

**THE PEOPLE’S VACCINE: INTELLECTUAL PROPERTY, ACCESS TO ESSENTIAL  
MEDICINES, AND COVID-19**

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**Abstract**

*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.*

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## 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.<sup>1</sup> In the past, there has been concern about patent races in respect of medicines during public health epidemics.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> In the 1990's, there were dramatic conflicts between South Africa and large pharmaceutical companies over access to medicines sourced from India.<sup>5</sup> 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

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<sup>1</sup> 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).

<sup>2</sup> GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS, AND DEVELOPMENT (Peter Drahos & Ruth Mayne eds., 2003); 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); BURCU 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).

<sup>3</sup> Michael Kirby, *Foreword*, in MATTHEW RIMMER, INTELLECTUAL PROPERTY AND BIOTECHNOLOGY: BIOLOGICAL INVENTIONS (2008).

<sup>4</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

<sup>5</sup> Mark Heywood, *South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health*, 1 J. HUM. RIGHTS PRACT. 14 (2009); Amy Kapczynski & Jonathan Michael Berger, *The Story of the TAC Case: the Potential and Limits of Socio-economic Rights Litigation, in South Africa*, in HUMAN RIGHTS ADVOCACY STORIES 43 (Deena Hurwitz & Margaret Satterthwaite eds., 2009); NATHAN GEFFEN, DEBUNKING DELUSIONS: THE INSIDE OF THE TREATMENT ACTION CAMPAIGN (2010); DYLAN MOHAN GRAY, FIRE IN THE BLOOD: MEDICINE MONOPOLY MALICE (2012).

states could make use of flexibilities to address public health epidemics.<sup>6</sup> There have nonetheless been controversies when developing nations have made use of domestic compulsory licensing provisions – with pharmaceutical companies making procedural and substantive complaints about such measures.<sup>7</sup> The *WTO General Council Decision* 2003 was intended to assist the export of pharmaceutical drugs to developing nations and least developed nations – and has been encoded into the *TRIPS Agreement* 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.<sup>8</sup>

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

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<sup>6</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration]. See generally, ELLEN ‘T HOEN, *THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER: DRUG PATENTS, ACCESS, INNOVATION AND THE APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH* (2009).

<sup>7</sup> Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (Aug. 30, 2003). See generally, FREDERICK ABBOTT & RUDOLF VAN PUymbROECK, *COMPULSORY LICENSING FOR PUBLIC HEALTH A GUIDE AND MODEL DOCUMENTS FOR IMPLEMENTATION OF THE DOHA DECLARATION PARAGRAPH 6 DECISION* (2012).

<sup>8</sup> Matthew Rimmer, *Race against Time: The Export of Essential Medicines to Rwanda*, 1 (2) PUBLIC HEALTH ETHICS, 89-103 (2008); James Love, *Open letter asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured under Compulsory License in Another Country, under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INTERNATIONAL (2020), <https://www.keionline.org/32707>; Weinian Hu, *Compulsory Licensing and Access to Future COVID Medicines*, CEPS RESEARCH REPORT (2020); Brook Baker, *The Impracticality of Relying on Compulsory Licenses to Expand Production Capacity for COVID-19 Vaccines*, HEALTH GAP (June 6, 2021), <https://healthgap.org/the-impracticality-of-relying-on-compulsory-licenses-to-expand-production-capacity-for-covid-19-vaccines/>; and Muhammad Zaher Abbas, *World Trade Organization’s Export-oriented Compulsory Licensing Mechanism: Foreseen Policy Concern for Africa to Mitigate the COVID-19 Pandemic*, 17 (2) JOURNAL OF GENERIC MEDICINES 71-76 (2021).

<sup>9</sup> *Novartis v. Union of India & Others*, (2014) 6 SCC 1; Hafiz Aziz Ur Rehman, *The Pharmacy of the Developing World: India, Patent Law and Access to Essential Medicines*, (open access PhD thesis, Australian National University), <https://openresearch-repository.anu.edu.au/handle/1885/110380>; Ravinder Gabble & Jillian Clare Kohler, *To Patent or Not To Patent? The Case of Novartis’ Cancer Drug Glivec in India*, 10 GLOBALIZATION & HEALTH (2014).

<sup>10</sup> Muhammad Zaheer Abbas, *Community-Based Patent Opposition in India: Access to Essential Medicines, Right to Health, and Sustainable Development*, QUT ePrints (2019), <https://eprints.qut.edu.au/205327/>.

epidemics.<sup>11</sup> There has been complex politics in respect of disease outbreaks in the wider South-East Asia as well.<sup>12</sup>

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.<sup>13</sup> There has been an under-investment by pharmaceutical drug companies in relation to tuberculosis.<sup>14</sup> 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.*”<sup>15</sup> The emergence of new strains of influenza – such as avian influenza<sup>16</sup> and porcine influenza<sup>17</sup> – have also tested the intellectual property regime.<sup>18</sup> There was a patent race in respect of genetic sequencing the severe acute respiratory syndrome [“SARS”] virus – and discussion as to whether a patent pool would be appropriate to share key technologies.<sup>19</sup> There has also been controversy over patents being granted in respect of the Middle East respiratory syndrome [“MERS.”<sup>20</sup> Furthermore, complicated geopolitical factors were involved in terms of

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<sup>11</sup> Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491 (2007); HANS LOFGREN, *THE POLITICS OF THE PHARMACEUTICAL INDUSTRY AND ACCESS TO MEDICINES: WORLD PHARMACY AND INDIA* (2018); MURPHY HALLIBURTON, *INDIA AND THE PATENT WARS: PHARMACEUTICALS IN THE NEW INTELLECTUAL PROPERTY REGIME* (2017).

<sup>12</sup> Sara E. DAVIES, *CONTAINING CONTAGION: THE POLITICS OF DISEASE OUTBREAKS IN SOUTHEAST ASIA* (2019).

<sup>13</sup> SONIA SHAH, *HOW MALARIA HAS RULED HUMANKIND FOR 500,000 YEARS* (2010); *see also, Malaria*, MÉDECINS SANS FRONTIÈRES, <https://www.msf.org/malaria>.

<sup>14</sup> Jisnu Das et al., *Use of Standardised Patients to Assess Quality of Tuberculosis Care: A Pilot, Cross-Sectional Study*, 15 (11) LANCET INFECT. DIS. 1305 (2015); Madhukar Pai et. al, *Tuberculosis*, in NATURE REVIEWS DISEASE PRIMERS 16076 (2016); Madhukar Pai et al., *Reducing Global Tuberculosis Deaths - Time for India to Step Up*, 389 (10075) THE LANCET 1174 (2017).

<sup>15</sup> *Tuberculosis*, MÉDECINS SANS FRONTIÈRES, <https://www.msf.org/tuberculosis>.

<sup>16</sup> Andrew Torrance, *Patents to the Rescue – Disasters and Patent Law*, 10 (3) DEPAUL J. HEALTH CARE L. 309 (2007); Dennis Crouch, *Nil: 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).

<sup>17</sup> Dawn Dziuba, *TRIPS Article 31Bis and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection*, 20 (2) IND. INT'L & COMP. L. REV. 195 (2010).

<sup>18</sup> WORLD HEALTH ORGANIZATION, *PATENT LANDSCAPE FOR THE H5 VIRUS: INTERIM REPORT* (Nov. 17, 2007), [https://www.who.int/influenza/resources/documents/avian\\_flu\\_landscape.pdf?ua=1](https://www.who.int/influenza/resources/documents/avian_flu_landscape.pdf?ua=1); WORLD INTELLECTUAL PROPERTY ORGANIZATION, *WIPO PATENT SEARCH REPORT ON PANDEMIC INFLUENZA PREPAREDNESS (PIP)-RELATED PATENTS AND PATENT APPLICATIONS* (Apr. 1, 2011), [https://www.who.int/influenza/resources/Influenza\\_FullReport\\_01Apr2011.pdf](https://www.who.int/influenza/resources/Influenza_FullReport_01Apr2011.pdf).

<sup>19</sup> 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. INT'L L.MJIL 335 (2004); James Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: the Possible Role of Patent Pooling*, 83 (9) BULL. WORLD HEALTH ORG. 707 (2005).

<sup>20</sup> Carsten Richter, *European Patent Office Grants Controversial Patent Protecting Virus: Lessons from the Middle East Respiratory Syndrome Coronavirus Outbreak*, 39 NATURE BIOTECHNOLOGY 287 (2021).

patent filings in respect of diagnostics and medicines developed in relation to the Ebola outbreak.<sup>21</sup> There has also been intellectual property raised in relation to the Zika outbreak.<sup>22</sup> 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 policy-makers. The Independent Panel for Pandemic Preparedness and Response has lamented: “*As soon as a health threat or deadly outbreak fades from memory, complacency takes over in what has been dubbed a cycle of panic and neglect.*”<sup>23</sup>

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.<sup>24</sup> 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.<sup>25</sup> 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 been better prepared for the issues around intellectual property and access to medicines arising in the context of the covid-19 virus.

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<sup>21</sup> Amir Attaran & Jason Nickerson, *Is Canada Patent Deal obstructing Ebola Vaccine Development?*, 384 (9958) THE LANCET 61 (2014); Matthew Herder et al., *From Discovery to Delivery: Public Sector Development of the rVSV-ZEBOV Ebola Vaccine*, 7 (1) J. L. & BIOSCIENCES (2020), <https://academic.oup.com/jlb/article/7/1/lasz019/5706941>; PAUL FARMER, FEVERS, FEUDS, AND DIAMONDS: EBOLA AND THE RAVAGES OF HISTORY (2020).

<sup>22</sup> KNOWLEDGE ECOLOGY INTERNATIONAL, *An Exclusive License to Patents on a New Zika Vaccine to Sanofi is Contrary to the Provisions of 35 U.S.C. 209(a)(1)* (12 January 2017), <https://www.keionline.org/wp-content/uploads/Zika-12Jan2016-KEI-AFSCME-PFAM-UAEM-BAKER-35USC209a1.pdf>; Ana Santos Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine*, 127 YALE L.J. 651 (2017).

<sup>23</sup> Main Report, *COVID-19: Make It The Last Pandemic*, THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE (2021), [https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic\\_final.pdf](https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf).

<sup>24</sup> *Ban Establishes Eminent Panel to Help Broaden Access to Quality Medicines at Affordable Costs*, UNITED NATIONS NEWS (Nov. 20, 2015), <https://news.un.org/en/story/2015/11/516102-ban-establishes-eminent-panel-help-broaden-access-quality-medicines-affordable>.

<sup>25</sup> Ruth Dreifuss et al., REPORT OF THE UNITED NATIONS SECRETARY-GENERAL’S HIGH LEVEL PANEL ON ACCESS TO MEDICINES: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES (2016), <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

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*”.<sup>26</sup> 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.*”<sup>27</sup> 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*”.<sup>28</sup> 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.*”<sup>29</sup> Brook Baker cautions: “*This unbridled nationalism, interlinked with a broken, profit-driven pharmaceutical system risks obstructing access to life-saving medicines worldwide.*”<sup>30</sup> 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.*”<sup>31</sup> Fatima Bhutto has questioned the morality of vaccine hoarding by wealthy nations.<sup>32</sup> There have been concerns that vaccine nationalism will prolong the pandemic.<sup>33</sup> 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

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<sup>26</sup> WHO Director-General, WHO Director-General's Opening Remarks at the Media Briefing on COVID-19, (Jan. 8, 2021), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-8-january-2021>.

<sup>27</sup> *Id.*

<sup>28</sup> Jason Nickerson & Matthew Herder, *COVID-19 Vaccines as Global Public Goods*, in *VULNERABLE: THE LAW, POLICY AND ETHICS OF COVID-19*, 591 (Colleen Flood et al. eds., 2020).

<sup>29</sup> Colum Lynch, ‘*America First*’ vs. ‘*The People’s Vaccine*’, *FORBES POLICY* (July 6, 2020), <https://foreignpolicy.com/2020/07/06/coronavirus-vaccine-nationalism-america-first-covax/>.

<sup>30</sup> Brook Baker, *US-, China- and EU-First Nationalism and COVID-19 Technology Hoarding Push the Rest of the World to the End of the Line*, *INFOJUSTICE* (June 8, 2020), <http://infojustice.org/archives/42383>

<sup>31</sup> Richard Hass, *The Politics of a COVID-19 Vaccine*, *PROJECT SYNDICATE* (July 14, 2020), <https://prosyn.org/WCaVyfd>.

<sup>32</sup> Fatima Bhutto, *The World's Richest Countries are Hoarding Vaccines. This is Morally Indefensible*, *THE GUARDIAN* (Mar. 17, 2021), [https://theguardian.com/commentisfree/2021/mar/17/rich-countries-hoarding-vaccines-us-eu-africa?CMP=share\\_btn\\_tw](https://theguardian.com/commentisfree/2021/mar/17/rich-countries-hoarding-vaccines-us-eu-africa?CMP=share_btn_tw).

<sup>33</sup> Elizabeth Melimopoulos, *Why Hoarding COVID Vaccines Could Prolong Pandemic*, *AL JAZEERA* (Feb. 19, 2021), <https://aje.io/c9ccv>.

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 rights, and sustainable development.<sup>34</sup> Taking its cue from such research, this paper focuses upon the People’s Vaccine campaign – which has evolved into the broad-based People’s Vaccine Alliance. This paper also considers the work of other key non-government organisations and civil society groups – such as the MSF Access Campaign, Universities Allied for Essential Medicines, and Human Rights Watch. This paper is also informed by the economic scholarship of Mariana Mazzucato.<sup>35</sup> Her work has been focused upon the reform of health innovation – particularly of late in respect of the coronavirus crisis. This paper also draws upon innovation policy in its understanding of the responses of governments and corporations to the coronavirus crisis.<sup>36</sup>

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

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<sup>34</sup> DUNCAN MATTHEWS, *INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT: THE ROLE OF NGOS AND SOCIAL MOVEMENTS* (2011). See also Duncan Matthews, *Reappraising the Relationship between Intellectual Property Rights and Human Rights: A COVID-19 Pandemic Response*, Queen Mary Law Research Paper No. 366/2021, (September 9, 2021).

<sup>35</sup> KNOWLEDGE ACCUMULATION AND INDUSTRY EVOLUTION: THE CASE OF PHARMA-BIOTECH (Mariana Mazzucato & Giovanni Dosi eds., 2006); MARIANA MAZZUCATO, *THE ENTREPRENEURIAL STATE: DEBUNKING PUBLIC VS. PRIVATE SECTOR MYTHS* (2014); MARIANA MAZZUCATO, *THE VALUE OF EVERYTHING: MAKING AND TAKING IN THE GLOBAL ECONOMY* (2018); Joad Medeiros, *This Economist Has a Plan to Fix Capitalism. It’s Time We All Listened*, WIRED (Oct. 8, 2019), <https://www.wired.co.uk/article/mariana-mazzucato>; Mariana Mazzucato, *How Does Innovation Really Happen?*, WIRED SMARTER (Feb. 21, 2020), <https://www.youtube.com/watch?v=uXWhwereXYo>; MARIANA MAZZUCATO, *MISSION ECONOMY: A MOONSHOT GUIDE TO CHANGING CAPITALISM* (2021).

<sup>36</sup> JOSHUA GANS, *THE PANDEMIC INFORMATION GAP AND THE BRUTAL ECONOMICS OF COVID-19: DESIGN THINKING, DESIGN THEORY* (2020).

– 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.<sup>37</sup> 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.*”<sup>38</sup> They also called for a similar approach to other treatments, diagnostics, and technologies related to COVID-19.<sup>39</sup>

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.*”<sup>40</sup> The group observes that in order to achieve a “People’s Vaccine” it will be necessary to “[b]reak the shackles

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<sup>37</sup> *COVID-19 Vaccine Open Letter*, UNAIDS (July 14, 2020), [https://www.unaids.org/en/resources/presscentre/featurestories/2020/may/20200514\\_covid19-vaccine-open-letter](https://www.unaids.org/en/resources/presscentre/featurestories/2020/may/20200514_covid19-vaccine-open-letter).

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *What is the People’s Vaccine Alliance?*, THE PEOPLE’S VACCINE ALLIANCE, <https://peoplesvaccine.org/faq/>.

*of intellectual property on vaccines and COVID-19 knowledge.*<sup>41</sup> 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.*”<sup>42</sup> 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.*”<sup>43</sup> The members of the organization include 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.<sup>44</sup>

Having witnessed the tragedy of the HIV/AIDS epidemic in Uganda, Winnie Byanyima has long been a steadfast advocate for access to essential medicines.<sup>45</sup> 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.<sup>46</sup> 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.<sup>47</sup> 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.<sup>48</sup> 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.*”<sup>49</sup> In her view, “*A vaccine should be a global public good and free of charge for all.*”<sup>50</sup> Byanyima has sought to frame the question of the People’s Vaccine

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<sup>41</sup> *Id.*

<sup>42</sup> *Our Demands*, THE PEOPLE’S VACCINE ALLIANCE, <https://peoplesvaccine.org/our-demands/>.

<sup>43</sup> *Id.*

<sup>44</sup> Zain Rizvi, *The People’s Vaccine*, PUBLIC CITIZEN (June 11, 2020), <https://www.citizen.org/article/the-peoples-vaccine/>.

<sup>45</sup> Jon Cohen, “*I’m Known as An Activist.*” *New UNAIDS Leader Takes Charge*, SCIENCE (27 November 2019), <https://www.sciencemag.org/news/2019/11/i-m-known-activist-new-unaid-leader-takes-charge>.

<sup>46</sup> Dreifuss, *supra* note 25.

<sup>47</sup> Winnie Byanyima & Matthew Kavanaugh, *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\\_tw](https://www.theguardian.com/global-development/2020/dec/01/this-world-aids-day-the-global-response-to-hiv-stands-on-a-precipice?CMP=share_btn_tw).

<sup>48</sup> Winnie Byanyima, *Opening Remarks at the High-Level Meeting on AIDS*, UNAIDS (June 8, 2021), [https://www.unaids.org/en/resources/presscentre/featurestories/2021/june/20210608\\_opening-remarks-unaid-executive-director-hlm](https://www.unaids.org/en/resources/presscentre/featurestories/2021/june/20210608_opening-remarks-unaid-executive-director-hlm).

<sup>49</sup> 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](https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/september/20200929_covid-19-survivors-write-to-pharmaceutical-bosses-to-demand-a-peoples-vaccine).

