This paper explores intellectual property and access to essential medicines in the context of the COVID-19 public health crisis. It considers policy solutions to counteract vaccine nationalism and profiteering by pharmaceutical companies and vaccine developers. It discusses the campaign for the development of a People's Vaccine led by the People's Vaccine Alliance, UNAIDS, Oxfam and Public Citizen. This paper charts the ACT Accelerator developed by the WHO in order to boost research, development, and deployment of COVID-19 technologies. It comments on the role of the Medicines Patent Pool in the coronavirus crisis, as well as Costa Rica's proposed for a COVID-19 Technology Access Pool. In the context of the coronavirus public health crisis, the article also discusses the use of compulsory licensing and Crown use to counteract profiteering and anti-competitive behaviour. The article takes note of the growing Open Science movement in response to the assertion of proprietary rights in respect of COVID-19 technologies. 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; however, this has been opposed by multiple countries. This paper makes the case that international intellectual property law should accommodate a People's Vaccine.

* Dr Matthew Rimmer (B.A. LLB ANU, Phd. UNSW) is a Professor in Intellectual Property and Innovation Law at the Faculty of Business and Law in the Queensland University of Technology (QUT). He is also a chief investigator in the Australian Centre for Health Law Research (ACHLR) and the QUT Centre for Behavioural Economics, Society and Technology (QUT BEST). This paper has been supported by a QUT Edge Grant on Intellectual Property and 3D Printing: Public Health, and the Coronavirus. Earlier versions of this paper have been delivered at the QUT Conference on Intellectual Property and Education in the Age of COVID-19 on the 29th July 2020, and the Creative Commons Global Summit 2020 on the 21st October 2020 – as well as during international trade law courses at QUT. The author would like to acknowledge his collaborators in the field of access to essential medicines – including Dr Hafiz Aziz ur Rehman, Dr Muhammad Zaheer Abbas, Associate Professor Bruce Arnold, Associate Professor Wendy Bonython, and Professor Natalie Stoianoff. He would also acknowledge his fellow teachers in international trade law – Dr Anne Matthew and Associate Professor Felicity Deane. The author is also grateful for the assistance of the editorial team of the Journal of Intellectual Property Studies.
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 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 U.S.³ The Agreement on Trade-Related Aspects of Intellectual Property Rights [“TRIPS Agreement”] 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 on the TRIPS Agreement and Public Health [“Doha Declaration”] in 2001 – which recognized that nation states could make use of flexibilities to address public health epidemics.⁶ There have nonetheless

---

¹ DAVID WALTNER-TOEWS, ON PANDEMICS: DEADLY DISEASES FROM BUBONIC PLAGUE TO CORONAVIRUS (2020); JONATHAN QUICK & BRONWYN FRYER, THE END OF EPIDEMICS: HOW TO STOP VIRUSES AND SAVE HUMANITY NOW (2020); PETER S. DOHERTY, PANDEMICS: WHAT EVERYONE NEEDS TO KNOW (2013); JOHN FABIAN WITT, AMERICAN CONTAGIONS: EPIDEMICS AND THE LAW FROM SMALLPOX TO COVID-19 (2020).

² GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS, AND DEVELOPMENT (Peter Drahos & Ruth Mayne eds., 2005); INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO MEDICINES (Thomas Pogge, Matthew Rimmer & Kim Rubenstein eds., 2010); CYNTHIA HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS (2011); BURÇI KILIC, BOOSTING PHARMACEUTICAL INNOVATION IN THE POST-TRIPS ERA: REAL-LIFE LESSONS FOR THE DEVELOPING WORLD (2014); ELLEN ‘T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH: CHANGING INTELLECTUAL PROPERTY RULES FOR ACCESS TO MEDICINES (2016); INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES: TRIPS AGREEMENT, HEALTH AND PHARMACEUTICALS (Srividhya Ragavan & Amaka Vanni eds., 2021); ACCESS TO MEDICINES AND VACCINES: IMPLEMENTING FLEXIBILITIES UNDER INTELLECTUAL PROPERTY LAW (Carlos Correa & Reto Hilty eds., 2021).


been controversies when developing nations have made use of domestic compulsory licensing provisions – with pharmaceutical companies making procedural and substantive complaints about such measures.\textsuperscript{7} The \textit{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 \textit{TRIPS Agreement} in Article 31bis. But in practice, this export mechanism has proven difficult to use – with generic pharmaceutical companies being reluctant to go through the convoluted, bureaucratic steps at a national level; to obtain a compulsory license for the export of medicines.\textsuperscript{8}

There has been major litigation over patent law and access to medicines in India – particularly because it has been seen as a “\textit{pharmacy of the developing world}”.\textsuperscript{9} 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.\textsuperscript{10} There has been much debate accordingly about the use of intellectual property flexibilities in India to address public health

---


epidemics. There has been complex politics in respect of disease outbreaks in the wider South-East Asia as well. There have also been public policy 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 worry about a lack of new treatments for malaria. There has been an under-investment by pharmaceutical drug companies in relation to tuberculosis. As the Médecins Sans Frontières (“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.” The emergence of new strains of influenza – such as avian influenza and porcine influenza – have also tested the intellectual property regime. There was a patent race in respect of genetic sequencing the SARS Genome Patent: Symptom or Disease?, 361 (9374) LANCET (2003); Matthew Rimmer, The Race To Patent The SARS Virus: The TRIPS Agreement And Access To Essential Medicines, 5 (2) MELB. J. INTL. L., 10, 1125 (2003); Eileen Kane, Achieving Clinical Equality in an Influenza Pandemic: Patent Realities, 39 SETON HALL L. REV. 1137 (2009); Samuel Oddi, Plagues, Pandemics, and Patents: Legality and Morality, 51 (1) IDEA (2011). There has also been controversy over patents being granted in respect of the Middle East respiratory syndrome “MERS.” Furthermore, complicated geopolitical factors were involved in terms of patent filings in respect of diagnostics and medicines developed in relation to the Ebola virus.

Dennis Crouch, Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic, 15 (3) DEPAUL J. HEALTH CARE L. 309 (2007); Andrew Torrance, Patents to the Rescue – Disasters and Patent Law, 10 (3) DEPAUL J. HEALTH CARE L. 309 (2007); Dennis Crouch, Nik: The Value of Patents in a Major Crisis Such as an Influenza Pandemic, 39 SETON HALL L. REV. 1125 (2009); Eileen Kane, Achieving Clinical Equality in an Influenza Pandemic: Patent Realities, 39 SETON HALL L. REV. 1137 (2009); Samuel Oddi, Plagues, Pandemics, and Patents: Legality and Morality, 51 (1) IDEA (2011). There has also been controversy over patents being granted in respect of the Middle East respiratory syndrome “MERS.” Furthermore, complicated geopolitical factors were involved in terms of patent filings in respect of diagnostics and medicines developed in relation to the Ebola virus.


13 Sonia Shah, How Malaria Has Ruled Humankind for 500,000 Years (2010); see also, Malaria, MEDECINS SANS FRONTIERES, https://www.msf.org/malaria.


16 Andrew Torrance, Patents to the Rescue – Disasters and Patent Law, 10 (3) DEPAUL J. HEALTH CARE L. 309 (2007); Dennis Crouch, Nik: The Value of Patents in a Major Crisis Such as an Influenza Pandemic, 39 SETON HALL L. REV. 1125 (2009); Eileen Kane, Achieving Clinical Equality in an Influenza Pandemic: Patent Realities, 39 SETON HALL L. REV. 1137 (2009); Samuel Oddi, Plagues, Pandemics, and Patents: Legality and Morality, 51 (1) IDEA (2011). There has also been controversy over patents being granted in respect of the Middle East respiratory syndrome “MERS.” Furthermore, complicated geopolitical factors were involved in terms of patent filings in respect of diagnostics and medicines developed in relation to the Ebola virus.


19 E. Richard Gold, SARS Genome Patent: Symptom or Disease?, 361 (9374) LANCET (2003); Matthew Rimmer, The Race To Patent The SARS Virus: The TRIPS Agreement And Access To Essential Medicines, 5 (2) MELB. J. INTL. L., 1125 (2003); Eileen Kane, Achieving Clinical Equality in an Influenza Pandemic: Patent Realities, 39 SETON HALL L. REV. 1137 (2009); Samuel Oddi, Plagues, Pandemics, and Patents: Legality and Morality, 51 (1) IDEA (2011). There has also been controversy over patents being granted in respect of the Middle East respiratory syndrome “MERS.” Furthermore, complicated geopolitical factors were involved in terms of patent filings in respect of diagnostics and medicines developed in relation to the Ebola virus.

outbreak. There has also been intellectual property raised in relation to the Zika outbreak. The need is 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 policymakers. 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.”

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 and access to medicines. The report by former President of Switzerland, Ruth Dreifuss, and other eminent figures made a number of recommendations – such as suggesting that countries make use of intellectual property flexibilities to address public health epidemics. Nonetheless, there was resistance to the implementation of the report from a number of developed nations – most notably the U.S. – 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 better prepared for the issues around intellectual property and access to medicines arising in the context of the covid-19 virus.

