’, *Medicines Law & Policy*, October 2020, <https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf>

³³⁶ *Ibid.*, 12.

³³⁷ *Ibid.*, 12.

³³⁸ *Ibid.*, 16.

However, others have been critical of Oxford's COVID19 vaccine deal with AstraZeneca.³³⁹ Ameet Sarpatwari, an epidemiologist and lawyer at Harvard Medical School, regretted that 'it is business as usual, where the manufacturers are getting exclusive rights and we are hoping on the basis of public sentiment that they will price their products responsibly.'³⁴⁰ Professor Duncan Matthews also lamented the secrecy surrounding such public-private partnerships: 'The biopharma industry is applying old rules of commercial confidentiality in a situation that is unprecedented.'³⁴¹

In the United Kingdom, a number of legislators have questioned why publicly funded vaccines have not been publicly licensed. On behalf of a bevy of politicians, Dr Philippa Whitford MP wrote to the Prime Minister Boris Johnson and relevant ministers, emphasizing: 'The government needs to impose public interest conditions on all UK funding committed to develop COVID-19 vaccines and treatments to ensure widespread access and transparency.'³⁴² She also commented that 'conditions should include full transparency in all stages of R&D, including registration and public reporting of clinical trial data, R&D costs, manufacturing costs and product prices.'³⁴³ Whitford also called for transparency in respect of public funding agreements: 'Any contracts agreed with companies and partners using public funds should also be made publicly available.'³⁴⁴ She stressed: 'We need to use global governance mechanisms to ensure equitable distribution and supply of health technologies according to public health need.'³⁴⁵

C. European Union

³³⁹ Jay Hancock, 'Oxford's COVID Vaccine Deal with AstraZeneca raises Concerns about Access and Pricing', *Fortune*, 24 August 2020, <https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/>

³⁴⁰ Ibid.

³⁴¹ Ibid.

³⁴² The Hon. Philippa Whitford MP, 'Equitable Access to COVID-19 Diagnostics, Vaccines and Treatments', the All-Parliamentary Group for Vaccines for All, House of Commons, April 2020, <https://stopaids.org.uk/wp-content/uploads/2020/04/Equitable-access-to-COVID-19-diagnostics-vaccines-and-treatments-1-1.pdf>

³⁴³ Ibid.

³⁴⁴ Ibid.

³⁴⁵ Ibid.

The European Union has made extensive investments in vaccine development for COVID-19.³⁴⁶

The European Parliament has observed that ‘vaccines are a textbook case where huge positive externalities require them to be treated as global public goods and to be provided for free; whereas in developed countries, all citizens are getting free vaccines.’³⁴⁷ The European Parliament noted that ‘huge amounts of private and public funds and resources have been invested in research and development, clinical trials and procurement in order to develop vaccines and COVID-19 treatments in an open and accessible way.’³⁴⁸ The European Parliament also observed that ‘private and public sector research, health institutions, frontline workers, scientists, researchers and patients have all gathered information on the virus, which pharmaceutical companies have utilized.’³⁴⁹ Samira Rafaela – a Dutch member of the European Parliament – has been an eloquent advocate for the need for access to essential medicines and the adoption of the TRIPS Waiver.³⁵⁰

D. Australia

³⁴⁶ European Commission, ‘EU Research and Innovation Supporting Vaccine Development for COVID-19’, February 2021, https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_cc-vaccine-development_factsheet.pdf

³⁴⁷ European Parliament, *Meeting the Global COVID-19 Challenge: Effects of Waiver of the WTO TRIPS Agreement on Covid-19 Vaccines, Treatment, Equipment and Increasing Production and Manufacturing Capacity in Developing Countries*. 10 June 2021, 2021/2692 (RSP), P9_TA(2021)0283, https://www.europarl.europa.eu/doceo/document/TA-9-2021-0283_EN.html

³⁴⁸ Ibid.

³⁴⁹ Ibid.

³⁵⁰ Samira Rafaela, ‘Plenary Speech on COVID-19 Challenge’, European Parliament, 19 May 2021, <https://www.youtube.com/watch?v=DDbIUSsHF44>

There was also discussion about the terms of the partnership for an Australian vaccine effort led by the University of Queensland, which was ultimately unsuccessful.³⁵¹ In the end, this vaccine project did not proceed further.³⁵²

During the coronavirus crisis, there has been regret about the past privatization of the Commonwealth Serum Laboratories (CSL) – as that has meant that Australia has lacked a key public facility for local vaccine production and dissemination.

The Australian Greens have called for the establishment of a public pharmaceutical company to develop life-saving vaccines.³⁵³ In Queensland, the Australian Greens would establish a Queensland Public Pharmaceutical Company that would: ‘(1) Focus on crucial research and production of vaccines, antibiotics, drugs and other supplies that private pharmaceutical corporations deem unprofitable, including potential future coronavirus vaccines; (2) Work with universities and public medical research teams to produce new drugs, keeping the benefits, revenue and jobs in Queensland; and (3) Produce cheap generic drugs as an alternative supply for Queensland Health, reducing the amount of public money that goes into the pockets of private pharmaceutical corporations.’³⁵⁴ The Australian Greens contend that such a public pharmaceutical company ‘would reduce drug costs for Queensland Health, produce life saving vaccines and antibiotics, and develop the state’s capacity to rapidly produce crucial vaccines in the future.’³⁵⁵ This is an interesting model to realise a People’s Vaccine in Australia.

VII. Patent Pledges, Open Licensing, and Open Innovation

A. Patent Pledges

³⁵¹ The University of Queensland, ‘COVID-19 Vaccine Agreement: UQ and CEPI partner with CSL to Advance COVID-19 Vaccine’, Press Release, 5 June 2020, <https://stories.uq.edu.au/news/2020/covid-19-vaccine-agreement/index.html>

³⁵² Jess Rendall and Lily Nothling, ‘Cancellation of University of Queensland's COVID-19 vaccine trial 'reassuring'', *ABC News*, 12 December 2020, <https://www.abc.net.au/news/2020-12-12/coronavirus-queensland-vaccine-uq-trial-cancellation-setback/12973724>

³⁵³ Queensland Greens, ‘Public Pharmaceutical Company’, <https://greens.org.au/qld/publicpharma>

³⁵⁴ Ibid.

³⁵⁵ Ibid.

A group of researchers, scientists, and lawyers developed the Open COVID Pledge to help companies make their ‘intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease.’³⁵⁶ Such patent pledges enable scientists and researchers to have the freedom to work on their research, without fear of patent infringement actions.

Professor Jorge Contreras has been a key researcher in respect of patent pledges.³⁵⁷ He has been one of the architects of the Open COVID Pledge. He has also highlighted the importance of identifying intellectual property available under the Open COVID Pledge.³⁵⁸ Contreras and his collaborators have made a case for the adoption of voluntary pledges made by patent holders in respect of COVID-19 technologies.³⁵⁹ They contend: ‘Such pledges — temporary in duration and narrow in scope — can enable critical public health research and manufacturing of crisis-critical products, while preserving for their owners the prospect of financial rewards and influence over markets after the pandemic ends.’³⁶⁰ Contreras and his collective of collaborators claim that patent pledges will be an efficient mechanism: ‘By the same token, such pledges are lightweight and efficient, avoiding the administrative, legal and political delays that have hindered previous pooling proposals in response to public health emergencies.’³⁶¹

Professor Mark Lemley of Stanford Law School observed: ‘Companies might be reluctant to do this if they thought they were the only ones, so the commitment provides a way for universities and companies to feel comfortable that they are not alone.’³⁶² He was hopeful that the scheme would boost co-operation and collaboration:

³⁵⁶ Open COVID-19 Pledge <https://opencovidpledge.org/>

³⁵⁷ Jorge L. Contreras and Meredith Jacob, eds., *Patent Pledges: Global Perspectives On Patent Law’s Private Ordering Frontier*, Cheltenham and Northampton (MA): Edward Elgar, 2017.

³⁵⁸ Jorge Contreras, ‘Putting Pledged IP to work - Identifying IP available under the Open COVID Pledge’, *InfoJustice*, 12 June 2020, <http://infojustice.org/archives/42399>

³⁵⁹ Jorge Contreras, Michael Eisen, Ariel Ganz, Mark Lemley, Jenny Molloy, Diane Peters and Frank Tietze, ‘Pledging Intellectual Property for COVID-19’ (2020) 38 *Nature Biotechnology* 1146-1149.

³⁶⁰ Ibid.

³⁶¹ Ibid.

³⁶² Sharon Driscoll, ‘Stanford’s Mark Lemley on Effort to Make IP Available to End COVID-19 Pandemic’, Stanford Law School, 1 April 2020, <https://law.stanford.edu/2020/04/01/stanfords-mark-lemley-on-call-to-make-ip-available-to-end-covid-19-pandemic/>

Our aim is to boost cooperation and make IP widely available to end the coronavirus pandemic. Companies, institutions, and universities would give free licenses to their patents, copyrights and certain other property rights to anyone developing technologies for the diagnosis, prevention, or treatment of COVID-19, the disease caused by the new coronavirus. These licenses would last until a year after the World Health Organization has declared the coronavirus pandemic to be over. This is not a permanent grant of rights, but a temporary measure to make sure that we aren't restricting research, testing, or treatment during the pandemic.³⁶³

Lemley noted: 'The pledge prevents them from being sued for things they do during the pandemic.'³⁶⁴ He commented: 'Once things return to normal, we hope companies will work together to come up with commercially reasonable license terms, but they can go back to owning and asserting their Intellectual Property.'³⁶⁵ Stanford Postdoctoral student Ariel Ganz also played a part in the development of the Open COVID Pledge.³⁶⁶

A range of information technology companies – including HP Enterprise, Intel, IBM, Amazon, Facebook, Uber, AT&T, Fujitsu, Seagate Technology, and SAP – have taken up the pledge thus far.³⁶⁷ Public research organisations such as NASA's Jet Propulsion Laboratory, Sandia National Laboratories and the New Jersey Institute Technology have joined the Open COVID Pledge. There has been a concern that pharmaceutical drug companies, biotechnology developers, and medical device companies have not participated in the Open COVID Pledge.

Diane Peters of the Creative Commons has been a key contributor to the development of the Open COVID Pledge.³⁶⁸ The Creative Commons played a leadership role in taking over the

³⁶³ Ibid.