<sup>50</sup> *Id.*

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.”<sup>51</sup> She feared that anything short of that would lead to more deaths and economic chaos, forcing millions into destitution.<sup>52</sup> She called upon the Big Pharma to share their intellectual property to achieve a People’s Vaccine.<sup>53</sup>

Helen Clark, the former Prime Minister of New Zealand, and Winnie Byanyima have expanded upon the case for a People’s Vaccine.<sup>54</sup> 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.”<sup>55</sup> They argued: “This extraordinary moment calls for a better approach than our current regime of monopoly rights.”<sup>56</sup> 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.”<sup>57</sup> 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.”<sup>58</sup>

Helen Clark expanded upon such concerns about access to medicines as part of her Independent Panel report into the global response to COVID-19.<sup>59</sup> For her part, Byanyima has been distressed by the lack of progress on vaccine equity in 2021.<sup>60</sup> 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

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<sup>51</sup> 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\\_pressident-nigeria-unites-behind-call-for-peoples-vaccine-for-covid19](https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201016_pressident-nigeria-unites-behind-call-for-peoples-vaccine-for-covid19).

<sup>52</sup> *Id.*

<sup>53</sup> 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/59393e03-20ac-466b-81d1-5773ddf86449>.

<sup>54</sup> Helen Clark & Winnie Byanyima, *The World Needs A “People’s Vaccine” for Coronavirus, Not a Big-Pharma Monopoly*, THE GUARDIAN (July 23, 2020), [https://www.theguardian.com/commentisfree/2020/jul/23/world-needs-coronavirus-vaccine-big-pharma-monopoly-astrazeneca-patent-pandemic?CMP=share\\_btn\\_tw](https://www.theguardian.com/commentisfree/2020/jul/23/world-needs-coronavirus-vaccine-big-pharma-monopoly-astrazeneca-patent-pandemic?CMP=share_btn_tw).

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> Press Release, OXFAM, *World Leaders Unite in Call for a People’s Vaccine Against COVID-19* (May 14, 2020), <https://www.oxfam.org/en/press-releases/world-leaders-unite-call-peoples-vaccine-against-covid-19>.

<sup>59</sup> THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 23.

<sup>60</sup> Winnie Byanyima, *We Are Seeing a Global Vaccine Apartheid. People’s Lives Must Come Before Profit*, THE GUARDIAN (Jan. 29, 2021), <https://theguardian.com/global-development/2021/jan/29/a-global-vaccine-apartheid-is-unfolding-peoples-lives-must-come-before-profit>.

*this crisis.*<sup>61</sup> 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.*”<sup>62</sup> 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 could render the vaccines we have and the vaccines some people in rich countries have already received, less effective or ineffective.*”<sup>63</sup>

## **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.<sup>64</sup> 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*”.<sup>65</sup> 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.*”<sup>66</sup> Ramaphosa observed: “*All the science must be shared between governments.*”<sup>67</sup> 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.*”<sup>68</sup> He noted that “*a bold international agreement cannot wait.*”<sup>69</sup> 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.*”<sup>70</sup> 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.*”<sup>71</sup>

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<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> Communication from India and South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, IP/C/W/669 (Oct. 2, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

<sup>65</sup> Press Release, OXFAM, *supra* note 58.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> UNAIDS, *supra* note 51.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> OXFAM, *supra* note 58.

Nelson Barbosa, former Finance Minister of Brazil, noted: “*Market solutions are not optimal to fight a pandemic.*”<sup>72</sup> He commented: “*A public health care system, including free vaccination and treatment when that becomes available, is essential to deal with the problem.*”<sup>73</sup> 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 Bolsonaro Government has been an opponent of the TRIPS Waiver.<sup>74</sup> The Brazilian Senate, though, has voted to suspend patent protection on COVID-19 vaccines.<sup>75</sup>

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.<sup>76</sup> 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.*”<sup>77</sup> 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.*”<sup>78</sup> One of the signatories, Dilafroz 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.*”<sup>79</sup> Heidi Chow from Global Justice Now, a member

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<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *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>

<sup>75</sup> Ricardo Brito, *Brazil Senate Votes to Suspend Patent Protection on COVID-19 Vaccines*, REUTERS (Apr. 30, 2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-senate-votes-suspend-patent-protection-covid-19-vaccines-2021-04-30/>.

<sup>76</sup> UNAIDS, *supra* note 49.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

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.*"<sup>80</sup>

The economist Professor Mariana Mazzucato has also lent her support to the People's Vaccine Campaign. She has written a piece with Els Torrele and Henry Lish on the challenges and proposals for delivering the People's Vaccine.<sup>81</sup> Torrele, 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.*"<sup>82</sup> Mazzucato has called for a mission-focused approach to biomedical innovation.<sup>83</sup> 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.*"<sup>84</sup>

Sanjay Reddy and Arnab Acharya have articulated the economic case for a People's Vaccine.<sup>85</sup> They commented that "*the current challenge provides a stark demonstration of what is needed for research and development to serve the broader public interest.*"<sup>86</sup> 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.*"<sup>87</sup>

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

### C. Opposition to the People's Vaccine Campaign

Ellen 't Hoen laments that there has been little support for the rhetoric about the People's Vaccine amongst wealthy nations.<sup>88</sup> She noted: "*Unfortunately, despite the lofty promises of the vaccine as*

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<sup>80</sup> *Id.*

<sup>81</sup> Els Torrele et al., *Delivering the People's Vaccine: Challenges and Proposals for the Biopharmaceutical Innovation System*, 12 UCL INST. FOR INNOVATION & PUB. PURPOSE POLY BRIEF, (2021), [https://www.ucl.ac.uk/bartlett/public-purpose/sites/public-purpose/files/iipp-pb12\\_delivering-the-peoples-vaccine\\_final.pdf](https://www.ucl.ac.uk/bartlett/public-purpose/sites/public-purpose/files/iipp-pb12_delivering-the-peoples-vaccine_final.pdf).

<sup>82</sup> *Id.*

<sup>83</sup> MAZZUCATO, MISSION ECONOMY, *supra* note 35.

<sup>84</sup> *Id.* at 83.

<sup>85</sup> Sanjay Reddy & Arnab Acharya, *The Economic Case for a People's Vaccine*, BOSTON REVIEW (Sept. 15, 2020), <http://bostonreview.net/science-nature/sanjay-g-reddy-arnab-acharya-economic-case-peoples-vaccine#.X492ccXLblc.twitter>.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> Ellen 't Hoen, *COVID-19 Crisis and WTO: Why India and South Africa's Proposal on Intellectual Property is Important*, THE WIRE (Oct. 12, 2020), <https://thewire.in/law/covid-19-crisis-wto-intellectual-property-vaccine-public-health>.

*a global public good, wealthy nations are not making such demands.”<sup>89</sup> 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”.<sup>90</sup> They have advocated: “As the COVID-19 pandemic aggressively advances, the WTO has the opportunity to sway the planet away from monopoly medicine, and towards a new planetary health system.”<sup>91</sup> They presented the debate as a choice between “People or profit; a people’s vaccine or a debilitating vaccine apartheid.”<sup>92</sup>*

### III. THE ACT ACCELERATOR

In April 2020, the World Health Organization [“WHO”] and its partners launched the Access to COVID-19 Tools [“ACT Accelerator”].<sup>93</sup> 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.<sup>94</sup> 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.”<sup>95</sup>

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<sup>89</sup> *Id.*

<sup>90</sup> Achal Prabhala et al., *We can't let the WTO get in the way of a “People's Vaccine”*, THE GUARDIAN (Oct. 15, 2020), [http://www.theguardian.com/commentisfree/2020/oct/15/peoples-vaccine-coronavirus-covid-wto?CMP=share\\_btn\\_tw](http://www.theguardian.com/commentisfree/2020/oct/15/peoples-vaccine-coronavirus-covid-wto?CMP=share_btn_tw). See also Achal Prabhala, *On the Margins of Creative Commons and Open*, CREATIVE COMMONS, YOUTUBE, (October 14, 2021), <https://youtu.be/HIM29oZ6KGE>

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> The Access to COVID-19 Tools (ACT) Accelerator, WORLD HEALTH ORGANIZATION, <https://www.who.int/initiatives/act-accelerator>.

<sup>94</sup> Access to COVID-19 Tools (ACT) Accelerator, WORLD HEALTH ORGANIZATION (Apr. 24, 2020), [https://www.who.int/publications/m/item/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator).

<sup>95</sup> ACT-Accelerator – Frequently Asked Questions, WORLD HEALTH ORGANIZATION, <https://www.who.int/initiatives/act-accelerator/faq>.

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.<sup>96</sup>

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”], 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.<sup>97</sup>

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.*”<sup>98</sup> 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.*”<sup>99</sup> Likewise New Zealand’s Prime Minister Jacinda Ardern has said:

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<sup>96</sup> *Id.*

<sup>97</sup> ACT-Accelerator Investment Case, UNITAID (June 26, 2020), <https://unitaid.org/assets/act-consolidated-investment-case-at-26-june-2020-vf.pdf>.

<sup>98</sup> European Commission Press Release IP/20/952, Coronavirus Global Response: Kick Off Of New Campaign with Support of Global Citizen (May 28, 2020), [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_20\\_952](https://ec.europa.eu/commission/presscorner/detail/en/ip_20_952).

<sup>99</sup> Prime Minister of Australia, Transcript of Video Message - Coronavirus Global Response International Pledging Event (May 5, 2020), <https://www.pm.gov.au/media/coronavirus-global-response-international-pledging-event>.

“*We will advocate for universal access for any treatments and vaccines.*”<sup>100</sup> 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.*”<sup>101</sup> The letter emphasized that “*we must urgently ensure that vaccines will be distributed according to a set of transparent, equitable and scientifically sound principles.*”<sup>102</sup> 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.*”<sup>103</sup> 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.*”<sup>104</sup> Lisa Herzog and her colleagues maintain that COVAX must go beyond a proportional allocation of COVID vaccines to ensure fair and equitable access.<sup>105</sup> *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.*”<sup>106</sup>

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<sup>100</sup> Press Release, Global Citizen, Statements of Support for the ‘Global Goal: Unite For Our Future’ Campaign (June 22, 2020), <https://www.globalcitizen.org/en/enquiries/press/global-citizen-and-european-commission-announce-global-goal-unit/statements-of-support/>.

<sup>101</sup> Justin Trudeau et al., *The International Community Must Guarantee Equal Global Access to a COVID-19 Vaccine*, THE WASHINGTON POST (July 16, 2020), <https://www.washingtonpost.com/opinions/2020/07/15/international-community-must-guarantee-equal-global-access-covid-19-vaccine/>.

<sup>102</sup> *Id.*

<sup>103</sup> Mark Eccleston-Turner & Harry Upton, *International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility*, 99 (2) THE MILBANK Q. 426 (2021).

<sup>104</sup> *Id.*

<sup>105</sup> Lisa Herzog et al., *COVAX must go beyond Proportional Allocation of Covid Vaccines to ensure Fair and Equitable Access*, 372 BRITISH MED. J. (2021).

<sup>106</sup> Editorial, *Access to COVID-19 Vaccines: Looking Beyond COVAX*, 397 (10278) THE LANCET (2021).

In practice, though, there have been difficulties with the COVAX scheme struggling to obtain sufficient supplies in the face of vaccine nationalism and shortages.<sup>107</sup> In April 2021, the WHO published its priorities, strategies, and budget for the ACT-Accelerator for 2021.<sup>108</sup> 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.*”<sup>109</sup> 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;
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.<sup>110</sup>

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.*”<sup>111</sup> The report observed: “*Investing in ACT-Accelerator dwarfs the potential multiplier benefits of domestic fiscal support investments.*”<sup>112</sup>

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.*”<sup>113</sup> It was observed

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<sup>107</sup> Donato Paolo Mancini & Michael Peel, “*Vaccine Nationalism*” delays WHO’s Struggling COVAX Scheme, FINANCIAL TIMES (Sept. 2, 2020), <https://www.ft.com/content/502df709-25ac-48f6-ae1-aec7ac03c759>.

<sup>108</sup> Meeting Report, *ACT-A Prioritized Strategy and Budget for 2021*, WORLD HEALTH ORGANIZATION (12 April 2021), <https://www.who.int/publications/m/item/act-a-prioritized-strategy-and-budget-for-2021>.

<sup>109</sup> *Id.* at 4.

<sup>110</sup> *Id.* at 12.

<sup>111</sup> *Id.* at 3.

<sup>112</sup> *Id.*

<sup>113</sup> *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.

that an approach based on pledges of excess doses was insufficient.<sup>114</sup> 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.*”<sup>115</sup> 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.<sup>116</sup>

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.<sup>117</sup> In its summary, the Panel acknowledged: “*The uneven access to vaccination is one of today’s pre-eminent global challenges.*”<sup>118</sup> 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 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.*”<sup>119</sup>

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.<sup>120</sup> The study noted: “*Some said COVAX failed to push for the IP sharing that will be needed to produce sufficient vaccines.*”<sup>121</sup> 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.”<sup>122</sup>

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<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> THE INDEPENDENT PANEL ON PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 23.

<sup>118</sup> *Id.* at 12.

<sup>119</sup> *Id.* at 14 and 63.

<sup>120</sup> Olivia Goldhill, Rosa Furneaux, and Madlen Davies, “*Naively Ambitious*”: *How COVAX Failed On Its Promise to Vaccinate the World*, STAT, (October 8, 2021), <https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/>

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

There has been further controversy that developed nations, such as Canada and Australia, have purchased medicines and vaccines from COVAX.<sup>123</sup> 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.<sup>124</sup> 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*”.<sup>125</sup> 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.*”<sup>126</sup> 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.*”<sup>127</sup> The Shadow Foreign Affairs Minister Penny Wong commented: “*If Mr Morrison has had to resort to accessing vaccines intended for developing countries, he should be upfront about that.*”<sup>128</sup>

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.*”<sup>129</sup> He feared that this situation would “*undoubtedly prolong the pandemic.*”<sup>130</sup>

### 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

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<sup>123</sup> Anthony Galloway, *Australia Dipped into COVAX Pfizer Stockpile Intended for Poor Nations*, THE SYDNEY MORNING HERALD (Aug. 17, 2021), <https://www.smh.com.au/politics/federal/australia-dipped-into-covax-pfizer-stockpile-intended-for-poor-nations-20210816-p58j2j.html>; Paul Karp, *Australia’s Pfizer Purchase from Vaccine-Sharing COVAX Stockpile Under Fire*, THE GUARDIAN (Aug. 17, 2021), <https://www.theguardian.com/australia-news/2021/aug/17/australia-pfizer-purchase-from-vaccine-sharing-covax-stockpile-under-fire>; Chris Barrett & Karuni Rompies, *Australia Should Return COVAX Vaccines, Says Ex-Indonesian Minister*, THE SYDNEY MORNING HERALD (Aug. 18, 2021), <https://www.smh.com.au/world/asia/australia-should-return-covax-vaccines-says-ex-indonesian-minister-20210817-p58jkm.html>.

<sup>124</sup> The Hon. Greg Hunt, Transcript – COVID-19 Vaccine Rollout, Minister for Health and Aged Care, AUSTRALIA PARLIAMENT (June 6, 2021), [https://parlinfo.aph.gov.au/parlInfo/download/media/pressrel/8000210/upload\\_binary/8000210.pdf;fileType=application%2Fpdf#search=%22hunt%20covax%20%20minister%20for%20health%20and%20aged%20care%22](https://parlinfo.aph.gov.au/parlInfo/download/media/pressrel/8000210/upload_binary/8000210.pdf;fileType=application%2Fpdf#search=%22hunt%20covax%20%20minister%20for%20health%20and%20aged%20care%22).

<sup>125</sup> Galloway, *supra* note 123.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> Karp, *supra* note 123.

<sup>129</sup> Julia Kollewe, *Pfizer raises Covid-19 vaccine sales forecast to \$36bn for 2021*, THE GUARDIAN, (November 2, 2021), <https://www.theguardian.com/business/2021/nov/02/pfizer-covid-19-vaccine-sales-2021-biotech>

<sup>130</sup> *Id.*

2022.<sup>131</sup> 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.*”<sup>132</sup> 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.*”<sup>133</sup> 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.*”<sup>134</sup> The Alliance also laments the lack of democratic input into the decision-making process of the organization from civil society and 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.*”<sup>135</sup> 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.<sup>136</sup>

#### 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”.<sup>137</sup> Patent pools have been used to

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<sup>131</sup> Dalberg, ACT ACCELERATOR STRATEGIC REVIEW: AN INDEPENDENT REVIEW, (October 8, 2021) <https://www.who.int/publications/m/item/act-accelerator-strategic-review>

<sup>132</sup> *Id.*, 66.

<sup>133</sup> FAQ, THE PEOPLE’S VACCINE ALLIANCE, <https://peoplesvaccine.org/faq/>.

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> World Intellectual Property Organization, PATENT POOLS AND ANTITRUST: A COMPARATIVE ANALYSIS, March 2014. [https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent\\_pools\\_report.pdf](https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf)

address access issues - particularly where there are patent thickets, which are impeding access to essential technologies.<sup>138</sup> Michael Heller has discussed the role of patent pools as a means of addressing the “*gridlock economy*”.<sup>139</sup> Increasingly, patent pools have been deployed in the context of medicine, biotechnology, and healthcare.<sup>140</sup> 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.*”<sup>141</sup> The People’s Vaccine Alliance has also been a supporter of patent pools during the coronavirus crisis.<sup>142</sup>

### 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.<sup>143</sup> The Medicines Patent Pool [“MPP”] was established as an independent public health entity in 2010 - with the support 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”].”<sup>144</sup> The MPP discusses its strategies: “*We do this through an innovative approach to voluntary licensing and patent pooling.*”<sup>145</sup> It emphasized that it takes a collaborative approach to patent licensing: “*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.*”<sup>146</sup>

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<sup>138</sup> Anne Layne-Farrar and Josh Lerner, *To Join or Not to Join: Examining Patent Pool Participation and Rent Sharing Rules*, 29 (2) INTERNATIONAL JOURNAL OF INDUSTRIAL ORGANIZATION 294-303 (2011).

<sup>139</sup> MICHAEL HELLER, *THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES* (2009).

<sup>140</sup> David Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come*, 3 (1) THE JOURNAL OF PHILOSOPHY, SCIENCE & LAW 1-22 (2003); GEERTRUI VAN OVERWALLE, *GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES* (2009); DEVDATTA MALSHE, *PATENT POOLS, COMPETITION AND BIOTECHNOLOGY* (2020).

<sup>141</sup> Joseph Stiglitz et al., *Patents vs. the Pandemic*, PROJECT SYNDICATE (Apr. 23, 2020), <https://www8.gsb.columbia.edu/articles/chazen-global-insights/patents-vs-pandemic>.

<sup>142</sup> THE PEOPLE’S VACCINE ALLIANCE, *supra* note 133.