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. Dr Tedros Adhanom Ghebreyesus, the Director-General of WHO, has said: “Vaccine nationalism hurts us all and is self-defeating.”26 He also 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.”27 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 COVID-19 vaccine, then it cannot devolve into vaccine nationalism”.28 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.”29 Brook Baker cautions: “This unbridled nationalism, interlinked with a broken, profit-driven pharmaceutical system risks obstructing access to life-saving medicines worldwide.”30 Richard Hass is fearful that the approach of vaccine nationalism will be disastrous, because “only a handful of countries will be able to produce viable vaccines.”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 regimes to engage in price hiking and profiteering in the past.

This paper will explore how the COVID-19 pandemic has tested the strengths, limits, and flexibilities of patent law, policy, and practice. It will look at what patent flexibilities could be used to ensure the fair and equitable distribution of COVID-19 technologies. It will also examine long-term law reform in respect of intellectual property rights, which will better prepare us for global challenges like the 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


27 Id.


Drawing upon past research in the field of access to essential medicines, this paper considers a variety of options to address intellectual property and vaccines during the COVID-19 public health crisis. By design, this paper is intended to be an overview and a survey 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, Joint United Nations Programme on HIV and AIDS (“UNAIDS”), Oxfam, Public Citizen, and various other leaders. Part III provides an early evaluation of the Access to COVID-19 Tools Accelerator (“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 the WHO to establish a Coronavirus Technology Access Pool (“C-TAP”). 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. After 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 to enable countries to combat the coronavirus [“TRIPS Waiver”]. While the U.S. 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, and the United Kingdom – which have opposed the adoption of a TRIPS Waiver. In the conclusion, this paper makes the case that the international intellectual property regime should accommodate a People’s Vaccine.

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.\(^{37}\) 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.”\(^{38}\) They also called for a similar approach to other treatments, diagnostics, and technologies related to COVID-19.\(^{39}\)

The People’s Vaccine Alliance [“PVA”] 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.”\(^{40}\) The group observes that in order to achieve a “People’s Vaccine” it will be necessary to “[b]reak the shackles of intellectual property on vaccines and COVID-19 knowledge.”\(^{41}\) The PVA elaborates that every nation needs to be able 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.”\(^{42}\) The PVA has called on nation states to “force pharmaceutical companies to share their COVID-19-related technology and know-how through the World Health Organization’s COVID-19 Technology Access Pool.”\(^{43}\) The members of the organization include


\(^{38}\) Id.

\(^{39}\) Id.

\(^{40}\) What is the People’s Vaccine Alliance?, THE PEOPLE’S VACCINE ALLIANCE, https://peoplesvaccine.org/faq/.

\(^{41}\) Id.


\(^{43}\) Id.
Free the Vaccine, Global Justice Now, the Yunus Centre, Frontline AIDS, Amnesty International, Oxfam, SumOfUs and UNAIDS. The Washington DC based civil society organization Public Citizen have also supported this initiative for a People’s Vaccine.\footnote{Zain Rizvi, \textit{The People’s Vaccine}, PUBLIC CITIZEN (June 11, 2020), https://www.citizen.org/article/the-peoples-vaccine/} Having witnessed the tragedy of the HIV/AIDS epidemic in Uganda, Winnie Byanyima has long been a steadfast advocate for access to essential medicines.\footnote{Jon Cohen, “I’m Known as An Activist.” New UNAIDS Leader Takes Charge, \textit{SCIENCE} (27 November 2019), https://www.sciencemag.org/news/2019/11/i-m-known-activist-new-unaids-leader-takes-charge.} She was a panel member of the UN Secretary General’s High Level Panel on Access to Medicines in her capacity as the Executive Director of Oxfam International.\footnote{Dreifuss, supra note 25.} 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.\footnote{Winnie Byanyima & Matthew Kavanaugh, \textit{This World Aids Day: The Global Response to HIV Stands on a Precipice}, THE GUARDIAN (Dec. 1, 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_twitter.} She has emphasized the need for a human-rights based approach to the COVID-19 response, ensuring that there is health for all, and freedom from discrimination and stigma.\footnote{Winnie Byanyima, \textit{Opening Remarks at the High-Level Meeting on AIDS}, UNAIDS (June 8, 2021), https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2021/june/20210608-opening-remarks-unaids-executive-director-hlm.} As the Executive Director of UNAIDS, Byanyima has been a champion of the People’s Vaccine: “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.”\footnote{Press Release, UNAIDS, As pandemic deaths pass 1 million, COVID survivors from 37 countries write to pharmaceutical bosses to demand a People’s Vaccine (Sept. 29, 2020), https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/september/20200929_covid-19-survivors-write-to-pharmaceutical-bosses-to-demand-a-peoples-vaccine.} In her view, “A vaccine should be a global public good and free of charge for all.”\footnote{Id.} Byanyima 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. She 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.”\footnote{Press Release, UNAIDS, President of Nigeria Unites Behind the Call for a People’s Vaccine for COVID-19 (Oct. 16, 2020), https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201016_president-nigeria-unites-behind-call-for-peoples-vaccine-for-covid19.} She feared that anything short of that would lead to more deaths and
economic chaos, forcing millions into destitution.\textsuperscript{52} She called upon the Big Pharma to share their intellectual property to achieve a People’s Vaccine.\textsuperscript{53}

Helen Clark, the former Prime Minister of New Zealand, and Winnie Byanyima have expanded upon the case for a People’s Vaccine.\textsuperscript{54} 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.”\textsuperscript{55} They argued: “This extraordinary moment calls for a better approach than our current regime of monopoly rights.”\textsuperscript{56} 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.”\textsuperscript{57} Clark has added that there is a need for legal guarantees for access to essential medicines: “The COVID-19 vaccine must not belong to anyone and must be free for everyone.”\textsuperscript{58}

Helen Clark expanded upon such concerns about access to medicines as part of her Independent Panel report into the global response to COVID-19.\textsuperscript{59} For her part, Byanyima has been distressed by the lack of progress on vaccine equity in 2021.\textsuperscript{60} She said that the current situation was inequitable and intolerable: “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.”\textsuperscript{61} She 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.”\textsuperscript{62} Byanyima observed that the costs of vaccine inequality would be global: “The longer the virus is allowed to continue in a context of patchy immunity, the greater the chance of mutations that

\textsuperscript{52} Id.
\textsuperscript{53} Winnie Byanyima, Letter: To Be a People’s Vaccine, Big Pharma Must Share Intellectual Property, Financial Times (Nov. 26, 2020), https://www.ft.com/content/59393e00-20ac-466b-81d1-5773d9f64494.
\textsuperscript{55} Id.
\textsuperscript{56} Id.
\textsuperscript{57} Id.
\textsuperscript{59} THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, supra note 23.
\textsuperscript{61} Id.
\textsuperscript{62} Id.
could render the vaccines we have and the vaccines some people in rich countries have already received, less effective or ineffective.”

**B. Endorsements of the People’s Vaccine Campaign**

The Government of South Africa has sponsored the TRIPS Waiver – alongside India - in order to realise this ambition of a People’s Vaccine. Cyril Ramaphosa – the President of South Africa – has supported the call for a People’s Vaccine. He has stressed: “Billions of people today await a vaccine that is our best hope of ending this pandemic.” 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.”

Ramaphosa observed: “All the science must be shared between governments.” 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.*”

He noted that “*a bold international agreement cannot wait.*” 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.*’

Imran Khan, the Prime Minister of Pakistan commented: “*We must pool all the knowledge, experience and resources at our disposal for the good of all humanity.*”

Nelson Barbosa, former Finance Minister of Brazil, noted: “*Market solutions are not optimal to fight a pandemic.*” He commented: “*A public health care system, including free vaccination and treatment when that becomes available, is essential to deal with the problem.*” Traditionally, the Government of Brazil has been a supporter of the use of TRIPS flexibilities to support access to essential medicines – especially during the HIV/AIDS crisis. However, strangely, the Bolsonar Government has been

---

63 Id.
65 Id.
66 Id.
67 Id.
68 UNAIDS, *supra* note 51.
69 Id.
70 Id.
71 OXFAM, *supra* note 58.
72 Id.
73 Id.
an opponent of the TRIPS Waiver.\textsuperscript{74} The Brazilian Senate, though, has voted to suspend patent protection on COVID-19 vaccines.\textsuperscript{75}

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 COVID-19 from 37 countries have also lent their support to a letter, which advocates for the People’s Vaccine.\textsuperscript{76} The signatories to the letter include 242 COVID-19 survivors from various countries, ranging from South Africa to Finland and New Zealand to Brazil. The signatories also included 190 people from 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: “We see no justification why your profit or monopolies should mean anyone else should go through this”.\textsuperscript{77} The letter called on industry leaders to “ensure COVID-19 vaccines and treatments reach everyone who needs them by preventing monopolies, ramping up production and sharing knowledge.”\textsuperscript{78} One of the signatories, Dilafruz Gafurova, 43, from Tajikistan, discussed the difficulties that her family faced during the coronavirus outbreak, and explained: “The reason I am signing this letter is to help others to get [a] vaccine.”\textsuperscript{79} 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.”\textsuperscript{80}

The economist Professor Mariana Mazzucato has also lent her support to the People’s Vaccine Campaign. She has written a piece with Els Torreele and Henry Lish on the challenges and

\begin{flushleft}
\textsuperscript{74} Brazil: Support Wider Vaccine Production at WTO, HUMAN RIGHTS WATCH (Mar. 9, 2021), https://www.hrw.org/news/2021/03/09/brazil-support-wider-vaccine-production-wto
\textsuperscript{76} UNAIDS, supra note 49.
\textsuperscript{77} Id.
\textsuperscript{78} Id.
\textsuperscript{79} Id.
\textsuperscript{80} Id.
\end{flushleft}
proposals for delivering the People’s Vaccine.\textsuperscript{81} 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.”\textsuperscript{82} Mazzucato has called for a mission-focused approach to biomedical innovation.\textsuperscript{83} 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.”\textsuperscript{84}

Sanjay Reddy and Arnab Acharya have articulated the economic case for a People’s Vaccine.\textsuperscript{85} They commented that “the current challenge provides a stark demonstration of what is needed for research and development to serve the broader public interest.”\textsuperscript{86} 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.”\textsuperscript{87}

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.