³⁶⁴ Ibid.

³⁶⁵ Ibid.

³⁶⁶ Hanae Armitage, 'Stanford Postdoc Ariel B Ganz helps to Spearhead Movement to Free Patented Technology for COVID-19 Fight', *Stanford Medicine*, 5 October 2020, <https://scopeblog.stanford.edu/2020/10/05/stanford-postdoc-helps-to-spearhead-movement-to-free-patented-technology-for-covid-19-fight/>

³⁶⁷ Creative Commons, 'Tech Giants - Amazon, Facebook, Hewlett Packard Enterprise, IBM, Microsoft, and Sandia National Laboratories - Join the CC-Supported Open COVID IP Pledge', Press Release, 20 April 2020, <https://creativecommons.org/2020/04/20/tech-giants-join-the-cc-supported-open-covid-pledge/>

³⁶⁸ Diane Peters, *Open Source Development Labs, Understanding Patent Pledges: an Overview of Legal Considerations*, 2006, https://patentcommons.org/publications/OSDL_Whitepaper_Final_final_4-12-06.pdf

management of the Open COVID Pledge during 2020.³⁶⁹ Diane Peters has sought to internationalise the Open COVID Pledge – translating the Pledge into all six of the official languages of the United Nations.³⁷⁰ Diane Peters has discussed the Open COVID Pledge on the ABC on Science Friction.³⁷¹ In May 2021, the American University assumed the stewardship of the Open COVID Pledge.³⁷²

B. Open Science

There has also been much interest in models of open science – open access, open medicine, and open data. Sean Flynn, Aidan Hollis, and Mike Palmedo argued that there was a compelling economic justification for open access to essential medicine patents in developing countries.³⁷³ Professor Ginny Barbour has discussed the importance of open access publishing during the coronavirus crisis.³⁷⁴ Krishna Ravi Srinivas been an advocate of open source approaches in relation to biotechnology and medicine.³⁷⁵ He has recommended that ‘India should promote

³⁶⁹ Diane Peters, and Eric Steuer, ‘Creative Commons is Now Leading the Open COVID Pledge – Here’s What That Means’, Creative Commons, 27 August 2020, <https://creativecommons.org/2020/08/27/cc-ocp/>

³⁷⁰ Diane Peters, ‘Internationalizing the Open COVID Pledge: Translations and Outreach’, Open COVID Pledge, 15 October 2020, <https://opencovidpledge.org/2020/10/15/internationalizing-the-open-covid-pledge-translations-and-outreach/>

³⁷¹ Natasha Mitchell, ‘The Rise of Vaccine Nationalism – Should We Be Worried?’, Science Friction, ABC Radio National, 6 September 2020, <https://abc.net.au/radionational/programs/sciencefriction/12630076>

³⁷² American University Washington College of Law, ‘Program on Information Justice and Intellectual Property Assumes Stewardship of the Open COVID Pledge’, April 2021, <https://www.wcl.american.edu/impact/initiatives-programs/pijip/news/pijip-assumes-stewardship-of-the-open-covid-pledge/>

³⁷³ Sean Flynn, Aidan Hollis, and Mike Palmedo, ‘An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries’ (2009) 37 (2) *Journal of Law, Medicine, and Ethics* 184-208.

³⁷⁴ Ginny Barbour, ‘How Open Access Suddenly Became the Norm’, Intellectual Property and Education in the Age of COVID-19’, QUT Faculty of Law, Wednesday, 29 July 2020 https://www.youtube.com/watch?v=_SueRnB0uCQ

³⁷⁵ Krishna Ravi Srinivas, ‘Intellectual Property Rights and Bio Commons: Open Source and Beyond’ (2006) 59 (188) *International Social Science Journal* 319-334; and Krishna Ravi Srinivas, ‘Open Source Drug Discovery: A Revolutionary Paradigm or a Utopian Model?’, in Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010, 263-283.

open innovation and open source drug discovery.’³⁷⁶ Amy Kapczynski has called for the establishment of an open science model to engage in research and development in respect of influenza.³⁷⁷ Open source advocates such as Professor Joshua Pearce have advocated the use of open licensing in respect of COVID-19 technologies.³⁷⁸ Henry Chesbrough has advocated open innovation models for the COVID-19 response and recovery.³⁷⁹

There has been a joint appeal for open science by a number of international organisations – including CERN, OHCHR, UNESCO, and WHO.³⁸⁰ The joint call emphasized the importance of open access to knowledge: ‘Worldwide people need States, international bodies, science and medical institutions and practitioners to ensure the broadest possible sharing of scientific knowledge, and the broadest possible access to the benefits of scientific knowledge.’³⁸¹ The joint call also insisted upon the principle of benefit-sharing: ‘The pandemic also gives new importance to the need to ensure non-discriminatory access to the benefits of science – such as any COVID-19 treatments and vaccines.’³⁸² The joint statement highlighted the importance of access to essential medicines: ‘Under international human rights law, States have a clear obligation to ensure international cooperation and access to a vaccine.’³⁸³ The joint call also emphasized the importance of health for all: ‘Everyone, including vulnerable or marginalised individuals and groups, is entitled to enjoy the benefits of scientific progress –

³⁷⁶ Krishna Ravi Srinivas, *Intellectual Property Rights and Innovation in the Times of Corona Epidemic*. RIS Policy Brief no. 89. Research and Information Systems for Developing Countries. April 2020. <http://infojustice.org/wp-content/uploads/2020/04/RaviSrinivas.pdf>

³⁷⁷ Amy Kapczynski, ‘Order without Intellectual Property Law: Open Science in Influenza’, (2017) 102 *Cornell Law Review* 1539-1648, <https://scholarship.law.cornell.edu/clr/vol102/iss6/3>

³⁷⁸ Joshua Pearce, ‘Distributed Manufacturing of Open-Source Medical Hardware for Pandemics’, (2020) 4 (2) *Journal of Manufacturing and Materials Processing* 49 <https://www.mdpi.com/2504-4494/4/2/49>

³⁷⁹ Henry Chesbrough, ‘To Recover Faster from Covid-19, Open Up: Managerial Implications from an Open Innovation Perspective’ (2020) 88 *Industrial Marketing Management* 410-413.

³⁸⁰ Michelle Bachelet, ‘A Joint Appeal for Open Science by CERN, OHCHR, UNESCO, and WHO’, Office of the Higher Commissioner for Human Rights, United Nations, 27 October 2020, <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26433&LangID=E>

³⁸¹ Ibid.

³⁸² Ibid.

³⁸³ Ibid.

and when the benefits of science are managed as a purely commercial product reserved for the wealthy, everyone is harmed.’³⁸⁴

The People’s Vaccine Alliance has perceived open licensing as a means of encouraging the open sharing of technology, intellectual property, and data.³⁸⁵

C. Open Innovation

Professor Richard Gold from McGill University has said that the coronavirus pandemic has shattered the status quo on drug development.³⁸⁶

Jeremy de Beer and Richard Gold have discussed the nexus of intellectual property, innovation policy, and international trade in respect of the coronavirus COVID-19 pandemic.³⁸⁷ The researchers commented:

This COVID-19 stimulated move away from proprietary science— in which we patent everything and keep it secret until we do— to open science—where we do not clog up the system and do share research outcomes, data, materials, and tools —reflects a longer-term dissatisfaction over drug and vaccine development generally: drugs are increasingly expensive to develop, and our investments are producing less and less. This is a global problem; one that Canada can only address in coordination with the international community.³⁸⁸

The researchers argued that ‘Canada should seize this chance to rethink the role of intellectual property acquisition vis-à-vis other domestic and international policy levers.’³⁸⁹ The

³⁸⁴ Ibid.

³⁸⁵ Oxfam America, ‘COVID-19: We Need A People’s Vaccine’, <https://www.oxfamamerica.org/explore/emergencies/covid-19-peoples-vaccine/>

³⁸⁶ Richard Gold, ‘The Coronavirus Pandemic Has Shattered the Status Quo on Drug Development. We Should Build on That’, *Fortune*, 26 March 2020, <https://fortune.com/2020/03/26/coronavirus-vaccine-drug-development-open-science-covid-19-treatment/>

³⁸⁷ Jeremy de Beer, and Richard Gold, ‘International Trade, Intellectual Property, and Innovation Policy: Lessons from a Pandemic’ in Colleen Flood, Vanessa MacDonnell, Jane Philpott, Sophie Theriault, and Sridhar Venkatapuram (ed.), *Vulnerable: The Law, Policy and Ethics of COVID-19*, Ottawa: the University of Ottawa, 2020, 579-589.

³⁸⁸ Ibid., 586.

³⁸⁹ Ibid., 589.

researchers concluded: ‘With a more nuanced approach to intellectual property and greater emphasis on open science, Canada can emerge from this pandemic with a healthier biomedical innovation ecosystem to fight or, better, prevent the next one.’³⁹⁰

In a report for the Royal Society Canada, Richard Gold and his collaborators have called for the Open Drug Discovery of Anti-Virals Critical for Canada’s Pandemic Strategy.³⁹¹ They have recommended that Canada should develop ‘a flexible, open and stable non-profit, virtual drug discovery entity that coordinates and invests in a pipeline for the proactive development of anti-viral drugs (and possibly vaccines) for viruses with pandemic potential.’³⁹² The researchers envisage: ‘The independent, non-profit should be provided with long-term, stable funding to insulate it from day-to-day politics.’³⁹³ The researchers maintain: ‘The non-profit and Canada’s pandemic innovation preparedness ought to be embedded in an international, open, effort to coordinate R&D of new products, such as the international environments in which the SGC and DNDi operate.’³⁹⁴ The researchers emphasize that ‘funding councils and other funding bodies ought to establish specific open science calls, with significant funding.’³⁹⁵

The researchers observed that ‘Governments, granting councils and philanthropies ought to establish funding to collect data on and analyse open science partnerships both in Canada and internationally to assess their impact, costs and barriers to use.’³⁹⁶ The researchers suggested that ‘all government or quasi-government grants or contracts supporting pandemic-related research ought to impose requirement of no patenting of research results and rapid dissemination of data and results in accordance with FAIR principles.’³⁹⁷ In their view, ‘Philanthropies ought to prioritize pandemic-related research projects that are open and eschew

³⁹⁰ Ibid., 589.

