

# An ethico-legal assessment of intellectual property rights and their effect on COVID-19 vaccine distribution: an Australian case study

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## ABSTRACT

This article posits that Australia, as an affluent country with increasing capacity to manufacture vaccines, has an obligation to assist its regional (and global) counterparts in implementing vaccination programs that protect their populations. First, the article explores the capacity of high-income nations to meet their obligations, assist their neighbours and refrain from vaccine nationalism. This inquiry involves an analysis of the optimal ethical strategy for distributing vaccines globally, and the role that Australia might play in this distribution strategy. Secondly, the article examines the intellectual property landscape for vaccines in Australia, focusing on the patents that cover vaccine compositions and manufacturing techniques (recognizing the potential for know-how and access to materials as well as patents to affect manufacturing capacity). This article then discusses the strategies the Australian Government has at its disposal to counter potential intellectual property impediments whilst complying with existing obligations under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), as an ethically appropriate response to the pandemic. This article also considers whether a so-called TRIPS waiver could provide better options and concludes that the challenge of compelling disclosure of know-how remains.

**KEYWORDS:** COVID-19, vaccines, innovation, patents, trade secrets, ethics

## I. INTRODUCTION

The race for effective vaccine candidates to fight the current COVID-19 pandemic has been like no other vaccine race in history. The extent of impacted populations, coupled with the rapid transmissibility of the virus, has prompted a push for vaccines on both public and private fronts that is unique in scale. In recognition of the fact that many nations lack both the capacity to manufacture vaccines and the funds to purchase them at market prices, COVAX was established in 2020 by the WHO, along with The Vaccine Alliance (GAVI) and the Coalition for Economic Preparedness Innovations (CEPI).<sup>1</sup> The stated purpose of COVAX is to ‘... support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing’.<sup>2</sup> To this end, COVAX negotiated supply agreements with vaccine manufacturers in earlier phases of the pandemic.<sup>3</sup>

Whilst COVAX was meant to be the primary avenue for the global vaccine rollout in response to COVID, the extent to which this goal was achieved was hampered by a number of factors.<sup>4</sup> One significant weakness was that nations which had secured supply of vaccines via bilateral agreements only decided to make them available once they had become surplus to their own needs.<sup>5</sup> Rutschman notes that if governments engage in this form of ‘vaccine nationalism’, reserving vaccine supplies for their own population, this will undermine public health outcomes in other nations, particularly low- and middle-income nations.<sup>6</sup> The tendency for nations in possession of vaccines surplus to their requirements to enter into bilateral agreements also appears to have increased the price of vaccines available via COVAX.<sup>7</sup>

This article uses Australia as a case study to examine the role and responsibility of high-income nations in contributing to the global effort to suppress this pandemic and respond to future pandemics. We suggest that nations such as Australia have an ethical

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- 1 Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility, WORLD HEALTH ORGANIZATION (2020), <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility> (accessed Sept. 15, 2021); COVAX Facility, (2021), <https://www.gavi.org/covax-facility> (accessed Dec 14, 2021).
  - 2 Seth Berkley, *COVAX Explained*, GAVI (2020), <https://www.gavi.org/vaccineswork/covax-explained> (accessed June 25, 2021).
  - 3 Olivier J. Wouters et al., *Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, Allocation, and Deployment*, THE LANCET, 6 (2021), <https://www.sciencedirect.com/science/article/pii/S0140673621003068> (accessed Mar. 11, 2021).
  - 4 Susi Geiger & Aisling McMahon, *Analysis of the Institutional Landscape and Proliferation of Proposals for Global Vaccine Equity for COVID-19: Too Many Cooks or Too Many Recipes?*, J. MED. ETHICS (2021), <https://jme.bmj.com/content/early/2021/11/29/medethics-2021-107684> (accessed Dec 13, 2021); Anand Giridharadas, *Of Patents and Power: ‘Doses are Charity. Knowledge is Justice’* (2021), <https://the.ink/p/doses-are-charity-knowledge-is-justice> (accessed Dec 13, 2021).
  - 5 Reidar K. Lie & Franklin G. Miller, *Allocating a COVID-19 Vaccine: Balancing National and International Responsibilities*, MILBANK Q (2020), <https://www.milbank.org/quarterly/articles/allocating-a-covid-19-vaccine-balancing-national-and-international-responsibilities/> (accessed Feb 5, 2021); Katelyn J. Yoo et al., *COVAX and Equitable Access to COVID-19 Vaccines*, 100 BULL WORLD HEALTH ORGAN 315–328, 326 (2022).
  - 6 Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation The Legal Impacts of COVID-19*, 64 WASH. UNIV. J. LAW POLICY 167–202, 183–7 (2021).
  - 7 *Id.* at 187; Geiger and McMahon, *supra* note 4; Giridharadas, *supra* note 4.

responsibility to engage in vaccine distribution grounded in moral cosmopolitanism extending beyond state borders. We recognize that this duty should include provision of assistance to low- and middle-income nations to assist them in developing their own domestic manufacturing capabilities, to fulfill their moral nationalist obligations to their own citizens. However, the primary focus of this article is not so much on the ways in which nations like Australia could fulfil this duty (which we recognize as a laudable long-term goal). Instead, this article focuses specifically on the responsibility and freedom that nations like Australia possess to manufacture vaccines for supply to those nations in response to pandemic diseases such as COVID-19. Through an assessment of the intellectual property landscape associated with approved vaccines, this article concludes that intellectual property rights over vaccines, including patents, know-how and bilateral licensing agreements, do have the capacity to hinder domestic manufacture of vaccines. As such, high-income nations like Australia need to consider utilizing the full armoury of current and proposed flexibilities under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) in attempting to fulfil their global responsibilities.<sup>8</sup>

The first section of this article involves an examination of what might be the optimal, ethical strategy for distributing vaccines globally, and the role that Australia can play in this distribution strategy. The Australian Government's primary focus was on vaccinating the Australian population, although it has also assisted with the global vaccination effort. These programs have involved both formalized global vaccine-sharing commitments and bilateral arrangements with Australia's nearest neighbours. Australia is a signatory to COVAX, and in this role the Government has committed to contribute to the distribution of vaccines for lower-income nations through the COVAX Advanced Market Commitment scheme.<sup>9</sup> Bilaterally, the Australian Government responded to acute COVID crises in India through donation of materials and equipment and in Papua New Guinea (PNG) through an initial donation of 8000 doses of AstraZeneca vaccine.<sup>10</sup> Notwithstanding the importance of these contributions to the welfare of peoples in the region, the potential negative impact of bilateral arrangements on the COVAX response should not go unmentioned.

In addition, the Australian Government was an early signatory to contracts with vaccine producers to allow it to gain access to large quantities of manufactured vaccine.<sup>11</sup> Given that the Australian Commonwealth Serum Laboratories (CSL) already

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8 TRIPS: 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, 33 I.L.M. 1197 (1994)

9 *Coronavirus (COVID-19)—Information about the COVAX Facility*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH (2020), <https://www.health.gov.au/resources/publications/coronavirus-covid-19-information-about-the-covax-facility> (accessed Sept. 15, 2021).

10 Natalie Whiting, *This Country's Vaccine Supply Is About to Pass Its Shelf Life. Here's Their Plan to Get the Jabs Done* (2021), <https://www.abc.net.au/news/2021-06-06/png-comes-up-with-creative-way-to-vaccinate-people/100177968> (accessed June 25, 2021).

11 Jade MacMillan, *Australia Secures 1 Million More Pfizer Vaccine Doses from Poland*, ABC NEWS, Aug. 15, 2021, <https://www.abc.net.au/news/2021-08-15/australia-to-receive-1-million-pfizer-vaccine-s-from-poland/100378332> (accessed Sept. 10, 2021); Stephen Dziedzic, *Extra 500,000 Pfizer Doses on the Way from Singapore in Vaccine Swap*, ABC NEWS, Aug. 31, 2021, <https://www.abc.net.au/news/2021-08-31/pfizer-doses-availability-australia-singapore-covid-19/100421462> (accessed Sept. 10, 2021).

had existing capacity to manufacture viral vector vaccines, the Government also made an early decision to contract CSL as a producer of AstraZeneca's Vaxzervria vaccine. However, CSL indicated that it would not renew this contract in late 2021.<sup>12</sup> The Government has since also announced an intention to build capacity to manufacture mRNA vaccines in collaboration with the State of Victoria and Moderna, with a view to commencing manufacture in 2024.<sup>13</sup> As such the Government appears to be prepared to work with the major vaccine producers in formulating its plans for domestic manufacture of COVID vaccines into the future.

In parallel, the Australian Government has expressed some support for a draft waiver proposed by the so-called Quadrilateral or 'Quad' of the United States, European Union, India and South Africa, currently before the TRIPS Council, to waive some COVID-related intellectual property rights. This proposal, initially sponsored by India and South Africa, sought to temporarily waive TRIPS provisions with respect to relevant intellectual property rights associated with COVID-19 vaccines, diagnostics and therapeutic tools.<sup>14</sup> As originally intended, the waiver might have applied not only to formal intellectual property rights, such as patents, copyright and geographical indications, but also to 'informal' intellectual property rights, such as trade secrets and know-how. However, the current waiver being considered is significantly narrower, and only applies to certain patents on COVID-19 vaccines.<sup>15</sup>

If the waiver is passed by the TRIPS Council and implemented domestically, intellectual property rights holders would no longer be able to enforce relevant rights against other manufacturers or nations producing versions of their therapeutics. Proponents of the waiver argue this needs to be implemented because intellectual property rights have been used to deter developed nations from fully participating in the global effort to defeat the COVID-19 pandemic. It should be noted, however, that there are other flexibilities already available under TRIPS, particularly those relating to uses without authorization under TRIPS Article 31, which could be used legitimately either by governments or by third-party manufacturers without authorization from the rights holders.<sup>16</sup>

The impact of intellectual property rights on the capacity of governments in developed nations to distribute COVID-19 vaccines to low- and middle-income nations, together with the utility of the TRIPS waiver, is a central theme of the later sections

12 Stephen Dziedzic & Liam Fox, 'Bewildering': Australia Plans to Stop AstraZeneca Production—But How Will It Affect Our Neighbours?, ABC News, Oct. 14, 2021, <https://www.abc.net.au/news/2021-10-14/oppositi-on-aid-groups-urge-government-extend-csl-astra-zeneca/100539494> (accessed Jan. 31, 2022).

13 Michelle Grattan, *New Facility to Be Built in Victoria to Produce mRNA Vaccines*, THE CONVERSATION (2021), <http://theconversation.com/new-facility-to-be-built-in-victoria-to-produce-mrna-vaccine-s-173674> (accessed Dec. 14, 2021).

14 TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19, WORLD TRADE ORGANIZATION (2021), [https://www.wto.org/english/news\\_e/news21\\_e/trip\\_20jul21\\_e.htm](https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm) (accessed Sep 15, 2021); Stephen Dziedzic, *Australia to Support Waiving Intellectual Property Rights for COVID-19 Vaccines*, ABC NEWS, Sept. 8, 2021, <https://www.abc.net.au/news/2021-09-08/australia-waive-intellectual-property-covid-vaccines/100445094> (accessed Sept. 10, 2021).

15 John Zarocostas, *Mixed Response to COVID-19 Intellectual Property Waiver*, 399 THE LANCET 1292–1293 (2022).

16 Sarah Matheson & Artemis Kirkinis, *Compulsory Licence and Crown Use Provisions in the Covid-19 Pandemic—The Australian Perspective*, 16 J. INTELLECT. PROP. LAW PRACT. 484–497 (2021).

of this article. This article examines the extent to which intellectual property rights have impeded Australia's capacity to contribute to this strategy in a meaningful way. This examination includes an analysis of the Australian intellectual property landscape surrounding the main vaccine candidates that have reached clinical trials and/or been approved for clinical use. The final section of the article analyses potential workarounds to intellectual property impediments (focusing particularly on existing legislative provisions permitted under TRIPS), to ascertain whether Australia is in fact in a legitimate position to assist other nations in surviving this pandemic and future pandemics.

## II. ETHICS OF VACCINE PRODUCTION AND DISTRIBUTION

This section explores the various ethical frameworks proposed for vaccine production and distribution. It first addresses the differences between moral nationalism and moral cosmopolitanism as principles guiding vaccine distribution. This section then examines the ethical challenges that face Australia and other developed nations with respect to distributing COVID-19 vaccines, both on a domestic and an international level. This section concludes by addressing the ethical frameworks that have been proposed for vaccine distribution. These frameworks include those proposed by international and national governing bodies, as well as ethical distribution guidelines in the published literature.