\textbf{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.\textsuperscript{88} She noted: “Unfortunately, despite the lofty promises of the vaccine as a global public good, wealthy nations are not making such demands.”\textsuperscript{89} 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”.\textsuperscript{90} 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

\begin{thebibliography}{99}
\bibitem{82} Id.
\bibitem{83} Mazzucato, Mission Economy, supra note 35.
\bibitem{84} Id. at 83.
\bibitem{86} Id.
\bibitem{87} Id.
\bibitem{89} Id.
\end{thebibliography}
planetary health system.”⁹¹ They presented the debate as a choice between “People or profit; a people’s vaccine or a debilitating vaccine apartheid.”⁹²

III. The ACT Accelerator

In April 2020, the World Health Organization [“WHO”] and its partners launched the Access to COVID-19 Tools [“ACT Accelerator”].⁹³ 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.

A. The Establishment of the ACT Accelerator

For its part, the 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.⁹⁴ This new institution was launched at the end of April 2020. According to the 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.”⁹⁵ WHO emphasized that a key principle underpinning the ACT-Accelerator was the need for equitable distribution of COVID-19 tools to those most in need.⁹⁶

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, as well as 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”],

⁹¹ Id.
⁹² Id.
⁹⁶ Id.
UNITAID, the Foundation for Innovative New Diagnostics ["FIND"], the Wellcome Trust, the World Bank Group and the WHO.

The ACT-Accelerator comprises four pillars - diagnostics, therapeutics, vaccines, and the strengthening of the health system. CEPI and GAVI would manage the vaccines program – which is known as COVAX. UNITAID and the Wellcome Trust would look after therapeutics. 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.97

Germany’s Chancellor Angela Merkel said in 2020 that the global response to the pandemic would be a “test of our generation’s human kindness”: “We will only be able to overcome the pandemic if we achieve a truly global solution to the COVID-19 crisis.”98 However, Merkel shifted her position in 2021 somewhat regarding the sharing of scientific knowledge and innovation in respect of COVID-19, becoming an opponent of the TRIPS Waiver.

Australia’s Prime Minister Scott Morrison has called for the development of “a safe vaccine, available to all, affordable to all.”99 Likewise New Zealand’s Prime Minister Jacinda Ardern has said: “We will advocate for universal access for any treatments and vaccines.”100 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. However, both nations only belatedly supported a TRIPS Waiver – after the Biden administration declared that it would support a TRIPS Waiver.

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.”101 The letter emphasized that “we must urgently ensure that vaccines will be distributed according to a set of transparent,
equitable and scientifically sound principles.” In spite of such sentiments, the Canadian Government has been uncommitted as to whether it will support a TRIPS waiver.

B. The Operation of the ACT Accelerator

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

Mark Eccleston-Turner and Harry Upton commented 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.” They observed that “a failure to adequately address the underlying lack of infrastructure in developing countries threatens to further limit the success of the COVAX Facility.” Lisa Herzog and her colleagues maintain that COVAX must go beyond a proportional allocation of COVID vaccines to ensure fair and equitable access. 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.”

In practice, though, there have been difficulties with the COVAX scheme struggling to obtain sufficient supplies in the face of vaccine nationalism and shortages. In April 2021, the WHO published its priorities, strategies, and budget for the ACT-Accelerator for 2021. In its report, the WHO highlighted the multitude of challenges posed by the COVID-19 crisis: “We are facing an economic, humanitarian, security, and human rights crisis.” The document highlighted the key achievements of the institution and discussed the ways and means that the ACT-Accelerator could maximise its impact. 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;

---

102 Id.
104 Id.
105 Lisa Herzog et al., COVAX must go beyond Proportional Allocation of Covid Vaccines to ensure Fair and Equitable Access, 372 BRITISH MED. J. (2021).
109 Id. at 4.
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.\textsuperscript{110}

The April 2021 document also highlights a significant funding gap. Delivering on the ACT-Accelerator’s promises requires an additional $US22.1 billion in 2021. The document discusses the issues around financing COVAX. It also makes an economic case for investing in the ACT-Accelerator, noting that: “In January 2021, a study commissioned by the ICC demonstrated that even with strong COVID-19 vaccine coverage in high-income countries, inequitable access to COVID-19 tools elsewhere would cost high income economies an additional US$ 2.4 trillion in 2021 alone.”\textsuperscript{111} The report observed: “Investing in ACT-Accelerator dwarfs the potential multiplier benefits of domestic fiscal support investments.”

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 produced.”\textsuperscript{112} It was observed that an approach based on pledges of excess doses was insufficient.\textsuperscript{113} 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.”\textsuperscript{114} In its resolution, the European Parliament underlined the need to prioritise supplying COVAX and regretted moves by the UK and the US in developing a secondary re-sale market to sell surplus vaccines to other industrialised countries.\textsuperscript{115}

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.\textsuperscript{116} In its summary, the Panel acknowledged: “The uneven access to vaccination is one of today’s pre- eminent global challenges.”\textsuperscript{117} The Panel expressed its concern about the international inequities in the distribution of vaccines and how any progress with regard to the COVAX goals of delivering vaccine doses to low- and middle-income countries was hampered by a lack of sufficient funds, vaccine nationalism, and

\begin{thebibliography}{99}
\bibitem{110} Id. at 12.
\bibitem{111} Id. at 3.
\bibitem{112} Id.
\bibitem{113} 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, EUR. PARL. DOC. P9_TA (2021) 0283.
\bibitem{114} Id.
\bibitem{115} Id.
\bibitem{116} Id.
\bibitem{117} THE INDEPENDENT PANEL ON PANDEMIC PREPAREDNESS AND RESPONSE, supra note 23.
\bibitem{118} Id. at 12.
\end{thebibliography}
vaccine diplomacy. The 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.”

Investigative journalism by STAT and the Bureau of Investigative Journalism has suggested that COVAX has been “naively ambitious” in its plans to vaccinate the world. The study noted: “Some said COVAX failed to push for the IP sharing that will be needed to produce sufficient vaccines.” One informant told the journalists: “Of course they understood this [intellectual property sharing] was necessary, but the focus was on developing the vaccines and getting them approved.”

There has been further controversy that developed nations, such as Canada and Australia, have purchased medicines and vaccines from COVAX. On June 6, 2021, the Health Minister Greg Hunt announced that Australia paid $123 million to buy the option to purchase 24 million doses from COVAX. The chief executive of the Australian Council for International Development, Marc Purcell, said that the Australian Government had shown “desperation to get the preferable vaccine, Pfizer, from any sources into Australia”. 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.”

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.” The Shadow Foreign Affairs

---

119 Id. at 14 and 63.
121 Id.
122 Id.
125 Galloway, supra note 123.
126 Id.
127 Id.
Minister Penny Wong commented: “If Mr Morrison has had to resort to accessing vaccines intended for developing countries, he should be upfront about that.”

Nick Dearden of Global Justice Now observed that key vaccine developers had ignored the COVAX mechanism: “Just 1% of Pfizer’s supplies have been sold to the international distribution mechanism COVAX, as the company has put sales of third and fourth doses in wealthy markets ahead of selling doses to where they’re most needed.” He feared that this situation would “undoubtedly prolong the pandemic.”

C. Reform of COVAX

Stakeholders have commissioned 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 considered the ACT Accelerator’s achievements, best practices, challenges, and gaps as a basis for recommendations to enhance its future work. The report emphasized the need to “close the equity gap in COVID-19 tools” and “support all communities around the world to access and use the life-saving tools they need to end the acute phase of the COVID-19 pandemic.”

The review also emphasized that recipient countries and their representatives must play a central role in shaping the work of the ACT Accelerator. The review also called for strengthened visibility and accountability – so that stakeholders could follow and evaluate the collective work of the ACT Accelerator. The review also discussed sequencing and prioritization; the mandate; health systems and country support; participation and engagement; communication and information-sharing; and external collaboration and co-ordination.