<sup>143</sup> Michelle Childs, *Towards a Patent Pool for HIV Medicines: The Background*, 4 THE OPEN AIDS J. 33 (2010); and Krista Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses* 4 HASTINGS SCIENCE & TECHNOLOGY LAW JOURNAL 291-324 (2012); Alberto Galasso and Mark Schankerman, *Licensing Life-Saving Drugs for Developing Countries: Evidence from the Medicines Patent Pool*, NATIONAL BUREAU OF ECONOMIC RESEARCH (2021) <https://www.nber.org/papers/w28545>

<sup>144</sup> Who We Are, MEDICINES PATENT POOL, <https://medicinespatentpool.org/who-we-are/about-us/>.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

The mandate of the MPP is to “*accelerate access to affordable quality treatments for people living with HIV, hepatitis C and tuberculosis, as well as HIV-associated co-morbidities.*”<sup>147</sup> Its role has evolved over the years: “*Since 2018, MPP has expanded its mandate to other patented essential medicines on the World Health Organization (WHO)’s Model List of Essential Medicines (EML) as well as medicines with strong potential for future inclusion on the EML.*”<sup>148</sup>

In 2020, the MPP temporarily expanded its mandate to include COVID-19 related technologies.<sup>149</sup> 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.<sup>150</sup> They offered to share their institutional expertise in terms of patent information and databases: “*This repository of patent intelligence was established to allow countries and procurement agencies to identify patents that could hinder access to new medical innovations.*”<sup>151</sup> 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.<sup>152</sup>

The chair of the Unitaid Executive Board, Marisol Touraine, has also offered her support for the initiative: “*Unitaid is fully engaged in the global response to COVID-19 and supports the call by the President of Costa Rica for voluntary pooling of intellectual property rights for medicines and diagnostics to promote the global fight against COVID-19.*”<sup>153</sup> 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.*”<sup>154</sup>

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*

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<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> Disease Areas COVID-19, MEDICINES PATENT POOL, <https://medicinespatentpool.org/what-we-do/disease-areas/#pills-COVID-19>.

<sup>150</sup> Marie-Paule Kieny & Charles Gore, *The World Needs a Master Plan for COVID-19 Patents. We’re Creating One*, BARRONS (Apr. 10, 2020), <https://barrons.com/articles/the-world-needs-a-master-plan-for-covid-19-patents-were-building-one-51586524940>.

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> Press Release, Medicines Patent Pool, The Medicines Patent Pool and Unitaid Respond to Access Efforts for COVID-19 Treatments and Technologies (Mar. 31, 2020), <https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies/>.

<sup>154</sup> *Id.*

*much of me-first.*<sup>155</sup> 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’.*”<sup>156</sup>

In July 2021, the MPP announced that it was joining a new consortium to boost vaccine capacity in South Africa and Sub-Saharan Africa.<sup>157</sup> 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.*”<sup>158</sup> 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.*”<sup>159</sup> 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.*”<sup>160</sup> 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.

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.<sup>161</sup> 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

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<sup>155</sup> Michael Safi, *WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began*, THE GUARDIAN (Jan. 22, 2021), <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began>.

<sup>156</sup> *Id.*

<sup>157</sup> Press Release, Medicines Patent Pool, *New Consortium Working to Boost Vaccine Production in South Africa* (July 30, 2021), <https://medicinespatentpool.org/news-publications-post/south-africa-tech-transfer-hub-loi-press-release/>.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> Press Release, Medicines Patent Pool, *The Medicines Patent Pool (MPP) and MSD enter into Licence Agreement for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle- income Countries*, (October 27, 2021), <https://medicinespatentpool.org/news-publications-post/mpp-msd-new-licence-announcement-molnupiravir/>

has announced in November 2021 that it would sell a generic version of the Merck COVID-19 pill.<sup>162</sup>

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*”.<sup>163</sup>

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).<sup>164</sup> 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.*”<sup>165</sup>

## 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”].<sup>166</sup>

Taking up the proposal, the WHO issued a Solidarity Call to Action in May 2020.<sup>167</sup> The 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.*”<sup>168</sup> WHO stressed: “*This initiative sets out an*

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<sup>162</sup> Sachin Ravikumar, *Bangladesh’s Beximco to sell First Generic Version of Merck COVID-19 Pill*, REUTERS, (November 9, 2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/asian-firm-beximco-sell-generic-version-merck-covid-19-pill-2021-11-09/>

<sup>163</sup> Ellen 't Hoen et al., *Scaling-Up Vaccine Production Capacity: Legal Challenges and Recommendations*, INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE (May 2021), <https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccination-legal-aspects.pdf>.

<sup>164</sup> THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 23.

<sup>165</sup> *Id.* at 14, 63.

<sup>166</sup> 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, *Medicines Patent Pool, Launch of the COVID-19 Technology Access Pool (C-TAP)*, (May 29, 2020), <https://medicinespatentpool.org/news-publications-post/launch-of-the-covid-19-technology-access-pool-c-tap/>.

<sup>167</sup> Solidarity Call to Action, WORLD HEALTH ORGANIZATION (May 29, 2020), <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>.

<sup>168</sup> *Id.*

*alternative, in line with WHO's efforts to promote global public health goods, based on equity, strong science, open collaboration and global solidarity.*"<sup>169</sup> 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."<sup>170</sup>

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".<sup>171</sup> 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.<sup>172</sup> 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."<sup>173</sup>

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."<sup>174</sup>

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.<sup>175</sup>

However, some pharmaceutical companies and biotechnology developers have been unwilling to join this voluntary initiative thus far.<sup>176</sup> Ellen 't Hoen reflected that "the success of C-TAP will depend

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<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> Carlos Alvarado Quesada & Tedros Adhanom Ghebreyesus, *Globalizing the Fight against the Pandemic*, PROJECT SYNDICATE (May 29, 2020), <https://www.project-syndicate.org/commentary/covid19-access-pool-vaccine-data-ip-sharing-by-carlos-alvarado-quesada-and-tedros-adhanom-ghebreyesus-2020-05>.

<sup>172</sup> *Id.*

<sup>173</sup> COVID-19 Technology Access Pool, WORLD HEALTH ORGANIZATION, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool>.

<sup>174</sup> *Id.*

<sup>175</sup> THE PEOPLE'S VACCINE ALLIANCE, *supra* note 133.

<sup>176</sup> World Health Organization, Summary Report: Special press conference to mark the first anniversary of the COVID-19 Technology Access Pool, (May 28, 2021), <https://www.who.int/publications/m/item/summary-report-special-press-conference-to-mark-the-first-anniversary-of-the-covid-19-technology-access-pool>

*on the political support it will receive.*<sup>177</sup> She noted that 40 countries had endorsed the initiative.<sup>178</sup> 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.*”<sup>179</sup>

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.<sup>180</sup> Dr Muhammad Zaheer Abbas has argued that Costa Rica’s proposal for the creation of a global pooling mechanism deserved serious consideration.<sup>181</sup> 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.*”<sup>182</sup>

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.<sup>183</sup> 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.*”<sup>184</sup> HAI said that the 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.*”<sup>185</sup> 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*

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<sup>177</sup> ‘t Hoen, *supra* note 88.

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> Brook Baker, *Rationale for Supporting Costa Rica’s Proposal for Emergency COVID-19 Technology IP Pool for All Countries*, INFOJUSTICE (Mar. 27, 2020), <http://infojustice.org/archives/42137>.

<sup>181</sup> Muhammad Zaheer Abbas, *Treatment of the novel COVID19: Why Costa Rica’s Proposal for the Creation of a Global Pooling Mechanism deserves Serious Consideration?*, 7 J. L. BIOSCI 1 (2020)

<sup>182</sup> *Id.*

<sup>183</sup> Safi, *supra* note 155.

<sup>184</sup> Thiru Balasubramaniam, *EB 148 – WHO’s COVID-19 Technology Access Pool (C-TAP) Comes Under Scrutiny*, KNOWLEDGE ECOLOGY INTERNATIONAL (Jan. 20, 2021), <https://www.keionline.org/35064>.

<sup>185</sup> *Id.*

*more transparent about its activities and proactive as regards its leadership of and advocacy for C-TAP if it is to succeed.*<sup>186</sup>

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 Versaevael despaired: “*The WHO’s C-TAP has so far received no contributions from industry.*”<sup>187</sup> They observed: “*The practice of pooling patented technologies for the production of medicines already occurs for HIV, hepatitis C and tuberculosis treatments.*”<sup>188</sup> They also emphasized that “*fees are typically lower when licences are negotiated as a bundle with generics producers, implying increased volume.*”<sup>189</sup> 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.*”<sup>190</sup>

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.*”<sup>191</sup> Spain is collaborating with the C-TAP initiative to openly licence a serological test for COVID-19 developed by CSIC researchers.<sup>192</sup> Sanchez stressed that “*only by leading by example will we be effective in preaching solidarity*” and “*only through*

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<sup>186</sup> Gabriela Bucher, *Letter to the Director-General of the World Health Organization from Oxfam on Behalf of the People’s Vaccine Alliance, and Health Action International*, KNOWLEDGE ECOLOGY INTERNATIONAL (Jan. 21, 2021), <https://www.keionline.org/wp-content/uploads/HE-Dr-Tedros-Letter-from-Peoples-Vaccine-Alliance-and-Health-Action-International.pdf>.

<sup>187</sup> Etienne Billette de Villemeur et al., *Pool Patents to get COVID Vaccines and Drugs to All*, NATURE (Mar. 19, 2021), <https://www.nature.com/articles/d41586-021-00759-9>.

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

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

<sup>192</sup> *Sánchez announces that Spain will donate an additional 15 million vaccines to fight COVID-19*, GOVERNMENT OF SPAIN (June 2, 2021), <https://www.lamoncloa.gob.es/lang/en/presidente/news/Paginas/2021/20210602gavicovax-summit.aspx>.

*solidarity can this crisis be overcome and the wounds of our societies healed?*<sup>193</sup> There has also been interest expressed in the initiative by the governments of Indonesia and Belgium.<sup>194</sup>

In the United Kingdom Parliament, Liberal Democrat Layla Moran has chided the United Kingdom Government for its lack of co-operation with C-TAP.<sup>195</sup> She posed the question: “*Why did we not endorse the WHO COVID technology access protocol?*”<sup>196</sup> 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.*”<sup>197</sup> 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.*”<sup>198</sup>

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.*”<sup>199</sup> In response, a number of legislators have called for the Government of Ireland to support C-TAP.<sup>200</sup> The Joint Committee on Foreign Affairs and Defence recommended formal endorsement of C-TAP by the

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<sup>193</sup> *Id.*

<sup>194</sup> World Health Organization, Summary Report: Special press conference to mark the first anniversary of the COVID-19 Technology Access Pool, (May 28, 2021), <https://www.who.int/publications/m/item/summary-report-special-press-conference-to-mark-the-first-anniversary-of-the-covid-19-technology-access-pool>

<sup>195</sup> 683 PARL DEB HC (Nov. 5, 2020) (UK) (Remarks of Layla Moran), <https://hansard.parliament.uk/Commons/2020-11-05/debates/78F58139-2878-4CC8-A220-1980A0025D6A/InternationalCovid-19ResponseInnovationAndAccessToTreatment#contribution-CD682B35-CCC2-4A90-8677-81A6DF6DA6DB>.

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

<sup>198</sup> The Hon. Philippa Whitford MP, *Equitable Access to COVID-19 Diagnostics, Vaccines and Treatments*, STOPAIDS UK (Apr. 2020), <https://stopaids.org.uk/wp-content/uploads/2020/04/Equitable-access-to-COVID-19-diagnostics-vaccines-and-treatments-1-1.pdf>.

<sup>199</sup> JOINT COMMITTEE ON FOREIGN AFFAIRS AND DEFENCE DEBATE, DISTRIBUTION OF COVID-19 VACCINES TO DEVELOPING COUNTRIES, (Feb. 9, 2021) (Ir.), [https://www.oireachtas.ie/en/debates/debate/joint\\_committee\\_on\\_foreign\\_affairs\\_and\\_defence/2021-02-09/2/](https://www.oireachtas.ie/en/debates/debate/joint_committee_on_foreign_affairs_and_defence/2021-02-09/2/).

<sup>200</sup> Press Release, Foreign Affairs Committee, Report on the Distribution of COVID-19 Vaccines to Developing Countries, (Mar. 11 2021), <https://www.oireachtas.ie/en/press-centre/press-releases/20210311-foreign-affairs-committee-launches-report-on-the-distribution-of-covid-19-vaccines-to-developing-countries/>; JOINT COMMITTEE ON FOREIGN AFFAIRS AND DEFENCE, REPORT ON THE DISTRIBUTION OF COVID-19 VACCINES TO DEVELOPING COUNTRIES (Mar. 2021), [https://data.oireachtas.ie/ie/oireachtas/committee/dail/33/joint\\_committee\\_on\\_foreign\\_affairs\\_and\\_defence/reports/2021/2021-03-05\\_report-on-the-distribution-of-covid-19-vaccines-to-developing-countries\\_en.pdf](https://data.oireachtas.ie/ie/oireachtas/committee/dail/33/joint_committee_on_foreign_affairs_and_defence/reports/2021/2021-03-05_report-on-the-distribution-of-covid-19-vaccines-to-developing-countries_en.pdf).

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 pharmaceutical companies to join C-TAP; and an increase of financial support for the WHO's ACT Accelerator.<sup>201</sup> The President of Ireland Michael Higgins has provided vocal support for C-TAP.<sup>202</sup> 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."*<sup>203</sup> 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."*<sup>204</sup>

The European Parliament has lent its support for the WHO effort to create C-TAP.<sup>205</sup> 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."*<sup>206</sup> 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*

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<sup>201</sup>JOINT COMMITTEE ON FOREIGN AFFAIRS AND DEFENCE, *supra* note 200, at 12.

<sup>202</sup> Costa Rica, UNAIDS and World Health Organization, *High Level Event – The Challenge of a Lifetime: Ensuring Universal Access to COVID-19 Health Technologies – with the President of Costa Rica Carlos Alvarado Quesada, the President of Ireland Michael Higgins, the Executive Director of UNAIDS Winnie Byanyima, and the Director-General of the World Health Organization, Tedros Adhanom Ghebreyesus*, FACEBOOK (Sep. 25, 2020), [https://www.facebook.com/watch/live/?v=3321649844589012&ref=watch\\_permalink](https://www.facebook.com/watch/live/?v=3321649844589012&ref=watch_permalink).

<sup>203</sup> President Michael Higgins, Address at the UN Meeting on Universal Access to Covid-19 Health Technologies (Sept. 25, 2020), <https://president.ie/en/diary/details/president-addresses-un-meeting-on-universal-access-to-covid-19-health-technologies/speeches>.

<sup>204</sup> *Id.*

<sup>205</sup> Ed Silverman, *European Parliament Backs WHO Effort to Create A COVID-19 Technology Access Pool*, STAT (July 13, 2020), <https://www.statnews.com/pharmalot/2020/07/13/europe-who-covid19-patents-vaccine-pandemic/>.

<sup>206</sup> EUR. PARL. DOC., *supra* note 113.

*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.”*<sup>207</sup>

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.<sup>208</sup> 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.<sup>209</sup> Moreover, leaders of pharmaceutical drug companies and vaccine developers have been uncooperative with sharing their data and technology with C-TAP.<sup>210</sup> 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.”<sup>211</sup> 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”.<sup>212</sup> 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.”<sup>213</sup> 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.<sup>214</sup> Mazzucato is the chair of a new WHO Council on the Economics of

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<sup>207</sup> T HOEN, *supra* note 163.

<sup>208</sup> *How WHO C-TAP Works?*, WORLD HEALTH ORGANISATION (Aug. 2021), <https://www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap>.

<sup>209</sup> Priti Patnaik, *WHO Donors seek a New Tech Transfer Hub under ACT-A, C-TAP Sideline*, GENEVA HEALTH FILES (Mar. 19, 2021), <https://genevahealthfiles.substack.com/p/who-donors-see-a-new-tech-transfer>.

<sup>210</sup> Ed Silverman, *Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on COVID-19 Products*, STAT (May 28, 2020), <https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/>.

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> Safi, *supra* note 155.

<sup>214</sup> KNOWLEDGE ACCUMULATION AND INDUSTRY EVOLUTION: THE CASE OF PHARMA-BIOTECH (Mariana Mazzucato & Giovanni Dosi eds., 2006); MAZZUCATO, *THE ENTREPRENEURIAL STATE*, *supra* note 35; Mazzucato,

Health for All – which seeks to incorporate lessons learned during the COVID-19 pandemic.<sup>215</sup> The Council has suggested that there is a need to rethink health innovation in light of the COVID-19 crisis.<sup>216</sup> 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.”<sup>217</sup> He was disappointed by the response of intellectual property holders to C-TAP.<sup>218</sup> 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.”*<sup>219</sup>

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

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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.

<sup>215</sup> *Global Experts of new WHO Council on the Economics of Health For All Announced*, WORLD HEALTH ORGANISATION (May 6, 2021), <https://www.who.int/news/item/06-05-2021-global-experts-of-new-who-council-on-the-economics-of-health-for-all-announced>.

<sup>216</sup> The WHO Council on the Economics of Health for All, *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>.

<sup>217</sup> 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>.

<sup>218</sup> Kerry Cullinan, *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/>.

<sup>219</sup> *Id.*

lead to more dramatic options such as compulsory licensing and Crown use being deployed to deal with the competition issue.

## V. COMPULSORY LICENSING AND CROWN USE/ GOVERNMENT USE

Under the *TRIPS Agreement* and the *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.<sup>220</sup>

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.*”<sup>221</sup> 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.*”<sup>222</sup>

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.*”<sup>223</sup>

### 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.<sup>224</sup> 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.

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<sup>220</sup> Dreifuss, *supra* note 25.

<sup>221</sup> *The TRIPS Agreement and COVID-19: Information Note*, WORLD TRADE ORGANIZATION (Oct. 15, 2020), [https://www.wto.org/english/tratop\\_e/covid19\\_e/trips\\_report\\_e.pdf](https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf).

<sup>222</sup> *Id.*

<sup>223</sup> THE PEOPLE'S VACCINE ALLIANCE, *supra* note 133.