### II.A. Moral Nationalism and Cosmopolitanism in Distributing COVID-19 Vaccines

Moral nationalism refers to an ethical perspective that individuals owe a heightened duty to their fellow citizens, and governments owe a heightened duty to their own citizens, in times of crisis. This heightened duty is predicated on the notion that morality is local and specific to different cultures, so that moral ordering is unlikely to be agreed upon by all cultures.<sup>17</sup> In contrast, moral cosmopolitanism refers to an ethical perspective, which dictates that all individuals are part of a singular global community. On this basis, the duties that citizens owe to their compatriots in times of crisis must apply equally to all members of society, irrespective of nationality.<sup>18</sup>

Neither moral nationalism nor moral cosmopolitanism is absolute, and variations can exist on a continuum. For instance, moral cosmopolitanism recognizes that, just because equivalent ethical duties exist to those far away, this does not mean that those in need locally should be rejected.<sup>19</sup> Further, a cosmopolitan approach that completely rejects national boundaries is unrealistic in that it fails to account for differences in national infrastructure.<sup>20</sup> Moral nationalists might also argue that moral cosmopolitanism might be used by some nations to disguise their own self-interest.<sup>21</sup> Accordingly,

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17 Greg Stapleton et al., *Global Health Ethics: An Introduction to Prominent Theories and Relevant Topics*, 7 GLOB. HEALTH ACTION 23569 (2014).

18 Luvuyo Gantsho & Christopher S. Wareham, *Medical Cosmopolitanism: The Global Extension of Justice in Healthcare Practice*, DEV. WORLD BIOETH. (2020), <https://onlinelibrary.wiley.com/doi/abs/10.1111/dewb.12278> (accessed May 4, 2021).

19 *Id.*

20 Lie and Miller, *supra* note 5, at 3.

21 Nancy S. Jecker, Aaron G. Wightman & Douglas S. Diekema, *Vaccine Ethics: An Ethical Framework for Global Distribution of COVID-19 Vaccines*, J. MED. ETHICS (2021), <https://jme.bmj.com/content/early/2021/02/16/medethics-2020-107036> (accessed Apr. 23, 2021).

determining an appropriate balance between moral nationalism and moral cosmopolitanism is important in determining the obligations on nations to manufacture and distribute COVID-19 vaccines.<sup>22</sup>

### II.B. Existing and Proposed Ethical Models for Distributing COVID-19 Vaccines

The WHO, along with the Strategic Advisory Group of Experts (SAGE) on Immunization recommended a staggered rollout of COVID vaccines, with multiple stages. This model involves proportionally distributing vaccines according to population, with an aim to reopen economies.<sup>23</sup> The first stage involves nations vaccinating 3 per cent of their population, including healthcare workers, essential workers, and people in high transmission settings. This process of vaccination continues until every country has vaccinated 20 per cent of its population. People from vulnerable populations, including individuals whose medical conditions put them at risk of a serious adverse COVID-19 outcome, are included in this cohort.<sup>24</sup> This distribution approach is designed to ensure that high-income nations cannot vaccinate more than 20 per cent of their population until low- and middle-income nations have vaccinated 20 per cent of their population.<sup>25</sup> It appears that this model has yet to succeed in achieving ethical distribution of COVID-19 vaccines. At the time of writing, 60 per cent of the world population has received at least one dose of COVID-19 vaccine. However, when analyzing vaccination rates in low-income nations, this figure drops to below 10 per cent.<sup>26</sup>

In developing a national plan for vaccinating the US population, a report published by the National Academies of Science, Engineering and Medicine (NASEM) recommended a similar phased roll out schedule.<sup>27</sup> In particular, the NASEM report proposed deploying a 10 per cent portion of vaccines for global allocation.<sup>28</sup> Despite this, at the time of writing, the US government has only recently committed to participating in international initiatives for globally allocating vaccines.<sup>29</sup> This refusal is despite the significant strategic, public health and ethical rationales for equitable distribution of vaccines, as identified in the NASEM report. Yet another national plan for distributing COVID-19 vaccines in the US is that of the Advisory Committee on Immunization Practices (ACIP). Applying the bioethical principles of beneficence and

22 Anna Mia Ekström et al., *The Battle for COVID-19 Vaccines Highlights the Need for a New Global Governance Mechanism*, NAT. MED. 1–2 (2021).

23 Jecker, Wightman, and Diekema, *supra* note 20 at 8.

24 *Fair Allocation Mechanism for COVID-19 Vaccines Through the COVAX Facility*, WORLD HEALTH ORGANIZATION (2020), <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility> (accessed Sept. 15, 2021).

25 Lie and Miller, *supra* note 5 at 3.

26 Hannah Ritchie et al., *Coronavirus Pandemic (COVID-19)*, OUR WORLD IN DATA (2022), <https://ourworldindata.org/covid-vaccinations> (accessed Jan. 31, 2022)

27 Jecker, Wightman, and Diekema, *supra* note 21 at 8.

28 NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE; HEALTH AND MEDICINE DIVISION; BOARD ON POPULATION HEALTH AND PUBLIC HEALTH PRACTICE; BOARD ON HEALTH SCIENCES POLICY; COMMITTEE ON EQUITABLE ALLOCATION OF VACCINE FOR THE NOVEL CORONAVIRUS, FRAMEWORK FOR EQUITABLE ALLOCATION OF COVID-19 VACCINE, 88 (Benjamin Kahn et al. eds., 2020), <http://www.ncbi.nlm.nih.gov/books/NBK562672/> (accessed Mar. 9, 2021).

29 HHS Press Office, *NIH Licenses COVID-19 Research Tools and Early-Stage Technologies to WHO Program*, HHS.GOV (2022), <https://www.hhs.gov/about/news/2022/05/12/nih-licenses-covid-19-research-tools-early-stage-technologies-who-program.html> (accessed May 26, 2022).

non-maleficence, along with health equity, ACIP also recommended a staggered rollout in the US.<sup>30</sup> Nevertheless, the ACIP proposal did not contain any plan for distributing vaccines on an international basis.<sup>31</sup> This absence is despite commitments by the US to engage in large-scale vaccine manufacturing and technology transfer.<sup>32</sup>

These approaches to distributing vaccines have also raised ethical concerns with certain scholars. One of these is that distributing vaccines proportionally by population does not reflect the differential burden that nations with more severe outbreaks may face. Comparing the current pandemic with the HIV crisis, Emanuel et al. argue it would have been unethical for the US to receive more HIV antiretrovirals merely by dint of a larger population.<sup>33</sup> A further ethical issue concerns advance orders of vaccines and the gulf in purchasing power of low- and middle-income nations relative to high-income nations.<sup>34</sup> Some estimates suggest high-income nations have secured enough vaccines to cover 150–500 per cent of their predicted needs.<sup>35</sup> In particular, So and Woo note that Japan, Australia and Canada have secured more than a billion doses of COVID-19 vaccines between them.<sup>36</sup> By contrast, it is estimated that most low-and-middle income nations will be unable to vaccinate their entire populations by 2024.<sup>37</sup>

These ethical concerns have driven a group of bioethicists and health policy researchers to define more morally cosmopolitan ethical frameworks for the international manufacturing and distribution of vaccines. Emanuel et al. describe a Fair Vaccine Distribution model centred around three bioethical principles: beneficence, non-maleficence, and justice. These bioethical principles are expressed within three phases of distributing vaccines, each with a separate incremental goal; reducing premature deaths, reducing serious economic and social deprivations, and reducing community transmission to restore normality. The first phase of the Fair Vaccine Distribution model would ensure priority to nations that would reduce standard expected years of life lost per dose of vaccine. The next phase would ensure priority to nations where more doses of vaccine would reduce poverty as measured by a decline in gross national income. The final phase would focus on prioritizing nations according to the spread of transmission in each nation.<sup>38</sup>

The Fair Vaccine Distribution model is not without its critics. Lie and Miller argue it does not provide guidance for balancing legitimate national concerns versus inter-

30 Beth P. Bell, José R. Romero & Grace M. Lee, *Scientific and Ethical Principles Underlying Recommendations from the Advisory Committee on Immunization Practices for COVID-19 Vaccination Implementation*, 324 JAMA 2025–2026, 2026 (2020).

31 Jecker, Wightman, and Diekema, *supra* note 21 at 9.

32 W. Nicholson Price, Arti K. Rai & Timo Minssen, *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 SCIENCE 912–914, 914 (2020).

33 Ezekiel J. Emanuel et al., *Enhancing the WHO's Proposed Framework for Distributing COVID-19 Vaccines Among Countries*, 111 AM. J. PUBLIC HEALTH 371 (2021).

34 Wouters et al., *supra* note 3 at 7; Bhaven N. Sampat & Kenneth C. Shadlen, *The COVID-19 Innovation System*, 40 HEALTH AFFAIRS 400–409, 405 (2021).

35 Ekström et al., *supra* note 22.

36 Anthony D. So & Joshua Woo, *Reserving Coronavirus Disease 2019 Vaccines for Global Access: Cross Sectional Analysis*, 371 BMJ m4750, 5 (2020).

37 Ekström et al., *supra* note 22.

38 Emanuel et al., *supra* note 33 at 372.

national concerns, particularly for the third phase. They note that the only proposed model that defines how to distribute vaccines remains the COVAX consortium model, which allows high-income nations to prioritize distributing the vaccine where necessary.<sup>39</sup> Since Lie and Miller published their article, the Serum Institute of India (SII) has committed to manufacturing 100 million doses for low- and middle-income nations and the US has joined COVAX. However, as Safi and Kirk note, the contributions from COVAX would fall short of that required to achieve acceptable vaccination targets.<sup>40</sup> Further, when India suffered a very significant COVID outbreak in May 2021, the SII was unable to deliver doses for COVAX to distribute to other low- and middle-income nations due to an export ban imposed by the Indian government.<sup>41</sup> These shortcomings demonstrate how voluntary schemes adopting a moral cosmopolitanism approach for international vaccine distribution can be subordinate to moral nationalism.<sup>42</sup>

Jecker, Wightman and Diekema have proposed another alternative to the Fair Vaccination Distribution model, which prioritizes preventing earlier deaths (that is, total life years saved) rather than overall deaths. In other words, this model prioritizes distributing vaccines to those who have more years left to live.<sup>43</sup> Although Jecker et al.'s framework prioritizes frontline and essential workers, they then focus on prioritizing members of 'health disparity groups'. Priority 2 includes people aged over 65 years in nursing homes, members of socio-economic groups that have a higher risk of infection, and people with underlying conditions who cannot self-isolate. Priority 3 includes people with underlying chronic conditions, high BMI or over 65 years of age who can self-isolate. Priority 4 includes healthy adults who work in crowded or high exposure environments, as well as healthy adult prisoners. The remaining vaccines are then distributed according to a random lottery to maintain public trust.<sup>44</sup>

Both Emanuel et al. and Jecker et al. concede that one of the major challenges in each of their respective models is that some nations lack adequate infrastructure to determine who receives priority. Emanuel et al. suggest that distributing vaccines to low- and middle-income nations could be coupled with infrastructure funding, on the condition these funds are spent on allocating vaccines according to priority.<sup>45</sup> Likewise, Jecker et al. note that an algorithmic method could be used to prioritize low- and middle-

39 Lie and Miller, *supra* note 5 at 8; Meghana Sharafudeen, James Fulker & Diane Abad-Vergara, *More Than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility*, WORLD HEALTH ORGANIZATION (2020), <https://www.who.int/news/item/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility> (accessed Mar. 9, 2021).

40 Michael Safi & Ashley Kirk, *Revealed: Big Shortfall in Covax Covid Vaccine-Sharing Scheme*, THE GUARDIAN (2021), <http://www.theguardian.com/world/2021/apr/22/revealed-big-shortfall-in-covax-covid-vaccine-sharing-scheme> (accessed July 1, 2021).

41 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* (2021), <https://papers.ssrn.com/abstract=3851737> (accessed July 6, 2021); Dinesh Thakur, *Vaccine 'Heist' by India Imperils Global Access to COVID-19 Vaccines*, STAT (2021), <https://www.statnews.com/2021/05/05/india-vaccine-heist-shoddy-regulatory-oversight-imperil-global-vaccine-access/> (accessed Sept. 14, 2021).

42 Aisling McMahon, *Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance*, 47 J. MED. ETHICS 142–148 (2021).

43 Jecker, Wightman, and Diekema, *supra* note 21 at 5.

44 *Id.* at 7.