The PVA has been critical of COVAX as a knowledge-sharing initiative, noting that “rich countries continue to cut bilateral supply deals with pharmaceutical companies which undermine this global effort and limit supply to poorer nations.” The 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 silent on how it will tackle monopolies.” The Alliance also laments the lack of democratic input into the decision-making process of the organization from civil society and

128 Karp, supra note 123.
130 Id.
131 Dalberg, ACT ACCELERATOR STRATEGIC REVIEW: AN INDEPENDENT REVIEW, (October 8, 2021) https://www.who.int/publications/m/item/act-accelerator-strategic-review
132 Id., 66.
134 Id.
developing countries. The Alliance has also been 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.” The Alliance was also deeply concerned at the prospect that COVAX would adopt a tiered pricing model. Accordingly, the Alliance has called for a reformation of COVAX.

IV. PATENT POOLS

Patent pools can be “defined as an agreement between two or more patent owners to license one or more of their patents to one another or to third parties”. Patent pools have been used to address access issues - particularly where there are patent thickets, which are impeding access to essential technologies. Michael Heller has discussed the role of patent pools as a means of addressing the “gridlock economy”. Increasingly, patent pools have been deployed in the context of medicine, biotechnology, and healthcare. 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.” The People’s Vaccine Alliance has also been a supporter of patent pools during the coronavirus crisis.

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. The Medicines Patent Pool [“MPP”] was established as an independent public health entity in 2010 - with the support

---

133 Id.
134 Id.
of UNITAID. According to the MPP, “[o]ur mission is to increase access to, and facilitate the development of, life-saving medicines for low- and middle income countries [“LMIC”].”\textsuperscript{144} The MPP discusses its strategies: “\textit{We do this through an innovative approach to voluntary licensing and patent pooling.}”\textsuperscript{145} It emphasized that it takes a collaborative approach to patent licensing: “\textit{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.}”\textsuperscript{146}

The mandate of the MPP is to “\textit{accelerate access to affordable quality treatments for people living with HIV, hepatitis C and tuberculosis, as well as HIV-associated comorbidities.}”\textsuperscript{147} Its role has evolved over the years: “\textit{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.}”\textsuperscript{148}

In 2020, the MPP temporarily expanded its mandate to include COVID-19 related technologies.\textsuperscript{149} Marie-Paule Kieny and Charles Gore from the MPP argued that there needs to be a master plan to address the licensing of COVID-19 patents.\textsuperscript{150} They offered to share their institutional expertise in terms of patent information and databases: “\textit{This repository of patent intelligence was established to allow countries and procurement agencies to identify patents that could hinder access to new medical innovations.}”\textsuperscript{151} Kieny and Gore observed that the MPP was in discussions with the WHO about how MPP could support the intellectual property pool and tap into their relationships with governments, industry, and key public health organizations to seek licensing agreements that could speed access to COVID-19 drugs, diagnostics, and vaccines.\textsuperscript{152}

The chair of the Unitaid Executive Board, Marisol Touraine, has also offered her support for the initiative: “\textit{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}\

\textsuperscript{144} Who We Are, MEDICINES PATENT POOL, https://medicinespatentpool.org/who-we-are/about-us/.
\textsuperscript{145} Id.
\textsuperscript{146} Id.
\textsuperscript{147} Id.
\textsuperscript{148} Id.
\textsuperscript{151} Id.
\textsuperscript{152} Id.
global fight against COVID-19.” 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.”

Charles Gore of the MPP 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.” He 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’.”

In July 2021, the MPP announced that it was joining a new consortium to boost vaccine capacity in South Africa and Sub-Saharan Africa. 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.” 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.” Charles Gore 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.” Other partners of the consortium include the biotechnology company Afrigen Biologics Vaccines; 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.

154 Id.
156 Id.
157 Id.
158 Id.
159 Id.
160 Id.
In October 2021, the MPP and MSD (the tradename of Merck & Co) entered into a license agreement for molnupiravir, an investigational oral antiviral COVID-19 medicine.\(^{161}\) This agreement will help create broad access for molnupiravir use in 105 low- and middle-income countries, subject to appropriate regulatory approvals. The MPP emphasized that this was its first agreement to provide access for a COVID-19 medical technology. Bangladesh’s Beximco has announced in November 2021 that it would sell a generic version of the Merck COVID-19 pill.\(^{162}\)

In a background paper for the Independent Panel, Ellen ‘t Hoen and her colleagues supported the involvement of the Medicines Patent Pool in licensing COVID-19 technologies: “The Medicine Patent Pool’s expertise in licensing 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”.\(^{163}\)

The Independent Panel made recommendations for the World Trade Organization and WHO to convene major vaccine-producing countries and manufacturers to get agreement on voluntary licensing and technology transfer arrangements for COVID-19 vaccines (including through the MPP).\(^{164}\) It was suggested: “If actions do not occur within three months, a waiver of intellectual property rights under the [TRIPS Agreement] should come into force immediately.”\(^{165}\)

**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”].\(^{166}\)

---


164 *The Independent Panel for Pandemic Preparedness and Response*, supra note 23.

165 Id. at 14, 63.

166 Knowledge Ecology International, *President Carlos Alvarado Quesada of Costa Rica at the C-TAP Solidarity Call to Action Launch*, YOUTUBE (May 29, 2020), https://www.youtube.com/watch?v=GQLjsDx115s; Press Release,
Taking up the proposal, the WHO issued a Solidarity Call to Action in May 2020. 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.” 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.” 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.”

President of Costa Rica, Carlos Alvarado Quesada and the Director-General of WHO, Tedros Adhanom Ghebreyesus contended: “When a COVID-19 vaccine does become available, it should be treated as a global public good.” 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. Costa Rica and the WHO have established a plan for the C-TAP: “The COVID-19 Technology Access Pool which 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.” 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.”


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 C-TAP.\textsuperscript{175}

However, some pharmaceutical companies and biotechnology developers have been unwilling to join this voluntary initiative thus far.\textsuperscript{176} Ellen ‘t Hoen reflected that “the success of C-TAP will depend on the political support it will receive.”\textsuperscript{177} She noted that 40 countries had endorsed the initiative.\textsuperscript{178} Ellen ‘t Hoen commented that “persuasion will need to come from governments 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.”\textsuperscript{179}

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.\textsuperscript{180} Dr Muhammad Zaheer Abbas has argued that Costa Rica’s proposal for the creation of a global pooling mechanism deserved serious consideration.\textsuperscript{181} He contended: “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.”\textsuperscript{182}

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.\textsuperscript{183} The civil society organizations Knowledge Ecology Action and Health Action International [“HAI”] expressed concerns about the WHO’s leadership of C-TAP. Knowledge Ecological International exhorted the WHO to “to 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.”\textsuperscript{184} HAI said that the

\textsuperscript{175} The People’s Vaccine Alliance, supra note 133.


\textsuperscript{177} ‘t Hoen, supra note 88.

\textsuperscript{178} Id.

\textsuperscript{179} Id.


\textsuperscript{182} Id.

\textsuperscript{183} Id.

Director-General’s report on the COVID-19 response should “acknowledge the C-TAP, a platform which, by gathering and channelling IP, know-how and other relevant data could play a critical role in transferring technology and scaling up production of vaccines, diagnostics and other health goods necessary to vanquish this pandemic.”

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.”

In February 2021, the Director-General of the WHO called on vaccine developers to do more to share their data and technology, seemingly making a renewed effort to get intellectual property holders to re-engage with C-TAP.

In correspondence with *Nature* in March 2021, the researchers, Etienne Billette de Villemeur, Vianney Dequiedt and Bruno Versaevel despaired: “The WHO’s C-TAP has so far received no contributions from industry.” They observed: “The practice of pooling patented technologies for the production of medicines already occurs for HIV, hepatitis C and tuberculosis treatments.” They also emphasized that “fees are typically lower when licences are negotiated as a bundle with generics producers, implying increased volume.” 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.”

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.”

Spain is collaborating with the C-TAP initiative to openly licence a serological test for COVID-19 developed by CSIC researchers. 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.” There has also been interest expressed in the initiative by the governments of Indonesia and Belgium.

In the United Kingdom Parliament, Liberal Democrat Layla Moran has chided the United Kingdom Government for its lack of co-operation with C-TAP. She posed the question: “Why did we not endorse the WHO COVID technology access protocol?” 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 vaccines, yet not back that protocol.” 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.”