<sup>224</sup> FREDERICK ABBOTT AND RUDOLF VAN PUYMBROECK, *COMPULSORY LICENSING FOR PUBLIC HEALTH: A GUIDE AND MODEL DOCUMENTS FOR IMPLEMENTATION OF THE DOHA DECLARATION PARAGRAPH 6 DECISION*, (2005); Charles Lawson, *Accessing and Affording Drugs despite the Patent Barrier: Compulsory Licensing and Like Arrangements*, 24 (2) AUSTRALIAN INTELLECTUAL PROPERTY JOURNAL 94-108 (2013); *COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD* (Reto Hilty & Kung-Chung Liu eds., 2014); VAN ANH LE, *COMPULSORY PATENT LICENSING AND ACCESS TO MEDICINES: A SILVER BULLET APPROACH TO PUBLIC HEALTH?* (2021).

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.<sup>225</sup> Germany has passed amendments to an Act on the Prevention and Control of Infectious Diseases in Humans.<sup>226</sup> 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.<sup>227</sup> 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.<sup>228</sup> The Parliament of Chile also supported compulsory licensing for coronavirus medicines and vaccines.<sup>229</sup> The Legislative Committee in Ecuador has approved a resolution on compulsory licensing of patents relating to the coronavirus.<sup>230</sup> A number of Latin American countries may well contemplate the use of compulsory licensing – given the aggressive, overbearing negotiating tactics of vaccine developers.<sup>231</sup>

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<sup>225</sup>An Act respecting certain measures in response to COVID-19, S.C. 2020, C-13 (Can.); Ed Silverman, *A Canadian Bill would make it easier to issue Compulsory Licenses for Covid-19 Products*, STAT (Mar. 25, 2020), <https://www.statnews.com/pharmalot/2020/03/25/canada-compulsory-license-coronavirus-covid19/>.

<sup>226</sup> Sebastian Fuchs, *COVID-19: New German Legislation to Fight Pandemic May Affect Granted German Patents*, BIRD & BIRD (May 2020), <https://www.twobirds.com/en/news/articles/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents>; Liat Sanz Martinez, *Compulsory Licensing Germany*, KLUWER PATENT BLOG (May 10, 2021), <http://patentblog.kluweriplaw.com/2021/05/10/compulsory-licensing-germany/>.

<sup>227</sup> WORLD TRADE ORGANIZATION, *supra* note 221.

<sup>228</sup> Steven Scheer & Julie Steenhuisen, *Israel Approves Generic HIV Drug to Treat COVID-19 Despite Doubts*, REUTERS (Mar. 19, 2020), <https://www.reuters.com/article/us-health-coronavirus-israel-drug-idUSKBN216237>; Ed Silverman, *AbbVie Will allow Generic Copies of its HIV pill in Israel after the Government Approved a License*, STAT (Mar. 20, 2020), <https://www.statnews.com/pharmalot/2020/03/20/abbvie-israel-hiv-kaletra-coronavirus-covid19/>; Thiru Balasubramaniam, *Israel Issues Compulsory License to Allow the Government to Import Generic Versions of Kaletra*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 23, 2020), <https://www.keionline.org/32503>.

<sup>229</sup> Ed Silverman, *Chilean Lawmakers Support Compulsory Licensing for Coronavirus Medicines and Vaccines*, STAT (Mar. 18, 2020), <https://www.statnews.com/pharmalot/2020/03/18/chile-compulsory-licensing-coronavirus-covid19-vaccines/>.

<sup>230</sup> Luis Gil Abinader, *Legislative Committee in Ecuador Approves Resolution on Compulsory Licensing of Patents Relating to the Coronavirus*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 20, 2020), <https://www.keionline.org/32429>; Ed Silverman, *Ecuador Becomes The Latest Country to Eye Compulsory Licensing for COVID-19 Products*, STAT (Mar. 23, 2020), <https://www.statnews.com/pharmalot/2020/03/23/ecuador-compulsory-licensing-covid19-coronavirus/>.

<sup>231</sup> Madlen Davies et al., *"Held to Ransom": Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal*, THE BUREAU OF INVESTIGATIVE JOURNALISM (Feb. 23, 2021),

In 2021, the Supreme Court of India considered the unprecedented humanitarian crisis in India, following the outbreak of the COVID-19 pandemic.<sup>232</sup> 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 implicates the right to life under Article 21 and right to equality under Article 14 of the Constitution.”*<sup>233</sup> 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.<sup>234</sup> 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.”*<sup>235</sup> 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”*.<sup>236</sup> 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.”*<sup>237</sup> The Supreme Court of India noted: *“The Central Government is free to choose any other course*

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<https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal>; *Investigation: Drugmaker “Bullied” Latin American Nations*, AL JAZEERA (Mar. 11, 2021), <https://www.aljazeera.com/news/2021/3/11/investigation-pfizer-bullied-latin-american-nations>.

<sup>232</sup> In Re: Distribution of Essential Supplies and Services During Pandemic, (2021) LL 2021 SC 2036 (India).

<sup>233</sup> *Id.*

<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

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”.<sup>238</sup> 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.”<sup>239</sup> 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.<sup>240</sup>

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.<sup>241</sup>

The African Group has discussed the need to make use of flexibilities – such as compulsory licensing.<sup>242</sup> 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.”<sup>243</sup> 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”.<sup>244</sup>

The South Centre, a policy research organization, has provided guidance as to the use of compulsory licenses during the COVID-19 crisis.<sup>245</sup>

Australian lawyers have contemplated the operation of compulsory licensing in the context of the COVID-19 crisis.<sup>246</sup>

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<sup>238</sup> *Id.*

<sup>239</sup> *Id.*

<sup>240</sup> *Id.*

<sup>241</sup> Priti Patnaik, *Where does India truly stand on the TRIPS Waiver: Q&A with Murali Neelakantan*, GENEVA HEALTH FILES (Aug. 6, 2021), <https://genevahealthfiles.substack.com/p/where-does-india-truly-stand-on-the?justPublished=true>.

<sup>242</sup> Ed Silverman, *Africa Union urges Member Countries to remove Intellectual Property Barriers to Covid-19 vaccines*, STAT (July 1, 2020), <https://www.statnews.com/pharmalot/2020/07/01/africa-covid19-coronavirus-vaccines-patents-intellectual-property/>; Yousuf Vawda, *The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property*, SOUTH CENTRE (2021), <https://www.southcentre.int/wp-content/uploads/2021/08/PB-99.pdf>.

<sup>243</sup> Chidi Oguamanam, *COVID-19 and Africa: Does “One Size Fit All”*, in *Public Health Intervention, in VULNERABLE: THE LAW, POLICY AND ETHICS OF COVID-19*, 591 (Colleen Flood et al. eds., 2020) at 553.

<sup>244</sup> *Id.*

<sup>245</sup> *Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic*, SOUTH CENTRE (Mar. 2021), <https://www.southcentre.int/covid-19-compulsory-licenses-table-march-2021/>; Carlos Correa, *Expanding the Production of COVID-19 Vaccines to Reach Developing Countries: Lift the Barriers to Fight the Pandemic in the Global South*, SOUTH CENTRE (Apr. 2021), <https://www.southcentre.int/policy-brief-92-april-2021/>.

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.<sup>247</sup> 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.*”<sup>248</sup> 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.<sup>249</sup> She emphasized that governments must do what is necessary to fight the present pandemic.<sup>250</sup> 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.<sup>251</sup> 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.*”<sup>252</sup>

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.<sup>253</sup> Moreover, the compulsory licensing decision is subject to judicial review which may suspend the execution of the compulsory license.<sup>254</sup> ‘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.’*”<sup>255</sup>

## 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.<sup>256</sup> Nobel Laureate Professor Joseph Stiglitz has expressed his concern about the operation

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<sup>246</sup> Sarah Matheson and Artemis Kirkinis, *Compulsory Licence and Crown Use Provisions in the Covid-19 Pandemic—The Australian Perspective*, 16 (6) JOURNAL OF INTELLECTUAL PROPERTY LAW & PRACTICE 484–497 (2021).

<sup>247</sup> Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 1 (2020), <http://www.jogh.org/documents/issue202001/jogh-10-010358.pdf>.

<sup>248</sup> *Id.*

<sup>249</sup> *Id.*

<sup>250</sup> *Id.*

<sup>251</sup> *Id.*

<sup>252</sup> *Id.*

<sup>253</sup> ‘T HOEN, *supra* note 158.

<sup>254</sup> *Id.*

<sup>255</sup> *Id.*

<sup>256</sup> DECISION OF THE GENERAL COUNCIL, *supra* note 7.

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.*”<sup>257</sup> 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.*”<sup>258</sup> 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.*”<sup>259</sup>

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.<sup>260</sup>

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

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.<sup>264</sup> In Canada, St. Catharines pharmaceutical company Biolyse Pharma has wanted to help with the global COVID-19 vaccine

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<sup>257</sup> James Love, *Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License in Another Country under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INTERNATIONAL (Apr. 7, 2020), <https://www.keionline.org/32707>.

<sup>258</sup> *Id.*

<sup>259</sup> *Id.*

<sup>260</sup> Amy Goodman, *Joseph Stiglitz: Trump’s “Trickle-Down” Economic Plans Are Not Enough to Meet Coronavirus Challenge*, DEMOCRACY NOW (Mar. 19, 2020), [https://www.democracynow.org/2020/3/19/us\\_economy\\_coronavirus\\_stimulus\\_joseph\\_stiglitz](https://www.democracynow.org/2020/3/19/us_economy_coronavirus_stimulus_joseph_stiglitz).

<sup>261</sup> REHMAN, *supra* note 8.

<sup>262</sup> Hafiz Aziz ur Rehman, *WTO, Compulsory Export Licences and Indian Patent Law*, NORD. J. COMMER. LAW 1 (2011).

<sup>263</sup> Laura Spinney, “*We Took a Huge Risk*”: *The Indian Firm Making More Covid Jabs Than Anyone*, THE GUARDIAN (Feb. 14, 2021), <https://www.theguardian.com/global-development/2021/feb/14/we-took-a-huge-risk-the-indian-firm-making-more-covid-jabs-than-anyone>.

<sup>264</sup> STEPHEN LEWIS, RACE AGAINST TIME: SEARCHING FOR HOPE IN AIDS-RAVAGED AFRICA (2006); Matthew Rimmer, *The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid*, 15 (7) EXPERT OPINION ON THERAPEUTIC PAT. 889 (2005); and Matthew Rimmer, *Race Against Time: The Export of Essential Medicines to Rwanda*, 1 (2) PUBLIC HEALTH ETHICS 89 (2008).

rollout.<sup>265</sup> The Government of Bolivia has expressed an interest in obtaining generic vaccines from Biolyse.<sup>266</sup> Accordingly, Biolyse have made a license request to Johnson & Johnson, but that was denied by that company in March 2021.<sup>267</sup> Biolyse has been critical of the obstacles that it has faced in its efforts to obtain compulsory licensing.<sup>268</sup> 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 use?*”<sup>269</sup> 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.*”<sup>270</sup> 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.<sup>271</sup> 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.*”<sup>272</sup>

In addition to Bolivia, Antigua and Barbuda have notified the WTO of their intent to import products using compulsory licences.<sup>273</sup> 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

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<sup>265</sup> Shelby Knox, *St. Catharines Pharmaceutical Company Wants to Help with Global COVID-19 Vaccine Rollout*, IHEARTRADIO (Mar. 11, 2021), <https://iheartradio.ca/610ctb/news/st-catharines-pharmaceutical-company-wants-to-help-with-global-covid-19-vaccine-rollout-1.14749000>.

<sup>266</sup> Luis Gil Abinader, *Bolivia seeks to import COVID-19 Vaccines from Biolyse, if Canada Grants them a Compulsory License*, KNOWLEDGE ECOLOGY INTERNATIONAL (May 11, 2021), <https://www.keionline.org/36119>.

<sup>267</sup> Kerry Cullinan, *Company Pushes Canada to Grant Compulsory License for Johnson & Johnson COVID-19 Vaccine*, HEALTH POLICY WATCH (May 11, 2021), <https://healthpolicy-watch.news/company-pushes-canada-to-grant-compulsory-license-for-johnson-johnson-covid-19-vaccine/>.

<sup>268</sup> Francesca Bruce, *Canadian Firm Scathing on Obstacles to Compulsory Licensing: Biolyse is Determined to Manufacture J&J’s COVID-19 Vaccine*, PINK SHEET: INFORMA PHARMA INTELLIGENCE (May 27, 2021), <https://pink.pharmaintelligence.informa.com/PS144384/Canadian-Firm-Scathing-On-Obstacles-To-Compulsory-Licensing>.

<sup>269</sup> *Id.*

<sup>270</sup> CULLINAN, *supra* note 264.

<sup>271</sup> Ahmar Khan, *Canada lacks ‘political will’ to waive COVID-19 vaccine patents, Bolivian minister says*, GLOBAL NEWS, (October 6 2021) <https://globalnews.ca/news/8243635/bolivian-minister-canada-covid-vaccine-waiver/>

<sup>272</sup> *Id.*

<sup>273</sup> Luis Gil Abinader, *Antigua and Barbuda Notified the WTO Of Their Intent to Import Products Using Compulsory Licences*, KNOWLEDGE ECOLOGY INTERNATIONAL (June 7, 2021), <https://www.keionline.org/36241>.

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.<sup>274</sup> 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.*”<sup>275</sup> 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 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.*”<sup>276</sup> 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.*”<sup>277</sup> Leaked documents have shown that the EU Council of Ministers defined its position on the TRIPS Waiver for vaccines in secret.<sup>278</sup> 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.<sup>279</sup> 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.*”<sup>280</sup> A collection of scholars have suggested that “*existing TRIPS flexibilities around compulsory licensing are incapable of*

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<sup>274</sup> Communication from the European Union to the Council for TRIPS, *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property* (Jun. 4, 2021), [https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc\\_159606.pdf](https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf); See generally, Ed Silverman, *EU Pushes Rival Plan to COVID-19 IP Waiver, But Some Deride It As “Meaningless”*, STAT (Jun. 4, 2021), <https://www.statnews.com/pharmalot/2021/06/04/covid19-vaccine-patents-europe-waiver/>.

<sup>275</sup> *Id.*

<sup>276</sup> *Id.*

<sup>277</sup> *Id.*

<sup>278</sup> *Leaked Documents show EU Council of Ministers defined its position on TRIPS Waiver for Vaccines in Secret*, CORPORATE EUROPE OBSERVATORY (Jul. 4, 2021), <https://corporateeurope.org/en/2021/06/leaked-documents-show-eu-council-ministers-defined-its-position-trips-waiver-vaccines>.

<sup>279</sup> *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>.

<sup>280</sup> *Id.*

*addressing the present pandemic context adequately, both in terms of procedure and legal substance.*<sup>281</sup> Jorge Contreras has considered the use of compulsory licensing, government use, and march-in rights during the coronavirus pandemic.<sup>282</sup>

### 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.<sup>283</sup> She commented: *“Where patents, monopolies or exclusivities already exist on medical products that are potentially useful for tackling COVID-19, the UK government should issue crown use licenses where necessary to ensure scale up of production and ensure affordable access to these products.”*<sup>284</sup> Whitford stressed: *“COVID-19 is unprecedented as a public health emergency, and access to these medical products cannot be restricted by intellectual property rights.”*<sup>285</sup>

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.<sup>286</sup> The Productivity Commission suggested that crown use was a “less costly and time-consuming alternative to compulsory licensing”.<sup>287</sup> 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*

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<sup>281</sup> Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic*, SSRN (May 24, 2021), <https://ssrn.com/abstract=3851737>.

<sup>282</sup> Jorge Contreras, *Patents and Coronavirus— Compulsory Licensing, Government Use and March-In Rights*, INFOJUSTICE (Mar. 28, 2020), <http://infojustice.org/archives/42184>.

<sup>283</sup> WHITFORD, *supra* note 197.

<sup>284</sup> *Id.*

<sup>285</sup> *Id.*

<sup>286</sup> Productivity Commission, *COMPULSORY LICENSING OF PATENTS*, Report No. 61, (March 28, 2013) <https://www.pc.gov.au/inquiries/completed/patents/report>

<sup>287</sup> *Id.*, 2.

*service.*<sup>288</sup> 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.*”<sup>289</sup>

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.*”<sup>290</sup> 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.*”<sup>291</sup> 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.<sup>292</sup>

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.<sup>293</sup>

## 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.<sup>294</sup> 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

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<sup>288</sup> Commonwealth, *Parliamentary Debates*, Senate, 25 July 2019, 844 (Jonathon Duniam, Senator).

<sup>289</sup> *Id.*

<sup>290</sup> Commonwealth, *Parliamentary Debates*, House of Representatives, 23 March 2020, 2801 (Brendan O’Connor, Member of Parliament (Austl.)).

<sup>291</sup> *Id.*

<sup>292</sup> Sarah Matheson and Artemis Kirkinis, *Compulsory Licence and Crown Use Provisions in the Covid-19 Pandemic—The Australian Perspective*, 16 (6) JOURNAL OF INTELLECTUAL PROPERTY LAW & PRACTICE 484–497 (2021).

<sup>293</sup> U.N. Secretary-General, *Access to Medicines: Promoting Innovation and Access to Health Technologies* (Sept. 14, 2016).

<sup>294</sup> CORYNNE MCSHERRY, WHO OWNS ACADEMIC WORK? BATTLING FOR CONTROL OF INTELLECTUAL PROPERTY (2001).

institutions.<sup>295</sup> Hans Radder has explored how the higher education system has been affected by commodification.<sup>296</sup> 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.<sup>297</sup>

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.<sup>298</sup> Public researchers were involved in patent races with private biotechnology firms like Myriad Genetics, in respect of genetic testing.<sup>299</sup> 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.<sup>300</sup> Amy Kapczynski and her colleagues called for an open licensing approach to university innovations in order to address global health inequities.<sup>301</sup> There have been significant clashes in respect of patent rights and stem cell research.<sup>302</sup> More recently, there have been patent races between rival universities in respect of CRISPR, gene-editing technologies.<sup>303</sup> There has also been emerging disputes over 3D

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<sup>295</sup> Jacob Rooksby, *Universities that Litigate Patents*, (May. 1, 2012)(unpublished thesis, University of Virginia)(on file with Online Archive of University of Virginia Scholarship); JACOB ROOKSBY, *BRANDING OF THE AMERICAN MIND: HOW UNIVERSITIES, CAPTURE, MANAGE, AND MONETIZE INTELLECTUAL PROPERTY AND WHY IT MATTERS* (2016); *RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER* (Jacob Rooksby ed., 2020); WILLIAM KAPLIN, BARBARA LEE, NEAL HUTCHENS AND JACOB ROOKSBY, *THE LAW OF HIGHER EDUCATION* (Jossey-Bass 6th ed. 2020).

<sup>296</sup> HANS RADDER, *FROM COMMODIFICATION TO THE COMMON GOOD: RECONSTRUCTING SCIENCE, TECHNOLOGY, AND SOCIETY* (2019).