³⁹¹ Tania Bubela, Aled Edwards, Richard Gold, Vivek Goel, Max Morgan, Karen Mossman, Jason Nickerson, and David Patrick, *Open Drug Discovery of Anti-Virals Critical for Canada’s Pandemic Strategy*, Ottawa: Royal Society of Canada, 2020, <https://mcgill.ca/x/4Kg>

³⁹² Ibid., 4.

³⁹³ Ibid., 4.

³⁹⁴ Ibid., 4.

³⁹⁵ Ibid., 4.

³⁹⁶ Ibid., 5.

³⁹⁷ Ibid., 5.

patents.’³⁹⁸ The report contends: ‘Canada ought to take a leadership role in advancing open science partnerships.’³⁹⁹ The report observes: ‘Canada ought to lead the world in open science policymaking, for example, by supporting Health Canada (and/or other regulators) to implement regulatory mechanisms that encourage open science drug development.’⁴⁰⁰

VIII. The TRIPS Waiver

The People’s Vaccine Alliance has been a champion of the TRIPS Waiver – given that such an approach would enable the open production and distribution of vaccines, treatments, diagnostics, and health equipment as global public goods during the coronavirus crisis.⁴⁰¹

A. The TRIPS Waiver

In 2020, India and South Africa have called for a waiver of parts of the *TRIPS Agreement* 1994 to enable countries to better respond to the coronavirus COVID-19.⁴⁰² They have argued: ‘In these exceptional circumstances, we request that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the *TRIPS Agreement* in relation to prevention, containment or treatment of COVID-19.’⁴⁰³ It is worth noting Section 1 concerns copyright law; Section 4 deals with designs; Section 5 relates to patents; and Section 7 deals with confidential information. South Africa and India argued that the waiver should apply to all WTO members but would not prejudice ‘the right of least developed country Members under paragraph 1 of Article 66 of the *TRIPS Agreement*.’⁴⁰⁴ In their view, ‘The waiver should

³⁹⁸ Ibid., 5.

³⁹⁹ Ibid., 5.

⁴⁰⁰ Ibid., 5.

⁴⁰¹ Oxfam International, ‘People’s Vaccine Alliance Lauds US Decision to Break Open COVID-19 Monopolies and Urges Others to Follow US Lead’, Press Release, 6 May 2021, <https://www.oxfam.org/en/press-releases/peoples-vaccine-alliance-lauds-us-decision-break-open-covid-19-monopolies-and-urges>

⁴⁰² Governments of India and South Africa, ‘Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19’, IP/C/W/669, 2 October 2020, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> and <https://www.keionline.org/34061>

⁴⁰³ Ibid.

⁴⁰⁴ Ibid.

continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity hence we propose an initial duration of [x] years from the date of the adoption of the waiver.'⁴⁰⁵ Apparently, though, developed countries have resisted the adoption of the waiver.⁴⁰⁶

Ellen t'Hoen has discussed the importance of the TRIPS Waiver proposal.⁴⁰⁷ She noted: 'The concern is that the development of and equitable access to the tools – such as vaccines and treatments – needed to fight the pandemic could be limited by patents and other IP barriers.'⁴⁰⁸

Ellen t'Hoen suggested: 'The waiver proposal [aims to lift] the barriers posed by patents and other forms of intellectual property to local production and distribution of generic and biosimilar products.'⁴⁰⁹

In its summary of the TRIPS Council meeting, the WTO noted: 'The proponents argued that many countries - especially developing countries - may face institutional and legal difficulties when using TRIPS flexibilities, including the special compulsory licensing mechanism provided for in Article 31bis, which they saw as a cumbersome process for the import and export of pharmaceutical products.'⁴¹⁰ They observed: 'While a number of developing and least developed country members welcomed the proposal as a contribution to the discussion, many were still studying it in their capitals and asked for clarification on certain points, particularly regarding its practical implementation and the possible economic and legal impact of the waiver at national level.'⁴¹¹ The WTO commented: 'A number of developing and developed country members opposed the waiver proposal, noting that there is no indication that intellectual property rights (IPRs) have been a genuine barrier to accessing COVID-19 related

⁴⁰⁵ Ibid.

⁴⁰⁶ Ibid.

⁴⁰⁷ Ellen t'Hoen, 'COVID-19 Crisis and WTO: Why India and South Africa's Proposal on Intellectual Property is Important', *The Wire*, 12 October 2020, <https://thewire.in/law/covid-19-crisis-wto-intellectual-property-vaccine-public-health>

⁴⁰⁸ Ibid.

⁴⁰⁹ Ibid.

⁴¹⁰ WTO, 'Members Discuss Intellectual Property Response to the COVID-19 Pandemic', News Item, 20 October 2020, https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm?utm_source=dlvr.it&utm_medium=twitter

⁴¹¹ Ibid.

medicines and technologies.’⁴¹² The developed countries apparently argued: ‘The suspension of IPRs, even for a limited period of time, was not only unnecessary but it would also undermine the collaborative efforts to fight the pandemic that are already under way.’⁴¹³

Alongside South Africa and India, a large number of nations have become co-sponsors of the TRIPS Waiver.⁴¹⁴ The TRIPS Waiver has been supported by African Group, Bolivia, Egypt, Eswatini, Fiji, Indonesia, Kenya, the Least Developed Countries Group, Maldives, Mozambique, Namibia, Pakistan, Vanuatu, Venezuela, and Zimbabwe. There have been further revisions made to refine the TRIPS Waiver. India’s Prime Minister Narendra Modi has been actively lobbying other nations to support the TRIPS Waiver.⁴¹⁵

B. The United States Shift of Position on the TRIPS Waiver

The Trump Administration supported Operation Warp Speed in the United States – but was unwilling to join in multilateral discussions about collaboration over COVID-19 technologies.⁴¹⁶ There was concern that the Trump Administration adopted a ‘America First’

⁴¹² Ibid.

⁴¹³ Ibid.

⁴¹⁴ Communication from the African Group and others, ‘Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19’, World Trade Organization, 21 May 2021, IP/C/W/669/Rev.1, https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=274186,273996,273770,273787,273460,273297,271981,271520,271383,271259&CurrentCatalogueIdIndex=0&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True

⁴¹⁵ The Hindu, ‘Modi Seeks Support of G-7 Nations for TRIPS Waiver at WTO’, *The Hindu Business Line*, 13 June 2021, <https://www.thehindubusinessline.com/news/modi-seeks-support-of-g-7-nations-for-trips-waiver-at-wto/article34802793.ece>; Reuters, ‘Indian Official Says There Is Widespread Support at G7 for TRIPS Waiver at WTO’, *Reuters*, 14 June 2021, <https://www.reuters.com/world/india/indian-official-says-there-is-widespread-support-g7-trips-waiver-wto-2021-06-13/>; and Shreya Nandi, ‘India Gets Wide Support on TRIPS Waiver for COVID-19 Vaccines at G-17 Meet’, *Business Standard*, 14 June 2021, https://www.business-standard.com/article/current-affairs/india-gets-wide-support-on-trips-waiver-for-covid-19-vaccines-at-g-7-meet-121061400029_1.html

⁴¹⁶ HHS, ‘Trump Administration Announces Framework and Leadership for Operation WarpSpeed’, Press Release, 15 May 2020, <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>

approach to COVID-19 diagnostics, therapeutics, and vaccines.⁴¹⁷ There has also been a debate about the transparency and accountability of this regime.

After the ‘America First’ approach taken by the Trump administration, Progressive Democrats pressed the Biden Administration to offer support for the TRIPS Waiver.⁴¹⁸ In the House of Representatives, Democratic Representatives Rosa DeLauro (Connecticut) Jan Schakowsky (Illinois), Earl Blumenauer (Oregon) and Lloyd Doggett (Texas) were key supporters of the TRIPS Waiver. Representative Ro Khanna (California) was also vocal about the need for the United States to assist India during the coronavirus crisis.⁴¹⁹ The Speaker of the House Nancy Pelosi (California) also expressed her support for a TRIPS Waiver. In the Senate, former Presidential candidates Senator Bernie Sanders (Vermont) and Senator Elizabeth Warren (Massachusetts) – and other leading progressive Democrats - were champions of a TRIPS Waiver.⁴²⁰ Sanders and his colleagues pleaded with President Joe Biden: ‘Your Administration has the opportunity to reverse the damage done by the Trump Administration to our nation’s global reputation and restore America’s public health leadership on the world stage’.⁴²¹ The Senators implored President Joe Biden to provide support for the TRIPS Waiver: ‘To bring the pandemic to its quickest end and save the lives of Americans and people around the world, we

⁴¹⁷ Michael Lewis, *The Premonition: A Pandemic Story*, New York: WW Norton & Company, 2021; Lawrence Wright, *The Plague Year: America in the Time of COVID*, New York: Alfred A. Knopf, 2021; Andy Slavitt, *Preventable: The Inside of How Leadership Failures, Politics, and Selfishness Doomed the U.S. Coronavirus Response*, New York: St Martin’s Press, 2021; Yasmeen Abutaleb and Damian Paletta, *Nightmare Scenario: Inside the Trump Administration’s Response to the Pandemic That Changed History*, New York: Harper, 2021; and Michael Wolff, *Landslide: The Final Days of the Trump Presidency*, London: The Bridge Street Press, 2021.