45 Emanuel et al., *supra* note 33 at 373.

income nations depending on their need.<sup>46</sup> However, challenges relating to vaccine prioritization are likely to remain some of the most formidable obstacles to vaccine distribution. A final consideration we note is that not all vaccine manufacturers have necessarily received regulatory approval for their target vaccines. Most of COVAX's estimated reserve shots are set to be produced by Novovax. However, Novovax has only received regulatory approval from a handful of nations (including Australia).<sup>47</sup> Likewise, the WHO has offered emergency approval for the Sinopharm vaccine offered by the China National Pharmacy Group. Finally, COVAX also purchased reserve doses from CureVac. However, CureVac's vaccine CVnCoV was abandoned in October 2021 after poor Stage 3 test results.<sup>48</sup> These disappointing clinical trial results have led to significant shortfalls in COVAX's distribution schedule, which is reflected in the disparity in COVID vaccination rates between high- and low-income nations discussed previously.<sup>49</sup>

From this analysis, it is clear that high-income nations must act more altruistically to assist vaccination efforts in low- and middle-income countries on a proportional basis if the COVAX model is to succeed. Despite the obvious merits of this framework (and recognizing its deficiencies, as outlined above), it has not prevented high-income nations from bypassing the COVAX purchasing model and purchasing excess doses of vaccine relative to their populations via bilateral purchasing agreements.<sup>50</sup> Accordingly, in the face of divergent health outcomes and novel, potentially vaccine-resistant strains, this article supports the argument that high-income nations should follow the head of global health authorities and strongly encourage a global strategy for distributing vaccines according to relative need. This approach would recognize the right of nations to prioritize some of their citizenry, whilst contributing to global efforts to distribute vaccines to reduce loss of life.<sup>51</sup> Nevertheless, this analysis of the growing body of emergent moral cosmopolitanism frameworks suggests that a priority system for distributing vaccines alone is not enough. Specifically, high-income nations must have adequate infrastructure and manufacturing capacity to prioritize distributing vaccines nationally, but also to low- and middle-income nations without vaccine manufacturing capacity.<sup>52</sup>

Despite these challenges, all the evidence points to the need for some form of moderate moral cosmopolitanism if there is ever to be any hope of defeating COVID-19 globally. This moral cosmopolitanism would necessitate as many nations as possible being

46 Jecker, Wightman, and Diekema, *supra* note 21 at 3; Yangzi Liu, Sanjana Salwi & Brian C. Drolet, *Multivalued Ethical Framework for Fair Global Allocation of a COVID-19 Vaccine*, 46 J. MED. ETHICS 499–501, 500 (2020).

47 Zain Rizvi, *Not Enough: Six Reasons Why COVID-19 Vaccine Manufacturing Must Be Rapidly Scaled-Up*, PUBLIC CITIZEN (2021), <https://www.citizen.org/article/not-enough-six-reasons-why-covid-19-vaccine-manufacturing-must-be-rapidly-scaled-up/> (accessed June 9, 2021).

48 Elie Dolgin, *CureVac COVID Vaccine Let-down Spotlights mRNA Design Challenges*, 594 NATURE 483–483 (2021).

49 Serena Tinari & Catherine Riva, *Covid-19: Whatever Happened to the Novavax Vaccine?* 375 BMJ n2965 (2021).

50 So and Woo, *supra* note 36 at 4; Yoo et al, *supra* note 5 at 315, 326.

51 Jecker, Wightman, and Diekema, *supra* note 21 at 2.

52 Felicitas Holzer et al., *A Matter of Priority: Equitable Access to COVID-19 Vaccines*, 151 SWISS MED. WKLY. 4 (2021), <https://smw.ch/article/doi/smw.2021.20488> (accessed Apr. 23, 2021); Wouters et al., *supra* note 3 at 7.

able to engage in distributed vaccine manufacturing. This need raises the question whether patents and other forms of intellectual property could act as an impediment to such global initiatives. Concern has been expressed that a major shortcoming of many of the vaccine distribution strategies is that the presence of intellectual property rights over vaccines and associated technologies could impede their implementation.<sup>53</sup> The next section considers the different intellectual property rights that might apply to COVID-19 vaccines.

### III. THE INTELLECTUAL PROPERTY LANDSCAPE FOR VACCINE CANDIDATES

Several promising vaccine candidates rapidly emerged as frontrunners to tackle the COVID pandemic during 2020 as the pandemic took hold. These candidates successfully proceeded through clinical trials and large numbers of doses have already been administered. As noted above; however, vaccine programs have been rolled out primarily in high-income nations, with lower-income nations yet to feel the benefits of mass vaccine production in any significant way.

The past three years have demonstrated that there are clear public health benefits in incentivizing vaccine development in the for-profit sector in a pandemic situation.<sup>54</sup> Several factors do, however, diminish the underlying rationale for a profit-driven R&D model where vaccines are concerned. In particular, the social welfare benefits for vaccine development are difficult to calculate, and markets for vaccines are usually smaller and more short-term than those for traditional medicines and treatments.<sup>55</sup> As viral pandemics are sporadic events, effective vaccines generate lower profits and fewer viable markets, significantly reducing incentives to invest in R&D in vaccines.<sup>56</sup> The sudden nature of pandemic breakouts also means that the breakout itself tends to drive vaccine R&D, rather than the promise of profit: innovation is dictated by ‘... disease epidemiology, burden, and severity’.<sup>57</sup>

This has certainly been true of the COVID outbreak: the catastrophic nature of the virus led to the rapid emergence of over 200 vaccine candidates,<sup>58</sup> a number that flies in the face of prior vaccine research paradigms. Public-private partnerships and enormous public funding poured into COVID vaccine research doubtless contributed to the development of this large volume of vaccine candidates. This section will examine the charges being levied for supply of the various COVID-19 vaccines, together with the patent landscape for the leading vaccine candidates in Australia.

53 Sampat and Shadlen, *supra* note 34 at 401.

54 Rutschman, *supra* note 6 at 173.

55 *Id.* at 173.

56 Mark Eccleston-Turner, *The Economic Theory of Patent Protection and Pandemic Influenza Vaccines: Do Patents Really Incentivize Innovation in the Field*, 42 AM. J. LAW MED. 572–597 (2016), 583.

57 Katherine Seib et al., *Policy Making for Vaccine Use as a Driver of Vaccine Innovation and Development in the Developed World*, 35 VACCINE 1380–1389, 1382 (2017).

58 COVID-19 Vaccine Tracker and Landscape, WORLD HEALTH ORGANIZATION (2021), <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> (accessed Sept. 15, 2021).

### III.A. Pricing, Patents and Patent Landscaping

Notwithstanding the myriad challenges confronting efforts to implement effective vaccine rollouts, there is no doubt that the potentially prohibitive cost involved in purchasing sufficient supplies of vaccine is a formidable barrier (although it is recognized that there are many others).<sup>59</sup> Wouters et al. have drawn attention to the high prices being charged for COVID vaccines relative to other vaccines. Although differential pricing structures are being adopted by some vaccine manufacturers, the fundamental pricing baselines are substantial for several vaccines. For example, as one of the more affordable options, AstraZeneca's vaccine is being offered to low- and middle-income nations for as little as US\$5 per course. Gamalaya's Sputnik V (US\$6), Johnston and Johnston (J&J) Janssen's (US\$9) and Novavax (US\$6) are offered on a comparable footing. But at the other end of the spectrum are Moderna's vaccine, at US\$31 per course, and Sinopharm, at US\$62 per course.<sup>60</sup> Further, it has been revealed that some low- and middle-income nations are paying twice as much for a single dose of AstraZeneca as European nations.<sup>61</sup> These pricing disparities are significant, particularly considering that most nations will need to vaccinate entire populations. Finally, an increasing number of developed nations (such as Israel and the United Kingdom) are now relying solely on mRNA vaccines in offering booster shots to segments of their populations. Given the limited number of manufacturing plants for these vaccines, demand for booster doses may create competition, increasing the price of doses even further.<sup>62</sup>

Notably, the development of the technology platforms for several of these vaccines was already well advanced prior to the pandemic, potentially reducing the cost of further vaccine development. Furthermore, given that many of the vaccines were developed with substantial public funding, developers committed to vaccine provision at low prices, particularly to low and middle-income nations. Arguably, then, some of the pricing decisions for vaccine supply were driven by altruism on the part of pharmaceutical companies, reflecting an ethical obligation on the part of private companies to 'do their part' to assist during a pandemic. Goodwill may be a not insubstantial contributor to this mindset, but so too might be a fear of reputational damage. It is difficult to do more than speculate as to the motivations for these pricing decisions. However, even AstraZeneca, which was initially lauded for selling its vaccine at cost, included in its non-profit contract a clause giving it the right to declare the pandemic at an end.<sup>63</sup> This means that once AstraZeneca declares the pandemic over, it can raise prices on doses beyond that specified in its bilateral agreements with governments (which, in any case, are not made public).<sup>64</sup> This clause would tend to suggest a desire on the part of AstraZeneca to carefully control and limit the duration of particular pricing structures.

59 Sampat and Shadlen, *supra* note 34 at 407.

60 Wouters et al., *supra* note 3, at 3.

61 Owen Dyer, *COVID-19: Countries Are Learning What Others Paid for Vaccines*, 372 *BMJ* n281 (2021).

62 Geiger and McMahon, *supra* note 4, at 2.

63 Donato Paolo Mancini, *AstraZeneca Vaccine Document Shows Limit of No-profit Pledge*, *FINANCIAL TIMES*, October 7, 2020, <https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686> (accessed Dec. 17, 2021).

64 Fatima Hassan, Gavin Yamey & Kamran Abbasi, *Profiteering from Vaccine Inequity: A Crime Against Humanity?*, 374 *BMJ* n2027 (2021).

Ultimately, a company that has developed and manufactured a vaccine has significant freedom to set pricing, because it possesses the relevant intellectual property, materials, tools and manufacturing know-how.<sup>65</sup> Patents, in particular, provide significant scope for control of the relevant market.<sup>66</sup> Patents provide patent holders with a period of exclusive use, including the right to exclude others from exploiting the invention as claimed for the patent period (generally 20 years). Patents are generally justified on the basis that they incentivize innovation, and permit recovery of the significant costs expended on research and development.<sup>67</sup> This justification is particularly pertinent for pharmaceutical and biotechnological innovation.<sup>68</sup>

In examining the extent to which governments are at liberty to contribute to the global vaccine rollout, it is necessary to have a clear picture of the relevant patents and other intellectual property rights held by vaccine developers to understand the extent to which this liberty is circumscribed. One aim of this research was to consider the patent landscape for COVID vaccines in Australia, and the potential impact of these patents on the delivery of vaccines on a broad scale. Our intention was not to evaluate the landscape for every COVID vaccine in use or development. Instead, this analysis is limited to several key vaccines, on the basis of the following criteria:

- The vaccine/candidate having been authorized by a domestic regulatory body (such as the TGA) or the WHO (and are therefore likely to be widespread use in fighting the COVID pandemic); and/or
- The vaccine/candidate being in Phase III trials or having already advanced to Phase IV.

Accordingly, this analysis focuses on vaccines that are either registered for use or close to being approved for use in developed nations. Further, this analysis is focused on promising candidates in the sense that agreements for widespread supply have been reached with the COVAX facility (as of September 2021).

For each of these vaccines, this landscape maps the type of vaccine technology, the parties with whom funding agreements have been reached and relevant Australian patents over the vaccine technology. Our methodology is based on a PRISMA guided scoping review methodology<sup>69</sup> of various patent office databases by using the Patent Lens, a patent data aggregator.<sup>70</sup> In addition, this article confirms and supplements

65 Marianne Meijer et al., *COVID-19 Vaccines a Global Public Good? Moving Past the Rhetoric and Making Work of Sharing Intellectual Property Rights, Know-how and Technology*, 31 EUROPEAN JOURNAL OF PUBLIC HEALTH 925–926, 926 (2021)

66 Eccleston-Turner, *supra* note 56 at 576.

67 Note that countries must provide protection to patents through domestic legislation, pursuant to restrictions on patentable subject matter; see the TRIPS Agreement, *supra* note 8. Patents are jurisdiction-specific: a patent granted under the patent legislation of one jurisdiction will protect the patentee only in that jurisdiction: Article 28. As such patentees will need to seek protection in each of the jurisdictions in which they seek to exploit their invention.

68 William M. Landes & Richard A. Posner, *The Economic Structure of Intellectual Property Law*, 315 (2003).

69 Hilary Arksey & Lisa O'Malley, *Scoping Studies: Towards a Methodological Framework*, 8 INT. J. SOC. RES. METHODOL. 19–32, 22–8 (2005); James A. Smith et al., *Evidence of Insufficient Quality of Reporting in Patent Landscapes in the Life Sciences*, 35 NAT. BIOTECHNOL. 210–214, 211 (2017).