<sup>297</sup> JOSEPH STIGLITZ AND BRUCE GREENWALD, *CREATING A LEARNING SOCIETY: A NEW APPROACH TO GROWTH, DEVELOPMENT, AND SOCIAL PROGRESS* (2014); DEAN BAKER, ARJUN JAYADEV, AND JOSEPH STIGLITZ, *INNOVATION, INTELLECTUAL PROPERTY, AND DEVELOPMENT: A BETTER SET OF APPROACHES FOR THE 21ST CENTURY* (2017), <http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf>.

<sup>298</sup> Matthew Rimmer, *Genentech and The Stolen Gene: Patent Law and Pioneer Inventions*, 5 *BIOSCI. L. REV.* 198, 198 (2004); and SALLY SMITH HUGHES, *GENENTECH: THE BEGINNINGS OF BIOTECH* (2011).

<sup>299</sup> Jessica Lai, *Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision*, 5 *IRVINE L. REV.* 1041, 1041-1076 (2015); Matthew Rimmer, *An Exorbitant Monopoly: The High Court of Australia, Myriad Genetics, and Gene Patents*, in *RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND THE LIFE SCIENCES* 56 (Duncan Matthews and Herbert Zech eds., 2017); Shubha Ghosh, *Myriad Post-Myriad*, 47 *SCIENCE AND PUBLIC POLICY* 638 (2020); and JORGE CONTRERAS, *THE GENOME DEFENSE: INSIDE THE EPIC LEGAL BATTLE TO DETERMINE WHO OWNS YOUR DNA* (2021).

<sup>300</sup> Pogge, *supra* note 2.

<sup>301</sup> Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 *BERKELEY TECHNOL. LAW J.* 1031 (2005).

<sup>302</sup> Matthew Rimmer, *The Attack of The Clones: Patent Law and Stem Cell Research*, 10 *J. LAW MED.* 488 (2003); and Matthew Rimmer, *The Last Taboo: Patenting Human Beings*, 14 *EXPERT OPIN. THER PAT* 1061 (2004).

<sup>303</sup> Jacob Sherkow, *The CRISPR Patent Landscape: Past, Present, and Future*, 1 *THE CRISPR J.*, (2018), JENNIFER DOUDNA AND SAMUEL STERNBERG, *A CRACK IN CREATION: GENE EDITING AND THE UNTHINKABLE POWER TO CONTROL EVOLUTION* (2018); HENRY GREELY, *CRISPR PEOPLE: THE SCIENCE AND ETHICS OF EDITING*

printing and bioprinting developed by public research institutions.<sup>304</sup> 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.<sup>305</sup>

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.<sup>306</sup> The People’s Vaccine Alliance have expressed concern that publicly-funded inventions are being exploited for private profit during the coronavirus crisis.<sup>307</sup> 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 opportunity.*”<sup>308</sup> She emphasized: “*We need to urgently end these monopolies so that we can scale up vaccine production, drive down prices and vaccinate the world.*”<sup>309</sup>

#### 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

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HUMANS (2021); WALTER ISAACSON, *THE CODE BREAKER: JENNIFER DOUDNA, GENE EDITING, AND THE FUTURE OF THE HUMAN RACE* (2021).

<sup>304</sup> Matthew Rimmer, *Make and Share: Intellectual Property, Higher Education, Technology Transfer, and 3D Printing in a Global Context*, in *RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER* 447 (Jacob Rooksby ed., 2020).

<sup>305</sup> *Patents for Humanity: COVID-19*, U.S. PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/ip-policy/patent-policy/patents-humanity-covid-19>. For a critique, see: Matthew Rimmer, *Patents for Humanity*, 3 *W.I.P.O.J.* 198 (2012).

<sup>306</sup> MAZZUCATO, *KNOWLEDGE ACCUMULATION AND INDUSTRY EVOLUTION*, *supra* note 37; MAZZUCATO, *THE ENTREPRENEURIAL STATE*, *supra* note 37.

<sup>307</sup> Press Release, OXFAM International, *COVID Vaccines Create 9 New Billionaires with Combined Wealth Greater than Cost of Vaccinating World’s Poorest Countries* (May 20, 2021), <https://www.oxfam.org/en/press-releases/covid-vaccines-create-9-new-billionaires-combined-wealth-greater-cost-vaccinating>.

<sup>308</sup> *Id.*

<sup>309</sup> *Id.*

mapping public investment in COVID-19 technologies.<sup>310</sup> The organization has called upon public research institutions to ‘free the vaccine.’<sup>311</sup>

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.<sup>312</sup> 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.*”<sup>313</sup> 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.*”<sup>314</sup> She stressed: “*We, the students, must speak up through our actions for the #FreeTheVaccine movement.*”<sup>315</sup>

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*”.<sup>316</sup> She said: “*The lives of my loved ones abroad matter as much as the life of any American.*”<sup>317</sup> 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.*”<sup>318</sup>

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

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.<sup>320</sup>

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<sup>310</sup> UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES, Tracking COVID-19 Investment, , (2021) <https://www.publicmeds4covid.org/>.

<sup>311</sup> *Id.*

<sup>312</sup> Klara Lou, *Dear Vanderbilt, Commit to A Free Vaccine*, VANDERBILT HUSTLER (Jul. 15, 2020), <https://vanderbilthustler.com/33236/featured/guest-editorial-dear-vanderbilt-commit-to-a-free-vaccine/>.

<sup>313</sup> *Id.*

<sup>314</sup> *Id.*

<sup>315</sup> *Id.*

<sup>316</sup> Jacqui Germain, *Vaccine Nationalism: What Is It and How Is It Playing Out During COVID-19*, TEEN VOGUE (May 6, 2021), <https://www.teenvogue.com/story/vaccine-nationalism-what-is>.

<sup>317</sup> *Id.*

<sup>318</sup> *Id.*

<sup>319</sup> Ed Silverman, *Most U.S. Universities Get an “F” on Ensuring Access to Drugs They Discover*, STAT (Mar. 30, 2021), <https://www.statnews.com/pharmalot/2021/03/30/universities-covid19-patents-drug-prices-clinical-trials/>.

<sup>320</sup> Goldie Blumenstyk, *Graduate Students Press for “Humanitarian Licensing” Vow in U. of California Patent Policy*, THE CHRONICLE OF HIGHER EDUCATION (Dec. 14, 2011), <https://www.chronicle.com/article/graduate-students-press->

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.<sup>321</sup> The COVID-19 Technology Access Framework declares its commitment to implement the COVID-19 patenting and licensing strategies to enable global access,<sup>322</sup> 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.<sup>323</sup> 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.*”<sup>324</sup> 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 on coronavirus relevant inventions.<sup>325</sup> 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.*”<sup>326</sup>

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for-humanitarian-licensing-vow-in-u-of-california-patent-policy/ and *University Licensing Guidelines*, UNIVERSITY OF CALIFORNIA (2012), [https://www.ucop.edu/research-policy-analysis-coordination/\\_files/licensing\\_guidelines\\_2012.pdf](https://www.ucop.edu/research-policy-analysis-coordination/_files/licensing_guidelines_2012.pdf).

<sup>321</sup> Stanford Office of Technology Licensing, *COVID-19 Technology Access Framework*, STANFORD UNIVERSITY, <https://otl.stanford.edu/covid-19-technology-access-framework>.

<sup>322</sup> *Id.*

<sup>323</sup> *Id.*

<sup>324</sup> *Id.*

<sup>325</sup> James Love, *Three Areas in Section 202 of the Bayh-Dole Act that Require Action to Ensure Sufficient Rights in Patents on Coronavirus Relevant Inventions*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 14, 2020), <https://www.keionline.org/32364>.

<sup>326</sup> Mark Rohrbaugh, *Letter Concerning Section 202 of the Bayh-Dole Act and the Novel Coronavirus Pandemic*, KNOWLEDGE ECOLOGY INTERNATIONAL (Apr. 6, 2020), [https://www.keionline.org/wp-content/uploads/NIH\\_Response\\_to\\_KEI\\_Azar\\_Bayh\\_Dole\\_Coronavirus\\_Letter\\_6April2020.pdf](https://www.keionline.org/wp-content/uploads/NIH_Response_to_KEI_Azar_Bayh_Dole_Coronavirus_Letter_6April2020.pdf).

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.’<sup>327</sup> The economist Mariana Mazucatto has lamented: “*And even though there are march-in rights under the Bayh-Dole Act, which allowed publicly financed research to be patented, unfortunately, the NIH seems not to be interested in using them effectively.*”<sup>328</sup>

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.”*<sup>329</sup>

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.<sup>330</sup> In particular, Public Citizen has highlighted that the Moderna vaccine was the result of public investment in the research of the National Institutes of Health [“NIH”].<sup>331</sup> 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.”*<sup>332</sup>

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<sup>327</sup> CONTRERAS, *supra* note 280.

<sup>328</sup> Mazzucato, *supra* note 87.

<sup>329</sup> RIZVI, *supra* note 63.

<sup>330</sup> Katherine J. Wu., *Some Vaccine Makers Say They Plan to Profit From Coronavirus Vaccine*, THE NEW YORK TIMES (Jul. 21, 2020), <https://www.nytimes.com/2020/07/21/health/covid-19-vaccine-coronavirus-moderna-pfizer.html>.

<sup>331</sup> *Moderna Vaccine Belongs to the People*, PUBLIC CITIZEN (Nov. 16, 2020), <https://citizen.org/news/statement-moderna-vaccine-belongs-to-the-people/>.

<sup>332</sup> *Id.*

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.*”<sup>333</sup>

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.<sup>334</sup> 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.*”<sup>335</sup> 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.*”<sup>336</sup> 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.<sup>337</sup> Moderna has filed a patent application – naming several of its employees as the only inventors of a crucial component of its coronavirus vaccine.<sup>338</sup> 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 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.*”<sup>339</sup>

## **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.<sup>340</sup> Oxford University vowed that “*the default*

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<sup>333</sup> *Id.*

<sup>334</sup> 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>.

<sup>335</sup> *Id.*

<sup>336</sup> *Id.*

<sup>337</sup> Sheryl Gay Stolberg and Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, *The New York Times*, (November 9, 2021), <https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html>

<sup>338</sup> *Id.*

<sup>339</sup> *Id.*

<sup>340</sup> SARAH GILBERT AND CATHERINE GREEN, *VAXXERS: THE INSIDE STORY OF THE OXFORD ASTRAZENECA VACCINE AND THE RACE AGAINST THE VIRUS* (2021).

*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.*<sup>341</sup> Nonetheless, urged by the Bill & Gates Foundation, Oxford University entered into an exclusive vaccine deal with AstraZeneca.<sup>342</sup>

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.<sup>343</sup> 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.*”<sup>344</sup> 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.*”<sup>345</sup>

However, others have been critical of Oxford’s COVID-19 vaccine deal with AstraZeneca.<sup>346</sup> Ameet Sarpatwari, an epidemiologist and lawyer at Harvard Medical School, regretted that “*it is business as usual, where the manufacturers are getting exclusive rights and we are hoping on the basis of public sentiment that they will price their products responsibly.*”<sup>347</sup> 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.*”<sup>348</sup>

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*

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<sup>341</sup> *Expedited Access for COVID-19 Related IP*, OXFORD UNIVERSITY INNOVATION, <https://innovation.ox.ac.uk/technologies-available/technology-licensing/expedited-access-covid-19-related-ip/>.

<sup>342</sup> Jay Hancock, *Oxford’s COVID vaccine deal with AstraZeneca raises concerns about access and pricing*, FORTUNE (Aug. 2020), <https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/>.

<sup>343</sup> Christopher Garrison, *How the “Oxford” COVID-19 Vaccine Became the “AstraZeneca” COVID-19 Vaccine*, MEDICINES LAW & POLICY (Oct. 2020), <https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf>.

<sup>344</sup> *Id.*, at 12.

<sup>345</sup> *Id.*, at 16.

<sup>346</sup> Jay Hancock, *Oxford’s COVID Vaccine Deal with AstraZeneca raises Concerns about Access and Pricing*, FORTUNE (Aug. 23, 2020), <https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/>.

<sup>347</sup> *Id.*

<sup>348</sup> *Id.*

*needs to impose public interest conditions on all UK funding committed to develop COVID-19 vaccines and treatments to ensure widespread access and transparency.*”<sup>349</sup> 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.*”<sup>350</sup> 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.*”<sup>351</sup> She stressed: “*We need to use global governance mechanisms to ensure equitable distribution and supply of health technologies according to public health need.*”<sup>352</sup>

### C. The European Union

The EU has made extensive investments in vaccine development for COVID-19.<sup>353</sup> 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.*”<sup>354</sup> 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.*”<sup>355</sup> 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.*”<sup>356</sup> Samira Rafaela – a Dutch member of the European Parliament – has been an eloquent advocate for the need for access to essential medicines and the adoption of the TRIPS Waiver.<sup>357</sup>

### D. Australia

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<sup>349</sup> WHITFORD, *supra* note 197.

<sup>350</sup> *Id.*

<sup>351</sup> *Id.*

<sup>352</sup> *Id.*

<sup>353</sup> EU Research and Innovation Supporting Vaccine Development for COVID-19, EUROPEAN COMMISSION (Feb 11, 2021), [https://ec.europa.eu/info/sites/default/files/research\\_and\\_innovation/research\\_by\\_area/documents/ec\\_rtd\\_cc-vaccine-development\\_factsheet.pdf](https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_cc-vaccine-development_factsheet.pdf).

<sup>354</sup> EUR. PARL. DOC., *supra* note 113.

<sup>355</sup> *Id.*

<sup>356</sup> *Id.*

<sup>357</sup> Samira Rafaela, *Plenary Speech on COVID-19 Challenge*, YOUTUBE (May 19, 2021), <https://www.youtube.com/watch?v=DDbIUSsHF44>.

There was also discussion about the terms of the partnership for an Australian vaccine effort led by the University of Queensland, which was ultimately unsuccessful.<sup>358</sup> In the end, this vaccine project did not proceed further.<sup>359</sup>

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.<sup>360</sup> 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.*”<sup>361</sup> 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.*”<sup>362</sup> This is an interesting model to realise a People’s Vaccine in Australia.

## VII. PATENT PLEDGES, OPEN LICENSING, AND OPEN INNOVATION

### A. Patent Pledges

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.*”<sup>363</sup> Such patent pledges enable scientists and

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<sup>358</sup> Press Release, THE UNIVERSITY OF QUEENSLAND, COVID-19 Vaccine Agreement: UQ and CEPI partner with CSL to Advance COVID-19 Vaccine (June 5, 2020), <https://stories.uq.edu.au/news/2020/covid-19-vaccine-agreement/index.html>.

<sup>359</sup> Jess Rendall & Lily Nothling, *Cancellation of University of Queensland’s COVID-19 vaccine trial ‘reassuring’*, ABC NEWS, (Dec. 12, 2020), <https://www.abc.net.au/news/2020-12-12/coronavirus-queensland-vaccine-uq-trial-cancellation-setback/12973724>.

<sup>360</sup> *Public Pharmaceutical Company*, QUEENSLAND GREENS, <https://greens.org.au/qld/publicpharma>.

<sup>361</sup> *Id.*

<sup>362</sup> *Id.*

<sup>363</sup> OPEN COVID PLEDGE, <https://opencovidpledge.org/>

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.<sup>364</sup> He has been one of the architects of the Open COVID Pledge. He has also highlighted the importance of identifying intellectual property available under the Open COVID Pledge.<sup>365</sup> Contreras and his collaborators have made a case for the adoption of voluntary pledges made by patent holders in respect of COVID-19 technologies.<sup>366</sup> 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.*”<sup>367</sup> 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.*”<sup>368</sup>

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.*”<sup>369</sup> 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.*”<sup>370</sup> 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.*”<sup>371</sup> Lemley noted: “*The pledge prevents them from being sued for things they do during the pandemic.*”<sup>372</sup> He commented: “*Once things return to normal, we hope companies will work together to come up with commercially reasonable*

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<sup>364</sup> PATENT PLEDGES: GLOBAL PERSPECTIVES ON PATENT LAW’S PRIVATE ORDERING FRONTIER (Jorge L. Contreras & Meredith Jacob eds., 2017).

<sup>365</sup> Jorge Contreras, *Putting Pledged IP to work - Identifying IP available under the Open COVID Pledge*, INFOJUSTICE (June 12, 2020), <http://infojustice.org/archives/42399>.

<sup>366</sup> Jorge Contreras et al., *Pledging Intellectual Property for COVID-19*, 38 NATURE BIOTECHNOLOGY 1146 (2020).

<sup>367</sup> *Id.*

<sup>368</sup> *Id.*

<sup>369</sup> Sharon Driscoll, *Stanford’s Mark Lemley on Effort to Make IP Available to End COVID-19 Pandemic*, STAN. L. SCH. (Apr. 1, 2020), <https://law.stanford.edu/2020/04/01/stanfords-mark-lemley-on-call-to-make-ip-available-to-end-covid-19-pandemic/>.

<sup>370</sup> *Id.*

<sup>371</sup> *Id.*

<sup>372</sup> *Id.*

*license terms, but they can go back to owning and asserting their Intellectual Property.*<sup>373</sup> Stanford Postdoctoral student Ariel Ganz also played a part in the development of the Open COVID Pledge.<sup>374</sup>

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.<sup>375</sup> 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.<sup>376</sup> The Creative Commons played a leadership role in taking over the management of the Open COVID Pledge during 2020.<sup>377</sup> Peters has sought to internationalise the Open COVID Pledge – translating the Pledge into all six of the official languages of the United Nations.<sup>378</sup> Peters has discussed the Open COVID Pledge on the ABC on Science Friction.<sup>379</sup> In May 2021, the American University assumed the stewardship of the Open COVID Pledge.<sup>380</sup>

## B. Open Science

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<sup>373</sup> *Id.*

<sup>374</sup> Hanae Armitage, *Stanford Postdoc Ariel B Ganz helps to Spearhead Movement to Free Patented Technology for COVID-19 Fight*, STAN. MED. (Oct. 5, 2020), <https://scopeblog.stanford.edu/2020/10/05/stanford-postdoc-helps-to-spearhead-movement-to-free-patented-technology-for-covid-19-fight/>.

<sup>375</sup> *Tech Giants- Amazon, Facebook, Hewlett Packard Enterprise, IBM, Microsoft, and Sandia National Laboratories- Join the CC-Supported Open COVID IP Pledge*, CREATIVE COMMONS (Apr. 20, 2020), <https://creativecommons.org/2020/04/20/tech-giants-join-the-cc-supported-open-covid-pledge>.