⁴¹⁸ Peter Sullivan, ‘Progressives Up Pressure on Biden to Back COVID Vaccine Patent Waiver’, *The Hill*, 24 March 2021, <https://thehill.com/policy/healthcare/544620-progressives-up-pressure-on-biden-to-back-covid-vaccine-patent-waiver>

⁴¹⁹ Rep. Ro Khanna, ‘It’s Vital That The US Drop Barriers to Vaccine Production and Aid COVID-Ravaged India’, Press Release, 7 May 2021, <https://khanna.house.gov/media/in-the-news/ro-khanna-it-s-vital-us-drop-barriers-vaccine-production-and-aid-covid-ravaged>

⁴²⁰ Senator Bernie Sanders, ‘Senators Urge Biden to Approve Vaccine Patent Waiver to Boost Production and End Pandemic’, Press Release, 17 April 2021, <https://www.sanders.senate.gov/press-releases/news-senators-urge-biden-to-approve-vaccine-patent-waiver-to-boost-production-and-end-pandemic/>

⁴²¹ Ibid.

ask that you prioritize people over pharmaceutical company profits by reversing the Trump position and announcing U.S. support for the WTO TRIPS waiver.’⁴²²

The People’s Vaccine lobbied the new Biden Administration to support a TRIPS Waiver. Former Heads of State and Nobel Laureates called on President Biden to waive intellectual property rules for COVID Vaccines.⁴²³ Their letter stressed:

With your leadership, we can ensure COVID-19 vaccine technology is shared with the world. Supporting the emergency waiver of COVID-19 related intellectual property rules will give people around the globe a chance to wake up to a world free from the virus. We need a people’s vaccine. Many of us know, first-hand, the reality of political office and the pressures, challenges and constraints of leadership. However, we believe this would be an unparalleled opportunity for the U.S. to exercise solidarity, cooperation and renewed leadership, one we hope will inspire many more to do the same.⁴²⁴

The dignitaries said that Biden should ‘let this moment be remembered in history as the time we chose to put the collective right to safety for all ahead of the commercial monopolies of the few.’⁴²⁵ This broad-based social movement has been successful in shifting the position of the Biden administration.⁴²⁶

After much deliberation,⁴²⁷ the new Biden Administration has agreed to support a version of the TRIPS Waiver, which is focused on vaccines. The United States Trade Representative Ambassador Katherine Tai commented upon the decision:

⁴²² Ibid.

⁴²³ People’s Vaccine Alliance, ‘Open Letter: Former Heads of State and Nobel Laureates Call on President Biden to Waive Intellectual Property Rules for COVID Vaccines’, 15 April 2021, <https://peoplesvaccinealliance.medium.com/open-letter-former-heads-of-state-and-nobel-laureates-call-on-president-biden-to-waive-e0589edd5704>

⁴²⁴ Ibid.

⁴²⁵ Ibid.

⁴²⁶ Lev Facher and Nicholas Florke, ‘How David Beat Goliath: Advocacy Groups Seized A Moment, And Found Allies, In Bid to Loosen Vaccine Patent Rights’, *STAT*, 7 May 2021, <https://www.statnews.com/2021/05/07/how-david-beat-goliath-advocacy-groups-seized-a-moment-and-found-allies-in-bid-to-loosen-vaccine-patent-rights/>

⁴²⁷ White House Press secretary Jen Psaki said of President Joe Biden’s decision-making process on the TRIPS Waiver: ‘He’s a details guy and he wants to dig into the pros and cons and all of the considerations for any decision.’ – Patsy Widakuswara, ‘Biden Agrees to Waive COVID-19 Vaccine Patents, But It’s Still Complicated’,

This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines. We will actively participate in text-based negotiations at the World Trade Organization (WTO) needed to make that happen. Those negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved.⁴²⁸

Katharine Tai insisted: ‘The Administration’s aim is to get as many safe and effective vaccines to as many people as fast as possible.’⁴²⁹ She observed: ‘As our vaccine supply for the American people is secured, the Administration will continue to ramp up its efforts – working with the private sector and all possible partners – to expand vaccine manufacturing and distribution’.⁴³⁰ The Ambassador also said that the United States administration ‘will also work to increase the raw materials needed to produce those vaccines.’⁴³¹

The Speaker of the House Nancy Pelosi commended the Biden Administration on its decision to support a TRIPS Waiver for Vaccines.⁴³² She observed: ‘Accelerating the production and distribution of life-saving vaccines across the globe is both a moral imperative and an urgent necessity to crush the virus pandemic and prevent the spread of more virulent coronavirus

Voice of America News, 5 May 2021, <https://www.voanews.com/covid-19-pandemic/biden-agrees-waive-covid-19-vaccine-patents-its-still-complicated>. The Press Secretary has also said that President Biden has been a ‘strong proponent’ of the TRIPS Waiver - Jen Psaki, ‘Press Briefing’, The White House, 9 July 2021, <https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/09/press-briefing-by-press-secretary-jen-psaki-july-9-2021/>

⁴²⁸ United States Trade Representative, ‘Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver’, Press Release, 5 May 2021, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>

⁴²⁹ Ibid.

⁴³⁰ Ibid.

⁴³¹ Ibid.

⁴³² Speaker of the House Nancy Pelosi, ‘Statement on Biden Administration Support for Vaccine Patents Waiver at WTO’, Press Release, United States Congress, 5 May 2021, <https://www.speaker.gov/newsroom/5521-3>

variants.’⁴³³ Pelosi stressed: ‘We cannot be fully safe from the virus anywhere until we defeat it everywhere.’⁴³⁴

There were a number of countries who followed the leadership of the United States on the TRIPS Waiver. After previously being non-committal on the topic,⁴³⁵ Jacinda Ardern’s New Zealand Government said that it would support a TRIPS Waiver for vaccines.⁴³⁶ Her trade minister the Hon. Damien O’Connor observed: ‘New Zealand supports equitable access to COVID vaccines for all.’⁴³⁷ O’Connor observed: ‘No one is safe from the virus until everyone is safe from it, so it is in all our interest to remove any blocks to access and distribution of the vaccine.’⁴³⁸ The Minister commented: ‘New Zealand supports the waiver of IP protections on vaccines as an important part of our collective efforts to address the human catastrophe of the pandemic.’⁴³⁹

There were remain a clutch of countries who are non-committal about the TRIPS Waiver. The Australian Government, for instance, has been equivocal about the TRIPS Waiver in public.⁴⁴⁰

⁴³³ Ibid.

⁴³⁴ Ibid.

⁴³⁵ The Hon. Golriz Ghahraman, ‘Question to the Foreign Minister Nanaia Mahuta on the New Zealand Government’s Position on the TRIPS Waiver’, New Zealand Parliament, 24 March 2021, https://www.parliament.nz/en/pb/hansard-debates/rhr/document/HansS_20210324_051300000/10-question-no-10-foreign-affairs <https://vimeo.com/528104636>

⁴³⁶ Thomas Manch, ‘New Zealand To Support Effort to Waive COVID-19 Vaccine Patents, After United States Backs WTO Bid’, *Stuff NZ*, 6 May 2021, <https://www.stuff.co.nz/national/health/coronavirus/125048729/new-zealand-to-support-effort-to-waive-covid19-vaccine-patents-after-united-states-backs-wto-bid>

⁴³⁷ The Hon. Damien O’Connor, ‘NZ Backs Moves To Improve Global Access to COVID Vaccines’, New Zealand Government, 6 May 2021, <https://www.beehive.govt.nz/release/nz-backs-moves-improve-global-access-covid-vaccines>

⁴³⁸ Ibid.

⁴³⁹ Ibid.

⁴⁴⁰ Elias Visontay, ‘India Wants Access to Cheap Copies of Vaccines. So Why Is Australia Holding Out?’, *The Guardian*, 30 April 2021, <https://www.theguardian.com/australia-news/2021/apr/30/india-wants-access-to-cheap-copies-of-covid-vaccines-so-why-is-australia-holding-out> and Lyndal Rowlands, ‘Australia Stalls Vaccine Supply’, *The Saturday Paper*, 21 August 2021, <https://www.thesaturdaypaper.com.au/news/politics/2021/08/21/australia-stalls-vaccine-supply/162946800012311#mtr>

While expressing enthusiasm for President Joe Biden’s stance,⁴⁴¹ the Australian Government seems wary of offending the vaccine developer, Pfizer, and other biomedical companies, who are strident opponents of the TRIPS Waiver.⁴⁴² Opposition parties such as the Australian Labor Party and the Australian Greens have pressed the Coalition Government to support the TRIPS Waiver.⁴⁴³ Senator Penny Wong and her colleagues in the Australian Labor Party stressed that the need for the adoption of the TRIPS Waiver was urgent – especially given that ‘India is in the grips of a heartbreaking emergency, and Africa, with 16 per cent of the world’s population, has less than two per cent of vaccines.’⁴⁴⁴ Senator Rachel Siewert of the Australian Greens said in a speech: ‘The Morrison government should be following suit and should be contributing to the global discussion and supporting the waiver of intellectual property rights on COVID vaccines to ensure that we enable an equal distribution of the vaccines.’⁴⁴⁵ In an impassioned speech, Senator Mehreen Faruqi of the Australian Greens implored the Australian Government: ‘If you have a skerrick of decency or any sense of morality and responsibility left in you, value

⁴⁴¹ Matthew Knott and Bianca Hall, “‘Monumental Moment’: Australia Applauds US Push for Patent-Free COVID Vaccines”, *Brisbane Times*, 6 May 2021, <https://www.brisbanetimes.com.au/world/north-america/biden-administration-backs-covid-vaccines-patent-waiver-20210506-p57pal.html>

⁴⁴² Paul Karp, ‘Pfizer Warns Australia a COVID Vaccine Patent Waiver Could Harm Supply and Safety’, *The Guardian*, 13 May 2021, <https://www.theguardian.com/australia-news/2021/may/13/pfizer-warns-australia-a-covid-vaccine-intellectual-property-patent-waiver-could-harm-supply-and-safety>; and Medicines Australia, ‘Updated Position on Intellectual Property (In Light of TRIPS Waiver)’, Press Release, 6 May 2021, <https://www.medicinesaustralia.com.au/media-release/medicines-australia-updated-position-on-intellectual-property-in-light-of-trips-waiver/>

⁴⁴³ Elias Visontay, ‘Pressure Mounts on Australia to Support COVID Vaccine Intellectual Property Waiver for Developing Nations’, *The Guardian*, 6 May 2021, <https://www.theguardian.com/australia-news/2021/may/06/pressure-mounts-on-australia-to-support-covid-vaccine-intellectual-property-waiver-for-developing-nations>

⁴⁴⁴ Senator Penny Wong, Mark Butler MP, and Madeleine King MP, ‘Morrison Must Ensure Developing Nations Have Access to Vaccines’, Australian Labor Party, Press Release, 30 April 2021, <https://www.pennywong.com.au/media-hub/media-statements/morrison-must-ensure-developing-nations-have-access-to-vaccines/>