70 Osmat Azzam Jefferson et al., *Mapping Innovation Trajectories on SARS-CoV-2 and Its Variants*, 39 NAT. BIOTECHNOL. 401–403, 402 (2021).

our results using secondary literature published in both peer reviewed and non-peer reviewed literature by other scholars, as well as non-academic organizations.<sup>71</sup> A summary of our results is contained in Table 1.

Our results present some somewhat surprising data, in that the patent landscape is congested for some vaccines, and relatively sparse for others. The BioNTech/Pfizer, Janssen and Moderna vaccines are each associated with a larger number of patents. Some of these patents apply to the method of manufacturing (such as the Janssen and BioNTech vaccines), whereas others apply to the vaccines themselves. By contrast, the AstraZeneca and Novavax vaccines are associated with relatively fewer patents. It is also worth noting that patents covering many of the vaccines examined in this study were granted *prior* to the COVID outbreak. These patents generally cover pre-existing processes developed for the respective vaccine technologies. For example, the Janssen Ad.26 vaccine patents applied to technology originally used to manufacture Ebola vaccines. Likewise, most of Novavax's patents apply to proprietary Matrix-M technology, without which Novavax's NXV-CoV2373 vaccine candidate cannot be manufactured.<sup>72</sup> Finally, other landscaping conducted by Martin and Lowery indicates that BioNTech/Pfizer, Moderna and Curevac have applied for patents on mRNA vaccines for other viruses. Some of these patents are in force, despite the patent holders not having applied for regulatory approval for these vaccines in the US or Australia.

Finally, it is worth observing that the patent landscape shows that more patents have been filed and granted in the US than in Australia. This result is not altogether surprising given patenting tendencies more generally in the pharmaceutical and biotechnology industries. In particular, there is a longstanding practice of coupling patent filing within jurisdictions where regulatory approval is sought.<sup>73</sup>

The patent landscape surrounding COVID vaccines is a picture of complexity. For the TRIPS waiver to be effective, the feasibility of waiving patent rights over entire patent families would need to be carefully examined. In particular, many of the patents we have included apply to general purpose vaccine manufacturing technologies and are not specific to COVID-19 vaccines. Nevertheless, the existence of patents over vaccines and associated technologies only tells part of the story. The frequently cited

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- 71 Mario Gaviria & Burcu Kilic, *BioNTech and Pfizer's BNT162 Vaccine Patent Landscape*, PUBLIC CITIZEN (2020), <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/> (accessed Mar. 11, 2021); Mario Gaviria & Burcu Kilic, *mRNA-1273 Vaccine Patent Landscape (For NIH-Moderna Vaccine)*, PUBLIC CITIZEN (2020), <https://www.citizen.org/article/moderna-s-mrna-1273-vaccine-patent-landscape/> (accessed Mar. 11, 2021); Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NAT. BIOTECHNOL. 546–548, 548 (2021); Kunmeng Liu et al., *Global Landscape of Patents Related to Human Coronaviruses*, 17 INT. J. BIOL. SCI. 1588–1599, 1589 (2021); Cecilia Martin & Drew Lowery, *mRNA Vaccines: Intellectual Property Landscape*, 19 NAT. REV. DRUG DISCOV. 578–578, 578 (2020); Zachary Silbersher, *Which Patents Cover the COVID-19 Vaccine Candidates for Moderna, AstraZeneca, J&J and Novavax?*, MARKMAN ADVISORS (2020), <https://www.markmanadvisors.com/blog/2020/7/21/which-patents-cover-the-covid-19-vaccine-candidates-for-moderna-astrazeneca-jampj-and-novavax/> (accessed Mar. 11, 2021); VaxPaL—COVID-19 Vaccines Patent Landscape, MEDICINES PATENT POOL (2021), <https://medicinespatentpool.org/what-we-do/disease-areas/vaxpal/> (accessed Sept. 14, 2021).
- 72 Silbersher, *supra* note 71; Abdou Nagy & Bader Alhatlani, *An Overview of Current COVID-19 Vaccine Platforms*, 19 COMPUT. STRUCT. BIOTECHNOL. J. 2508–2517, 2512 (2021).
- 73 Ole Kristian Aars, Michael Clark & Nina Schwalbe, *Increasing Efficiency in Vaccine Production: A Primer for Change*, 8 VACCINE X 100104, 100109 (2021).

**Table 1.** Breakdown of the different COVID-19 vaccine patents filed in Australia and the United States. Patents in the same row belong to the same family

Vaccine developer	Vaccine type	Supply agreement with COVAX	Public/private funding	Approved by WHO/stringent regulatory body? <sup>74</sup>	Authorized for use in Australia? <sup>75</sup>	Patent portfolio in Australia	Patent Portfolio in the US
Astrazeneca with Oxford University	Viral vector vaccine	Yes	CEPI, UK Government, US Government	Yes	Yes	Active: AU2012/270144B2 <sup>76</sup>	Active: US10646587B2 <b>Pending:</b> US2020/0360533A1 Active: US10286060B2 Active: US10124048B2 Active: US9950065B2 US10576146B2 <b>Pending</b> US2020/0155671A1 Active: US10485884B2 <b>Pending:</b> US2020/0085974A1 Active: US9486519B2 Active: US10729784B2 US10207009B2 Active: US11020477B2 Active: US10717982B2 <b>Pending:</b> US2020/0392518A1 Active: US7504248B2 US8802417B2
BioNTech with Pfizer	mRNA based vaccine	Yes	German Government	Yes	Yes	Active: AU2013401479B2  Active: AU2013242512B2 AU2017279565B2 <b>Pending:</b> AU2020202152A1 Active: AU2009326524B2 Active: AU2013343864B2  Active: AU2008303483B2 Active: AU2015/286820A8 <b>Pending:</b> AU2015286820A1	Active: US7285265B2 US8052967B2 Active: US7468181B2 US7820440B2 US8221971B2
J&J with Beth Israel Deaconess Medical Centre (Crucell NV/Janssen NV/Merus NV)	Viral vector vaccine	Yes	US Government	Yes	Yes	Active: AU200327138B2 <b>Amended Patent:</b> AU2003271738C1 Active: AU2003271737B2	

**Table 1.** Continued

Vaccine developer	Vaccine type	Supply agreement with COVAX	Public/private funding	Approved by WHO/stringent regulatory body? <sup>74</sup>	Authorized for use in Australia? <sup>75</sup>	Patent portfolio in Australia	Patent Portfolio in the US
					Active: AU2003250074B2 AU20053321246B2 AU2010249150B2 <b>Amended</b> Patent: AU2010249150B9	Active: US7262028B2 US7297680B2 US7429486B2 US7491532B2 US7833753B2 US7927834B2 US7932360B2 US8236561B2 US8524477B2 US9303081B2 US10934571B2 <b>Amended</b> Patent: USRE047770E Active: US7291484B2 US7608431B2 US8008043B2 Active: US8076131B2 US8227243B2 US7598078B2 Active: US8236293B2 Active: US7741099B2 Active: US10041049B2	
					Active: AU2004236440B2		Active: US9701718B2 Active: US9974737B2 US10272032B2 <b>Pending:</b> US2019/0240146 A1 <b>Pending:</b> US2020/0101153A1 <b>Pending:</b> US2020/034740SA1
					Active: AU2009/319254B2 Active: AU2011/214262B2 Active: AU2011203144B2 Active: AU2011343798B2 Active: AU2014323230B2		
					Pending: AU2018/359494A1		

Table 1. Continued

Vaccine developer	Vaccine type	Supply agreement with COVAX	Public/private funding	Approved by WHO/stringent regulatory body? <sup>74</sup>	Authorized for use in Australia? <sup>75</sup>	Patent portfolio in Australia	Patent Portfolio in the US
Novavax (Isconova)	Protein subunit vaccine	Yes	Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), US Government	No (pending trials)	No (pending trials)	<b>Pending:</b> AU 2018/359492 A1	<b>Pending:</b> US 2020/0323977 A1
						<b>Active:</b> AU2004224487B2	<b>Active:</b> US78338019B2 US9205147B2 US9901634B2 <sup>77</sup> US10813994B2 <b>Amended</b> <b>Application:</b> US2020/0323979A9 <b>Active:</b> US8821881B2 <b>Active:</b>
Moderna	mRNA based vaccine	Yes	CEPI, Dolly Parton COVID-19 Research Fund, US Government (National Institute of Health)	Yes	Yes	<b>Active:</b> AU2004254152B2	US10953089B1 <b>Active:</b> US9334328B2 US9657295B2 US9701965B2 US10064959B2 <b>Pending:</b> US2019/0160185A1 <b>Active:</b> US9504734B2 US9587003B2 US9283287B2 US9782462B2 US9828416B2 US10385106B2 US10577403B2 US10703789B2 <b>Pending:</b> US2020/0354423A1

**Table 1. Continued**

Vaccine developer	Vaccine type	Supply agreement with COVAX	Public/private funding	Approved by WHO/stringent regulatory body? <sup>74</sup>	Authorized for use in Australia? <sup>75</sup>	Patent portfolio in Australia	Patent Portfolio in the US
Curevac/Acutas	mRNA based vaccine	Yes	German government	No (undergoing trials)	No	<p><b>Active:</b> AU2016324310B2</p> <p><b>Pending:</b> AU2016342048A1</p> <p>AU2016341311A1</p>	<p><b>Active:</b> US9868691B2</p> <p>US9868692B2</p> <p>US9868693B2</p> <p>US9867888B2</p> <p>US10392341B2</p> <p>US10266485B2</p> <p>US10442756B2</p> <p><b>Pending:</b></p> <p>US2020/0123100A1</p> <p><b>Active:</b> US9872900B2</p> <p>US10022435B2</p> <p>US10709779B2</p> <p><b>Active:</b> US9334328B2</p> <p>US9657295B2</p> <p>US9701965B2</p> <p>US10064959B2</p> <p><b>Pending:</b></p> <p>US2019/0160185A1</p> <p><b>Active:</b></p> <p>US10702600B1</p> <p>US10933127B2</p> <p><b>Active:</b></p> <p>US11007260B2</p> <p><b>Active:</b> US9572874B2</p> <p><b>Pending:</b></p> <p>US2021/0046179A1</p> <p><b>Active:</b> US8968746B2</p>

**Table 1.** Continued

Vaccine developer	Vaccine type	Supply agreement with COVAX	Public/private funding	Approved by WHO/stringent regulatory body? <sup>7,4</sup>	Authorized for use in Australia? <sup>7,5</sup>	Patent portfolio in Australia	Patent Portfolio in the US
					Active: AU2011/289021B2		Active: US9234013B2 US9839697B2 US10663799B2 <b>Pending:</b> US2020/0276336A1 Active: US9421255B2 US10568958B2 Active: US9690899B2 US10166283B2 US10682406B2 US10799577B2 US10912826B2 <b>Pending:</b> US2021/0128716A1 Active: US9683233B2 US10738306B2 <b>Pending:</b> US2020/0332293A1 Active: US9737595B2 Active: US9890391B2 Active: US9974845B2 US10117920B2 US10434158B2 <b>Pending:</b> US2019/0381155A1
					Active: AU2013/220748B2		
					Active: AU2013/242404B2 AU2018/264081B2		
					Active: AU2013/242403B2 Active: AU2018/241156B2		

**Table 1.** Continued

Vaccine developer	Vaccine type	Supply agreement with COVAX	Public/private funding	Approved by WHO/stringent regulatory body? <sup>74</sup>	Authorized for use in Australia? <sup>75</sup>	Patent portfolio in Australia	Patent Portfolio in the US
					Active: AU2013/242405B2		Active: US10080809B2
					Active: AU2014/375402B2		Active: US10047375B2
							Pending: US2019/0032077A1
							Pending: US2019/0125857A1
					Pending: AU2017/350488A1		Pending: US2020/0163878A1
					Active: AU2014/310933B2		Active: US10293060B2
							US10799602B2
							Active: US10307472B2
							Pending: US2020/0030422A1
					Active: AU2014/310933B2		Active: US10588959B2
							Pending: US2020/0155668A1

<sup>74</sup>Wouters et al., *supra* note 3 at 2.

<sup>75</sup>Christine Soares & Travis Hartman, *Tracking the Vaccine Race*, REUTERS, Sept. 14, 2021, <https://graphics.reuters.com/HEALTH-CORONAVIRUS/VACCINE-TRACKER/xegpbqnlvqv/> (accessed Sept. 14, 2021).