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.” In response, a number of legislators have called for the Government of Ireland to support C-TAP. The Joint Committee on Foreign Affairs and Defence recommended formal endorsement of C-TAP by the government; Government advocacy for C-TAP and other mechanisms at an international level, particularly at the EU and at the UN Security Council; government assistance to encourage more

193 Id.
196 Id.
197 Id.
pharmaceutical companies to join C-TAP; and an increase of financial support for the WHO’s ACT Accelerator.\textsuperscript{201} The President of Ireland Michael Higgins has provided vocal support for C-TAP.\textsuperscript{202} He has called for co-operation in respect of the sharing of COVID-19 technologies: “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.”\textsuperscript{203} The President of Ireland underlined that access to essential medicines raised fundamental questions about global social justice: “Solidarity among nations is key if we are to optimise the world’s management and eventual exit from this pandemic.”\textsuperscript{204}

The European Parliament has lent its support for the WHO effort to create C-TAP.\textsuperscript{205} 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.”\textsuperscript{206} 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.”\textsuperscript{207}

\textsuperscript{201} JOINT COMMITTEE ON FOREIGN AFFAIRS AND DEFENCE, supra note 200, at 12.
\textsuperscript{204} Id.
\textsuperscript{206} EUR. PARL. DOC., supra note 113.
\textsuperscript{207} ‘T HOEN, supra note 163.
As of August 2021, C-TAP has assembled a number of implementing partners— including the MPP, the Open COVID Pledge, and the Tech Access Partnership. The role of these collaborators will be further discussed in some of the subsequent parts of the paper.

C. Opposition to Patent Pools

There remains concern that wealthy nations— who are donors to the WHO— have been trying to sideline and marginalise C-TAP. Moreover, leaders of pharmaceutical drug companies and vaccine developers have been uncooperative with sharing their data and technology with C-TAP. 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.” Similarly, AstraZeneca chief executive, Pascal Soriot, argued that, “if you don’t protect intellectual property, then essentially, there is no incentive for anybody to innovate.” 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.” 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. Mazzucato is the chair of a new WHO Council on the Economics of Health for All— which seeks to incorporate lessons learned during the COVID-19 pandemic. The Council has suggested that there is a need to rethink health innovation in light of the

---

211 Id.
212 Id.
213 Safi, supra note 155.
214 KNOWLEDGE ACCUMULATION AND INDUSTRY EVOLUTION: THE CASE OF PHARMA-BIOTECH (Mariana Mazzucato & Giovanni Dosi eds., 2006); MAZZUCATO, THE ENTREPRENEURIAL STATE, supra note 35; MAZZUCATO, THE VALUE OF EVERYTHING, supra note 35; MEDEIROS, supra note 35; MAZZUCATO, HOW DOES INNOVATION REALLY HAPPEN?, supra note 35; MAZZUCATO, MISSION ECONOMY, supra note 35.
COVID-19 crisis.\footnote{The WHO Council on the Economics of Health for All, \textit{Governing Health Innovation for the Common Good}, WORLD HEALTH ORGANISATION (June 9, 2021), https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/councilbrief-no1.pdf.} 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 corporate governance – particularly ensuring that the principle of Health for All governs public-private partnerships, and 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.”\footnote{WHO Director-General's Opening Remarks at the Media Briefing on COVID-19, WORLD HEALTH ORGANISATION (Feb. 5, 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.} He was disappointed by the response of intellectual property holders to C-TAP.\footnote{Kerry Cullinan, \textit{Indonesia and Bangladesh Reveal Massive Untapped Vaccine Production Capacity at C-TAP Anniversary}, HEALTH POLICY WATCH (May 28, 2021), https://healthpolicy-watch.news/indonesia-and-bangladesh-reveal-massive-untapped-vaccine-production-capacity-at-c-tap-anniversary/.} Dr Tedros reflected:

“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 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.”\footnote{Id.}

The recalcitrance of technology developers to participate in such cooperative 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.

\section*{V. Compulsory Licensing and Crown Use/ Government Use}

Under the \textit{TRIPS Agreement} and the \textit{Doha Declaration}, 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.\(^\text{220}\)

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.”\(^\text{221}\) 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.”\(^\text{222}\)

The People’s Vaccine Alliance has also supported the use of intellectual property flexibilities to provide access to essential medicines: “We are saying that in these unprecedented times, companies should share their knowledge and not enforce intellectual property rights in the interests of public health.”\(^\text{223}\)

### A. Compulsory Licensing for Domestic Purposes

Compulsory licensing is a mechanism which provides for access to patented inventions in return for compensation to the patent holders.\(^\text{224}\) Compulsory licensing has been used as a flexible policy doctrine in patent law to address unfair competition, public health concerns, as well as technology transfer.

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.\(^\text{225}\) Germany has passed amendments to an Act on the Prevention and Control

\(^{220}\) Dreifuss, \textit{supra} note 25.


\(^{222}\) \textit{Id.}

\(^{223}\) \textit{The People’s Vaccine Alliance, \textit{supra} note 133.}


of Infectious Diseases in Humans. 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. 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-19 patients. The Parliament of Chile also supported compulsory licensing for coronavirus medicines and vaccines. The Legislative Committee in Ecuador has approved a resolution on compulsory licensing of patents relating to the coronavirus. A number of Latin American countries may well contemplate the use of compulsory licensing – given the aggressive, overbearing negotiating tactics of vaccine developers.

In 2021, the Supreme Court of India considered the unprecedented humanitarian crisis in India, following the outbreak of the COVID-19 pandemic. It investigated 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

232 In Re: Distribution of Essential Supplies and Services During Pandemic, (2021) LL 2021 SC 2036 (India).
implicates the right to life under Article 21 and right to equality under Article 14 of the Constitution.” 233 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. 234 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.” 235 The Supreme Court of India made reference to intellectual property flexibilities available under the TRIPS Agreement, the Doha Declaration, 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”.236 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 Indian government to consider making use of intellectual property flexibilities to address the public health epidemic: “We have only outlined the legal framework within which the Central Government can possibly consider compulsory licensing and government acquisition of patents.”237 The Supreme Court of India noted: “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”.238 The Supreme Court of India encouraged the Government to take decisive action: “We clarify that it is up to the 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 could 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

---

233 Id.
234 Id.
235 Id.
236 Id.
237 Id.
238 Id.
239 Id.
240 Id.
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 “Africa needs to strengthen its own regional health bodies as important pathways to scaling and dispersal of R&D efforts.”\(^{243}\) He suggested: “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.”\(^{244}\)

The South Centre, a policy research organization, has provided guidance as to the use of compulsory licenses during the COVID-19 crisis.\(^{245}\)

Australian lawyers have contemplated the operation of compulsory licensing in the context of the COVID-19 crisis.\(^{246}\)

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.\(^{247}\) 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.”\(^{248}\) Wong noted that, 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.\(^{249}\)

---


\(^{244}\) Id.


\(^{248}\) Id.

\(^{249}\) Id.
She emphasized that governments must do what is necessary to fight the present pandemic. She also suggested 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. Wong warned 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.”

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. Moreover, the compulsory licensing decision is subject to judicial review which may suspend the execution of the compulsory license. ‘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.’”

**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, dealing with the export of pharmaceutical drugs. Nobel Laureate Professor Joseph Stiglitz has expressed his concern about the operation of the export mechanism under Article 31bis. He commented: “Life should always be put before profits, and never more so than in the midst of a pandemic.” In his view, “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.” Stiglitz maintained: “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.”
Given the nature of the coronavirus public health epidemic, the limited framework for compulsory licensing for the purposes of export must be reconsidered. Stiglitz has called for substantive action for reform of the export system in the face of the coronavirus crisis.260

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.261 As India needed to become TRIPS-compliant, there has been debate as to whether the compulsory expert licence system is effective in India.262 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.263

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.264 In Canada, St. Catharines pharmaceutical company Biolyse Pharma has wanted to help with the global COVID-19 vaccine rollout.265 The Government of Bolivia has expressed an interest in obtaining generic vaccines from Biolyse.266 Accordingly, Biolyse have made a license request to Johnson & Johnson, but that was denied by that company in March 2021.267 Biolyse has been critical of the obstacles that it has faced in its efforts to obtain compulsory licensing.268 John Fulton of Biolyse observed: “If we can’t get a compulsory licensing mechanism like this from the TRIPS Agreement to work right now, what’s the


Knowledge Ecology International noted that “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.”

Knowledge Ecology International recommended further patent law reform in Canada to promote access to essential medicines.

The government of Bolivia has been disappointed by the uncooperative approach to compulsory licensing for the purposes of export. Benjamin Blanco, Minister of Foreign Trade and Integration, Ministry of Foreign Relations for Bolivia, commented: “It is time to make decisions in the name of humanity.”

In addition to Bolivia, Antigua and Barbuda have notified the WTO of their intent to import products using compulsory licences. 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 – is broken. There is a need for fundamental overhaul of the regime to facilitate the distribution and dissemination of essential medicines during pandemics – like in respect of the coronavirus.

The European Union has opposed a proposal for a TRIPS Waiver. Instead, the EU has proposed a ‘third way’ of simplifying and streamlining the use of compulsory licensing under the TRIPS Agreement, the Doha Declaration, and the WTO General Council Decision 2003. The EU 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.” The EU suggested that WTO Members should agree to a number of propositions – including that “(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

---

269 Id.
270 Id.
272 Id.
275 Id.
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.”\textsuperscript{276} The EU 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.”\textsuperscript{277} Leaked documents have shown that the EU Council of Ministers defined its position on the TRIPS Waiver for vaccines in secret.\textsuperscript{278} There has been concern that the Big Pharma have had an undue influence on the formation of the EU position.

