

6. IF NOT NOW, WHEN? ACCESS TO COVID-19 TREATMENT AND PATENT LAW

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ABSTRACT

The COVID-19 pandemic has brought many intellectual property (IP) access issues to the forefront of international debate. While wealthier countries race to deliver vaccines to their residents, treat their patients and recover economically, developing countries struggle to access the knowledge and technologies to do the same. Once again, the balance between protecting IP rights and providing needed technology access and knowledge transfer has been called into question. Within international treaties and domestic laws, there are several methods in place that can be invoked to lawfully breach IP rights, ranging in degree of intrusiveness. This paper outlines the need for equitable global access to treatment and underlines the danger of vaccine nationalism. The paper responds to the concern of how to facilitate access to COVID-19 treatments given the current international framework. The paper describes two non-voluntary mechanisms related to the TRIPS Agreement: the compulsory licensing under Article 31*bis*, and the recent waiver proposal aiming to suspend IP rights related to the prevention, containment, or treatment of COVID-19. The implementation of these non-voluntary mechanisms is necessary to appropriately respond to the mitigation of COVID-19 globally and the paper advocates for a compulsory trade secrets license to facilitate developing countries' access to medical

information and technologies. The paper ends with describing insights to consider these methods of access for the benefit of international healthcare in times of crisis in the future.

Keywords: COVID-19; vaccine nationalism; compulsory license; TRIPS waiver; compulsory trade secrets license; technology transfer.

1. INTRODUCTION

First identified in December 2019, the World Health Organization (WHO) declared the coronavirus (COVID-19) outbreak a pandemic in March 2020.¹ According to the WHO Coronavirus Dashboard, there were over 182 million confirmed cases of COVID-19 and more than 3.9 million deaths as of 28 June 2021.²

Developing countries have been disproportionately affected by the COVID-19 pandemic during the past two years. The World Bank identified that in the average developing country, 36% of respondents stopped working when their country's social distancing measures were most stringent, and 64% of households reported decreased income.³ During school closures, only 41% of children from lower income countries continued to engage in learning activities, partly due to lack of internet, computer, television or radio access.⁴ If advanced economies fail to ensure equitable access to COVID-19 vaccines for developing countries, global costs could total USD 9.2 trillion, with advanced economies bearing up to half of the costs.⁵ Therefore, until the vaccine is widely available in developing countries, the

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¹ WHO, 'Listings of WHO's response to COVID-19' (Statement, 28 December 2020) <www.who.int/news/item/29-06-2020-covid-timeline> accessed 28 June 2021.

² WHO, 'WHO Coronavirus (COVID-19) Dashboard' <<https://covid19.who.int>> accessed 28 June 2021.

³ Bundervoet T, Dávalos ME, Garcia N, 'The Short-Term Impacts of COVID-19 on Households in Developing Countries: An Overview Based on a Harmonized Data Set of High-Frequency Surveys' (2021) World Bank Policy Research Working Paper No. 9582 <<https://openknowledge.worldbank.org/handle/10986/35290>> accessed 26 June 2021.

⁴ *ibid.*

⁵ Çakmaklı C, *et al.*, 'The Economic Case for Global Vaccinations: An Epidemiological Model with International Production Networks' (2021) International Chamber of Commerce Research Foundation Study, 35–36 <<https://iccwbo.org/publication/the-economic-case-for-global-vaccinations>> accessed 26 June 2021.

pandemic's societal and economic effects will continue to be felt across the globe.