<sup>376</sup> Diane Peters, *Understanding Patent Pledges: an Overview of Legal Considerations*, PAT. COMMONS (2006), [https://patentcommons.org/publications/OSDL\\_Whitepaper\\_Final\\_final\\_4-12-06.pdf](https://patentcommons.org/publications/OSDL_Whitepaper_Final_final_4-12-06.pdf).

<sup>377</sup> Diane Peters & Eric Steuer, *Creative Commons is Now Leading the Open COVID Pledge – Here’s What That Means*, CREATIVE COMMONS (Aug. 27, 2020), <https://creativecommons.org/2020/08/27/cc-ocp>.

<sup>378</sup> Diane Peters, *Internationalizing the Open COVID Pledge: Translations and Outreach*, OPEN COVID PLEDGE, (Oct. 15, 2020), <https://opencovidpledge.org/2020/10/15/internationalizing-the-open-covid-pledge-translations-asnd-outreach>.

<sup>379</sup> Natasha Mitchell, *Science Friction: The Rise of Vaccine Nationalism – Should We Be Worried?*, ABC RADIO NATIONAL (Sept. 6, 2020), <https://abc.net.au/radionational/programs/sciencefriction/12630076>.

<sup>380</sup> *PIJIP Assumes Stewardship of the Open COVID Pledge*, AM. U. WASH. C. OF L (Apr. 2021), <https://www.wcl.american.edu/impact/initiatives-programs/pijip/news/pijip-assumes-stewardship-of-the-open-covid-pledge>.

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

There has been a joint appeal for open science by a number of international organisations—including CERN, OHCHR, UNESCO, and WHO.<sup>388</sup> 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.*”<sup>389</sup> 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 –*

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<sup>381</sup> Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 (2) J. OF L., MED., AND ETHICS 184 (2009).

<sup>382</sup> Ginny Barbour, *How Open Access Suddenly Became the Norm*, YOUTUBE (July 29, 2020), [https://www.youtube.com/watch?v=\\_SueRnB0uCQ](https://www.youtube.com/watch?v=_SueRnB0uCQ).

<sup>383</sup> Krishna Ravi Srinivas, *Intellectual Property Rights and Bio Commons: Open Source and Beyond*, 59 (188) INTERNATIONAL SOCIAL SCIENCE JOURNAL 319 (2006); Krishna Ravi Srinivas, *Open Source Drug Discovery: A Revolutionary Paradigm or a Utopian Model?*, in *INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO MEDICINES*, 263 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein ed., 2010).

<sup>384</sup> Krishna Ravi Srinivas, *Intellectual Property Rights and Innovation in the Times of Corona Epidemic*, 89 RIS POLICY BRIEF (April 2020), <http://infojustice.org/wp-content/uploads/2020/04/RaviSrinivas.pdf>.

<sup>385</sup> Amy Kapczynski, *Order without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (Sept. 2017).

<sup>386</sup> Joshua M Pearce, *Distributed Manufacturing of Open-Source Medical Hardware for Pandemics*, 4 (2) J. OF MANUFACTURING AND MATERIALS PROCESSING 1(2020),

<sup>387</sup> Henry Chesbrough, *To Recover Faster from Covid-19, Open Up: Managerial Implications from an Open Innovation Perspective*, 88 INDUS. MARKETING MGMT. 410 (July 2020).

<sup>388</sup> U.N High Commissioner for Human Rights, A Joint Appeal for Open Science by CERN, OHCHR, UNESCO, and WHO, (Oct. 27, 2020), <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26433&LangID=E>.

<sup>389</sup> *Id.*

*such as any COVID-19 treatments and vaccines.*<sup>390</sup> There has been a broader discussion of access to genetic resources and benefit-sharing in the context of pathogens and vaccines.<sup>391</sup> The joint statement highlighted the importance of access to essential medicines: “*Under international human rights law, States have a clear obligation to ensure international cooperation and access to a vaccine.*”<sup>392</sup> The joint call also emphasized the importance of health for all: “*Everyone, including vulnerable or marginalised individuals and groups, is entitled to enjoy the benefits of scientific progress – and when the benefits of science are managed as a purely commercial product reserved for the wealthy, everyone is harmed.*”<sup>393</sup> 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.<sup>394</sup>

The People’s Vaccine Alliance has perceived open licensing as a means of encouraging the open sharing of technology, intellectual property, and data.<sup>395</sup>

### C. Open Innovation

Professor Richard Gold from McGill University has said that the coronavirus pandemic has shattered the status quo on drug development.<sup>396</sup>

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.<sup>397</sup> The researchers commented: “*This COVID-19 stimulated move away from proprietary science— in which we patent everything and keep it secret until we do— to open science—where we do not clog up the system and do*

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<sup>390</sup> *Id.*

<sup>391</sup> Mark Eccleston-Turner and Michelle Rourke, *Arguments Against the Inequitable Distribution of Vaccines Using the Access and Benefit Sharing Transaction*, 70 INTERNATIONAL AND COMPARATIVE LAW QUARTERLY 825-858 (2021); and Fran Humphries, Michelle Rourke, Todd Berry, Elizabeth Englezos and Charles Lawson, *COVID-19 Tests the Limits of Biodiversity Laws in a Health Crisis: Rethinking “Country of Origin” for Virus Access and Benefit sharing* 28 JOURNAL OF LAW AND MEDICINE 684-706 (2021).

<sup>392</sup> U.N High Commissioner for Human Rights, A Joint Appeal for Open Science by CERN, OHCHR, UNESCO, and WHO, (Oct. 27, 2020), <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26433&LangID=E>.

<sup>393</sup> *Id.*

<sup>394</sup> Dreifuss, *supra* note 25.

<sup>395</sup> COVID-19: We Need A People’s Vaccine, OXFAM AMERICA <https://www.oxfamamerica.org/explore/emergencies/covid-19-peoples-vaccine>.

<sup>396</sup> E. Richard Gold, *The Coronavirus Pandemic Has Shattered the Status Quo on Drug Development. We Should Build on That*, FORTUNE (Mar. 26, 2020), <https://fortune.com/2020/03/26/coronavirus-vaccine-drug-development-open-science-covid-19-treatment/>.

<sup>397</sup> Jeremy de Beer & E. Richard Gold, *International Trade, Intellectual Property, and Innovation Policy: Lessons from a Pandemic*, in VULNERABLE: THE LAW, POLICY AND ETHICS OF COVID-19, 591 (Colleen Flood et al. eds., 2020) at 579.

*share research outcomes, data, materials, and tools —reflects a longer-term dissatisfaction over drug and vaccine development generally: drugs are increasingly expensive to develop, and our investments are producing less and less*”.<sup>398</sup> 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.’<sup>399</sup> 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.*”<sup>400</sup> 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.<sup>401</sup> 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.*”<sup>402</sup> The researchers envisaged: “*The independent, non-profit should be provided with long-term, stable funding to insulate it from day-to-day politics.*”<sup>403</sup> 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.*”<sup>404</sup> The researchers emphasized that “*funding councils and other funding bodies ought to establish specific open science calls, with significant funding.*”<sup>405</sup> 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.*”<sup>406</sup>

## 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-

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<sup>398</sup> *Id.* at 586.

<sup>399</sup> *Id.* at 589.

<sup>400</sup> *Id.* at 589.

<sup>401</sup> Tania Bubela et al., *Open Drug Discovery of Anti-Virals Critical for Canada’s Pandemic Strategy*, 5 FACETS J. (Dec. 17, 2020), <https://www.facetsjournal.com/doi/pdf/10.1139/facets-2020-0079>.

<sup>402</sup> *Id.* at 4.

<sup>403</sup> *Id.*

<sup>404</sup> *Id.*

<sup>405</sup> *Id.*

<sup>406</sup> *Id.*

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.<sup>407</sup> 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.<sup>408</sup>

### 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.<sup>409</sup> 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.*”<sup>410</sup> 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.*”<sup>411</sup> 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.*”<sup>412</sup> Apparently, though, developed countries have resisted the adoption of the waiver.<sup>413</sup>

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<sup>407</sup> Peter Yu, *A Critical Appraisal of the COVID-19 TRIPS Waiver*, in *INTELLECTUAL PROPERTY RIGHTS IN THE POST PANDEMIC WORLD: AN INTEGRATED FRAMEWORK OF SUSTAINABILITY, INNOVATION AND GLOBAL JUSTICE*, (Taina E. Pihlajarinne, Jukka Mähönen and Pratyush Upreti, eds., 2021-2022).

<sup>408</sup> *People’s Vaccine Alliance Lauds US Decision to Break Open COVID-19 Monopolies and Urges Others to Follow US Lead*, OXFAM (May 6, 2021), <https://www.oxfam.org/en/press-releases/peoples-vaccine-alliance-lauds-us-decision-break-open-covid-19-monopolies-and-urges>.

<sup>409</sup> 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>.

<sup>410</sup> *Id.*

<sup>411</sup> *Id.*

<sup>412</sup> *Id.*

<sup>413</sup> *Id.*

Ellen t' Hoen has discussed the importance of the TRIPS Waiver proposal.<sup>414</sup> 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.”<sup>415</sup> 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.*”<sup>416</sup>

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.*”<sup>417</sup> 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.<sup>418</sup> 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.*”<sup>419</sup> 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.*”<sup>420</sup>

Alongside South Africa and India, a large number of nations have become co-sponsors of the TRIPS Waiver.<sup>421</sup> 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

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<sup>414</sup> HOEN, *supra* note 88.

<sup>415</sup> *Id.*

<sup>416</sup> *Id.*

<sup>417</sup> Press Release, World Trade Org., Members Discuss Intellectual Property Response to the COVID-19 Pandemic, (Oct. 20, 2020), [https://www.wto.org/english/news\\_e/news20\\_e/trip\\_20oct20\\_e.htm?utm\\_source=dlvr.it&utm\\_medium=twitter](https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm?utm_source=dlvr.it&utm_medium=twitter).

<sup>418</sup> *Id.*

<sup>419</sup> *Id.*

<sup>420</sup> *Id.*

<sup>421</sup> Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the African Group et al., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669/Rev.1 (May 21, 2021).

to refine the TRIPS Waiver. India's Prime Minister Narendra Modi has been actively lobbying other nations to support the TRIPS Waiver.<sup>422</sup>

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

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.<sup>423</sup> There was concern that the Trump Administration adopted a “America First” approach to COVID-19 diagnostics, therapeutics, and vaccines.<sup>424</sup> 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.<sup>425</sup> 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.<sup>426</sup> 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) –

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<sup>422</sup> *Modi Seeks Support of G-7 Nations for TRIPS Waiver at WTO*, THE HINDU BUSINESS LINE (June 13, 2021), <https://www.thehindubusinessline.com/news/modi-seeks-support-of-g-7-nations-for-trips-waiver-at-wto/article34802793.ece>; *Indian Official Says There Is Widespread Support at G7 for TRIPS Waiver at WTO*, REUTERS (June 14, 2021), <https://www.reuters.com/world/india/indian-official-says-there-is-widespread-support-g7-trips-waiver-wto-2021-06-13/>; Shreya Nandi, *India Gets Wide Support on TRIPS Waiver for COVID-19 Vaccines at G-17 Meet*, BUSINESS STANDARD (June 14, 2021), [https://www.business-standard.com/article/current-affairs/india-gets-wide-support-on-trips-waiver-for-covid-19-vaccines-at-g-7-meet-121061400029\\_1.html](https://www.business-standard.com/article/current-affairs/india-gets-wide-support-on-trips-waiver-for-covid-19-vaccines-at-g-7-meet-121061400029_1.html).

<sup>423</sup> *Trump Administration Announces Framework and Leadership for Operation Warp Speed*, HHS (15 May, 2020), <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>.

<sup>424</sup> MICHAEL LEWIS, THE PREMONITION: A PANDEMIC STORY (2021); LAWRENCE WRIGHT, THE PLAGUE YEAR: AMERICA IN THE TIME OF COVID (2021); ANDY SLAVITT, PREVENTABLE: THE INSIDE OF HOW LEADERSHIP FAILURES, POLITICS, AND SELFISHNESS DOOMED THE U.S. CORONAVIRUS RESPONSE (2021); YASMEEN ABUTALEB AND DAMIAN PALETTA, NIGHTMARE SCENARIO: INSIDE THE TRUMP ADMINISTRATION'S RESPONSE TO THE PANDEMIC THAT CHANGED HISTORY (2021); MICHAEL WOLFF, LANDSLIDE: THE FINAL DAYS OF THE TRUMP PRESIDENCY (2021).

<sup>425</sup> Peter Sullivan, *Progressives Up Pressure on Biden to Back COVID Vaccine Patent Waiver*, THE HILL (March 24, 2021), <https://thehill.com/policy/healthcare/544620-progressives-up-pressure-on-biden-to-back-covid-vaccine-patent-waiver>.

<sup>426</sup> Press Release, Congressman Ro Khanna, It's Vital That the US Drop Barriers to Vaccine Production and Aid COVID-Ravaged India (May 7, 2021), <https://khanna.house.gov/media/in-the-news/ro-khanna-it-s-vital-us-drop-barriers-vaccine-production-and-aid-covid-ravaged>.

and other leading progressive Democrats - were champions of a TRIPS Waiver.<sup>427</sup> 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*”.<sup>428</sup> 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.*”<sup>429</sup>

The People’s Vaccine lobbied 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.<sup>430</sup> 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*”.<sup>431</sup> 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.*”<sup>432</sup> This broad-based social movement has been successful in shifting the position of the Biden administration.<sup>433</sup>

After much deliberation,<sup>434</sup> 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

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<sup>427</sup> Letter from Senator Bernie Sanders et al., to President Joe Biden,(Apr. 17, 2021), <https://www.sanders.senate.gov/press-releases/news-senators-urge-biden-to-approve-vaccine-patent-waiver-to-boost-production-and-end-pandemic>.

<sup>428</sup> *Id.*

<sup>429</sup> *Id.*

<sup>430</sup> Petre Agre et al.,*Open Letter: Former Heads of State and Nobel Laureates Call on President Biden to Waive Intellectual Property Rules for COVID Vaccines*, PEOPLE’S VACCINE ALLIANCE (Apr. 15, 2021), <https://peoplesvaccinealliance.medium.com/open-letter-former-heads-of-state-and-nobel-laureates-call-on-president-biden-to-waive-e0589edd5704>.

<sup>431</sup> *Id.*

<sup>432</sup> *Id.*

<sup>433</sup> Lev Facher & Nicholas Florko, *How David Beat Goliath: Advocacy Groups Seized A Moment, And Found Allies, In Bid to Loosen Vaccine Patent Rights*, STAT (May 7, 2021), <https://www.statnews.com/2021/05/07/how-david-beat-goliath-advocacy-groups-seized-a-moment-and-found-allies-in-bid-to-loosen-vaccine-patent-rights/>.

<sup>434</sup> White House Press secretary Jen Psaki said of President Joe Biden’s decision-making process on the TRIPS Waiver: ‘He’s a details guy and he wants to dig into the pros and cons and all of the considerations for any decision.’ Patsy Widakuswara, *Biden Agrees to Waive COVID-19 Vaccine Patents, But It’s Still Complicated*, VOICE OF AMERICA NEWS (May 5, 2021), <https://www.voanews.com/covid-19-pandemic/biden-agrees-waive-covid-19-vaccine-patents-its-still-complicated>; Press Release, Jen Psaki, Press Secretary (July 9, 2021), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/09/press-briefing-by-press-secretary-jen>

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.”*<sup>435</sup>

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 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.”*<sup>436</sup> 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”*.<sup>437</sup> The Ambassador also said that the U.S. administration *“will also work to increase the raw materials needed to produce those vaccines.”*<sup>438</sup>

The Speaker of the House Nancy Pelosi commended the Biden Administration on its decision to support a TRIPS Waiver for Vaccines.<sup>439</sup> 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.”*<sup>440</sup> Pelosi stressed: *“We cannot be fully safe from the virus anywhere until we defeat it everywhere.”*<sup>441</sup>

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psaki-july-9-2021 (The Press Secretary has also said that President Biden has been a ‘strong proponent’ of the TRIPS Waiver).

<sup>435</sup> Press Release, Office of the U.S. Trade Representative, Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.

<sup>436</sup> *Id.*

<sup>437</sup> *Id.*

<sup>438</sup> *Id.*

<sup>439</sup> Press Release, Nancy Pelosi, Speaker, House of Representatives Pelosi Statement on Biden Administration Support for Vaccine Patents Waiver at WTO (May 5, 2021), <https://www.speaker.gov/newsroom/5521-3>.

<sup>440</sup> *Id.*

<sup>441</sup> *Id.*

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,<sup>442</sup> Jacinda Ardern's New Zealand Government said that it would support a TRIPS Waiver for vaccines.<sup>443</sup> Her Trade Minister, the Hon. Damien O'Connor observed that New Zealand supported equitable access to COVID vaccines for all.<sup>444</sup> 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.'<sup>445</sup> However, documents revealed under the Official Information Act showed that New Zealand Government had previously been frustrating efforts to promote a "People's Vaccine")<sup>446</sup>

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.<sup>447</sup> While expressing enthusiasm for President Joe Biden's stance,<sup>448</sup> the Australian Government seems wary of offending the vaccine developer, Pfizer, and other biomedical companies, who are strident opponents of the TRIPS Waiver.<sup>449</sup> Opposition parties such as the Australian Labor Party and the Australian Greens have pressed the Coalition Government to

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<sup>442</sup>(24 March 2021) 751 NZPD 1744, [https://www.parliament.nz/resource/en/NZ/HansD\\_20210324\\_20210324/566d2c95e499e0fab70c8bac98d8ccf0dfd1f00](https://www.parliament.nz/resource/en/NZ/HansD_20210324_20210324/566d2c95e499e0fab70c8bac98d8ccf0dfd1f00)

<sup>443</sup> Thomas Manch, *New Zealand To Support Effort to Waive COVID-19 Vaccine Patents, After U.S. Backs WTO Bid*, STUFF NZ (May 6, 2021), <https://www.stuff.co.nz/national/health/coronavirus/125048729/new-zealand-to-support-effort-to-waive-covid19-vaccine-patents-after-united-states-backs-wto-bid>.

<sup>444</sup> Damien O'Connor, *NZ Backs Moves To Improve Global Access to COVID Vaccines*, THE BEEHIVE (May 6, 2021), <https://www.beehive.govt.nz/release/nz-backs-moves-improve-global-access-covid-vaccines>.