⁴⁴⁵ Senator Rachel Siewert, ‘Second Reading Speech on the Appropriation Bill (no. 3) 2020-2021 and Appropriation Bill (No. 4) 2020-2021’, Hansard, Senate, Australian Parliament, 12 May 2021, 6, <https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansards%2F5d7154b6-80d6-4733-ad27-6f37db4fb595%2F0014%22>

people's lives and provide your full-throated support to the TRIPS waiver now.’⁴⁴⁶ A number of civil society groups – including Human Rights Watch, MSF Australia, and AFTINET – have encouraged the Coalition Government to adopt the TRIPS Waiver.⁴⁴⁷ Michele O’Neil of Unions Australia commented: ‘The growing COVID-19 crisis in India shows the urgent need for a ramp up of the production of vaccines to enable equitable access to end this pandemic as quickly as possible.’⁴⁴⁸ India’s Deputy High Commissioner to Australia, Palaniswamy Subramanyan Karthigeyan, has urged Australia to support a TRIPS Waiver: ‘Given the situation we find ourselves in, time is of the greatest essence and an effective response to the pandemic requires other countries to make these products accessible, to make it equitable, to make it affordable.’⁴⁴⁹

The Liberal Government of Canada has also been rather non-committal about support the TRIPS Waiver.⁴⁵⁰ This is disappointing given that past Liberal Governments have been leaders

⁴⁴⁶ Senator Mehreen Faruqi, ‘The TRIPS Waiver’, Hansard, Senate, Australian Parliament, 24 August 2021, 38,

<https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansards%2F62d6646b-aecc-456e-9883-4d7bd089f14e%2F0105%22>

⁴⁴⁷ Sophie McNeill, ‘Australia Should Back COVID-19 Waiver of Intellectual Property Rules: Waive TRIPS Amid Delta Outbreak, Vaccine Shortages’, *Human Rights Watch*, 25 July 2021, <https://www.hrw.org/news/2021/07/25/australia-should-back-covid-19-waiver-intellectual-property-rules>; MSF Australia, ‘Australia Must Stop Stalling Negotiations On Landmark Pandemic Monopoly Waiver’, MSF Australia Press Release, 8 June 2021, <https://msf.org.au/article/statements-opinion/australia-must-stop-stalling-negotiations-landmark-pandemic-monopoly>; and Patricia Ranauld, ‘Rich Countries are First in Line for COVID-19 Vaccines Because A Handful of Companies Control the Price and Quantity’, *The Guardian*, 22 July 2021, <https://www.theguardian.com/commentisfree/2021/jul/22/rich-countries-are-first-in-line-for-covid-vaccines-because-a-handful-of-companies-control-both-the-price-and-quantity>

⁴⁴⁸ Australian Council of Trade Unions, ‘Morrison Government Continues to Oppose Vaccine IP Waiver Despite US, NZ Support’, Press Release, 6 May 2021, https://www.actu.org.au/actu-media/media-releases/2021/morrison-government-continues-to-oppose-vaccine-ip-waiver-despite-us-nz-support?utm_source=miragenews&utm_medium=miragenews&utm_campaign=news

⁴⁴⁹ Bianca Hall, Rachel Clun, and Emma Koehn, ‘Australia Accused of Delaying Campaign To Allow Generic COVID Vaccines’, *The Sydney Morning Herald*, 29 April 2021, <https://www.smh.com.au/national/australia-accused-of-delaying-campaign-to-allow-generic-covid-vaccines-20210428-p57n09.html>

⁴⁵⁰ Government of Canada, ‘WTO TRIPS Council’, 23 February 2021, https://www.international.gc.ca/world-monde/international_relations-relations_internationales/wto-omc/2021-02-23-trips-adpic.aspx?lang=eng

on access to essential medicines,⁴⁵¹ and Prime Minister Justin Trudeau had previously made statements about the importance of universal access to essential medicines.⁴⁵² It has also been frustrating that the Liberal Government of Canada has been slow to respond to requests for compulsory licensing for the purposes of exporting medicines overseas during the coronavirus crisis.

C. Opposition to the TRIPS Waiver

In spite of the Biden administration's support for the TRIPS Waiver, there are a range of hold-outs to the TRIPS Waiver who have obstructing consensus on the proposal in the World Trade Organization. The European Commission has been steadfast in its opposition to the TRIPS Waiver.⁴⁵³ The Government of Germany has been particularly resistant to the adoption of a TRIPS Waiver.⁴⁵⁴ In 2020, Chancellor Angela Merkel maintained that vaccines for COVID-19 should be treated as global public goods. For instance, she stressed at the 73rd World Health Assembly that a 'vaccine must be accessible and affordable to everyone'.⁴⁵⁵ In 2021, Chancellor Angela Merkel engaged in backsliding from this position, and insisted that vaccines

⁴⁵¹ Stephen Lewis, *Race Against Time: Searching for Hope in AIDS-Ravaged Africa*, Toronto: House of Anansi Press, 2006; Matthew Rimmer, 'The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid' (2005) 15 (7) *Expert Opinion on Therapeutic Patents* 889-909; and Matthew Rimmer, 'Race Against Time: The Export of Essential Medicines to Rwanda' (2008) 1 (2) *Public Health Ethics* 89-103.

⁴⁵² Justin Trudeau, and others, 'The International Community Must Guarantee Equal Global Access to a COVID-19 Vaccine', *The Washington Post*, 16 July 2020, <https://www.washingtonpost.com/opinions/2020/07/15/international-community-must-guarantee-equal-global-access-covid-19-vaccine/>

⁴⁵³ Andrew Green, 'Europe Still Can't Get on Board with the TRIPS Waiver', *DevEx*, 31 May 2021, <https://www.devex.com/news/europe-still-can-t-get-on-board-with-the-trips-waiver-100027>

⁴⁵⁴ Joseph Choi, 'Merkel Breaks with Biden on US Plan to Waive Patent Protections for COVID-19 Vaccines', *The Hill*, 6 May 2021, <https://thehill.com/policy/international/552171-merkel-breaks-with-biden-on-us-plan-to-waive-patent-protections-for>

⁴⁵⁵ DW News, 'German Chancellor Angela Merkel on Access to Medicines', *DW News*, 19 May 2020, <https://twitter.com/DrRimmer/status/1262718696314638336?s=20> See also Reuters Staff, 'Merkel: Coronavirus Pandemic Will Be Overcome Quicker If World Works Together', *Reuters*, 18 May 2020, <https://www.reuters.com/article/us-health-coronavirus-who-merkel/merkel-coronavirus-pandemic-will-be-overcome-quicker-if-world-works-together-idUSKBN22U1HY> and DW News, 'G20: Angela Merkel Calls for Global Action to Beat Coronavirus', *DW News*, 21 November 2020, <https://www.dw.com/en/g20-angela-merkel-calls-for-global-action-to-beat-coronavirus/a-55686409?maca=en-Twitter-sharing>

for COVID-19 should still be subject to private intellectual property rights.⁴⁵⁶ A German government spokeswoman said: ‘The protection of intellectual property is a source of innovation and this has to remain so in the future.’⁴⁵⁷ This turnaround is perplexing and exasperating – given the previous calls for scientific collaboration and co-operation. Chancellor Angela Merkel came under particular criticism for this volte-face while she was visiting the United States in 2021.⁴⁵⁸ Various United States legislators and civil society groups engaged in vocal criticism of her stance – during her visit to the White House.⁴⁵⁹ The People’s Vaccine Campaign mounted a vigorous campaign to change the mind of German Chancellor Angela Merkel about her position on the TRIPS Waiver.⁴⁶⁰

The European Parliament, in a vote, called upon the European Commission to support a TRIPS Waiver.⁴⁶¹ In a resolution adopted with 355 votes in favour, 263 against and 71 abstentions, the European Parliament proposed negotiations start for a temporary waiver of the WTO TRIPS

⁴⁵⁶ Arne Delfs and Eric Martin, ‘Merkel Pushes Back on Vaccine Patent Waiver in Row with U.S.’, *Bloomberg*, 7 May 2021, <https://www.bloomberg.com/news/articles/2021-05-06/merkel-pushes-back-on-vaccine-patent-waiver-in-clash-with-biden>

⁴⁵⁷ Ibid.

⁴⁵⁸ Jake Johnson, ‘Biden-Merkel Meeting Fails to Move Forward Vaccine Patent Waiver’, *Truthout*, 16 July 2021, https://truthout.org/articles/biden-merkel-meeting-fails-to-move-forward-vaccine-patent-waiver/?utm_campaign=Truthout+Share+Buttons

⁴⁵⁹ Rep. Jan Schakowsky, ‘Schakowsky, Colleagues Request Meeting with Merkel To Discuss European Union Blocking TRIPS Waiver’, Press Release, 12 July 2021, <https://schakowsky.house.gov/media/press-releases/schakowsky-colleagues-request-meeting-merkel-discuss-european-union-blocking>; and Reuters, ‘U.S. lawmakers ask for Meeting on WTO Waiver with Merkel during Washington Visit’, *Reuters*, 13 July 2021, <https://www.reuters.com/world/us/us-lawmakers-ask-meeting-wto-waiver-with-merkel-during-washington-visit-2021-07-13/>

⁴⁶⁰ Public Citizen, ‘Biden-Merkel Summit Fail: Pres. Biden Unable to End Germany’s Blockade of COVID WTO TRIPS Waiver He Seeks to End Pandemic’, Public Citizen, Press Release, 15 July 2021, <https://www.citizen.org/news/biden-merkel-summit-fail-pres-biden-unable-to-end-germanys-blockade-of-covid-wto-trips-waiver-he-seeks-to-end-the-pandemic/> and Citizens Trade Campaign, ‘Protest Outside Merkel-Biden White House Summit Urges Germany to Stop Blocking Global COVID Vaccines’, Citizens Trade Campaign, Press Release, 15 July 2021, <https://www.citizenstrade.org/ctc/merkelprotests0715/>

⁴⁶¹ European Parliament, ‘Parliament Calls for Temporary COVID-19 Vaccine Patent Waiver’, Press Release, 10 July 2021, <https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-covid-19-vaccine-patent-waiver>

Agreement on patents to improve global access to affordable COVID-19-related medical products and to address global production constraints and supply shortages.⁴⁶²

After some equivocation, French President Emmanuel Macron has also called for the European Commission to support a TRIPS Waiver.⁴⁶³

Other opponents of the TRIPS Waiver include the Governments of the United Kingdom, Switzerland, Japan, Norway,⁴⁶⁴ and Brazil.