Pandemics usually pose global public health problems leading governments, health technology and pharmaceutical companies to increase efforts to invent ventilators, diagnostic tests, pharmaceutical drugs, disinfection technologies, vaccinations, personal protective equipment, and other medical technologies to combat infectious disease outbreaks.⁶ Many components of newly developed vaccines and related tools are protectible or protected by one or more patents.⁷

Patents are legal instruments intended to encourage innovation by providing exclusive rights to the inventor to help recover research and development (R&D) expenses in return for the disclosure of the invention. Between 1999 and 2018, over 11,000 inventions for technologies capable of combatting COVID-19 were patented globally, with 8,452 attributable to an institution.⁸ China and the United States (US) have largely led the growth among leading countries for pandemic-mitigating technologies.⁹

Under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO), patent owners may prevent others from making, using, offering for sale, selling, or importing a patented invention without their permission for a period of 20 years.¹⁰ However, several developing

countries and civil society advocates argue that intellectual property (IP) monopolies are blocking the rapid scale-up of vaccine manufacturing. The COVID-19 pandemic revealed issues of uncertainty and tension surrounding the role of IP rights, particularly patent laws, in hindering access to COVID-19 treatment and critical related products, from diagnostic kits to medical equipment, tracking systems, and other medical supplies.¹¹ The UN Committee on Economic, Social and Cultural Rights released a statement in April 2021 that the unequal global distribution of vaccines not only represents discrimination in terms of the right to access vaccinations at the global level, but also undermines progress on the UN Sustainable Development Goals (SDG), particularly SDG 3, 10, and 17.¹²

WAYS TO FACILITATE DEVELOPING COUNTRIES ACCESS TO COVID-19 TREATMENTS

Access to COVID-19 treatments can be facilitated through two contrasting avenues. On the one hand, there is voluntary provision of access via licensing agreements or collaborative mechanisms of innovation such as patent pools. Voluntary licensing refers to the practice of IP holders voluntarily granting licenses to their patents or other IP rights. The license usually sets quality requirements and defines markets where the licensee can sell the product(s).¹³ Another form of voluntary collaboration to embrace knowledge-sharing efforts in

⁶ Rutschman AS, 'The Intellectual Property of COVID-19' (2020) Saint Louis U Legal Studies Research Paper No. 2020-28 <<https://ssrn.com/abstract=3691239>> accessed 26 June 2021.

⁷ Rutschman AS, 'The Vaccine Race in the 21st Century' (2019) 61 Arizona L Rev 729.

⁸ Canadian Intellectual Property Office, 'Patenting to Fight Pandemics: The Canadian Story' (5 November 2020) <<https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04853.html>> accessed 26 June 2021.

⁹ *ibid.*

¹⁰ TRIPS Agreement (as amended on 23 January 2017, entered into force 23 January 2017), 15 April 1994, Marrakesh Agreement, Annex 1C, 1869 UNTS 299, Articles 28.1 and 33 <www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm> accessed 26 June 2021.

¹¹ Vijay SL, Fletcher ER, 'Gates Foundation: Technology Transfer, Not Patents Is Main Roadblock to Expanding Vaccine Production' (*Health Policy Watch*, 14 April 2021) <<https://healthpolicy-watch.news/patents-are-not-main-roadblock-to-expanding-vaccine-production-says-top-gates-foundation-official>> accessed 26 June 2021.

¹² UN Committee on Economic, Social and Cultural Rights, *Statement on universal affordable vaccination against coronavirus disease (COVID-19), international cooperation and intellectual property*, UN Doc E/C.12/2021/1 (23 April 2021)

<<https://digitallibrary.un.org/record/3921880?ln=en>> accessed 26 June 2021. See also OHCHR, 'UN expert says global coordination and more equitable sharing of COVID-19 vaccines key to recovery' (22 January 2021) <www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26683&LangID=E> accessed 26 June 2021.