<sup>76</sup>Silbersher, *supra* note 29; Masato Iida, *IP Trends on COVID-19 Vaccine-related Patents*, SSPRAHIGA INTERNATIONAL PATENT OFFICE (2020), <https://www.shigipatent.com/wp-content/uploads/2020/10/IP-Trends-on-COVID-19-vaccine-related-patents.pdf> (accessed Sept. 14, 2021); Christopher Garrison, *How the Oxford Covid-19 Vaccine Became the AstraZeneca Covid-19 Vaccine*, MEDICINES LAW AND POLICY (2020), <https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf> (accessed Sept. 14, 2021).

<sup>77</sup>Novavax, Inc., UNITED STATES SECURITIES AND EXCHANGE COMMISSION (2020), <https://www.sec.gov/Archives/edgar/data/10006694/000100069421000004/nvax-20201231.htm> (accessed Sept. 14, 2021).

patent bargain is that in return for a 20-year period of exclusivity, the invention must be disclosed, including the best method of performing it. However, adequacy of disclosure, in terms of satisfying patent law requirements, does not necessarily equip users with enough information to accurately manufacture vaccines once patents are no longer in force. Biologic medicines have been highlighted as uniquely difficult to replicate from patent disclosure alone.<sup>78</sup> As such, it is imperative if patent waivers are to be successfully implemented, that they facilitate access to other associated data. Patent waivers alone may be necessary, but not sufficient to facilitate vaccine production by manufacturers independent of the rights holder.<sup>79</sup> The next section discusses the other types of information that may need to be disclosed for the production of COVID vaccines, and the ways in which interests in these types of information are protected at law.

### III.B. Data, Materials and Know-how

Perhaps the most obvious category of distinctive information is the clinical trials data that must be provided to regulatory authorities for a vaccine to be approved for clinical supply. In most jurisdictions, a period of exclusivity is provided by the regulatory authority administering the approvals system to the applicant seeking approval. Although the data continue to remain confidential following the expiry of the exclusivity period, other applicants seeking approvals for equivalent formulations are allowed to rely on the data from that point. In some jurisdictions the exclusivity period is five years. In Australia, for example, the five-year data protection period is specified by section 25A of the *Therapeutic Goods Act 1989* (Cth). However, some jurisdictions have longer exclusivity periods. For example, the European Union has an eight- to ten-year data exclusivity period. In the US a longer period of 12 years is provided for biologics (which would include vaccines).<sup>80</sup>

Article 39.3 of TRIPS obliges members to provide protection from unfair commercial use in respect of undisclosed test or other data that they require to be collected as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities. Bilateral agreements reinforce (and in some cases extend) the levels of protection required through TRIPS. Australia, for example, is bound by the Australia-US Free Trade Agreement (AUSFTA), Article 17.10 of which contains more specific provisions than TRIPS limiting the disclosure of undisclosed test or other data. In particular, it requires that the period of protection must be at least five years for pharmaceutical chemical products. Australia is currently compliant with this AUSFTA requirement.

Equivalent provisions on undisclosed test data relating to pharmaceutical and agricultural chemical products are also found in Article 18.50 of the Trans-Pacific Partnership Agreement (the TPP). It should be noted that there are further obligations relating to new indications, formulations and methods of administration in Article 18.50.2 and

78 W. Nicholson Price & Arti K. Rai, *Are Trade Secrets Delaying Biosimilars?*, 348 *SCIENCE* 188–189, 189 (2015).

79 Louise C. Druedahl, Timo Minssen & W. Nicholson Price, *Collaboration in Times of Crisis: A Study on COVID-19 Vaccine R&D Partnerships*, 39 *VACCINE* 6291–6295, 6293 (2021).

80 TONY HARRIS, DIANNE NICOL & NICHOLAS GRUEN, *Pharmaceutical Patents Review* 178 (2013), <http://pharmapatentsreview.govspace.gov.au/> (accessed Sept. 14, 2021).

biologics in Article 18.51. Bearing in mind that the TPP has not entered into force, Article 18.50 is listed in the annex to the Comprehensive and Progressive Agreement on the Trans-Pacific Partnership (CPTPP) as one of the Articles of the TPP in respect of which application should be suspended, pursuant to Article 2 of the CPTPP and Annex. Yet Australia appears unable to rely on this suspension to reduce the protection it currently offers to undisclosed test data, because it is separately required to remain compliant with Article 17.10 of the AUSFTA. Australia can, however, take advantage of the current suspension relating to the extra protection required for new indications, formulations, and methods of administration in Article 18.50.2 and biologics in Article 18.51 of the TPP, in reliance on Article 2 and the Annex of the CPTPP.

Aside from the data required for regulatory approval, there are other varieties of subject matter that are relevant to the successful development and approval of vaccines, often referred to as the technical know-how necessary for manufacture.<sup>81</sup> Know-how, broadly defined, is the tacit, technical knowledge necessary to engage in manufacturing a product, and includes knowledge as to materials and processes required for manufacture. It is the main form of intellectual property protecting the knowledge necessary for vaccine manufacturing.<sup>82</sup> This large-scale manufacturing requires firms to engage in the exchange in methods and know-how, which would normally be protected through trade secrecy. The prevalence of trade secrecy in this area can act as a significant impediment to the sharing of manufacturing data between nations. Know-how is especially important in the context of manufacturing biologics, which is far more technically complex than manufacturing small molecule drugs. In particular, biologics manufacturing involves the identification and implementation of very specific development pathways.<sup>83</sup> This process is subject to a series of random events, all of which can alter the final product. In addition, the early point at which patent applications are filed limits the amount of manufacturing information disclosed in patent documentation.<sup>84</sup>

The protection of know-how, or ‘undisclosed information’, is provided for in article 39 of TRIPS, requiring that member states must protect undisclosed information against unauthorized use, or use ‘in a manner contrary to honest commercial practices . . .’. Under Australian law, know-how is protected through the equitable doctrine of breach of confidence, and through contract law. It is clear from the Australian case of *Coco v AN Clark (Engineers) Ltd*<sup>85</sup> that the threshold requirements for protection under Australian law accord with the TRIPS requirements for protection, in that information will be protected where it has ‘the necessary quality of confidence about it, is ‘imparted in circumstances that impose an obligation of confidence’ and is used in an unauthorized manner. Bilateral trade agreements to which Australia is a party impose similar obligations, although it is worth noting again that they potentially require a greater level of protection than TRIPS.

81 Price, Rai & Minssen, *supra* note 32 at 913.

82 Benedetta Spadaro, *COVID-19 Vaccines: Challenges and Promises of Trials, Manufacturing and Allocation of Doses*, 3 *FUTURE DRUG DISCOV. FDDS7*, 3 (2020); HILDE STEVENS ET AL., *VACCINES: ACCELERATING INNOVATION AND ACCESS* 1–32, 19 (2017).

83 Sampat and Shadlen, *supra* note 34 at 405.

84 W. Nicholson II Price & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 *IOWA LAW REV.* 1023–1064, 1046–7 (2015).

85 *Coco v AN Clark (Engineers) Ltd* [1969] RPC 41, 47 (Austl.).

As noted above, the CPTPP incorporates the provisions of the TPP. Article 18.78.1 of the TPP defines trade secrets as, at a minimum, undisclosed information as defined in Article 39.2 of TRIPS. This provision would appear to provide scope for an extension of the meaning of know-how under Australian law.<sup>86</sup> The laws of know-how and trade secrecy in some jurisdictions, particularly the US, are more stringent in relation to the protection of this subject matter than Australian law. This is reflected in the bilateral agreements already mentioned. Under US law, for example, the misappropriation of trade secrets is criminalized through the Economic Espionage Act of 1996,<sup>87</sup> and a private, civil right of action for misappropriation has also been enshrined in the Defend Trade Secrets Act of 2016.<sup>88</sup> In contrast, Australian law (unlike New Zealand law) offers no legislative protection of trade secrets, instead relying on more nebulous common law protection for those alleging misappropriation.<sup>89</sup>

Given these challenges, some proponents of the TRIPS waivers have suggested imposing a waiver of all intellectual property rights, which would include know-how. Early discussion of the proposed TRIPS waiver canvassed the possibility of a broad waiver of patents and other associated IP rights. However, the proposed waiver in its current form is limited to patents directly related to COVID-19 vaccines. Therefore, it would not extend to more general-purpose patents. In the absence of a broad waiver, it is questionable whether nations have the capacity to force vaccine manufacturers to disclose confidential know-how, as discussed below in the Australian context. In the interim, some pharmaceutical manufacturers such as Afrigen Biologics in South Africa have attempted to reverse engineer Moderna's Spikevax COVID vaccine manufacturing process.<sup>90</sup> Afrigen is currently attempting this process without the aid of Moderna, which, despite having pledged not to enforce their patents, is not sharing know-how.

The next section considers whether these overlapping rights have impeded the capacity (if not willingness) of nations such as Australia to contribute to the global vaccination campaign. This section also examines what mechanisms might be available, both on a global level and to the Australian government, to ameliorate any difficulties encountered.

#### IV. THE COMPLEX RELATIONSHIP BETWEEN INTELLECTUAL PROPERTY AND ETHICAL DISTRIBUTION OF COVID-19 VACCINES

##### IV.A. Are Patents and Other Intellectual Property Rights the Primary Barrier to the Ethical Distribution of Vaccines?

As argued in Section II, the most ethically appropriate strategy for distributing vaccines is some form of moderate moral cosmopolitanism. The ethically maximal strategy

86 Akiko Kato, *Understanding the IP-related Contents of the Trans-Pacific Partnership Agreement*, in *EMERGING GLOBAL TRADE GOVERNANCE: MEGA FREE TRADE AGREEMENTS AND IMPLICATIONS FOR ASEAN 97*, 129 (Lurong Chen et al. eds., 2018).

87 18 U.S.C. § 1831–1839.

88 18 U.S.C. § 1836.

89 Anna Kingsbury, *The Trans-Pacific Partnership Agreement and the Protection of Commercial Confidential Information and Trade Secrets in New Zealand Law*, 38 *EUR. INTELLECT. PROP. REV.* 237–245, 241 (2016).

90 Wendell Roelf, *Afrigen Gears up to Deliver Africa's First COVID-19 mRNA Vaccine*, *REUTERS*, June 24, 2021, <https://www.reuters.com/world/africa/afrigen-gears-up-deliver-africas-first-covid-19-mrna-vaccine-2021-06-24/> (accessed Dec. 13, 2021)

to achieve this end is to encourage decentralized vaccine production. Decentralizing vaccine production would allow governments to ensure they could prioritize vaccinating vulnerable members of their own population whilst fulfilling their cosmopolitan obligations to other nations.<sup>91</sup> To achieve this ethically maximalist goal, Australia and other like nations should arguably take steps to assist low- and middle-income nations in building their own domestic vaccine manufacturing programs.

However, given the complexities involved in vaccine manufacture, achievement of this goal to a level that would ameliorate vaccine inequality cannot realistically be achieved in the short term. As mentioned in the introduction to this article, it is estimated that Australian domestic manufacture of the Moderna vaccine will not commence until 2024, even though Australia has some existing manufacturing capacity and will be working with Moderna. It will take many more years for low- and middle-income nations to develop comparable manufacturing capability. This limited manufacturing capacity, combined with the complexity of vaccine production compared to small molecule biologics, represents a considerable impediment to widespread vaccine distribution.<sup>92</sup> Delays in the transfer of essential materials for vaccine manufacture resulting from travel restrictions imposed by the pandemic also create barriers to timely vaccine distribution.<sup>93</sup> The focus of this section is thus on the impact of intellectual property rights on domestic vaccine manufacturing in Australia for distribution to low- and middle-income nations. Specifically, this section considers what short term measures are available to ameliorate the effects of restrictive licensing on manufacturing and distribution of vaccines.<sup>94</sup>

Nations have expressed varying degrees of support for a TRIPS waiver.<sup>95</sup> For example, the Australian Government has confirmed its support for the draft 'Quad waiver' proposed by the US, India, South Africa and the European Union.<sup>96</sup> Yet the UK and Switzerland (as nations housing major vaccine manufacturers) remain notably opposed.<sup>97</sup> Further, the initial waiver proposal to the TRIPS Council submitted by South Africa and India extended to *all* intellectual property associated with COVID-19 technologies (including trade secrets), whereas the Quad waiver extends only to COVID-19 vaccine patents.<sup>98</sup> This distinction is important, because, as demonstrated above, waiving patent rights (even over an entire portfolio of patents) does not

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91 Emanuel et al., *supra* note 33 at 373.

92 Sampat and Shadlen, *supra* note 34 at 407; Wouters et al., *supra* note 3 at 7.

93 National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Board on Health Sciences Policy; Committee on Equitable Allocation of Vaccine for the Novel Coronavirus, *supra* note 28 at 39.