The Conservative Government led by Boris Johnson has resisted entreaties to support the TRIPS Waiver.⁴⁶⁵ Former British Prime Minister Gordon Brown has pressed the current United Kingdom government and other members of the G7 do more on access to essential medicines.⁴⁶⁶ 80 Members of Parliament signed a petition on Intellectual Property and the

⁴⁶² European Parliament, *Meeting the Global COVID-19 Challenge: Effects of Waiver of the WTO TRIPS Agreement on Covid-19 Vaccines, Treatment, Equipment and Increasing Production and Manufacturing capacity in Developing Countries*, 10 June 2021, 2021/2692 (RSP), P9_TA(2021)0283, https://www.europarl.europa.eu/doceo/document/TA-9-2021-0283_EN.html

⁴⁶³ Lotte Leicht, 'European Commission Increasingly Isolated On COVID Patent Waivers: French President Emmanuel Macron and the European Parliament Endorsed Making Vaccines More Available', *Human Rights Watch*, 11 June 2021, <https://www.hrw.org/news/2021/06/11/european-commission-increasingly-isolated-covid-patent-waivers>

⁴⁶⁴ Norway in Geneva, 'Norwegian Statement in regard to a Proposal from Eswatini, India, Kenya and South Africa for a Waiver from certain provisions of the TRIPs Agreement for the Prevention, Containment and Treatment of Covid-19', TRIPS Council, 16 October 2020, <https://www.norway.no/en/missions/wto-un/nig/latest-news/trips1610/>

⁴⁶⁵ Hannah Summers, 'Britain in Talks to Waive Covid Vaccine Patents to improve Global Access to Jabs', *The Guardian*, 20 May 2021, <https://www.theguardian.com/global-development/2021/may/20/britain-in-talks-to-waive-covid-vaccine-patents-to-improve-global-access-to-jabs>; Larry Elliott, 'Labour says UK must "Get off the Fence" over Global Covid Vaccine Access', *The Guardian*, 20 May 2021, <https://www.theguardian.com/world/2021/may/20/labour-uk-global-covid-vaccine-access-patent-waiver>; and Aubrey Allegretti, 'MPs Tell Johnson: You Have A Duty to Help Vaccinate the World', *The Guardian*, 1 June 2021, <https://www.theguardian.com/society/2021/may/31/mps-boris-johnson-donate-vaccines-poorer-countries>

⁴⁶⁶ Gordon Brown, 'The G7 must push for Global Vaccination. Here's How it Could Do It', *The Guardian*, 12 April 2021, <https://www.theguardian.com/commentisfree/2021/apr/12/g7-global-vaccination-covid>; Gordon Brown, 'Despite the Grand Words, This G7 Falls Devastatingly Short On Vaccines', *The Guardian*, 14 June 2021, <https://www.theguardian.com/commentisfree/2021/jun/14/grand-words-g7-vaccines-summit-failure-gordon-brown>; Gordon Brown, 'The World Is Making Billions of COVID Vaccine Doses, So Why Is Africa Not Getting

COVID-19 response.⁴⁶⁷ The co-sponsors included Caroline Lucas from the Green Party, Navendu Mishra and Clive Lewis of the British Labor Party, Layla Moran and Wendy Chamberlain of the Liberal Democrats, and Independent Claudia Webbe. The petition ‘urges the Government to recognise that intellectual property barriers are hindering equitable access to covid-19 health technologies, reconsider its position and support the waiver proposal at upcoming TRIPS Council and WTO General Council Meetings.’⁴⁶⁸ Navendu Mishra has lamented: ‘It was incredibly short-sighted of the UK to oppose the TRIPS waiver at the WTO last October and it must now reconsider its position and heed the calls of more than 150 former heads of state (including Gordon Brown) and Nobel laureates for a people’s vaccine, which would help to overcome Covid vaccine inequality.’⁴⁶⁹ He emphasized: ‘During a time of global crisis countries must collaborate and do all they can to ensure there is fair and equitable access to the vaccine, including compelling pharmaceutical companies to keep costs low and increase distribution and access.’⁴⁷⁰ Richard Burgon MP has called for the United Kingdom to support a ‘People’s Vaccine.’⁴⁷¹

The Gates Foundation has a history of supporting intellectual property maximalist positions in the debate over access to essential medicines.⁴⁷² The Gates Foundation was initially supportive of private intellectual property holders being in charge of the distribution of vaccines,

Them’, *The Guardian*, 16 August 2021, <https://www.theguardian.com/commentisfree/2021/aug/16/world-billions-covid-vaccine-doses-africa-unprotected>; and Gordon Brown, *Seven Ways To Change The World: How to Fix the Most Pressing Problems We Face*, London: Simon & Schuster UK, 2021.

⁴⁶⁷ United Kingdom Parliament, ‘Intellectual Property and COVID-19 response’, EDM (Early Day Motion)1451: tabled on 08 February 2021, <https://edm.parliament.uk/early-day-motion/58063/intellectual-property-and-covid19-response>

⁴⁶⁸ Ibid.

⁴⁶⁹ Hon. Navendu Mishra, ‘India’s COVID Spiral is Nothing Short of Horrifying – And The UK Must Act’, *Mirror*, 30 April 2021, <https://www.mirror.co.uk/news/politics/indias-covid-spiral-nothing-short-24015159> See also Hon. Navendu Mishra, ‘There Should Be No Monopolies in a Pandemic’, *Politics.co.uk*, 20 November 2020, <https://politics.co.uk/comment-analysis/2020/11/20/there-should-be-no-monopolies-in-a-pandemic>

⁴⁷⁰ Ibid.

⁴⁷¹ Hon. Richard Burgon, ‘A Vaccine That Serves All of Humanity – Not Private Profit’, *Morning Star*, <https://morningstaronline.co.uk/article/f/vaccine-serves-all-humanity-not-private-profit>

⁴⁷² Matthew Rimmer, ‘The Lazarus Effect: The (RED) Campaign, and Creative Capitalism’ in Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (ed.) *Incentives for Global Public Health: Patent Law and Access to Medicines*. Cambridge: Cambridge University Press, 2010, 313-340.

treatments, and diagnostics. However, there has been major challenges and barriers to the delivery of COVID-19 technologies. Bill Gates has warned of a ‘longer, more unjust, deadlier pandemic’ if market forces are left to distribute medicines.⁴⁷³ The Gates Foundation was a reluctant, late supporter of the TRIPS Waiver.⁴⁷⁴ There is a need to set in place mechanisms to ensure the fair and equitable distribution of COVID-19 technologies in the United States and elsewhere.

Big pharmaceutical companies and vaccine developers are clearly seeking to delay, frustrate, and block the passage of the TRIPS Waiver.⁴⁷⁵ There has been an extensive lobbying campaign by intellectual property owners to nation governments against the adoption of the TRIPS Waiver.⁴⁷⁶ Vaccine developers have also been placing great pressure upon nation states during negotiations to acquire vaccines.⁴⁷⁷ It remains to be seen whether the TRIPS Waiver proposed by South Africa and India will be realized in a timely fashion – if it all.

⁴⁷³ John Miller, ‘Bill Gates calls for COVID-19 Meds to Go to People Who Need Them, Not “Highest Bidder”’, *The Sydney Morning Herald*, 10 June 2020, <https://t.co/pAp3g9QXgT?amp=1>

⁴⁷⁴ Catherine Cheney, ‘Gates Foundation Reverses Course on COVID-19 Vaccine Patents’, *DevEx*, 7 May 2021, <https://www.devex.com/news/gates-foundation-reverses-course-on-covid-19-vaccine-patents-99810>

⁴⁷⁵ Paul Karp, ‘Pfizer Warns Australia a COVID Vaccine Patent Waiver Could Harm Supply and Safety’, *The Guardian*, 13 May 2021, <https://www.theguardian.com/australia-news/2021/may/13/pfizer-warns-australia-a-covid-vaccine-intellectual-property-patent-waiver-could-harm-supply-and-safety>

⁴⁷⁶ Lee Fang, ‘Pharmaceutical Industry Dispatches Army of Lobbyists to Block Generic COVID-19 Vaccines’, *The Intercept*, 23 April 2021, <https://theintercept.com/2021/04/23/covid-vaccine-ip-waiver-lobbying/>; Lee Fang, ‘Hollywood Lobbyists Intervene Against Proposal to Share Vaccine Technology’, *The Intercept*, 28 April 2021, <https://theintercept.com/2021/04/27/covid-vaccine-copyright-hollywood-lobbyists/>; Lee Fang, ‘Documents Reveal Pharma Plot to Stop Generic COVID-19 Vaccine Waiver’, *The Intercept*, 15 May 2021, <https://theintercept.com/2021/05/14/covid-vaccine-waiver-generic-pharma-lobby/>; and Brett Wilkins, ‘Big Pharma Plotting to Derail Biden’s COVID Vaccine Waiver: Report’, *Salon*, 17 May 2021, https://www.salon.com/2021/05/17/big-pharma-plotting-to-derail-covid-vaccine-waiver-report_partner/

⁴⁷⁷ Madlen Davies, Rosa Furneaux, Ivan Ruiz and Jill Langlois, “‘Held to Ransom’: Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal”, *The Bureau of Investigative Journalism*, 23 February 2021, <https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal>; and Al Jazeera, ‘Investigation: Drugmaker “Bullied” Latin American Nations’, *Al Jazeera*, 11 March 2021, <https://www.aljazeera.com/news/2021/3/11/investigation-pfizer-bullied-latin-american-nations>

If the TRIPS Waiver does get up, many countries will also have to consider their commitments under TRIPS+ and TRIPS++ agreements like the bilateral trade agreement, the *Australia-United States Free Trade Agreement* 2004⁴⁷⁸ and the regional trade agreement, the *Trans-Pacific Partnership*.⁴⁷⁹ It may well be complicated seeking additional waivers in respect of the obligations and commitments under TRIPS+ and TRIPS ++ agreements.

D. Community Support for the TRIPS Waiver

Human rights bodies have made supporting statements about the need for universal, affordable vaccination for COVID-19.⁴⁸⁰

There has been an open petition by over 100 academics, scholars, and researchers, calling for the adoption of the TRIPS Waiver.⁴⁸¹ The letter stressed: ‘The temporary TRIPS waiver - as

⁴⁷⁸ *Australia-United States Free Trade Agreement (AUSFTA)*, signed 18 May 2004 (entered into force 1 January 2005). For commentary, see Matthew Rimmer, 'Robbery Under Arms: Copyright Law and the Australia-United States Free Trade Agreement' (2006) 11 (3) *First Monday* <http://firstmonday.org/ojs/index.php/fm/article/view/1316> and Ken Harvey, Thomas Faunce, Buddhima Lokuge, and Peter Drahos, 'Will the Australia-United States Free Trade Agreement Undermine the Pharmaceutical Benefits Scheme?' (2004) 181 (5) *Medical Journal of Australia* 256-259.