¹³ Voluntary licenses are, in essence, private commercial contracts that enable third parties to sell generic versions of a patented product. In the past, voluntary licenses have been used to mitigate the impacts of several pandemics or, in some cases, used as a bargaining tool in response to threats of compulsory licensing. See Raju KD, 'Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries' (2017) 22 J IP Rights 23; Médecins Sans Frontières, 'Voluntary Licenses and Access to Medicines' (Technical brief, October 2020) <<https://msfaccess.org/voluntary-licenses-access-medicines>> accessed 26 June 2021.

response to the COVID-19 pandemic is the patent pools. They are defined as ‘an agreement between two or more patent owners to license one or more of their patents to one another or to third parties’.¹⁴ Patent pools can benefit innovation and competition by promoting the voluntary sharing of IP assets, improving the efficiency of developing goods and services, reducing transaction costs, and reducing the need to seek alternatives to existing patents.¹⁵

On the other hand, the non-voluntary mechanisms to facilitate access to COVID-19 treatments can be invoked in situations when a voluntary license agreement or collaboration is not viable. These non-voluntary mechanisms range from compulsory licensing under Article 31*bis* and the security exception under Article 73 of the TRIPS Agreement to the recently proposed COVID-19 waiver aiming to suspend IP rights related to the prevention, containment, or treatment of COVID-19.

This paper begins with underlining the danger of vaccine nationalism and outlines the need for equitable global access to treatment (II). The paper then explores two of the non-voluntary legal mechanisms that may be adopted by countries to facilitate access to COVID-19 treatment and medical technologies. First, it analyses the compulsory license system and the government use or the crown privilege for non-commercial use to reduce vaccine scarcity (III). Second, the paper examines the

TRIPS Waiver proposal submitted by India and South Africa to temporarily suspend certain TRIPS obligations related to the prevention, containment or treatment of COVID-19 (IV). The paper concludes with insights on the way forward for striking a balance between protecting IP rights through patent law and making knowledge transfer available in times of crisis (V).

2. VACCINE NATIONALISM

While the vaccines developed by several pharmaceutical companies seemed to be beacons of hope upon their creation, the world is facing a new wave of vaccine hoarding.¹⁶ Countries are prioritizing their national interests and acquiring stocks of vaccines and related technologies that exceed the necessary amounts for their populations. In February 2021, the UN Secretary-General declared that 10 countries had administered 75% of all vaccinations, while over 130 countries had not yet received a single dose of a COVID-19 vaccine.¹⁷ In December 2020, wealthy nations representing 14% of the world’s population had bought up to 53% of the most promising vaccines.¹⁸

Vaccine Nationalism, or the ‘my country first’ approach, occurs when governments sign agreements with pharmaceutical manufacturers to supply their own populations with vaccines ahead of the vaccines becoming available for other countries.¹⁹ These pre-

¹⁴ WIPO, ‘Patent Pools and Antitrust: A Comparative Analysis’ (March 2014) <www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf> accessed 26 June 2021; Contreras JL, *et al.*, ‘Pledging IP for COVID-19’ (2020) 38 *Nat Biotechnol* 1146.

¹⁵ In May 2020, the WHO and other partner organizations launched the COVID-19 Technology Access Pool (C-TAP) to facilitate access to COVID-19 health products. This voluntary patent pool, signed on to by 40+ countries, aims to leverage collective research and incentivize international cooperation by reducing license-related transaction costs. Implementing partners of C-TAP include the Medicines Patent Pool (MPP), the Open COVID Pledge and the Tech Access Partnership (TAP). See WHO, ‘How WHO C-TAP Works? Commitments to share knowledge, IP and data’ (27 October 2020) <www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap> accessed 26 June 2021.

¹⁶ See Felner C, ‘A Guide to Global COVID-19 Vaccine Efforts’ (*Council on Foreign Relations*, 27 April 2021) <www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts> accessed 26 June 2021.

¹⁷ UNSC, ‘Secretary-General Calls Vaccine Equity Biggest Moral Test for Global Community, as Security Council Considers Equitable Availability of

Doses’ (17 February 2021) <www.un.org/press/en/2021/sc14438.doc.htm> accessed 26 June 2021.