94 Thambisetty et al., *supra* note 41 at 3.

95 *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> (accessed Sept. 10, 2021); Dziedzic, *supra* note 14.

96 Dziedzic, *supra* note 14.

97 Sanath Wijesinghe, Chaminya Adikari & Ruwanthika Ariyaratna, *The Proposal for Waiver of WTO's TRIPS Agreement to Prevent, Contain and Treat COVID-19: Investigating the Benefits and Challenges for Low- and Middle-income Countries*, 17 J. INTELLECT. PROP. LAW PRACT. 179–192, 186 (2022).

98 Amy Maxmen, *In Shock Move, US Backs Waiving Patents on COVID Vaccines*, NATURE (2021), <https://www.nature.com/articles/d41586-021-01224-3> (accessed Dec. 17, 2021); Zarocostas, *supra* note 15 at 1292.

necessarily remove all intellectual property impediments.<sup>99</sup> In addition, even this compromised waiver might not offer a pathway for governments to acquire general purpose patents used in COVID-19 vaccine manufacturing.

As advocates for intellectual property waivers have asserted, the argument that material shortages and lack of manufacturing capacity in low- and middle-income nations represent the greatest limit on vaccine manufacturing belies a flawed logic. If these factors are the basis for vaccine shortages, why are patent holders aggressively lobbying against waivers?<sup>100</sup> Since the Biden administration announced its support for a waiver of COVID-19 vaccine patents, Pfizer and other vaccine producers have argued against the waiver, both in the US and internationally.<sup>101</sup> As a further indication that patents play at least some role in limiting vaccine distribution, attempts by generic vaccine manufacturers to obtain compulsory licences to produce COVID-19 vaccines in some high-income nations (including Canada, Denmark and Israel) have been rebuffed by manufacturers such as Johnson and Johnson.<sup>102</sup> In response, the CEO of Canada's Biolyse publicly denounced bureaucratic hurdles imposed by the Canadian government to compulsorily licence Johnson and Johnson vaccines for the benefit of low- and middle-income nations.<sup>103</sup>

Moreover, actions by Moderna and others illustrate patents are not the only intellectual property rights at stake. Although Moderna announced in 2020 that it would not enforce its patent portfolio for the duration of the pandemic, it clarified that this pledge did not extend to technical know-how following the Biden administration's announcement. Further, both pharmaceutical companies and high-income nations have spurned voluntary collaborative agreements in favour of bilateral supply agreements, thereby deterring local manufacture.<sup>104</sup> Rights holders can thus combine bilateral purchasing agreements, patent licensing, materials, and access to know-how to control COVID-19 vaccine manufacture.

In many cases, individual nations are poorly placed to override intellectual property rights. Even where nations have provision in their patent laws for compulsory licensing of patents, they do not have equivalent provisions allowing for waiver of data exclusivity rights,<sup>105</sup> nor to compel disclosure of know-how and access to materials. Proponents of the initial TRIPS waiver argued a broad waiver could ameliorate this problem by proposing that obligations under TRIPS relating to patents, copyright, designs, and undisclosed information be waived in relation to prevention, containment, or treatment

99 Thambisetty et al., *supra* note 41 at 41.

100 Hyo Yoon Kang, Jocelyn Bosse & Siva Thambisetty, *Trips Waiver: There's More to the Story than Vaccine Patents*, THE CONVERSATION (2021), <http://theconversation.com/trips-waiver-theres-more-to-the-story-than-vaccine-patents-160502> (accessed May 18, 2021).

101 Kevin Breuninger, *Pfizer CEO Opposes U.S. Call to Waive Covid Vaccine Patents, Cites Manufacturing and Safety Issues*, CNBC (2021), <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html> (accessed Jan. 31, 2022).

102 Thambisetty et al., *supra* note 41 at 38.

103 Ronald Labonté et al., *Canada, Global Vaccine Supply, and the TRIPS Waiver*, 112 CAN. J. PUBLIC HEALTH. 543–547, 543–4 (2021).

104 So and Woo, *supra* note 36 at 3; Yoo et al, *supra* note 5 at 315.

105 Katrina Pehudoff, Ellen't Hoen & Pascale Boulet, *Overriding Drug and Medical Technology Patents for Pandemic Recovery: A Legitimate Move for High-Income Countries, Too*, 6 BMJ GLOB. HEALTH e005518 3 (2021).

of COVID-19, for a fixed period.<sup>106</sup> The question, then, is whether, in the absence of a TRIPS waiver, nations like Australia could nevertheless take action to work around the perceived intellectual property impediments to fulfil moral cosmopolitan obligations. The next part of this section considers what steps the Australian government could take to fulfil vaccine equity ambitions.

#### IV.B. What Can Nations like Australia Do to Overcome Perceived Intellectual Property Barriers?

##### *IV.B.1. Compulsory licensing and government use of patented inventions*

Article 31 of TRIPS already provides that member states may include provisions in their patent legislation providing for use of patented inventions without the permission of the rights holder. Article 31 *bis* is particularly relevant to the present discussion, allowing member states to include provision for use without authorization to supply pharmaceuticals to other states that lack manufacturing capabilities. There is an extensive body of literature critiquing Article 31 *bis* because of the obligations it imposes on states seeking to make use of this facility.<sup>107</sup> It is not necessary to restate these critiques for the purpose of the present discussion, other than to say that it will at best provide a partial solution. Despite these limitations, this TRIPS flexibility remains one of the armoury of weapons available to states to facilitate moral cosmopolitanism, and as such there is good reason for it to be implemented into national law.<sup>108</sup>

Australia is one of several nations that has implemented Article 31 *bis* by creating a regime for compulsory licensing for export. Australia also has other provisions in its patent legislation to facilitate access to medicines domestically through its government use provisions. A compulsory licence is a court or administrative order requiring a patentee to grant a licence to work an invention as claimed. Government use encompasses use of an invention as claimed by the government for the purposes of the state. In Australia, government use is referred to in patent law as Crown exploitation.<sup>109</sup>

Section 136B of the *Patents Act 1990* (Cth) was introduced by the *Intellectual Property Laws Amendment Act 2015* (Cth). It provides that the Federal Court may make an order requiring the grant of a compulsory licence to exploit a patented pharmaceutical invention (referred to by the acronym PPI in the legislation) for manufacture and export to an eligible importing country. The circumstances in which the court may make such an order are limited to addressing a public health issue in the eligible importing country including a national emergency (or other extremely urgent circumstance) or through the public, non-commercial use of the product. The COVID-19 pandemic would clearly qualify as a national emergency.

106 Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19, IP/C/W/669 (2 October 2020) (Communication from South Africa and India), para. 3; Thambisetty et al., *supra* note 41 at 38.

107 Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 *JOURNAL OF INTERNATIONAL ECONOMIC LAW* 535–561, 552 (2020); Aisling McMahon, *Patents, Access to Health and COVID-19—The Role of Compulsory and Government-use Licensing in Ireland*, 71 *NILQ* 331–358 (2020).

108 Dianne Nicol & Olasupo Owoeye, *Using TRIPS Flexibilities to Facilitate Access to Medicines*, 91 *BULL. WORLD HEALTH ORGAN.* 533–539, 536 (2013).

109 Jane Nielsen et al., *Another Missed Opportunity to Reform Compulsory Licensing and Crown Use in Australia*, 25 *AUST. INTELLECT. PROP. J.* 74–92, 77 (2014).

The existing government use provisions in Australian patent law were also recently amended by the *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020*. Section 163A allows government use for emergencies, including national emergencies under the *National Emergency Declaration Act 2020* (Cth). This provision would permit use of patented vaccines under prescribed conditions for domestic use without the permission of the patent holder. However, it is limited to national emergencies. Another provision, s 168, allows government use 'Where the Commonwealth has made an agreement with a foreign country to supply to that country products required for the defence of the country'. Whether responding to a global pandemic could be considered as 'defence of the country' is yet to be determined.

As such, some tools are in place in Australia which would allow reliance on the use without authorization provisions under TRIPS. However, there are significant limitations. Existing Australian compulsory licensing provisions are restricted to individual patents in Australian law (and through Article 31 of TRIPS). One challenge this creates is that because multiple patents impinge on a single vaccine candidate or method of manufacture (as indicated in Table 1), separate licences would be required for each patent. Arguably, it would be easier to rely on government use, since this relies on an order from the relevant Minister rather than an application to the court. However, there is some doubt as to whether the existing government use provisions in Australian patent law could be relied on for supply to other nations.

To date, there is no evidence that there has been utilization of these provisions, thereby adding to the chorus of criticism about the utility of this particular TRIPS flexibility. The mere fact that these provisions exist, however, may have more indirect value, both symbolic and practical (for example, by encouraging voluntary licensing).<sup>110</sup>

#### *IV.B.2. Acquisition of know-how*

Another challenge is that TRIPS is silent on the question of whether national legislation could permit the compulsory acquisition of know-how,<sup>111</sup> and there are currently no specific provisions in Australian patent law. Despite this, there are potentially a range of legal mechanisms that might be used to facilitate access to vaccine manufacturing know-how.

**IV.B.2.a. Ancillary orders** Arguably, even in the absence of specific legislation, the Australian courts may be able to use their inherent jurisdiction to facilitate access. Orders under the compulsory licensing provisions of the *Patents Act 1990* (Cth) are required to be made by the Federal Court of Australia, and there is no doubt that, as a court of superior jurisdiction, the Federal Court would have an inherent jurisdiction to make ancillary orders, provided there is no conflict with relevant international instruments (discussed further below). Similarly, although authorizations for government use are made by the relevant Minister under section 163 of the *Patents Act 1990* (Cth) rather than the courts, the Minister could also presumably include ancillary

110 McMahan, *supra* note 42, at 146.

111 Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines Via Involuntary Technology Transfer*, 16 JOURNAL OF INTELLECTUAL PROPERTY LAW & PRACTICE 1242–1261, 1251 (2021).

authorizations. In either case, access to associated know-how could conceivably be included.

Although TRIPS contains no restrictions on incorporating access to know-how in uses without authorization, article 17.9.7(b)(iii) of the AUSFTA provides a significant limitation. As a starting point, article 17.9.7 limits use without authorization to: (a) remedying anticompetitive conduct; and (b) circumstances of public non-commercial use, national emergency, or other circumstances of extreme urgency. Article 17.9.7(b)(iii) provides that, in making laws to provide for the second category of uses without authorization, the parties to the agreement:

may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorized for use in accordance with this paragraph.

This provision would thus appear to prevent the courts from making ancillary orders to grant access to know-how. As such, it constitutes a significant impediment to the capacity of prospective vaccine manufacturers to mobilize compulsory licensing and government use provisions under the *Patents Act 1990* (Cth). Other nations that have included similar intellectual property clauses in their bilateral or regional free trade agreements may likewise be prevented from making ancillary orders of this nature.

**IV.B.2.b. Sui generis legislation** Other options for acquiring access to know-how outside of compulsory licensing and government use schemes might be contemplated. For example, the Brazilian Senate has passed a bill that, if ratified by the Brazilian Congress, would require vaccine manufacturers to disclose know-how associated with vaccines, diagnostic tests, and pharmaceutical products in the event of a public emergency.<sup>112</sup> If manufacturers or licence holders refuse to reveal this information, they may be denied patent protection for a patent application or have their patents revoked.<sup>113</sup> The Brazilian Government signalled its opposition to this bill on the grounds that it would endanger the Brazilian Government's current manufacturing contracts with AstraZeneca and Sinovac.<sup>114</sup> The Brazilian President used his veto powers to remove the clauses pertaining to compulsory licensing of regulatory data and patents.<sup>115</sup>

Further, despite the public health crisis in Brazil, and the imperative to produce more vaccine doses, it is unclear whether this legislation would comply with Brazil's TRIPS obligations. On the one hand, Article 39(3) prohibits member states from passing legislation to allow for the disclosure of regulatory data used in pharmaceutical

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112 Ricardo Brito, *Brazil Senate Votes to Suspend Patent Protection on COVID-19 Vaccines*, REUTERS (2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-senate-votes-suspend-patent-protection-covid-19-vaccines-2021-04-30/> (accessed July 5, 2021).

113 Roberto Castro de Figueiredo, *Brazilian Senate Approves Bill on the Compulsory Licensing of COVID-19 Vaccines' Patents*, KLUWER PATENT BLOG (2021), <http://patentblog.kluweriplaw.com/2021/05/12/brazilian-senate-approves-bill-on-the-compulsory-licensing-of-covid-19-vaccines-patents/> (accessed Jan. 28, 2022).