<sup>445</sup> *Id.*

<sup>446</sup> Max Harris & Phoebe Carr, *New Zealand's stance on 'People's Vaccine' for COVID Undermines its Principled Reputation*, THE GUARDIAN, (25 August 2021), <https://www.theguardian.com/world/commentisfree/2021/aug/25/new-zealands-stance-on-peoples-vaccine-for-covid-undermines-its-principled-reputation>

<sup>447</sup> Elias Visontay, *India Wants Access to Cheap Copies of Vaccines. So Why Is Australia Holding Out?*, THE GUARDIAN (Apr. 30, 2021), <https://www.theguardian.com/australia-news/2021/apr/30/india-wants-access-to-cheap-copies-of-covid-vaccines-so-why-is-australia-holding-out>; Lyndal Rowlands, *Australia Stalls Vaccine Supply*, THE SATURDAY PAPER (Aug. 21, 2021), <https://www.thesaturdaypaper.com.au/news/politics/2021/08/21/australia-stalls-vaccine-supply/162946800012311#mtr>.

<sup>448</sup> Matthew Knott & Bianca Hall, *"Monumental Moment": Australia Applauds US Push for Patent-Free COVID Vaccines*, BRISBANE TIMES (May 6, 2021), <https://www.brisbanetimes.com.au/world/north-america/biden-administration-backs-covid-vaccines-patent-waiver-20210506-p57pal.html>.

<sup>449</sup> Paul Karp, *Pfizer Warns Australia a COVID Vaccine Patent Waiver Could Harm Supply and Safety*, THE GUARDIAN (May 13, 2021), <https://www.theguardian.com/australia-news/2021/may/13/pfizer-warns-australia-a-covid-vaccine-intellectual-property-patent-waiver-could-harm-supply-and-safety>; *Medicines Australia Updated Position on Intellectual Property (In Light of TRIPS Waiver)*, MED. AUSTRAL. (May 6, 2021), <https://www.medicinesaustralia.com.au/media-release/medicines-australia-updated-position-on-intellectual-property-in-light-of-trips-waiver>.

support the TRIPS Waiver.<sup>450</sup> 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.*”<sup>451</sup> Senator Rachel Siewert of the Australian Greens said in a speech: “*The Morrison government should be following suit and should be contributing to the global discussion and supporting the waiver of intellectual property rights on COVID vaccines to ensure that we enable an equal distribution of the vaccines.*”<sup>452</sup> 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.*”<sup>453</sup> A number of civil society groups – including Human Rights Watch, MSF Australia, and AFTINET – have encouraged the Coalition Government to adopt the TRIPS Waiver.<sup>454</sup> Michele O’Neil of Unions Australia commented: “*The growing COVID-19 crisis in India shows the urgent need for a ramp up of the production of vaccines to enable equitable access to end this pandemic as quickly as possible.*”<sup>455</sup> India’s Deputy High Commissioner to Australia, Palaniswamy Subramanian Karthigeyan, has urged Australia to support a TRIPS Waiver: “*Given the situation we find ourselves in,*

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<sup>450</sup> Elias Visontay, *Pressure Mounts on Australia to Support COVID Vaccine Intellectual Property Waiver for Developing Nations*, THE GUARDIAN (May 6, 2021), <https://www.theguardian.com/australia-news/2021/may/06/pressure-mounts-on-australia-to-support-covid-vaccine-intellectual-property-waiver-for-developing-nations>.

<sup>451</sup> Senator Penny Wong, Mark Butler MP & Madeleine King MP, *Morrison Must Ensure Developing Nations Have Access to Vaccines*, AUSTRALIAN LABOR PARTY (Apr. 30, 2021), <https://www.pennywong.com.au/media-hub/media-statements/morrison-must-ensure-developing-nations-have-access-to-vaccines>.

<sup>452</sup> Commonwealth, *Parliamentary Debates*, Senate, 12 May 2021, 6 (Rachel Siewert, Senator) (Austl.), <https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansards%2F5d7154b6-80d6-4733-ad27-6f37db4fb595%2F0014%22>.

<sup>453</sup> Commonwealth, *Parliamentary Debates*, Senate, 24 August 2021, 38 (Mehreen Faruqi, Senator) (Austl.), <https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansards%2F62d6646b-aecc-456e-9883-4d7bd089f14e%2F0105%22>.

<sup>454</sup> Sophie McNeill, *Australia Should Back COVID-19 Waiver of Intellectual Property Rules: Waive TRIPS Amid Delta Outbreak, Vaccine Shortages*, HUMAN RIGHTS WATCH (July 25, 2021), <https://www.hrw.org/news/2021/07/25/australia-should-back-covid-19-waiver-intellectual-property-rules>; *Australia Must Stop Stalling Negotiations On Landmark Pandemic Monopoly Waiver*, MEDECINS SANS FRONTIERES (June 8, 2021), <https://msf.org.au/article/statements-opinion/australia-must-stop-stalling-negotiations-landmark-pandemic-monopoly>; Patricia Ranald, *Rich Countries are First in Line for COVID-19 Vaccines Because A Handful of Companies Control the Price and Quantity*, THE GUARDIAN (22 July 2021), <https://www.theguardian.com/commentisfree/2021/jul/22/rich-countries-are-first-in-line-for-covid-vaccines-because-a-handful-of-companies-control-both-the-price-and-quantity>.

<sup>455</sup> Press Release, AUSTRALIAN COUNCIL OF TRADE UNIONS, *Morrison Government Continues to Oppose Vaccine IP Waiver Despite US, NZ Support* (May 6, 2021), [https://www.actu.org.au/actu-media/media-releases/2021/morrison-government-continues-to-oppose-vaccine-ip-waiver-despite-us-nz-support?utm\\_source=miragenews&utm\\_medium=miragenews&utm\\_campaign=news](https://www.actu.org.au/actu-media/media-releases/2021/morrison-government-continues-to-oppose-vaccine-ip-waiver-despite-us-nz-support?utm_source=miragenews&utm_medium=miragenews&utm_campaign=news).

*time is of the greatest essence and an effective response to the pandemic requires other countries to make these products accessible, to make it equitable, to make it affordable.*<sup>456</sup>

In the end, the Australian Government finally committed to support a TRIPS Waiver for vaccines in September 2021.<sup>457</sup> The Australian Government, though, refused to co-sponsor the TRIPS Waiver.<sup>458</sup> The pharmaceutical and biotechnology industries were aggrieved by the decision of the Australian Government to support a TRIPS Waiver – calling on them to reconsider their decision.<sup>459</sup>

The Liberal Government of Canada has also been rather non-committal about support the TRIPS Waiver.<sup>460</sup> This is disappointing given that past Liberal Governments have been leaders on access to essential medicines,<sup>461</sup> and Prime Minister Justin Trudeau had previously made statements about the importance of universal access to essential medicines.<sup>462</sup> 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

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<sup>456</sup> Bianca Hall, Rachel Clun & Emma Koehn, *Australia Accused of Delaying Campaign To Allow Generic COVID Vaccines*, THE SYDNEY MORNING HERALD (Apr. 29, 2021), <https://www.smh.com.au/national/australia-accused-of-delaying-campaign-to-allow-generic-covid-vaccines-20210428-p57n09.html>.

<sup>457</sup> Paul Karp and Elias Visontay, *Australia to Support Vaccine Waiver After Months of Pressure from Human Rights Groups*, THE GUARDIAN (September 8, 2021), <https://www.theguardian.com/society/2021/sep/08/australia-to-support-vaccine-waiver-after-months-of-pressure-from-human-rights-groups>; Deborah Gleeson, *Australia has Finally Backed a Plan to Let Developing Countries Make Cheap COVID-19 Vaccines — What Matters is What it Does Next*, THE CONVERSATION (September 14, 2021), <https://theconversation.com/australia-has-finally-backed-a-plan-to-let-developing-countries-make-cheap-covid-19-vaccines-what-matters-is-what-it-does-next-167630>; and Stephanie Dalzell, *Australia Backs International Push for Generic COVID-19 Vaccines, but Several Countries Remain Unconvinced*, ABC NEWS (October 6, 2021) <https://www.abc.net.au/news/2021-10-06/cph-australia-backs-push-for-generic-covid-19-vaccines/100516060>

<sup>458</sup> Denham Sadler, *Australia Refuses to Co-Sponsor COVID-19 Vaccine IP Waiver*, INNOVATIONAUS, (November 4, 2021), <https://www.innovationaus.com/australia-refuses-to-co-sponsor-covid-19-vaccine-ip-waiver/>

<sup>459</sup> Press Release, AUSBIOTECH AND MEDICINES AUSTRALIA, *COVID-19 Vaccine Patent Waiver will not Speed Up Global Vaccination*, <https://www.ausbiotech.org/news/covid-19-vaccine-patent-waiver-will-not-speed-up-global-vaccination-say-ausbiotech-and-medicines-australia>

<sup>460</sup> Government of Canada, Statement by Canada at WTO TRIPS Council (Feb. 23, 2021), [https://www.international.gc.ca/world-monde/international\\_relations-relations\\_internationales/wto-omc/2021-02-23-trips-adpic.aspx?lang=eng](https://www.international.gc.ca/world-monde/international_relations-relations_internationales/wto-omc/2021-02-23-trips-adpic.aspx?lang=eng).

<sup>461</sup> STEPHEN LEWIS, RACE AGAINST TIME: SEARCHING FOR HOPE IN AIDS-RAVAGED AFRICA (2006); Matthew Rimmer, *The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid*, 15 (7) EXPERT OPINION ON THERAPEUTIC PAT. 889 (2005); Matthew Rimmer, *Race Against Time: The Export of Essential Medicines to Rwanda* 1 (2) PUB. HEALTH ETHICS 89 (2008).

<sup>462</sup> TRUDEAU ET AL., supra note 101.

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.*”<sup>463</sup>

### C. Opposition to the TRIPS Waiver

In spite of the Biden administration’s support for the TRIPS Waiver, there are a range of hold-outs to the TRIPS Waiver who have been obstructing consensus on the proposal in the World Trade Organization. The European Commission has been steadfast in its opposition to the TRIPS Waiver.<sup>464</sup> The Government of Germany has been particularly resistant to the adoption of a TRIPS Waiver.<sup>465</sup> 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.*”<sup>466</sup> 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.<sup>467</sup> A German government spokeswoman said: “*The protection of intellectual property is a source of innovation and this has to remain so in the future.*”<sup>468</sup> 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.<sup>469</sup> During her visit to the White House, various U.S. legislators and civil society groups engaged in vocal criticism of her

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<sup>463</sup> Ahmar Khan, *Canada lacks ‘political will’ to waive COVID-19 vaccine patents, Bolivian minister says*, GLOBAL NEWS, (October 6 2021) <https://globalnews.ca/news/8243635/bolivian-minister-canada-covid-vaccine-waiver/>

<sup>464</sup> Andrew Green, *Europe Still Can’t Get on Board with the TRIPS Waiver*, DEVEX (May 31, 2021), <https://www.devex.com/news/europe-still-can-t-get-on-board-with-the-trips-waiver-100027>.

<sup>465</sup> Joseph Choi, *Merkel Breaks with Biden on US Plan to Waive Patent Protections for COVID-19 Vaccines*, THE HILL (May 6, 2021), <https://thehill.com/policy/international/552171-merkel-breaks-with-biden-on-us-plan-to-waive-patent-protections-for>.

<sup>466</sup> Matthew Rimmer (@DrRimmer), TWITTER (May 19, 2020, 5:46 PM), <https://twitter.com/DrRimmer/status/1262718696314638336?s=20>; See also, *Merkel: Coronavirus Pandemic Will Be Overcome Quicker If World Works Together*, REUTERS (May 18, 2020), <https://www.reuters.com/article/us-health-coronavirus-who-merkel/merkel-coronavirus-pandemic-will-be-overcome-quicker-if-world-works-together-idUSKBN22U1HY; G20: Angela Merkel Calls for Global Action to Beat Coronavirus>, DW NEWS (Nov. 21, 2020), <https://www.dw.com/en/g20-angela-merkel-calls-for-global-action-to-beat-coronavirus/a-55686409?maca=en-Twitter-sharing>.

<sup>467</sup> Arne Delfs & Eric Martin, *Merkel Pushes Back on Vaccine Patent Waiver in Row with U.S.*, BLOOMBERG (May 7, 2021), <https://www.bloomberg.com/news/articles/2021-05-06/merkel-pushes-back-on-vaccine-patent-waiver-in-clash-with-biden>.

<sup>468</sup> *Id.*

<sup>469</sup> Jake Johnson, *Biden-Merkel Meeting Fails to Move Forward Vaccine Patent Waiver*, TRUTHOUT (July 16, 2021), [https://truthout.org/articles/biden-merkel-meeting-fails-to-move-forward-vaccine-patent-waiver/?utm\\_campaign=Truthout+Share+Buttons](https://truthout.org/articles/biden-merkel-meeting-fails-to-move-forward-vaccine-patent-waiver/?utm_campaign=Truthout+Share+Buttons).

stance.<sup>470</sup> 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.<sup>471</sup>

The European Parliament, in a vote, called upon the European Commission to support a TRIPS Waiver.<sup>472</sup> 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.<sup>473</sup>

After some equivocation, French President Emmanuel Macron has also called for the European Commission to support the TRIPS Waiver.<sup>474</sup>

Other opponents of the TRIPS Waiver include the Governments of the United Kingdom, Switzerland,<sup>475</sup> Norway,<sup>476</sup> and Brazil. Somewhat indecisively, Japan has said that it would not oppose the TRIPS Waiver but it would not endorse the TRIPS Waiver either.<sup>477</sup>

The Conservative Government led by Boris Johnson has resisted entreaties to support the TRIPS Waiver.<sup>478</sup> Former British Prime Minister Gordon Brown has pressed the current United

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<sup>470</sup> Press Release, Rep. Jan Schakowsky, *Schakowsky, Colleagues Request Meeting with Merkel To Discuss European Union Blocking TRIPS Waiver* (12 July 2021), <https://schakowsky.house.gov/media/press-releases/schakowsky-colleagues-request-meeting-merkel-discuss-european-union-blocking>; *U.S. lawmakers ask for Meeting on WTO Waiver with Merkel during Washington Visit*, REUTERS (July 13, 2021), <https://www.reuters.com/world/us/us-lawmakers-ask-meeting-wto-waiver-with-merkel-during-washington-visit-2021-07-13>.

<sup>471</sup> *Biden-Merkel Summit Fail: Pres. Biden Unable to End Germany's Blockade of COVID WTO TRIPS Waiver He Seeks to End Pandemic*, PUBLIC CITIZEN (July 15, 2021), <https://www.citizen.org/news/biden-merkel-summit-fail-pres-biden-unable-to-end-germanys-blockade-of-covid-wto-trips-waiver-he-seeks-to-end-the-pandemic/>.

<sup>472</sup> European Parliament Press Release IPR/05/514, *Parliament Calls for Temporary COVID-19 Vaccine Patent Waiver* (July 10, 2021), <https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-covid-19-vaccine-patent-waiver>.

<sup>473</sup> EUR. PARL. DOC., *supra* note 113.

<sup>474</sup> Lotte Leicht, *European Commission Increasingly Isolated On COVID Patent Waivers: French President Emmanuel Macron and the European Parliament Endorsed Making Vaccines More Available*, HUMAN RIGHTS WATCH (June 11, 2011), <https://www.hrw.org/news/2021/06/11/european-commission-increasingly-isolated-covid-patent-waivers>.

<sup>475</sup> IGE, *Suspension of the TRIPS Agreement During the COVID-19 Pandemic?* (2020) <https://www.ige.ch/en/intellectual-property/ip-and-society/swiss-health-foreign-policy-and-access-to-therapeutic-products/suspension-of-the-trips-agreement>

<sup>476</sup> Norway in Geneva, *Statement by Norway at WTO TRIPS Council* (Oct. 16, 2020), <https://www.norway.no/en/missions/wto-un/nig/latest-news/trips1610>.

<sup>477</sup> Human Rights Watch, *Quad Leaders Should Back Covid-19 Intellectual Property Waiver*, (September 23, 2021) <https://reliefweb.int/report/world/quad-leaders-should-back-covid-19-intellectual-property-waiver>

<sup>478</sup> Hannah Summers, *Britain in Talks to Waive Covid Vaccine Patents to Improve Global Access to Jabs*, THE GUARDIAN (May 20, 2021), <https://www.theguardian.com/global-development/2021/may/20/britain-in-talks-to-waive-covid-vaccine-patents-to-improve-global-access-to-jabs>; Larry Elliott, *Labour says UK must "Get off the Fence" over Global Covid Vaccine Access*, THE GUARDIAN (May 20, 2021), <https://www.theguardian.com/world/2021/may/20/labour-uk->

Kingdom government and other members of the G7 do more on access to essential medicines.<sup>479</sup> 80 Members of Parliament signed a petition on Intellectual Property and the COVID-19 response.<sup>480</sup> 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.*”<sup>481</sup> 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.*”<sup>482</sup> Richard Burgon MP has also called for the United Kingdom to support a ‘People’s Vaccine.’<sup>483</sup>

The Gates Foundation has a history of supporting intellectual property maximalist positions in the debate over access to essential medicines.<sup>484</sup> The Gates Foundation was initially supportive of 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

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global-covid-vaccine-access-patent-waiver; Aubrey Allegretti, *MPs Tell Johnson: You Have A Duty to Help Vaccinate the World*, THE GUARDIAN (June 1, 2021), <https://www.theguardian.com/society/2021/may/31/mps-boris-johnson-donate-vaccines-poorer-countries>.

<sup>479</sup> Gordon Brown, *The G7 must push for Global Vaccination. Here’s How it Could Do It*, THE GUARDIAN (Apr. 12, 2021), <https://www.theguardian.com/commentisfree/2021/apr/12/g7-global-vaccination-covid>; Gordon Brown, *Despite the Grand Words, This G7 Falls Devastatingly Short On Vaccines*, THE GUARDIAN (June 14, 2021), <https://www.theguardian.com/commentisfree/2021/jun/14/grand-words-g7-vaccines-summit-failure-gordon-brown>; Gordon Brown, *The World Is Making Billions of COVID Vaccine Doses, So Why Is Africa Not Getting Them*, THE GUARDIAN (Aug. 16, 2021), <https://www.theguardian.com/commentisfree/2021/aug/16/world-billions-covid-vaccine-doses-africa-unprotected>; GORDON BROWN, SEVEN WAYS TO CHANGE THE WORLD: HOW TO FIX THE MOST PRESSING PROBLEMS WE FACE (2021).

<sup>480</sup> EDM 1451 - Intellectual Property and COVID-19 Response, UNITED KINGDOM PARLIAMENT (08 Feb. 2021), <https://edm.parliament.uk/early-day-motion/58063/intellectual-property-and-covid19-response>.