Human Rights Watch have questioned the justifications of the EU for opposing the TRIPS Waiver.\textsuperscript{279} It also observed that “there are significant barriers to making compulsory licenses a practical solution to the severe supply shortages the world is facing now.”\textsuperscript{280} 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.”\textsuperscript{281} Jorge Contreras has considered the use of compulsory licensing, government use, and march-in rights during the coronavirus pandemic.\textsuperscript{282}

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.\textsuperscript{283} 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

\textsuperscript{276} Id.
\textsuperscript{277} Id.
\textsuperscript{279} Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver, HUMAN RIGHTS WATCH (Jun. 3, 2021), https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver.
\textsuperscript{280} Id.
\textsuperscript{283} WHITFORD, supra note 197.
and ensure affordable access to these products.” Whitford stressed: “COVID-19 is unprecedented as a public health emergency, and access to these medical products cannot be restricted by intellectual property rights.”

There has been a parliamentary debate about this topic of patent law and crown use in Australia. In 2013, the Productivity Commission discussed the merits of compulsory licensing and crown use in a law reform review. The Productivity Commission suggested that crown use was a “less costly and time-consuming alternative to compulsory licensing”. The Productivity Commission made some recommendations as to how to improve the clarity, transparency and accountability of the crown use provisions. The Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2019 (Cth) sought to modernise the Crown use provisions. Senator Duniam, the Assistant Minister, noted: “There is some uncertainty about when Crown use can be invoked at the present, and this Bill makes it clear that while it is rarely used, it can be invoked when any Australian Federal, State or Territory government has the primary responsibility for providing or funding a service.” The Assistant Minister observed that the bill “ensures that Crown use can cover the full range of services that the public expects our Government to provide.”

During the coronavirus public health crisis, a 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 for repurposed manufacturing businesses, to address shortages of essential goods impacted by disrupted supply chains.” He commented that the Minister should explore the use of this provision, “particularly for urgent manufacturing of suppliers, such as facial masks or goods in short supply due to disrupted supply chains.” The Australian Government has warned that it will use its Crown Use powers if patent inventors engage in profiteering in respect of essential inventions. Australian lawyers have considered the dynamics of Crown use in the context of the COVID-19 crisis.

284 Id.
285 Id.
287 Id., 2.
289 Id.
290 Commonwealth, Parliamentary Debates, House of Representatives, 23 March 2020, 2801 (Brendan O’Connor, Member of Parliament (Austl.).
291 Id.
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.293

VI. PUBLIC SECTOR LICENSING

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

There has been a growing corpus of literature on intellectual property, education, and technology transfer. Corynne McSherry, the Legal Director of the Electronic Frontier Foundation, wrote a classic book about the battle for the control of intellectual property in academia.294 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.295 Hans Radder has explored how the higher education system has been affected by commodification.296 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.297

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.298 Public researchers were involved in patent

---

races with private biotechnology firms like Myriad Genetics, in respect of genetic testing. 299 There have also been controversies over access to essential medicines in respect of HIV/AIDS, malaria, and tuberculosis, which had been developed by public institutions. 300 Amy Kapczynski and her colleagues called for an open licensing approach to university innovations in order to address global health inequities. 301 There have been significant clashes in respect of patent rights and stem cell research. 302 More recently, there have been patent races between rival universities in respect of CRISPR, gene-editing technologies. 303 There has also been emerging disputes over 3D printing and bioprinting developed by public research institutions. 304 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. 305

Economist Mariana Mazucatto has highlighted that the pharmaceutical and biotechnology industries have benefitted enormously from publicly-funded blue sky research and state policies designed to facilitate commercialization. 306 The People’s Vaccine Alliance have expressed concern that publicly-funded inventions are being exploited for private profit during the coronavirus crisis. 307 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, not a private profit


300 Pogge, supra note 2.


306 MAZZUCATO, KNOWLEDGE ACCUMULATION AND INDUSTRY EVOLUTION, supra note 37; MAZZUCATO, THE ENTREPRENEURIAL STATE, supra note 37.

She emphasized: “We need to urgently end these monopolies so that we can scale up vaccine production, drive down prices and vaccinate the world.”

A. U.S.

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. 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. The organization has called upon public research institutions to ‘free the vaccine’.

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. 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.” 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.” She stressed: “We, the students, must speak up through our actions for the #FreetheVaccine movement.”

Navya Dasari, a 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”. She said: “The lives of my loved ones abroad matter as

308 Id.
309 Id.
310 Id.
311 Id.
313 Id.
314 Id.
315 Id.
much as the life of any American.”³¹⁷ 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.”³¹⁸

UAEM have campaigned vigorously for universities and research institutions to better transfer their technologies to combat global public health challenges – like the coronavirus.³¹⁹

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.³²⁰

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 COVID-19 during the pandemic.³²¹ The COVID-19 Technology Access Framework declares its commitment to implement the COVID-19 patenting and licensing strategies to enable global access,³²² noting that this usually involves use of “rapidly executable non-exclusive royalty-free licenses to intellectual property rights” which they have the right to license during the pandemic.³²³ The Framework further 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.”³²⁴ The initial signatories included Stanford University, Harvard University, and the Massachusetts Institute of Technology. Additional signatories included the Broad Institute, Cornell University, Dartmouth University, and a range of other universities.

In a letter to the U.S. Government, Knowledge Ecology International has argued that the U.S. Government should make use of its powers under the Bayh-Dole Act to ensure access to patents

³¹⁷ Id.
³¹⁸ Id.
³²¹ Id.
³²² Id.
³²³ Id.
³²⁴ Id.
on coronavirus relevant inventions. The Civil Society Organization have 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 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.”

Professor Jorge Contreras has observed that the U.S. 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.’ The economist Mariana Mazucatto has lamented: “And even though there are march-in rights under the Bayb-Dole Act, which allowed publicly financed research to be patented, unfortunately, the NIH seems not to be interested in using them effectively.”

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

“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.”

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

Some companies such as Moderna have given no guarantees that they will not seek to profit from vaccines. In particular, Public Citizen has highlighted that the Moderna vaccine was the

327 CONTRERAS, supra note 280.
328 Mazucatto, supra note 87.
329 RIZVI, supra note 63.
result of public investment in the research of the National Institutes of Health [“NIH”].

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.”

He argued that the U.S. 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.”

Dr 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. 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.”

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.” It remains to be seen whether the Biden Administration will use this patent power to secure better production and distribution of these key vaccines.

There is an emerging dispute between Moderna and the U.S. Government over patent rights in respect of named inventors. Moderna has filed a patent application – naming several of its employees as the only inventors of a crucial component of its coronavirus vaccine. The NIH says that three scientists at its Vaccine Research Center - Dr. John Mascola, the center’s director; Dr. Barney Graham; and Dr. Kizzmekia Corbett – should be named as inventors on the principal patent application. Kathy Stover, a spokeswoman for the National Institute for Allergy

332 Id.
333 Id.
334 Donato Paolo Mancini and Kiran Stacey, Vaccine Patent Gives US “Leverage” Over Manufacturers, FINANCIAL TIMES (Apr. 21, 2001), https://www.ft.com/content/d0c70cc2-0ffa-42dd-b0d0-0f76eeb273f0.
335 Id.
336 Id.
338 Id.
and Infectious Diseases, commented: “Omitting N.I.H. inventors from the principal patent application deprives N.I.H. of a co-ownership interest in that application and the patent that will eventually issue from it.”

B. United Kingdom

In the United Kingdom, Oxford University played a key role in the development of what has become known as the Oxford AstraZeneca vaccine. 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.” Nonetheless, urged by the Bill & Gates Foundation, Oxford University entered into an exclusive vaccine deal with AstraZeneca.

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.

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.” 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.”

However, others have been critical of Oxford’s COVID-19 vaccine deal with AstraZeneca. 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

339 Id.
344 Id., at 12.
345 Id., at 16.
sentiment that they will price their products responsibly.”

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.”

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.”

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.” 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.”

She stressed: “We need to use global governance mechanisms to ensure equitable distribution and supply of health technologies according to public health need.”

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.”

She stressed: “We need to use global governance mechanisms to ensure equitable distribution and supply of health technologies according to public health need.”

**C. The European Union**

The EU has made extensive investments in vaccine development for COVID-19. 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.” 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.” It 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.”

Samira Rafaela – a

---

347 Id.
348 Id.
349 WHITFORD, supra note 197.
350 Id.
351 Id.
352 Id.
354 EUR. PARL. DOC., supra note 113.
355 Id.
356 Id.
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.  

D. Australia

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.  

In the end, this vaccine project did not proceed further.  

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.  

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.”  

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.”  This is an interesting model to realise a People’s Vaccine in Australia.

VII. PATENT PLEDGES, OPEN LICENSING, AND OPEN INNOVATION

A. Patent Pledges

361 Id.  
362 Id.
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.” 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. He has been one of the architects of the Open COVID Pledge. Contreras and his collaborators have made a case for the adoption of voluntary pledges made by patent holders in respect of COVID-19 technologies. 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.” 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.”