⁴⁷⁹ *Trans-Pacific Partnership* 2015 (TPP) <https://www.dfat.gov.au/trade/agreements/not-yet-in-force/tpp/Pages/tpp-text-and-associated-documents> and *Comprehensive and Progressive Agreement for Trans-Pacific Partnership* 2018 <https://www.dfat.gov.au/sites/default/files/tpp-11-treaty-text.pdf> For commentary, see Matthew Rimmer, 'The Trans-Pacific Partnership: Intellectual Property, Public Health, and Access to Essential Medicines' (2017) 29 *Intellectual Property Journal* 277-332; Deborah Gleeson, and Ronald Labonte, *Trade Agreements and Public Health: A Primer for Health Policy Makers, Researchers and Advocates*, Singapore: Palgrave Macmillan, 2020; and Matthew Rimmer, *The Trans-Pacific Partnership: Intellectual Property and Trade in the Pacific Rim*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, December 2020.

⁴⁸⁰ *Committee on Economic, Social and Cultural Rights - Statement on Universal Affordable Vaccination for COVID-19, International Cooperation and Intellectual Property*, E/C.12/2021/1, 12 March 2021 <https://t.co/YbLQw8bq3G?amp=1> and United Nations Human Rights Council, *Ensuring Equitable, Affordable, Timely and Universal Access for All Countries to Vaccines in Response to the Coronavirus Disease (COVID-19) Pandemic*, 17 March 2021, A/HRC/46/L.25/Rev.1, <https://undocs.org/A/HRC/46/L.25/Rev.1>

⁴⁸¹ Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal. July 2021, <https://docs.google.com/forms/d/e/1FAIpQLSfS497FZW5oNf2tk46rzdUAYswABW91OT91QarsaFTvoBLHvQ/viewform> and The London School of Economics and Political Science, 'Waive Intellectual Property Protection for COVID Vaccines urge over 100 IP Academic Experts', Press Release, 13 July 2021,

proposed by India and South Africa and supported by more than 100 countries - is a necessary and proportionate legal measure towards the clearing of existing intellectual property barriers to scaling up of production of COVID-19 health technologies in a direct, consistent and effective fashion.’⁴⁸² The community of scholars demanded: ‘We call on the governments of the United Kingdom of Great Britain and Northern Ireland, Australia, Brazil, Japan, Norway, Switzerland and the European Union to drop their opposition to the TRIPS Waiver proposal at the World Trade Organisation and to support the waiver.’⁴⁸³ In addition to the passage of the TRIPS Waiver, the scholars called for the adoption of a package of measures – including the ‘global co-ordination of supply chains; streamlining regulatory approval processes and sharing exclusive data from regulatory dossiers; and investment in the WHO’s C-TAP and the mRNA technology transfer hub in South Africa.’⁴⁸⁴

In July 2021, MSF has complained that opposing countries have been filibustering negotiations on the TRIPS Waiver at the WTO.⁴⁸⁵ Dr Tom Ellman, director of MSF’s Southern Africa Medical Unit, despaired: ‘It is outrageous to see countries blocking the TRIPS Waiver that is desperately needed as an important tool to remove legal barriers and allow production to be scaled up by multiple manufacturers for critical COVID-19 drugs, diagnostics and vaccines.’⁴⁸⁶ Ellman commented: ‘At a moment when we are in race against time to save lives and control the spread of unchecked transmission and development of new dangerous variants, pharmaceutical corporation’s business-as-usual approach is intolerable.’⁴⁸⁷ Ellman called for a broad version of the TRIPS Waiver to be adopted: ‘With potentially promising treatments in the pipeline, opposing countries must stop filibustering the waiver proposal and support it to cover not just vaccines, but also treatments, diagnostics and other health technologies.’⁴⁸⁸ The

<https://lse.ac.uk/News/Latest-news-from-LSE/2021/g-July-21/Waive-intellectual-property-protection-for-COVID-vaccines.aspx>

⁴⁸² Ibid.

⁴⁸³ Ibid.

⁴⁸⁴ Ibid.

⁴⁸⁵ MSF Access Campaign, ‘Opposing Countries Must Stop Filibustering Negotiations on ‘TRIPS Waiver’ at WTO’, Press Release, 26 July 2021, <https://msfaccess.org/opposing-countries-must-stop-filibustering-negotiations-trips-waiver-wto>

⁴⁸⁶ Ibid.

⁴⁸⁷ Ibid.

⁴⁸⁸ Ibid.

surge of the Delta strain of the coronavirus in 2021 has made the need for an effective response to global need for access to essential medicines all the more urgent.

IX. Conclusion

This paper has told the story of the People’s Vaccine Alliance – a ragtag group of advocates, activists, and rebels who have challenged the status quo in respect of intellectual property and access to essential medicines. This social movement has questioned profiteering by pharmaceutical companies, vaccine developers, and medical diagnostics entities who have sought to maximise their intellectual property rights related to COVID-19 technologies. The People’s Vaccine Alliance has also highlighted that vaccine nationalism has been raging during the public health coronavirus crisis. There have been profound inequities in the distribution of COVID-19 vaccines, treatments, diagnostics, and other technologies.

There have been a variety of alternative models of intellectual property advanced in the public policy debates – but they have been slow to gain traction, and have faced considerable opposition and resistance from established biomedical industries. Susi Geiger and Aisling McMahon have questioned the proliferation of proposals for vaccine equity for COVID-19.⁴⁸⁹ It is true that many of the proposals for intellectual property sharing are still at an immature stage of development. The campaign for a People’s Vaccine is a new social movement – although it has had some early successes, it still has much work to do. The ACT-Accelerator – and its constituent parts like COVAX – have struggled to obtain sufficient health financing to achieve its goals to promoting research, development, and deployment of COVID-19 technologies. The Medicines Patent Pool and C-TAP have had to contend with uncooperative intellectual property holders. Compulsory licensing and crown use have been mooted by a number of nation states in response to the demands of vaccine developers and other intellectual property rights holders. Although there have been massive public investments in COVID-19 technologies, public sector licensing has been patchy. There has been an experimentation with patent pledges – but so far the take-up has been largely by private information technology companies, and public sector research organisations. The TRIPS Waiver advanced by South

⁴⁸⁹ Susi Geiger and Aisling McMahon, ‘Too Many Cooks or Too Many Recipes? An Analysis of the Institutional Landscape and Proliferation of Proposals for Global Vaccine Equity’, Working Papers, Geary Institute, University College Dublin, 2021, <https://ideas.repec.org/p/ucd/wpaper/202108.html>

Africa and India has made some progress in the WTO – with the Biden Administration expressing a willingness to support a TRIPS Waiver for Vaccines. However, there remains entrenched resistance to a TRIPS Waiver from a number of developed nations – particularly states like Germany, Switzerland, Japan, and Norway, with close ties to biomedical industries.

By its nature, this study is a provisional overview of a panoply of policy proposals – rather than an in-depth, exhaustive study of a single particular option. No doubt future research by this author and other scholars in the field of access to essential medicines will delve further into the evolution of these particular policy options, and evaluate the success or otherwise of these endeavours and ventures in their own right and through combinations. Ellen ‘t Hoen and her collaborators have noted: ‘Several initiatives have been proposed that begin to address key challenges of scaling up vaccine production capacity, but so far in limited or piecemeal ways.’⁴⁹⁰ The background paper concludes: ‘What is ultimately needed is a cohesive global action plan that addresses the legal, technical and financial barriers to rapid scale-up of vaccine production.’⁴⁹¹ The research and development of vaccines, treatments, and diagnostics has also been proceeding apace. Successful COVID-19 technologies will no doubt be in high demand, and will raise complex questions about intellectual property and access to medicines. The nature of the coronavirus public health crisis has also been evolving, particularly with the appearance of new variants.

The coronavirus public health crisis may well lead to a realignment of international intellectual property law. Reflecting upon the coronavirus crisis, the novelist Arundhati Roy has observed that there is an opportunity for a reform of economic and social structures:

Historically, pandemics have forced humans to break with the past and imagine their world anew. This one is no different. It is a portal, a gateway between one world and the next. We can choose to walk through it, dragging the carcasses of our prejudice and hatred, our avarice, our data banks and dead

⁴⁹⁰ Ellen ‘t Hoen, Christopher Garrison, Pascale Boulet, Kaitlin Mara and Katrina Perekhodoff, *Scaling-Up Vaccine Production Capacity: Legal Challenges and Recommendations*, Background Paper 6, Commissioned by the Independent Panel for Pandemic Preparedness and Response, May 2021, <https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccinationlegal-aspects.pdf>

⁴⁹¹ Ibid.

ideas, our dead rivers and smoky skies behind us. Or we can walk through lightly, with little luggage, ready to imagine another world. And ready to fight for it.⁴⁹²

It is certainly the case that there is scope to reimagine intellectual property in the wake of the coronavirus crisis. Professor Myra Tawfik from Windsor Law School from Canada has argued that ‘the worldwide COVID-19 public health crisis highlights the inequities and biases within the international and domestic intellectual property (IP) legal orders that were already being scrutinized prior to this extraordinary global upheaval.’⁴⁹³ She contends: ‘If countries hoard medical supplies and IP rights holder extract usurious prices for access to treatments and supplies, then the fallout from these individualistic actions will compel an alternative IP future the next time around.’⁴⁹⁴ Otherwise Tawfik suggests: ‘If, on the other hand, the global community emerges from the COVID-19 pandemic having adopted collaborative IP strategies that ensure equitable and fair access to COVID-19 treatments and supplies, the success of this approach and the global co-operation it will have engendered will carry forward into the future.’⁴⁹⁵ Tawfik imagines: ‘A post-pandemic IP legal order will be built on greater collaboration, balance and inclusion.’⁴⁹⁶ She is hopeful that the intellectual property regime will find a new equilibrium: ‘By imposing checks and balances on individualistic and maximalist approaches, it will curb the abuses of the current IP environment, which privileges the dominant players’.⁴⁹⁷ Tawfik contends: ‘Greater cooperation among countries will level the field should any IP superpower, current or future, refuse to play by these new rules’.⁴⁹⁸ She suggests: ‘This framework will provide a fairer, stronger and more resilient system to ensure that IP facilitates, rather than impedes, solutions to other intractable global challenges, with the climate crisis at the top of the list.’⁴⁹⁹

⁴⁹² Arundhati Roy, ‘The Pandemic is a Portal’, *Financial Times*, 4 April 2020, <https://www.ft.com/content/10d8f5e8-74eb-11ea-95fe-fcd274e920ca>

⁴⁹³ Myra Tawfik, ‘The Post-Pandemic IP Legal Order: Collaborative, Balanced and Inclusive’, Center for International Governance Innovation, 8 July 2020, <https://www.cigionline.org/articles/post-pandemic-ip-legal-order-collaborative-balanced-and-inclusive>

⁴⁹⁴ Ibid.