<sup>481</sup> *Id.*

<sup>482</sup> Navendu Mishra, *India’s COVID Spiral is Nothing Short of Horrifying – And The UK Must Act*, MIRROR (Apr. 30, 2021), <https://www.mirror.co.uk/news/politics/indias-covid-spiral-nothing-short-24015159>; *See also*, Navendu Mishra, *There Should Be No Monopolies in a Pandemic*, POLITICS (Nov. 20, 2020), <https://politics.co.uk/comment-analysis/2020/11/20/there-should-be-no-monopolies-in-a-pandemic>.

<sup>483</sup> Richard Burgon, *A Vaccine That Serves All of Humanity – Not Private Profit*, MORNING STAR, <https://morningstaronline.co.uk/article/f/vaccine-serves-all-humanity-not-private-profit>.

<sup>484</sup> Matthew Rimmer, *The Lazarus Effect: The (RED) Campaign, and Creative Capitalism*, in *INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO MEDICINES*, 313 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein ed., 2010).

market forces are left to distribute medicines.<sup>485</sup> The Gates Foundation was a reluctant, late supporter of the TRIPS Waiver.<sup>486</sup> 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.<sup>487</sup> There has been an extensive lobbying campaign by intellectual property owners to nation governments against the adoption of the TRIPS Waiver.<sup>488</sup> Vaccine developers have also been placing great pressure upon nation states during negotiations to acquire vaccines.<sup>489</sup> 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<sup>490</sup> and the regional trade agreement, the *Trans-Pacific Partnership*.<sup>491</sup> It

<sup>485</sup> John Miller, *Bill Gates calls for COVID-19 Meds to Go to People Who Need Them, Not “Highest Bidder”*, THE SYDNEY MORNING HERALD (June 10, 2020), <https://t.co/pAp3g9QXgT?amp=1>.

<sup>486</sup> Catherine Cheney, *Gates Foundation Reverses Course on COVID-19 Vaccine Patents*, DEVEX (May 7, 2021), <https://www.devex.com/news/gates-foundation-reverses-course-on-covid-19-vaccine-patents-99810>.

<sup>487</sup> Paul Karp, *Pfizer Warns Australia a COVID Vaccine Patent Waiver Could Harm Supply and Safety*, THE GUARDIAN (May 13, 2021), <https://www.theguardian.com/australia-news/2021/may/13/pfizer-warns-australia-a-covid-vaccine-intellectual-property-patent-waiver-could-harm-supply-and-safety>.

<sup>488</sup> Lee Fang, *Pharmaceutical Industry Dispatches Army of Lobbyists to Block Generic COVID-19 Vaccines*, THE INTERCEPT (Apr. 23, 2021), <https://theintercept.com/2021/04/23/covid-vaccine-ip-waiver-lobbying>; Lee Fang, *Hollywood Lobbyists Intervene Against Proposal to Share Vaccine Technology*, THE INTERCEPT (Apr. 28, 2021), <https://theintercept.com/2021/04/27/covid-vaccine-copyright-hollywood-lobbyists>; Lee Fang, *Documents Reveal Pharma Plot to Stop Generic COVID-19 Vaccine Waiver*, THE INTERCEPT (May 15, 2021), <https://theintercept.com/2021/05/14/covid-vaccine-waiver-generic-pharma-lobby>; Brett Wilkins, *Big Pharma Plotting to Derail Biden’s COVID Vaccine Waiver: Report*, SALON (May 17, 2021), [https://www.salon.com/2021/05/17/big-pharma-plotting-to-derail-covid-vaccine-waiver-report\\_partner](https://www.salon.com/2021/05/17/big-pharma-plotting-to-derail-covid-vaccine-waiver-report_partner)

<sup>489</sup> Madlen Davies et al., *“Held to Ransom”: Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal*, THE BUREAU OF INVESTIGATIVE JOURNALISM (Feb. 23, 2021), <https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal>; *Investigation: Drugmaker “Bullied” Latin American Nations*, AL JAZEERA (Mar. 11, 2021), <https://www.aljazeera.com/news/2021/3/11/investigation-pfizer-bullied-latin-american-nations>; Zain Rizvi, *Pfizer’s Power*, PUBLIC CITIZEN, (October 19, 2021), <https://www.citizen.org/article/pfizers-power/>; Adam Taylor, *In Secret Vaccine Contracts with Governments, Pfizer took Hard Line in Push for Profit, Report says*, THE WASHINGTON POST, (October 19, 2021) <https://www.washingtonpost.com/world/2021/10/19/secret-vaccine-contracts-with-governments-pfizer-took-hard-line-push-profit-report-says/> and Zain Rizvi, *Public Citizen Blasts Pfizer for Putting Corporate Profit Over Increasing Access to COVID Vaccines*, DEMOCRACY NOW!, (October 22, 2021), [https://www.democracynow.org/2021/10/22/public\\_citizen\\_researcher\\_exposes\\_pfizer\\_vaccines](https://www.democracynow.org/2021/10/22/public_citizen_researcher_exposes_pfizer_vaccines)

<sup>490</sup> Australia-U.S. Free Trade Agreement, Austl.-U.S., May 18, 2004, 118 Stat. 919; *See generally*, Matthew Rimmer, *Robbery Under Arms: Copyright Law and the Australia-U.S. Free Trade Agreement* 11 (3) FIRST MONDAY (March 2006) <http://firstmonday.org/ojs/index.php/fm/article/view/1316> and Ken Harvey et al., *Will the Australia-U.S. Free Trade Agreement Undermine the Pharmaceutical Benefits Scheme?*, 181 (5) MED. J. OF AUS. 256 (October 2004).

<sup>491</sup> Trans-Pacific Partnership (TPP), 4 Feb. 2016, and *Comprehensive and Progressive Agreement for Trans-Pacific Partnership* (2018), <https://www.dfat.gov.au/sites/default/files/tpp-11-treaty-text.pdf>; *See generally*, Matthew Rimmer, *The Trans-*

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.<sup>492</sup>

There has been an open petition by over 100 academics, scholars, and researchers, calling for the adoption of the TRIPS Waiver.<sup>493</sup> 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.*”<sup>494</sup> 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.*”<sup>495</sup> In addition to the passage of the TRIPS Waiver, the academics called for the adoption of a package of measures – including the “*global co-ordination of supply chains; streamlining regulatory approval processes and sharing exclusive data from regulatory dossiers; and investment in the WHO’s C-TAP and the mRNA technology transfer hub in South Africa.*”<sup>496</sup>

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*Pacific Partnership: Intellectual Property, Public Health, and Access to Essential Medicines* 29 INTELL. PROP. J. 277 (2017); DEBORAH GLEESON, & RONALD LABONTE, TRADE AGREEMENTS AND PUBLIC HEALTH: A PRIMER FOR HEALTH POLICY MAKERS, RESEARCHERS AND ADVOCATES (2020); MATTHEW RIMMER, THE TRANS-PACIFIC PARTNERSHIP: INTELLECTUAL PROPERTY AND TRADE IN THE PACIFIC RIM (2020).

<sup>492</sup> Statement by Committee on Economic, Social and Cultural Rights on Universal Affordable Vaccination for COVID-19, International Cooperation and Intellectual Property, E/C.12/2021/1 (March 12, 2021) <https://t.co/YbLQw8bq3G?amp=1>; U.N. Human Rights Council, Ensuring Equitable, Affordable, Timely and Universal Access for All Countries to Vaccines in Response to the Coronavirus Disease (COVID-19) Pandemic, A/HRC/46/L.25/Rev.1 (March 17, 2021).

<sup>493</sup> Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal (July 2021), <https://docs.google.com/forms/d/e/1FAIpQLSfS497FZW5oNf2tk46rzdUAYswABW91OT91QarsaFTvoBLHvQ/viewform>; *Waive Intellectual Property Protection for COVID Vaccines urge over 100 IP Academic Experts*, THE LONDON SCH. OF ECON. AND POL. SCI. (July 13, 2021), <https://lse.ac.uk/News/Latest-news-from-LSE/2021/g-July-21/Waive-intellectual-property-protection-for-COVID-vaccines.aspx>.

<sup>494</sup> *Id.*

<sup>495</sup> *Id.*

<sup>496</sup> *Id.*

In July 2021, MSF has complained that opposing countries have been filibustering negotiations on the TRIPS Waiver at the WTO.<sup>497</sup> 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.*"<sup>498</sup> 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.*"<sup>499</sup> 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.<sup>500</sup> 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.<sup>501</sup> 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*".<sup>502</sup> 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.*"<sup>503</sup>

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<sup>497</sup> *Opposing Countries Must Stop Filibustering Negotiations on 'TRIPS Waiver' at WTO*, MEDECINS SANS FRONTIERES ACCESS CAMPAIGN (July 26, 2021), <https://msfaccess.org/opposing-countries-must-stop-filibustering-negotiations-trips-waiver-wto>.

<sup>498</sup> *Id.*

<sup>499</sup> *Id.*

<sup>500</sup> *Id.*

<sup>501</sup> International Commission of Jurists, *Global Jurists call for Waiver of Global Intellectual Property Rights for COVID-19 Vaccines and Therapeutics*, (November 8, 2021), <https://www.icj.org/global-jurists-call-for-waiver-of-global-intellectual-property-rights-for-covid-19-vaccines-and-therapeutics/>; and International Commission of Jurists, *Human Rights Obligations of States to not Impede the Proposed COVID-19 TRIPS Waiver*, (November 2021) <https://www.icj.org/wp-content/uploads/2021/11/Human-Rights-Obligations-States-Proposed-COVID-19-TRIPS-Waiver.pdf>

<sup>502</sup> International Commission of Jurists, *Human Rights Obligations of States to not Impede the Proposed COVID-19 TRIPS Waiver*, (November 2021), 1, <https://www.icj.org/wp-content/uploads/2021/11/Human-Rights-Obligations-States-Proposed-COVID-19-TRIPS-Waiver.pdf>

<sup>503</sup> *Id.*, 17.

## IX. CONCLUSION

This paper has told the story of the People's Vaccine Alliance – a ragtag group of advocates, activists, and rebels who have challenged the status quo in respect of intellectual property and access to essential medicines. This social movement has questioned profiteering by pharmaceutical companies, vaccine developers, and medical diagnostics entities who have sought to maximise their intellectual property rights related to COVID-19 technologies. The 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.<sup>504</sup> 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.

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<sup>504</sup> Susi Geiger & Aisling McMahon, *Too Many Cooks or Too Many Recipes? An Analysis of the Institutional Landscape and Proliferation of Proposals for Global Vaccine Equity* (Geary Inst., U. C. Dublin, Working Paper No. 202108, 2021).

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.’<sup>505</sup> 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.’<sup>506</sup> 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.*’<sup>507</sup> It is certainly the case that there is scope to reimagine intellectual property in the wake of the coronavirus crisis. Professor Myra Tawfik from Windsor Law School from Canada has argued that ‘*the worldwide COVID-19 public health crisis highlights the inequities and biases within the international and domestic intellectual property (IP) legal orders that were already being scrutinized prior to this extraordinary global upheaval.*’<sup>508</sup> 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.*’<sup>509</sup> 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*

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<sup>505</sup> HOEN ET AL., *supra* note 163.

<sup>506</sup> HOEN ET AL., *supra* note 163.

<sup>507</sup> Arundhati Roy, *The Pandemic is a Portal*, FINANCIAL TIMES (Apr. 4, 2020), <https://www.ft.com/content/10d8f5e8-74eb-11ea-95fe-fcd274e920ca>.

<sup>508</sup> Myra Tawfik, *The Post-Pandemic IP Legal Order: Collaborative, Balanced and Inclusive*, Center for International Governance Innovation (July 8, 2020), <https://www.cigionline.org/articles/post-pandemic-ip-legal-order-collaborative-balanced-and-inclusive>.

<sup>509</sup> *Id.*

*engendered will carry forward into the future.*<sup>510</sup> Tawfik imagines: “*A post-pandemic IP legal order will be built on greater collaboration, balance and inclusion.*”<sup>511</sup> She is hopeful that the intellectual property regime will find a new equilibrium: “*By imposing checks and balances on individualistic and maximalist approaches, it will curb the abuses of the current IP environment, which privileges the dominant players*”.<sup>512</sup>

Susi Geiger and Aisling McMahon have expressed concern about the complicated, fragmented nature of the institutional landscape.<sup>513</sup> 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.<sup>514</sup> 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,<sup>515</sup> the WTO has hosted debates in the TRIPS Council over proposals such as the TRIPS Waiver.<sup>516</sup> 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*”.<sup>517</sup> 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

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<sup>510</sup> *Id.*

<sup>511</sup> *Id.*

<sup>512</sup> *Id.*

<sup>513</sup> Geiger and McMahon, *Supra* note 504.

<sup>514</sup> THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 23.

<sup>515</sup> *Members Discuss Intellectual Property Response to the COVID-19 Pandemic* (Oct. 20, 2020), WORLD TRADE ORG., [https://www.wto.org/english/news\\_e/news20\\_e/trip\\_20oct20\\_e.htm?utm\\_source=dlvr.it&utm\\_medium=twitter](https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm?utm_source=dlvr.it&utm_medium=twitter).

<sup>516</sup> COVID-19: Measures Regarding Trade-Related Intellectual Property Rights, WORLD TRADE ORG (Aug. 31, 2021), [https://www.wto.org/english/tratop\\_e/covid19\\_e/trade\\_related\\_ip\\_measure\\_e.htm](https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm); World Trade Organization, Information Note on the TRIPS Agreement and COVID-19 (Oct. 15, 2020), [https://www.wto.org/english/tratop\\_e/covid19\\_e/trips\\_report\\_e.pdf](https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf).

<sup>517</sup> *WTO Chief Lays Out Global Action To Increase Vaccine Access*, REUTERS (Apr. 15, 2021), <https://www.reuters.com/article/us-trade-wto-vaccines-idUSKBN2C12YU>; *Statement of Director-General Ngozi Okonjo-Iweala on USTR Tai's statement on the TRIPS Waiver*, WORLD TRADE ORGANIZATION (May 6, 2021) [https://www.wto.org/english/news\\_e/news21\\_e/dgno\\_06may21\\_e.htm](https://www.wto.org/english/news_e/news21_e/dgno_06may21_e.htm).

property, public health, and trade.<sup>518</sup> 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.<sup>519</sup> The leaders of the international institutions stressed: “*We underscored our commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies – a commitment anchored in the understanding that this is an urgent moral imperative in need of immediate practical action.*”<sup>520</sup> 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.<sup>521</sup> There is certainly a pressing need to ensure better financing for global public health.<sup>522</sup>

There has also been discussion as to whether there should be an international pandemic treaty to better protect the world from future health crises.<sup>523</sup> 25 heads of government and international agencies made a joint call for more robust international health architecture.<sup>524</sup> The joint statement noted: “*The COVID-19 pandemic has been a stark and painful reminder that nobody is safe until everyone is safe.*”<sup>525</sup> 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.*”<sup>526</sup> The joint statement stressed that vaccines should be treated as global

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<sup>518</sup> 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., 2<sup>nd</sup> ed. 2020).

<sup>519</sup> Press Release, WHO, Directors General of WHO, WIPO and the WTO agree on intensified cooperation in support of access to medical technologies worldwide to tackle the COVID-19 pandemic (June 24, 2021), <https://www.who.int/news/item/24-06-2021-directors-general-of-who-wipo-and-the-wto-agree-on-intensified-cooperation-in-support-of-access-to-medical-technologies-worldwide-to-tackle-the-covid-19-pandemic>.

<sup>520</sup> *Id.*

<sup>521</sup> Dreifuss et al., *supra* note 25.

<sup>522</sup> Iona Kickbush, *The COVID-19 Crisis Is A Signal – Need To ‘Reset’ Global Health Financing*, HEALTH POLICY WATCH (Nov. 11, 2020), <https://healthpolicy-watch.news/the-covid-19-crisis-is-a-signal-to-reset-global-health-financing>.

<sup>523</sup> *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>.

<sup>524</sup> *COVID-19 Shows Why United Action is Needed for More Robust International Health Architecture*, WORLD HEALTH ORGANIZATION (30 Mar., 2021), <https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture>.

<sup>525</sup> *Id.*

<sup>526</sup> *Id.*

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.*”<sup>527</sup>

There is certainly a need to consider the role that intellectual property law, policy, and practice will play not only in the COVID-19 response, but in the COVID-19 recovery. United Nations Secretary-General Antonio Guterres has called for a COVID-19 recovery plan, which upholds the Sustainable Development Goals and human rights: “*By respecting human rights in this time of crisis, we will build more effective and inclusive solutions for the emergency of today and the recovery for tomorrow.*”<sup>528</sup> There have been a host of proposals for COVID-19 recovery plans.<sup>529</sup> There has been a call for a reinvestment in public health, sustainable development, and climate action as part of a successful for COVID-19 recovery.<sup>530</sup> 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.*”<sup>531</sup> 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.*”<sup>532</sup>

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<sup>527</sup> *Id.*

<sup>528</sup> U.N. Sec. Gen., We are all in this Together: Human Rights and COVID-19 Response and Recovery, (Apr. 23, 2020), <https://www.un.org/en/un-coronavirus-communications-team/we-are-all-together-human-rights-and-covid-19-response-and>.

<sup>529</sup> For a discussion of COVID-19 recovery policies, see TANYA PLIBERSEK, A BETTER NORMAL AFTER COVID-19 (2020); KLAUS SCHWAB & THIERRY MALLERET, COVID-19: THE GREAT RESET (2020); ROSS GARNAUT, RESET: RESTORING AUSTRALIA AFTER THE GREAT CRASH OF 2020 (2021).

<sup>530</sup> *Beyond Recovery: Towards 2030*, UNITED NATIONS DEV. PROGRAMME (2020), [https://global.undp.acsitefactory.com/sites/g/files/zskgke326/files/publications/undp-COVID-19\\_UNDP\\_2.0\\_Offer.pdf](https://global.undp.acsitefactory.com/sites/g/files/zskgke326/files/publications/undp-COVID-19_UNDP_2.0_Offer.pdf); *The OECD Green Recovery Database: Examining the Environmental Implications of COVID-19 Recovery Policies*, OECD (Apr. 19, 2021), <https://www.oecd.org/coronavirus/policy-responses/the-oecd-green-recovery-database-47ae0f0d/#section-d1e334>.

<sup>531</sup> U.N. Sec. Gen., Secretary-General's remarks at the launch of the Statement of Commitment and Call for Support for the Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 Tools, (Apr. 24, 2020), <https://www.un.org/sg/en/content/sg/statement/2020-04-24/secretary-generals-remarks-the-launch-of-the-statement-of-commitment-and-call-for-support-for-the-global-collaboration-accelerate-the-development-production-and>.

<sup>532</sup> *Id.*