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.” He was hopeful that the scheme would boost co-operation and collaboration 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.” Lemley noted that such licenses were time-bound, and would last until a year after WHO declared the end of the coronavirus pandemic. He also stressed: “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 OPEN COVID PLEDGE, https://opencovidpledge.org/
364 PATENT PLEDGES: GLOBAL PERSPECTIVES ON PATENT LAW’S PRIVATE ORDERING FRONTIER (Jorge L. Contreras & Meredith Jacob eds., 2017).
365 Jorge Contreras, Putting Pledged IP to work - Identifying IP available under the Open COVID Pledge, INFOJUSTICE (June 12, 2020), http://infojustice.org/archives/42399.
367 Id.
368 Id.
370 Id.
371 Id.
noted: “The pledge prevents them from being sued for things they do during the pandemic.” 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.” Stanford Postdoctoral student Ariel Ganz also played a part in the development of the Open COVID Pledge.

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. 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. The Creative Commons played a leadership role in taking over the management of the Open COVID Pledge during 2020. Peters has sought to internationalise the Open COVID Pledge – translating the Pledge into all six of the official languages of the United Nations. Peters has discussed the Open COVID Pledge on the ABC on Science Friction. In May 2021, the American University assumed the stewardship of the Open COVID Pledge.

B. Open Science

372 Id.
373 Id.
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.\textsuperscript{381} Professor Ginny Barbour has discussed the importance of open access publishing during the coronavirus crisis.\textsuperscript{382} Krishna Ravi Srinivas has been a trailblazing advocate of open source approaches in relation to biotechnology and medicine.\textsuperscript{383} He has recommended that ‘India should promote open innovation and open source drug discovery.’\textsuperscript{384} Amy Kapczynski has called for the establishment of an open science model to engage in research and development in respect of influenza.\textsuperscript{385} Open source advocates such as Professor Joshua Pearce have advocated the use of open licensing in respect of COVID-19 technologies.\textsuperscript{386} Henry Chesbrough has advocated open innovation models for the COVID-19 response and recovery.\textsuperscript{387}

There has been a joint appeal for open science by a number of international organisations–including CERN, OHCHR, UNESCO, and WHO.\textsuperscript{388} This statement promoted models of open access, open data, open medicine, open publishing, and open innovation. 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.”\textsuperscript{389} The joint call also insisted upon recognition of the principle of benefit-sharing in respect of scientific inventions: “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.”\textsuperscript{390} There has been a broader discussion of access to

\textsuperscript{381} Sean Flynn, Aidan Hollis & Mike Palmedo, \textit{An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries}, 37 (2) J. OF L., MED., AND ETHICS 184 (2009).

\textsuperscript{382} Ginny Barbour, \textit{How Open Access Suddenly Became the Norm}, \textsc{YouTube} (July 29, 2020), https://www.youtube.com/watch?v=-SueRnB0uCQ.


\textsuperscript{386} Joshua M Pearce, \textit{Distributed Manufacturing of Open-Source Medical Hardware for Pandemics}, 4 (2) J. OF MANUFACTURING AND MATERIALS PROCESSING 1(2020).

\textsuperscript{387} Henry Chesbrough, \textit{To Recover Faster from Covid-19, Open Up: Managerial Implications from an Open Innovation Perspective}, 88 \textsc{Indus. Marketing MGMT.} 410 (July 2020).


\textsuperscript{389} \textit{Id.}

\textsuperscript{390} \textit{Id.}
genetic resources and benefit-sharing in the context of pathogens and vaccines.\textsuperscript{391} The joint statement highlighted the importance of access to essential medicines: “\textit{Under international human rights law, States have a clear obligation to ensure international cooperation and access to a vaccine.}”\textsuperscript{392} The joint call also emphasized the importance of health for all: “\textit{Everyone, including vulnerable or marginalised individuals and groups, is entitled to enjoy the benefits of scientific progress — and when the benefits of science are managed as a purely commercial product reserved for the wealthy, everyone is harmed.}”\textsuperscript{393} This statement echoes a previous call for the adoption of open models of medical innovation by the United Nations Secretary General’s High Level Panel on Access to Medicines.\textsuperscript{394}

The People’s Vaccine Alliance has perceived open licensing as a means of encouraging the open sharing of technology, intellectual property, and data.\textsuperscript{395}

C. Open Innovation

Professor Richard Gold from McGill University has said that the coronavirus pandemic has shattered the status quo on drug development.\textsuperscript{396}

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.\textsuperscript{397} The researchers commented: “\textit{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}


\textsuperscript{393} Id.

\textsuperscript{394} Dreifuss, supra note 25.


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.’ The 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.”

Jeremy de Beer and Richard Gold emphasized that there is a need for an open, networked international response to pandemics – such as the coronavirus.

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. 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.” The researchers envisaged: “The independent, non-profit should be provided with long-term, stable funding to insulate it from day-to-day politics.” The researchers maintained: “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.”

The researchers emphasized that “funding councils and other funding bodies ought to establish specific open science calls, with significant funding.” The report concluded: “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.”

VIII. THE TRIPS WAIVER

The governments of India and South Africa have put forward a broad proposal for a TRIPS Waiver in respect of COVID-19 technologies. Meanwhile, the U.S. Government has supported a TRIPS Waiver for vaccines. A number of European countries have put forward counter-proposals to the TRIPS Waiver – focusing upon intellectual property flexibilities, such as compulsory licensing and voluntary licensing. There has been debate about the nature, scope,
and duration of the proposals of the TRIPS Waiver.\(^\text{407}\) It has proven to be difficult to obtain consensus amongst nation states as to an acceptable form for a 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, the People’s Vaccine Alliance has been a champion of the TRIPS Waiver.\(^\text{408}\)

### 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.\(^\text{409}\) 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.”\(^\text{410}\) 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 and trade secrets. 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.”\(^\text{411}\) In their view, “The waiver should 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.”\(^\text{412}\) Apparently, though, developed countries have resisted the adoption of the waiver.\(^\text{413}\)

Ellen t’ Hoen has discussed the importance of the TRIPS Waiver proposal.\(^\text{414}\) 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.”\(^\text{415}\)

---


\(^{409}\) COMMUNICATION FROM INDIA AND SOUTH AFRICA, supra note 64; See also, Thiru Balasubramaniam, WTO TRIPS Council: India and South Africa submit draft decision text on a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19, KNOWLEDGE ECOLOGY INT’L (Oct. 2, 2020), https://www.keionline.org/34061.

\(^{410}\) Id.

\(^{411}\) Id.

\(^{412}\) Id.

\(^{413}\) Id.

\(^{414}\) Hoen, supra note 88.

\(^{415}\) Id.
She 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.”

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.” Though many developing and least developed country members reacted positively to the proposal, some sought clarifications about its practical implementation and potential nation-wide impact of the waiver. 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 medicines and technologies.” 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.”

Alongside South Africa and India, a large number of nations have become co-sponsors of the TRIPS Waiver. 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.

B. The Shift of the Position of the U.S. on the TRIPS Waiver

---

416 Id.
418 Id.
419 Id.
420 Id.
The Trump Administration supported Operation Warp Speed in the U.S., but was unwilling to join in multilateral discussions about collaboration over COVID-19 technologies.\textsuperscript{423} There was concern that the Trump Administration adopted a “America First” approach to COVID-19 diagnostics, therapeutics, and vaccines.\textsuperscript{424} 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.\textsuperscript{425} 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 U.S. to assist India during the coronavirus crisis.\textsuperscript{426} 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.\textsuperscript{427} 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”.\textsuperscript{428} 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 ask that you prioritize people over pharmaceutical company profits by reversing the Trump position and announcing U.S. support for the WTO TRIPS waiver.”\textsuperscript{429}


\textsuperscript{428} Id.

\textsuperscript{429} Id.
The People’s Vaccine lobbyed the new Biden Administration to support a TRIPS Waiver. Former Heads of State and Nobel Laureates called on President Joe Biden to waive intellectual property rules for COVID Vaccines.430 Their letter stressed that, with the leadership of the U.S. President COVID-19 vaccine technologies could be shared with the world: “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”.431 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.”432 This broad-based social movement has been successful in shifting the position of the Biden administration.433

After much deliberation,434 the new Biden Administration has agreed to support a version of the TRIPS Waiver, which is focused on vaccines. The U.S. Trade Representative Ambassador Katherine Tai commented upon the justifications for the decision to support a TRIPS Waiver for Vaccines:

“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.”435

The Ambassador promised that the U.S. would actively participate in text-based negotiations over the TRIPS Waiver in the WTO – but noted that those negotiations would take time, given the consensus-based nature of the institution, and the complexity of the issues involved with

431 Id.
432 Id.
intellectual property and access to essential medicines. Katharine Tai insisted: “The Administration’s aim is to get as many safe and effective vaccines to as many people as fast as possible.” 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”.

The Ambassador also said that the U.S. administration “will also work to increase the raw materials needed to produce those vaccines.”

The Speaker of the House Nancy Pelosi commended the Biden Administration on its decision to support a TRIPS Waiver for Vaccines. 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 variants.” Pelosi stressed: “We cannot be fully safe from the virus anywhere until we defeat it everywhere.”