¹⁸ Oxfam International, ‘Campaigners warn that 9 out of 10 people in poor countries are set to miss out on COVID-19 vaccine next year’ (9 December 2020) <www.oxfam.org/en/press-releases/campaigners-warn-9-out-10-people-poor-countries-are-set-miss-out-covid-19-vaccine> accessed 26 June 2021. See also Mary Brophy Marcus, ‘Ensuring Everyone in the World Gets a COVID Vaccine’ (20 January 2021) <<https://globalhealth.duke.edu/news/ensuring-everyone-world-gets-covid-vaccine>> accessed 26 June 2021.

¹⁹ Vaccine Nationalism is different from Vaccine Diplomacy where vaccines are used to improve a country’s diplomatic relationship and influence with other countries. The vaccine is used as a vehicle to assist countries that may not otherwise have access to emerging vaccines. Vaccine Diplomacy allows some countries to strengthen bilateral and regional ties and enhance their international relations. See Balasubramanian S, ‘Vaccine Diplomacy: A New Frontier In International Relations’ (*Forbes*, 24 February 2021) <www.forbes.com/sites/saibala/2021/02/24/vaccine-diplomacy-a-new-frontier-in-international-relations/?sh=58642a6622bc> accessed 26 June 2021.

production agreements reserve a substantial number of emergent vaccines for domestic use or for a limited number of jurisdictions.²⁰ Several vaccine manufacturers received funding internationally from governments and public sector entities to develop a COVID-19 vaccine while providing the funding countries with preferential treatment such as the right to pre-purchase vaccines in development or priority access to emerging vaccines.²¹

Vaccine Nationalism can also, as Evenett, *et al.*, describe, take the form of overt export bans or limits to increase the domestic availability of vaccines at the expense of foreign supply.²² Faced with domestic vaccine shortages, several countries established a formal export control system to limit the commercial exports of COVID-19 vaccines out of their territory. In early March 2021, Italy and the European Union (EU) blocked a shipment of over a quarter million vaccine doses produced by AstraZeneca-Oxford destined for Australia from leaving the EU.²³ The EU is the only jurisdiction to introduce an export authorization regime for COVID-19 vaccines.²⁴ More recently, in April 2021, the Indian government temporarily banned the exports of the active pharmaceutical ingredients (API) and injections of the

anti-viral drug remdesivir due to the rise of COVID-19 cases in the country.²⁵

The export bans can also be less formal and could include administrative delays in shipments or using other regulations to prioritize domestic consumption.²⁶ For example, to accelerate mass domestic vaccinations, the US President invoked the Defense Production Act, allowing the government to control distribution and direct suppliers to fulfil certain contracts ahead of others.²⁷

Vaccine Nationalism is not a novel concept. During the H1N1 pandemic in 2009, developed countries directly negotiated pre-production contracts with manufacturers of H1N1 vaccines. This resulted in the UN being unable to purchase vaccines, causing a delay of global distribution and many lives being unnecessarily lost.²⁸ After the WHO requested donations, Australia, Canada, the US and six other countries agreed to share 10% of their H1N1 vaccines, only after they first met their domestic needs.²⁹ Similarly, in the context of the current pandemic, the WHO Director-General has warned that if vaccine nationalism continues, it could exacerbate inequalities

²⁰ Rutschman AS, 'The Reemergence of Vaccine Nationalism' (2020) Saint Louis U Legal Studies Research Paper No. 2020-16 <<https://ssrn.com/abstract=3642858>> accessed 26 June 2021.

²¹ Thomas K, 'Sanofi and GlaxoSmithKline Snag Biggest Coronavirus Vaccine Deal Yet' (*The New York Times*, 31 July 2020) <www.nytimes.com/2020/07/31/health/covid-19-vaccine-sanofi-gsk.html> accessed 26 June 2021; Bloomberg, 'COVID-19 Deals Tracker: 9.6 Billion Doses Under Contract' (9 March 2021) <<https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/contracts-purchasing-agreements.html>> accessed 26 June 2021.