114 Brito, *supra* note 112.

115 Joseph E. Stiglitz, Achal Prabhala & Felipe Carvalho, *Brazil's Pioneering Solution to Vaccine Shortages*, PROJECT SYNDICATE (2021), <https://www.project-syndicate.org/commentary/brazilian-solution-vaccine-ip-waiver-stuck-at-wto-by-joseph-e-stiglitz-et-al-2021-12> (accessed Jan. 28, 2022).

or agricultural know-how.<sup>116</sup> On the other hand, as Abbott and Reichman note, Article 73 of the TRIPS agreement provides substantial powers to member states to protect their essential security interests in times of emergency.<sup>117</sup> Accordingly, the Brazilian legislation appears to provide a replicable model for Australia to legislate for acquisition of vaccine manufacturing know-how.<sup>118</sup> Nevertheless, the restrictions on Australia's legislative capacity imposed by the AUSFTA are a major limitation where the know-how relates to a patented invention. As our analysis has demonstrated, all the vaccines currently being supplied in Australia are protected by one or more patents. Any measures for compulsory acquisition would need to apply to both know-how and patents. The next section discusses some legal strategies that could be used to execute similar arrangements in Australia.

**IV.B.2.c. Regulatory powers** Another strategy, proposed by Morten and Kapczynski in the US context in respect of regulatory approval data is to use the regulatory power of the Food and Drug Administration (FDA) to force disclosure.<sup>119</sup> Like the FDA, the Australian Therapeutic Goods Administration (TGA) receives regulatory data from the manufacturers of pharmaceutical products and medical devices before they are made available for sale in Australia. The TGA could use its regulatory powers to force the disclosure of COVID-19 vaccine manufacturing know-how (as well as manufacturing materials) in exchange for regulatory approval. Of the six candidate vaccines examined in this study, five have currently received regulatory approval in Australia (Astrazeneca, Pfizer-Biontech, Moderna, Johnson & Johnson and Novovax), and accordingly regulatory approvals data exists for each of these. However, even if this data could be made available for other uses, at best it would provide only partial assistance without access to relevant know-how.

**IV.B.2.d. Just acquisition of property** Perhaps the most significant legal tool available to the Australian Government for the acquisition of know-how (and materials) is the power to make laws with respect to the acquisition of property on just terms under section 51(xxxi) of the Australian Commonwealth Constitution. From a constitutional perspective, section 51(xxxi) is comparable to the Takings Clause under the Fifth Amendment of the United States Constitution. Specifically, the Fifth Amendment requires just compensation to be paid if private property is converted to public use. The issue in contention for hypothetical Australian legislation is whether private property can include intellectual property rights, specifically know-how.

There are similarities and differences between how US precedent has interpreted the Takings Clause and how the Australian High Court has interpreted section 51(xxxi). For example, in *Monsanto v Ruckelshaus*, the Environmental Protection Agency (EPA)

116 OLGA GURGULA, *Accelerating COVID-19 Vaccine Production via Involuntary Technology Transfer* (2021), <https://papers.ssrn.com/abstract=3926234> (accessed Jan. 28, 2022).

117 Abbott and Reichman, *supra* note 107, 560; Frederick M. Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic* (SSRN Scholarly Paper No ID 3682260, Social Science Research Network, Aug. 1, 2020) <https://papers.ssrn.com/abstract=3682260> (accessed Jan. 28, 2021).

118 Stiglitz, Prabhala and Carvalho, *supra* note 115.

119 Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 CALIF. LAW REV. 493–558, 495–6 (2021).

sought to disclose data submitted by the applicant for regulatory approval of a pesticide. The applicant successfully established that because the data had been registered as a trade secret in Missouri, it held a proprietary interest in that trade secret.<sup>120</sup> Accordingly, the EPA's disclosure required it to financially compensate the applicant under the Takings Clause.<sup>121</sup> However, the Supreme Court also held that Monsanto did not have an exclusive right to this data and was not entitled to prevent the EPA from using this information.<sup>122</sup>

The High Court of Australia has held that property can include both tangible and intangible property. In *JT International v Commonwealth of Australia*, the High Court held that taking trademarked cigarette advertisements amounted to the acquisition of property. The fact that the government had acquired these trademarks pursuant to a public health agenda did not change the fact that they were 'personal property' under the *Trade Marks Act 1995* (Cth).<sup>123</sup> Likewise, in *Smith Kline and French Laboratories v Department of Community Services and Health*, Gummow J of the Federal Court of Australia considered the weight of *Monsanto v Ruckelshaus* as authority in Australia. Gummow J concluded that whether confidential information could be considered proprietary, would depend on the nature and purpose of that information. In particular, Gummow J suggested that commercially valuable information would be more likely to be considered property [at paragraphs (161–171)].<sup>124</sup> This 'commercially valuable' approach is reflected in subsequent analysis of Australian law.<sup>125</sup>

It is unclear whether that know-how for manufacturing vaccines would be considered property for the purposes of section 51(xxxi) of the Constitution. However, it is unlikely that access to purely intangible property would be sufficient for Australia to start manufacturing vaccines. The Australian Government would therefore need to approach a vaccine manufacturer and seek both know-how and material for manufacturing vaccines. The status of equipment and know-how concerning vaccine manufacturing as property raises the question as to what 'just terms' might look like were the Australian Government to acquire this property and know-how under section 51(xxxi). Loss of exclusive rights to exploit intellectual property would need to be compensated by the federal government.<sup>126</sup> However, this compensation would need to be balanced against the significant public health benefits flowing from wider scale manufacturing of COVID-19 vaccines.<sup>127</sup> Further, the World Trade Organization has previously stated that the TRIPS agreement should not be used to stymie public health initiatives. Therefore, the Australian Government taking steps to purchase know-how

120 *Monsanto Co. v. Ruckelshaus*, 467 US 986, 1003–1004 (1984).

121 *Id.* at 1019.

122 *Id.* at 1020.

123 *JT International v Commonwealth of Australia* [2012] HCA 43 (Austl.).

124 *Smith Kline and French Laboratories v Department of Community Services and Health* [1990] FCA 206 (Austl.).

125 *Markwell Bros Pty Ltd v CPN Diesels* (1983) 2 QR 508 (Austl.); Katarzyna A. Czapracka, *Antitrust and Trade Secrets: The U.S. and the EU Approach*, 24 ST. CLARA COMPUT. HIGH TECHNOL. LAW J. 207–274, 215 (2007).

126 Andrew D. Mitchell & David M. Studdert, *Plain Packaging of Tobacco Products in Australia: A Novel Regulation Faces Legal Challenge*, 307 JAMA 261–262, 262 (2012).

127 Olasupo Owoeye, Oladapo Fabusuyi & Mathews Nkhoma, *The Australian Tobacco Plain Packaging Legislation: A Case Study on Intellectual Property Enforcement and Policy Intervention to Promote Public Health*, 16 J. INTELLECT. PROP. LAW PRACT. 164–178, 177 (2021).

would not necessarily be limited under Article 39(3) of the TRIPS Agreement, which prohibits unfair commercial use of regulatory data by competitors.<sup>128</sup> The actual costs of purchasing this subject matter could be politically justified through a one-off tax through the Medicare levy, or through deficit spending. Though article 39(3) may place further limitations on the Australian Government subsequently transferring know-how and vaccine manufacturing equipment to low- and middle-income regional partners, such as Indonesia.

**IV.B.2.e. Negotiation** A TRIPS waiver, whether in the broad form initially proposed by South Africa and India, or the more limited COVID-19 vaccine patent waiver proposal by the Quad, has been suggested as a pathway to ameliorate some of the restrictions presented by the current use without authorization provisions in Article 31 of TRIPS.<sup>129</sup> Whilst it would not be necessary to seek a compulsory licence for each individual patent, it would be difficult to assess which patents pertain to COVID-19 vaccine technology as opposed to vaccine manufacturing for other diseases. It is also difficult to see how nations could formulate adequate legislative or policy responses to the problem of compelling access to know-how, particularly if it requires individual manufacturers to disclose their ‘tools of trade’.<sup>130</sup>

Whilst the TRIPS waiver might not necessarily facilitate transfer of all the intellectual property needed to manufacture vaccines, its true value might be as an incentive to leverage cooperation. In other words, nations with sufficient financial resources could support the waiver to encourage rights holders to engage in voluntary licensing.<sup>131</sup> Australia, as a nation with independent vaccine manufacturing capacity and (until recently) low levels of community transmission, is ideally placed to heed this call. Moral cosmopolitanism demands that it should do so, given that many other nations in the region lack manufacturing capabilities and are faring far less favourably in the current pandemic climate.

As an alternative to mandatory waivers, the WHO has urged high-income nations to encourage vaccine manufacturers to pool know-how associated with COVID vaccines,<sup>132</sup> in addition to developing vaccines unencumbered by intellectual property.<sup>133</sup> However, as of the date of writing, no country has chosen to sign up or contribute to this know how pool. Røttingen, recently appointed as Norway’s Global Health Ambassador, made the point that, while waiving intellectual property rights might help in producing small molecular weight substances, ‘if you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological

128 Olasupo A. Owoeye, *Data Exclusivity and Public Health under the TRIPS Agreement*, 23 J. LAW INF. SCI. 106–133, 118 (2014).

129 Thambisetty et al., *supra* note 41 at 27–28.

130 Zarocostas, *supra* note 15 at 1292.

131 Aisling McMahon, *supra* note 42, at 146; Matheson & Kirkinis, *supra* note 16, 489.

132 UN experts to G7: *Production of Safe COVID-19 Vaccines Must Outweigh Profit*, UN News 7 (2021), <https://news.un.org/en/story/2021/06/1093672> (accessed Sept. 15, 2021).

133 Gail Dutton, *Rokote Lab’s COVID-19 Nasal Vaccine on Financing Fence Before Phase I Trials*, BIOSPACE (2021), <https://www.biospace.com/article/rokote-lab-s-covid-19-nasal-vaccine-on-financing-fence-before-phase-i-trials/> (accessed Dec. 17, 2021).

samples, cell lines, or bacteria’,<sup>134</sup> Instead, he argues that individual companies should be pressured to allow non-exclusive licences and technology transfer of their products, along the lines of the agreements that AstraZeneca and Novavax have established with the Serum Institute of India for vaccines. This partnership model would be much faster, he says—‘Instead of going for an unreachable, “ideal” solution that will not fly, they should identify where the barriers are and work on those’.<sup>135</sup>

While political pressure is certainly an option for compelling access, a more realistic, palatable and timely option is negotiation of access rights. Rather than compulsory acquisition, the Australian Government would no doubt be more inclined to negotiate the acquisition or licence of permission to use manufacturing know-how from the rights holders of COVID-19 vaccines if it is to establish domestic vaccine production. This production capacity could allow Australia, along with neighbouring nations with manufacturing capacity (such as South Korea), to reduce reliance on limited mRNA vaccine manufacturing capacity in the Northern Hemisphere.<sup>136</sup>

## V. CONCLUSION

To date, the Australian Government has adopted a clear morally nationalistic stance in combatting the COVID pandemic. While Australia has met its current national vaccination targets, it remains to be seen whether Australia’s future strategy includes a move to a more morally cosmopolitan approach to fighting this particular virus. To date, there have been indications that the Australian Government is not averse to assisting its regional neighbours during times of acute crisis. This extend to a more extensive and systematic strategy to provide sustained, long-term assistance that extends beyond providing surplus vaccine supplies to manufacture for export and, in the longer term, to assist with the development of domestic manufacturing capabilities. There is also the possibility that the change in government following the Australian Federal Election in May 2022 will see an altered vaccine strategy.

There is little doubt that low- and middle-income nations will be unable to combat current and future COVID waves, with their health-related, social, and economic consequences, without significant help from higher income nations. Most low- and middle-income nations lack the resources, and manufacturing and logistical capabilities to engage in any meaningful program of domestic manufacture. In the absence of altruism, significant cooperation between nations is imperative to easing the pandemic burden for poorer nations, not only for this current pandemic but for future pandemics. This must incorporate manufacture for export on the part of nations such as Australia. The question is whether the legal mechanisms in place permit such action to increase COVID-19 vaccine manufacturing in the face of strong intellectual property rights. In the context of COVID-19 vaccines, the research in this article shows the intellectual

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134 Jorge A. Goldstein, *Waiving Covid-19 Vaccine Patents Won't Solve the Global Need*, BLOOMBERG LAW (2021), <https://news.bloomberglaw.com/ip-law/waiving-covid-19-vaccine-patents-wont-solve-the-global-need> (accessed Sept. 15, 2021).