⁴⁹⁵ Ibid.

⁴⁹⁶ Ibid.

⁴⁹⁷ Ibid.

⁴⁹⁸ Ibid.

⁴⁹⁹ Ibid.

Susi Geiger and Aisling McMahon have expressed concern about the complicated, fragmented nature of the institutional landscape.⁵⁰⁰ There are a host of institutions – some well-established, others new – which have been grappling with the question of access to medicines during the COVID-19 crisis. The WHO has been engaged with a range of public policy issues as part of the COVID-19 crisis. It has also been instrumental in setting up new institutions – such as the ACT-Accelerator, COVAX, and C-TAP – to address various aspects of the COVID-19 crisis. The Independent Panel has made a number of recommendations as to the reformation of WHO.⁵⁰¹ After being paralysed by conflict between the superpowers of China and the United States, the WTO has appointed a new director, and has sought to progress the debate over access to essential medicines. As well as providing technical information,⁵⁰² the WTO has hosted debates in the TRIPS Council over proposals such as the TRIPS Waiver.⁵⁰³ The new WTO Director-General Ngozi Okonjo-Iweala has promised to advance discussions on the topic in the TRIPS Council, observing ‘we need to respond urgently to COVID-19 because the world is watching and people are dying’.⁵⁰⁴ With the change over of Director-Generals, WIPO has been relatively quiet in respect of the debate over intellectual property and access to medicines during the coronavirus crisis. The WHO, WTO, and WIPO have previously worked together on intersections between intellectual property, public health, and trade.⁵⁰⁵ In 2021, the directors

⁵⁰⁰ Susi Geiger and Aisling McMahon, ‘Too Many Cooks or Too Many Recipes? An Analysis of the Institutional Landscape and Proliferation of Proposals for Global Vaccine Equity’, Working Papers, Geary Institute, University College Dublin, 2021, <https://ideas.repec.org/p/ucd/wpaper/202108.html>

⁵⁰¹ The Independent Panel for Pandemic Preparedness and Response, *COVID-19: Make It The Last Pandemic*, Main Report, 2021, https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

⁵⁰² World Trade Organization, ‘Members Discuss Intellectual Property Response to the COVID-19 Pandemic’, News Item, 20 October 2020, https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm?utm_source=dlvr.it&utm_medium=twitter

⁵⁰³ World Trade Organization, ‘COVID-19: Measures Regarding Trade-Related Intellectual Property Rights’, October 2020, https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm and World Trade Organization, ‘The TRIPS Agreement and COVID-19: Information Note’, 15 October 2020, https://www.wto.org/english/tratop_e/covid19_e/trips

⁵⁰⁴ Reuters Staff, ‘WTO Chief Lays Out Global Action To Increase Vaccine Access’, *Reuters*, 15 April 2021, <https://www.reuters.com/article/us-trade-wto-vaccines-idUSKBN2C12YU> and World Trade Organization, ‘Statement of Director-General Ngozi Okonjo-Iweala on USTR Tai’s statement on the TRIPS Waiver’, Press Release, 6 May 2021, https://www.wto.org/english/news_e/news21_e/dgno_06may21_e.htm

⁵⁰⁵ World Health Organization, World Intellectual Property Organization, and World Trade Organization, *Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual*

of WHO, WTO, and WIPO agreed to engage in intensified co-operation in support of access to medical technologies worldwide to tackle the COVID-19 pandemic.⁵⁰⁶ The leaders of the international institutions stressed: ‘We underscored our commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies – a commitment anchored in the understanding that this is an urgent moral imperative in need of immediate practical action.’⁵⁰⁷ The upheaval of the coronavirus crisis has certainly underlined the need for an overhaul of the multilateral system to ensure that it is better prepared for global crises – such as the coronavirus pandemic. It is also a shame that the previous recommendations of the United Nations Secretary-General High Level Panel report on access to medicines about the need to build up the global infrastructure for public health were not heeded.⁵⁰⁸ There is certainly a pressing need to ensure better financing for global public health.⁵⁰⁹

There has also been discussion as to whether there should be an international pandemic treaty to better protect the world from future health crises.⁵¹⁰ 25 heads of government and international agencies made a joint call for more robust international health architecture.⁵¹¹ The

Property and Trade. 2nd Edition. Geneva: World Health Organization, World Intellectual Property Organization, and World Trade Organization, 2020, <https://www.wipo.int/publications/en/details.jsp?id=4511>

⁵⁰⁶ World Health Organization, World Intellectual Property Organization, and World Trade Organization, ‘Directors General of WHO, WIPO and the WTO agree on intensified cooperation in support of access to medical technologies worldwide to tackle the COVID-19 pandemic’, Press Release, Geneva, 24 June 2021, <https://www.who.int/news/item/24-06-2021-directors-general-of-who-wipo-and-the-wto-agree-on-intensified-cooperation-in-support-of-access-to-medical-technologies-worldwide-to-tackle-the-covid-19-pandemic>

⁵⁰⁷ Ibid.

⁵⁰⁸ Ruth Dreifuss, and others, *Report of the United Nations Secretary-General’s High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, United Nations, 2016, <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>

⁵⁰⁹ Ilona Kickbush, ‘The COVID-19 Crisis Is A Signal – Need To ‘Reset’ Global Health Financing’, *Health Policy Watch*, 11 November 2020, <https://healthpolicy-watch.news/the-covid-19-crisis-is-a-signal-to-reset-global-health-financing/>

⁵¹⁰ World Health Organization, ‘Global Leaders Unite In Urgent Call for International Pandemic Treaty’, Press Release, 30 March 2021, <https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty>

⁵¹¹ World Health Organization and others, ‘COVID-19 Shows Why United Action is Needed for More Robust International Health Architecture’, 30 March 2021, <https://www.who.int/news->

joint statement noted: ‘The COVID-19 pandemic has been a stark and painful reminder that nobody is safe until everyone is safe.’⁵¹² The joint statement called for access to essential medicines: ‘We are, therefore, committed to ensuring universal and equitable access to safe, efficacious and affordable vaccines, medicines and diagnostics for this and future pandemics.’⁵¹³ The joint statement stressed that vaccines should be treated as global public goods: ‘Immunization is a global public good and we will need to be able to develop, manufacture and deploy vaccines as quickly as possible.’⁵¹⁴

There is certainly a need to consider the role that intellectual property law, policy, and practice will play not only in the COVID-19 response, but in the COVID-19 recovery. United Nations Secretary-General Antonio Guterres has called for a COVID-19 recovery plan, which upholds the Sustainable Development Goals and human rights:

Looking ahead, we need to build back better. The Sustainable Development Goals — which are underpinned by human rights — provide the framework for more inclusive and sustainable economies and societies. Strengthening economic and social rights bolsters resilience for the long haul. The recovery must also respect the rights of future generations, enhancing climate action aiming at carbon neutrality by 2050 and protecting biodiversity. We are all in this together. The virus threatens everyone. Human rights uplift everyone. By respecting human rights in this time of crisis, we will build more effective and inclusive solutions for the emergency of today and the recovery for tomorrow.⁵¹⁵

There have been a host of proposals for COVID-19 recovery plans.⁵¹⁶ There has been a call for a reinvestment in public health, sustainable development, and climate action as part of a

[room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture](#)

⁵¹² Ibid.

⁵¹³ Ibid.

⁵¹⁴ Ibid.

⁵¹⁵ Antonio Guterres, ‘We are all in this Together: Human Rights and COVID-19 Response and Recovery’, United Nations, 23 April 2020, <https://www.un.org/en/un-coronavirus-communications-team/we-are-all-together-human-rights-and-covid-19-response-and>

⁵¹⁶ For a discussion of COVID-19 recovery policies, see Tanya Plibersek (ed.), *A Better Normal After COVID-19*, Sydney: New South Publishing, 2020; Klaus Schwab and Thierry Malleret, *COVID-19: The Great Reset*, Geneva: World Economic Forum, 2020; and Ross Garnaut, *Reset: Restoring Australia after the Great Crash of 2020*, Melbourne: Black Inc., 2021.

successful for COVID-19 recovery.⁵¹⁷ Guterres has said: ‘For too long, we have undervalued and underinvested in global public goods — a clean environment, cyber security, peace, the list goes on.’⁵¹⁸ He emphasizes that there is ‘one vital lesson of this pandemic: the need for new urgency in support of global public goods and universal health coverage.’⁵¹⁹

⁵¹⁷ United Nations Development Programme, *Beyond Recovery: Towards 2030*, New York: UNDP, 2020, <https://www.undp.org/publications/beyond-recovery-towards-2030> and OECD, *The OECD Green Recovery Database: Examining the Environmental Implications of COVID-19 Recovery Policies*, Geneva: OECD, 19 April 2021, <https://www.oecd.org/coronavirus/policy-responses/the-oecd-green-recovery-database-47ae0f0d/#section-d1e334>

⁵¹⁸ Antonio Guterres, ‘Secretary-General’s remarks at the launch of the Statement of Commitment and Call for Support for the Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 Tools’, 24 April 2020, <https://www.un.org/sg/en/content/sg/statement/2020-04-24/secretary-generals-remarks-the-launch-of-the-statement-of-commitment-and-call-for-support-for-the-global-collaboration-accelerate-the-development-production-and>

⁵¹⁹ Ibid.