There were a number of countries who followed the leadership of the U.S. on the TRIPS Waiver. After previously being non-committal on the topic, Jacinda Ardern’s New Zealand Government said that it would support a TRIPS Waiver for vaccines. Her Trade Minister, the Hon. Damien O’Connor observed that New Zealand supported equitable access to COVID vaccines for all. 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. However, documents revealed under the Official Information Act showed that New Zealand Government had previously been frustrating efforts to promote a “People’s Vaccine”.”

---

436 Id.
437 Id.
438 Id.
440 Id.
441 Id.
442 (24 March 2021) 751 NZPD 1744, https://www.parliament.nz/resource/en NZ/HansD_20210324_20210324/566d2e95e499e0fabc70e8bac98d8cecf0d61f00
445 Id.
There remains a clutch of countries who have been non-committal about the TRIPS Waiver. The Australian Government, for instance, was equivocal for a long time about the TRIPS Waiver in public.\(^447\) While expressing enthusiasm for President Joe Biden’s stance,\(^448\) the Australian Government seems wary of offending the vaccine developer, Pfizer, and other biomedical companies, who are strident opponents of the TRIPS Waiver.\(^449\) Opposition parties such as the Australian Labor Party and the Australian Greens have pressed the Coalition Government to support the TRIPS Waiver.\(^450\) 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 heart-breaking emergency, and Africa, with 16 per cent of the world’s population, has less than two per cent of vaccines.”\(^451\) 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 can enable an equal distribution of the vaccines.”\(^452\) 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 people’s lives and provide your full-throated support to the TRIPS waiver now.”\(^453\) A number of civil society groups – including Human Rights Watch, MSF Australia, and AFTINET – have encouraged the Coalition Government to adopt the TRIPS Waiver.\(^454\)


on access to essential medicines, and Prime Minister Justin Trudeau had previously made statements about the importance of universal access to essential medicines. 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. Professor Richard E. Gold of McGill University wonders whether the Canadian Government is fearful of a backlash from Big Pharma: “Any time that the government worries about exporting or decreasing IP, they’re going to get attacked by certain sectors, including the pharmaceutical sector.”

C. Opposition to the TRIPS Waiver

In spite of the Biden administration’s support for the TRIPS Waiver, there are a range of holdouts to the TRIPS Waiver who have been obstructing consensus on the proposal in the World Trade Organization. The European Commission has been steadfast in its opposition to the TRIPS Waiver. The Government of Germany has been particularly resistant to the adoption of a TRIPS Waiver. 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.” In 2021, Chancellor Angela Merkel engaged in backsliding from this position, and insisted that vaccines for COVID-19 should still be subject to private intellectual property rights. A German government spokeswoman said: “The protection of intellectual property is a source of innovation and this has to remain so

---


462 TRAID EU ET AL., supra note 101.


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 U.S. in 2021. During her visit to the White House, various U.S. legislators and civil society groups engaged in vocal criticism of her stance. 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.

The European Parliament, in a vote, called upon the European Commission to support a TRIPS Waiver. 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 Agreement on patents to improve global access to affordable COVID-19-related medical products and to address global production constraints and supply shortages.

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

Other opponents of the TRIPS Waiver include the Governments of the United Kingdom, Switzerland, Norway, and Brazil. Somewhat indecisively, Japan has said that it would not oppose the TRIPS Waiver but it would not endorse the TRIPS Waiver either.

468 Id.
473 EUR. PARL. DOC., supra note 113.
The Conservative Government led by Boris Johnson has resisted entreaties to support the TRIPS Waiver. 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. 80 Members of Parliament signed a petition on Intellectual Property and the COVID-19 response. The co-sponsors included Caroline Lucas from the Green Party, Navendu Mishra and Clive Lewis of the British Labour 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.”

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.”

Richard Burgon MP has also called for the United Kingdom to support a “People’s Vaccine.”

The Gates Foundation has a history of supporting intellectual property maximalist positions in the debate over access to essential medicines. The Gates Foundation was initially supportive of

---

481 *Id.*
private intellectual property holders being in charge of the distribution of vaccines, treatments, and diagnostics. However, there have 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.\(^485\) The Gates Foundation was a reluctant, late supporter of the TRIPS Waiver.\(^486\) There is a need to set in place mechanisms to ensure the fair and equitable distribution of COVID-19 technologies in the U.S. and elsewhere.

Big pharmaceutical companies and vaccine developers are clearly seeking to delay, frustrate, and block the passage of the TRIPS Waiver.\(^487\) There has been an extensive lobbying campaign by intellectual property owners to nation governments against the adoption of the TRIPS Waiver.\(^488\) Vaccine developers have also been placing great pressure upon nation states during negotiations to acquire vaccines.\(^489\) 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.

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-U.S. Free Trade Agreement 2004\(^490\) and the regional trade agreement, the Trans-Pacific Partnership.\(^491\) 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-19.492

There has been an open petition by over 100 academics, scholars, and researchers, calling for the adoption of the TRIPS Waiver.493 The letter stressed: “The temporary TRIPS waiver - as 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.”494 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.”495 In addition to the passage of the TRIPS Waiver, the academics called for the adoption of a package of measures – including the “global coordination 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.”496

494 Id.
495 Id.
496 Id.
In July 2021, MSF has complained that opposing countries have been filibustering negotiations on the TRIPS Waiver at the WTO. 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.” 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.”

Ellman called for a broad version of the TRIPS Waiver to be adopted, which covered not just vaccines, but also treatments, diagnostics, and other health technologies. The 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.

In November 2021, the International Commission of Jurists issued an opinion, calling for the waiver of global intellectual property rights for COVID-19 vaccines and therapeutics. The International Commission of Jurists recognised “that for the pandemic to end, or at least be brought under control, urgent access to vaccines is crucial, even if they are not the only determinant of the rights to health, science, equality and life”. The Opinion observed: “Failing to implement legitimate and legal, public health safeguards, as provided in the TRIPS Agreement, including by creating obstacles to the TRIPS waiver negotiations, constitutes a failure on the part of States parties to fulfil their human rights obligations under the rights to health, equality, science and life.”

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

498 Id.
499 Id.
500 Id.
503 Id., 17.
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 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 reach a critical mass, 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-19.504 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 various 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 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 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 established developed nations like Germany, Switzerland, and Norway, with close ties to biomedical industries.

By its nature, this study is a provisional overview of a panoply of policy proposal, 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.’\textsuperscript{505} 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.’\textsuperscript{506} 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.’\textsuperscript{507} It is certainly the case that there is scope to reimage 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.”\textsuperscript{508} 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.”\textsuperscript{509} 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.”\textsuperscript{510} Tawfik imagines: “A post-pandemic IP legal order will be built on greater collaboration, balance and inclusion.”\textsuperscript{511} She is hopeful that the intellectual property

\textsuperscript{505} HOEN ET AL., supra note 163.
\textsuperscript{506} HOEN ET AL., supra note 163.
\textsuperscript{507} Arundhati Roy, The Pandemic is a Portal, FINANCIAL TIMES (Apr. 4, 2020), https://www.ft.com/content/10d8f5e8-74eb-11ea-95fc-fcd274e920ca.
\textsuperscript{509} Id.
\textsuperscript{510} Id.
\textsuperscript{511} Id.
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”.

Susi Geiger and Aisling McMahon have expressed concern about the complicated, fragmented nature of the institutional landscape. 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.

After being paralysed by conflict between the superpowers of China and the U.S., 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, the WTO has hosted debates in the TRIPS Council over proposals such as the TRIPS Waiver. 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.”

With the changeover of Director-Generals, WIPO has been relatively quiet in respect of the debate over intellectual property and access to medicines during the coronavirus crisis. WHO, WTO, and WIPO have previously worked together on intersections between intellectual property, public health, and trade. In 2021, the directors 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. The leaders of the international institutions stressed: “We

---

512 Id.
513 Geiger and McMahon, supra note 504.
514 THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, supra note 23.
518 WORLD HEALTH ORGANIZATION, WORLD INTELLECTUAL PROPERTY ORGANIZATION & WORLD TRADE ORGANIZATION, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION - INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE (Charlotte Beauchamp et al., eds., 2nd ed. 2020).
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.”\footnote{Dreifuss et al., supra note 25.} 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.\footnote{Id.} There is certainly a pressing need to ensure better financing for global public health.\footnote{Id.} 

There has also been discussion as to whether there should be an international pandemic treaty to better protect the world from future health crises.\footnote{Id.} 25 heads of government and international agencies made a joint call for more robust international health architecture.\footnote{Id.} The joint statement noted: “The COVID-19 pandemic has been a stark and painful reminder that nobody is safe until everyone is safe.”\footnote{Id.} 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.”\footnote{Id.} 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.”\footnote{Id.}


---


\footnote{Global Leaders Unite In Urgent Call for International Pandemic Treaty, WORLD HEALTH ORGANIZATION (Mar. 30, 2021), https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty.}

There have been a host of proposals for COVID-19 recovery plans. 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.” 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.”


532 Id.