²² Evenett SJ, *et al.*, 'The Covid-19 Vaccine Production Club: Will Value Chains Temper Nationalism?' (2021) World Bank Policy Research Working Paper No. 9565 <<https://openknowledge.worldbank.org/handle/10986/35244>> accessed 26 June 2021.

²³ The Associated Press, 'EU, Italy halt AstraZeneca vaccine shipment to Australia' (*The Canadian Broadcasting Corporation*, 4 March 2021) <www.cbc.ca/news/world/italy-australia-vaccine-exports-1.5937467> accessed 26 June 2021.

²⁴ The European export control regime for COVID-19 put in place a measure requiring vaccine exports to be subject to an authorisation by the EU Member States. The objective of this measure is to ensure timely access to COVID-19 vaccines for all EU citizens and to address concerns over the lack of transparency around the ways some companies are operating in relation to vaccine exports outside the EU. See Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 making the

exportation of certain products subject to the production of an export authorisation [2021] OJ L 31I (EU Regulation).

²⁵ Global Trade Alert, 'India: Export of remdesivir medication banned' (11 April 2021, updated 14 June 2021) <www.globaltradealert.org/intervention/85106/> accessed 26 June 2021; Reuters, 'India bans exports of anti-viral drug Remdesivir as COVID-19 cases surge' (11 April 2021) <www.reuters.com/world/india/india-bans-exports-anti-viral-drug-remdesivir-covid-19-cases-surge-2021-04-11> accessed 26 June 2021.

²⁶ Evenett SJ, 'Export Controls on COVID-19 Vaccines: Has the EU Opened Pandora's Box?' (2021) 55 *Journal of World Trade* 397.

²⁷ The Defense Production Act gives the US President powers to allocate "materials, services, and facilities" and award contracts that take priority over any other contract to "promote the national defense." In extreme situations, the law can also be used to prevent companies from exporting certain goods to keep them within the US territory. See Isaac Stanley-Becker, 'Biden harnesses Defense Production Act to speed vaccinations and production of protective equipment' (*The Washington Post*, 5 February 2021) <www.washingtonpost.com/health/2021/02/05/biden-vaccines-tests-gloves> accessed 26 June 2021; *The Defense Production Act of 1950*, Pub L No. 81-774, 64 Stat 798 (codified as amended at 50 USC § 4501-4568 (2018)) (United States).

²⁸ Phelan AL, *et al.*, 'Legal agreements: barriers and enablers to global equitable COVID-19 access' (2020) 396 *The Lancet* 800.

²⁹ Bollyky TJ, Bown CP, 'The Tragedy of Vaccine Nationalism: Only Cooperation Can End the Pandemic' (2020) 99 *Foreign Aff* 96.

that lower-income countries already face in terms of acquiring doses.³⁰

The re-emergence of vaccine nationalism will have devastating global health and economic consequences on both the Global South and the Global North.³¹ The spread of the pandemic in the South without sufficient vaccines will disturb cross-border supply chains and global trade.³² Furthermore, inoculating the population of a single country may not lead to sustainable protection if the virus is able to spread and mutate somewhere else unchecked.³³ The urgent need for COVID-19 treatments in the Global South has once again raised questions about the effectiveness of non-voluntary IP mechanisms in responding to global challenges.

3. COMPULSORY LICENSE AND GOVERNMENT USE

Under the TRIPS Agreement, WTO Members have several obligations in relation to patents. Members are obligated to provide patent protection for any invention, whether it is a product (such as medicine, drugs, vaccines) or a process (such as a method of producing the chemical ingredients for a medicine), so long as it is novel, involves an inventive step, and is capable of industrial application.³⁴

Members may invoke a regulatory exception set out in Article 30 to permit the use of patented inventions for research in order to understand inventions more fully or to obtain marketing approval from public health authorities. Once a patent is granted, compulsory licensing and government use of patented inventions without the voluntary authorization of the right holder may be permitted in circumstances such as national

emergencies, subject to the provisions in Article 31 which protect the legitimate interests of the right holder.³⁵ This section briefly examines the historical background of non-voluntary licensing and provides examples of past and present use of compulsory licenses in times of crisis. This section concludes with advancing a proposal for non-voluntary licensing of trade secrets.