135 Ann Danaiya Usher, *South Africa and India Push for COVID-19 Patents Ban*, 396 THE LANCET 1790–1791 (2020).

136 Sangmi Cha, *S. Korea in Talks with mRNA Vaccine Makers to Make up to 1 bln Doses—Govt Official*, REUTERS, July 5, 2021, <https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-skorea-talks-wi-th-mrna-vaccine-makers-make-up-1-blm-doses-govt-2021-07-05/> (accessed July 14, 2021).

property landscape varies, but is typified by a web of COVID-19 specific and general purpose technology patents, as well as associated regulatory data and know-how.

A TRIPS waiver has been promoted as the optimal mechanism to make vaccines more broadly available to governments of low- and middle-income nations. However, to be effective, a TRIPS waiver would need to encompass not just patents, but also associated regulatory data, as well as product and manufacturing know-how. Whilst an extensive TRIPS waiver was initially proposed by India and South Africa, it has not been widely supported. The narrow Quad waiver, which only applies to COVID-19 vaccine patents, is unlikely to be agreed to in the current international vaccine climate. In any case, any waiver would be unlikely to solve the supply chain issues which also limit COVID-19 vaccine manufacturing.

As such, responsibility for implementing moral cosmopolitanism will likely fall to individual national governments. And yet these obligations will be difficult to discharge, as the legal landscape in nations such as Australia does not provide a clear pathway for gaining access to sufficient information to permit large-scale domestic manufacture for export. As our analysis reveals, although there is capacity to issue compulsory licences or government use authorizations in Australia, there is unlikely to be a current capacity under the Australian scheme to licence either regulatory data or know-how. In this way, vaccine manufacturers are protected against uses without authorization, and the system is set up to render the provisions in patent legislation designed to facilitate such uses ineffectual, even in the face of the greatest public health crisis to have afflicted humankind.

Without moral cosmopolitanism by high-income nations such as Australia, a future with rampant COVID outbreaks as well as other pandemics, causing excess rates of hospitalization and death in low- and middle-income nations, looms as a dark future. It is important that high income nations heed the lessons of the current pandemic to respond more decisively moving forwards. Urgent consideration by the governments of nations such as Australia of the options for implementing moral cosmopolitanism, is essential. This article has demonstrated that although the options for providing international assistance through domestic manufacture for export are not without difficulty, they do warrant consideration. This investigation should be undertaken with haste, and with a view to ensuring that moral cosmopolitanism is not evaded at the expense of national interest.

## VI. METHODOLOGY

The authors first searched for prior literature reviews that had been conducted on the COVID-19/Coronavirus patent landscape. These include studies by patent law firms, lobby groups, public thinktanks such as Public Citizen in the US and articles. The authors used these articles to construct a guided unstructured search of patents filed by certain companies, such as BioNTech/Pfizer and Modern-NIH.

The authors then sought to construct a structured search string to complete our patent search literature. Of the various patent search techniques, the two most popular techniques are keyword-based searches and with patent classification searches. Patent classification searches are useful for identifying trends amongst established sets of technology, whereas keyword-based searches are more useful for identifying trends in

emerging technology.<sup>137</sup> Nevertheless, it is important to use multiple search strategies in concert to identify any information that would have otherwise been missed through just using one search.<sup>138</sup>

Therefore, the authors conducted a secondary search by adapting a search string used by Liu et al. (2021). Liu use a keyword search strategy to identify all patents on coronavirus technology and products (including but not limited to COVID-19 related vaccine patents).<sup>139</sup> This search string relied on the following keywords: Topic = 'MERS-CoV' OR 'SARS-CoV' OR 'SARS CoV-2 OR COVID\*' OR '2019 nCoV' OR 'CoV-229E' OR 'CoV-OC43' OR 'CoV-NL63' OR 'CoV-HKU1' OR 'HCoV-229E' OR 'HCoV-OC43' OR 'HCoV-NL63' OR 'HCoV-HKU1' OR 'corona virus\*' OR 'coronavirus\*' OR 'severe acute respiratory syndrome' OR 'Middle East respiratory syndrome' OR 'sars' OR 'mers'. The search was listed to documents published between 1963 to 2020. Liu et al. then applied a PRISMA guided approach to identify duplicates, screen irrelevant patents and assess the full text for eligibility. From this, Liu generated a dataset of 16,605 patent documents and 5156 DWPI patent families, including 1556 patent documents and 1524 DWPI patent families.

Although the authors did not have access to the Derwent World Patent Index that Liu et al. have access to, the authors did have access to the free PatentLens. The initial search string was first repeated using the date rate, with an adapted search strategy: (title:(MERS-CoV) OR abstract:(MERS-CoV) OR claims:(MERS-CoV)) OR (title:(SARS-CoV) OR abstract:(SARS-CoV) OR claims:(SARS-CoV)) OR (title:(SARS-CoV-2) OR abstract:(SARS-CoV-2) OR claims:(SARS-CoV-2)) OR (title:(COVID\*) OR abstract:(COVID\*) OR claims:(COVID\*)) OR (title:(2019-nCoV) OR abstract:(2019-nCoV) OR claims:(2019-nCoV)) OR (title:(2019 nCoV) OR abstract:(2019 nCoV) OR claims:(2019 nCoV)) OR (title:(CoV-229E) OR abstract:(CoV-229E) OR claims:(CoV-229E)) OR (title:(CoV-OC43) OR abstract:(CoV-OC43) OR claims:(CoV-OC43)) OR (title:(CoV-NL63) OR abstract:(CoV-NL63) OR claims:(CoV-NL63)) OR (title:(CoV-HKU1) OR abstract:(CoV-HKU1) OR claims:(CoV-HKU1)) OR (title:(corona virus\*) OR abstract:(corona virus\*) OR claims:(corona virus\*)) OR (title:(coronavirus\*) OR abstract:(coronavirus\*) OR claims:(coronavirus\*)) OR (title:(severe acute respiratory syndrome) OR abstract:(severe acute respiratory syndrome) OR claims:(severe acute respiratory syndrome)) OR (title:(Middle East respiratory syndrome) OR abstract:(Middle East respiratory syndrome) OR claims:(Middle East respiratory syndrome)) OR (title:(sars) OR abstract:(sars) OR claims:(sars)) OR (title:(mers) OR abstract:(mers) OR claims:(mers)).

This search string returned 25,874 'simple' patent families and 42,715 patents.

Adding the keywords 'adenovirus' and 'adenoviral' resulted in the following search string:

137 Leah S. Larkey, *A Patent Search and Classification System*, in PROCEEDINGS OF THE FOURTH ACM CONFERENCE ON DIGITAL LIBRARIES 179–187, 180 (1999), <https://doi.org/10.1145/313238.313304> (accessed May 19, 2021); Hyo Yoon Kang, *Science Inside Law: The Making of a New Patent Class in the International Patent Classification*, 25 SCI. CONTEXT 551–594, 555 (2012).

138 Christopher L. Benson & Christopher L. Magee, *A Hybrid Keyword and Patent Class Methodology for Selecting Relevant Sets of Patents for a Technological Field*, 96 SCIENTOMETRICS 69–82, 71 (2013).

139 Liu et al, *supra* note 71 at 1590.

title:MERS-CoV OR abstract:MERS-CoV OR claims:MERS-CoV OR title:SARS-CoV OR abstract:SARS-CoV OR claims:SARS-CoV OR title:SARS-CoV-2 OR abstract:SARS-CoV-2 OR claims:SARS-CoV-2 OR title:COVID OR abstract:COVID OR claims:COVID OR title:2019-nCoV OR abstract:2019-nCoV OR claims:2019-nCoV OR title:(2019 nCoV) OR abstract:(2019 nCoV) OR claims:(2019 nCoV) OR title:CoV-229E OR abstract:CoV-229E OR claims:CoV-229E OR title:CoV-OC43 OR abstract:CoV-OC43 OR claims:CoV-OC43 OR title:CoV-NL63 OR abstract:CoV-NL63 OR claims:CoV-NL63 OR title:CoV-HKU1 OR abstract:CoV-HKU1 OR claims:CoV-HKU1 OR title:(‘corona virus’) OR abstract:(‘corona virus’) OR claims:(‘corona virus’) OR title:coronavirus OR abstract:coronavirus OR claims:coronavirus OR title:(‘severe acute respiratory syndrome’) OR abstract:(‘severe acute respiratory syndrome’) OR claims:(‘severe acute respiratory syndrome’) OR title:(‘Middle East respiratory syndrome’) OR abstract:(‘Middle East respiratory syndrome’) OR claims:(‘Middle East respiratory syndrome’) OR title:sars OR abstract:sars OR claims:sars OR title:mers OR abstract:mers OR claims:mers OR title:adenovirus OR abstract:adenovirus OR claims:adenovirus OR title:adenoviral OR abstract:adenoviral OR claims:adenoviral.

This string returned 34,402 ‘simple’ patent families and 65,211 patents.

Unfortunately, some of the patents that were defined above through structured searching were not included in this list. This included US10576146B2 (Particles Comprising a Shell with RNA) and other mRNA vaccines.

The next phase was to combine the search string above with another search string adapted from Martin and Lowery, who created a patent landscape of mRNA vaccine patents. Accordingly, the following search strings were added: OR (title:(ribonucleic acid) OR abstract:(ribonucleic acid) OR claims:(ribonucleic acid)) OR (title:(RNA) OR abstract:(RNA) OR claims:(RNA)) OR (title:(messenger ribonucleic acid) OR abstract:(messenger ribonucleic acid) OR claims:(messenger ribonucleic acid)) OR (title:(mRNA) OR abstract:(mRNA) OR claims:(mRNA)) OR (title:(messenger RNA) OR abstract:(messenger RNA) OR claims:(messenger RNA)).

In addition, the authors focused patent search on vaccine technology to narrow search criteria. Accordingly, the authors introduced the following search terms: AND (title:(vaccin\*) OR abstract:(vaccin\*) OR claims:(vaccin\*)). This resulted in the following search string:

(title:(ribonucleic acid) OR abstract:(ribonucleic acid) OR claims:(ribonucleic acid) OR title:RNA OR abstract:RNA OR claims:RNA OR title:(messenger ribonucleic acid) OR abstract:(messenger ribonucleic acid) OR claims:(messenger ribonucleic acid) OR title:mRNA OR abstract:mRNA OR claims:mRNA OR title:(messenger RNA) OR abstract:(messenger RNA) OR claims:(messenger RNA)) AND (title:vaccin\* OR abstract:vaccin\* OR claims:vaccin\*)

This search query resulted in 14,834 patents being returned amongst 6781 families.

The next phase was to narrow patents down by jurisdiction to only include patent documents where there was a family member from Australia or the United States. This filtering was achieved using the functionality in the Lens.

For the COVID-19 patent search, this resulted in 24,324 patents from 14,276 families. For the mRNA patent search, this resulted in 6717 patents from 3708 families.

### VI.A. Record Screening

The authors focused on patent families assigned to pharmaceutical companies or governments that had had been assessed by Wouters et al. as leading vaccine candidates.<sup>140</sup>

These included the following candidates:

- AstraZeneca with Oxford University (ISIS Innovation)
- Johnson & Johnson (Janssen NV/Crucell Holland BV)
- Moderna-NIH (including US Health)
- Novavax

This filtering produced 363 patent documents and 141 simple families. In addition, mRNA vaccine patents by those which, according to Martin and Lowery, are in or have passed Phase 3 trials were also included:

- BioNTech with Pfizer
- CureVac
- Moderna

This filtering strategy resulted in 427 patent documents belonging to 186 families.

### VI.B. Full Text Eligibility Assessment

The next stage was abstract based filtering. In a PRISMA based model, this would normally involve reading the abstract and title of the article. This was run separately on each collection.

#### VI.B.1. COVID-19 Vaccine Patents

After checking titles, claims and abstracts for eligibility, out of 363 patents, 86 patent documents were included.

#### VI.B.2. mRNA Vaccine Patents

After checking titles, claims and abstracts for eligibility, out of 427 patents, 81 patent documents were included.

A standard PRISMA assessment would involve checking the full text of each article for eligibility. However, the Lens allows for a user to view the patent family that a document belongs to, as well as whether that patent is active, pending, discontinued (that is, the applicant has abandoned the application) or expired. Normally, patents are filed at the World Intellectual Property Organization (WIPO). The applicant then enters the patents into national operation. Therefore, for this patent landscaping model, the following documents associated with each family from our search results that were published in the United States and Australia were included:

- Granted patents
- Patent applications that were pending
- Amended applications

After this full text assessment was complete, 139 patent documents were included in the final assessment.

The authors then cross referenced our results with the other published literature on COVID-19 vaccine patents. The authors included an additional 39 documents for a total of 168 patent results.

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#### **CONFLICT OF INTEREST STATEMENT**

The authors have no financial, academic or other conflicts of interest in the subject matter discussed in this manuscript.

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