A. RATIONALE AND HISTORICAL BACKGROUND OF COMPULSORY LICENSING

A compulsory license is an authorization given for public policy reasons by a national authority to a natural or legal person for the exploitation of the subject matter protected by a patent without the right holder's authorization.³⁶ Compulsory licenses are a legitimate and effective tool in supporting equitable distribution of medicines, access to COVID-19 treatments and patented technologies for research. However, there is concern that compulsory licensing may not be a sustainable method of encouraging long-term innovation as it may disincentivize private investment in R&D.³⁷ In the meantime, compulsory licensing might provide solutions to the right holder's exclusive rights. Nevertheless, access to vaccine technologies and information sharing of undisclosed information remains a critical and fundamental problem that needs additional measures.

The rationale for non-voluntary licensing related to patent law resides in prioritizing the public's interest of accessing an invention over the private interests of patent owners seeking to exploit their exclusive rights. Failure to exploit the invention in the countries granting patents can result in states ordering a compulsory license as a sanction for non-working patents in their territory or

³⁰ Blum B, 'Threat of vaccine nationalism reinforces global need for better pandemic planning' (*The Canadian Broadcasting Corporation*, 31 January 2021) <www.cbc.ca/news/health/vaccine-nationalism-pandemic-planning-1.5894323> accessed 26 June 2021.

³¹ Abbas MZ, 'Practical Implications of 'Vaccine Nationalism': A Short-Sighted and Risky Approach in Response to COVID-19' (2020) South Centre Research Paper No. 124 <www.southcentre.int/research-paper-124-november-2020> accessed 26 June 2021; Bollyky (n 29).

³² Çakmaklı C (n 5).

³³ Rutschman AS, 'The Reemergence of Vaccine Nationalism' (n 20).

³⁴ TRIPS Agreement, Article 27.1.

³⁵ TRIPS Agreement, Articles 30 and 31.

³⁶ Correa CM, 'Compulsory Licensing: How to Gain Access to Patented Technology' in Krattiger A, et al. (eds), *IP Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR (Oxford, UK) and PIPRA (Davis, USA) 2007) <www.iphandbook.org/handbook/ch03/p10/> accessed 26 June 2021.

³⁷ Koukakis N, 'Countries worldwide look to acquire the intellectual property rights of COVID-19 vaccine makers' (*CNBC*, 22 January 2021) <www.cnbc.com/2021/01/22/countries-look-to-acquire-the-ip-of-vaccine-makers-to-fight-pandemic.html> accessed 26 June 2021.

preventing abuses of the patentee's exclusive rights. Historically, compulsory licensing of patented inventions existed in 15th century Venetian law and in British law in the 19th century.³⁸ In order to defend the public interest, the Crown reserved the right to use patented inventions without compensation or consent of the patent holder. The concept was later introduced in the multilateral system in the Paris Convention for the Protection of Industrial Property during the 1925 Hague revision.³⁹ However, recourse to compulsory licensing was only allowed after a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever date came second.⁴⁰

The opposing views taken by developed and developing countries in the 1980s and early 1990s on the powers that governments should possess to issue these compulsory licenses interrupted all efforts to revise the Paris Convention.⁴¹ The failure of these Diplomatic efforts persuaded technology-exporting countries to link future negotiations concerning international IP protection to the Multilateral Trade Negotiations.⁴²

The Uruguay Round (1986-1994) became the next available forum to review the compulsory licensing mechanisms. The negotiation concluded with the signature of the Marrakesh Agreement Establishing the WTO in 1994 and its Annex 1C, the TRIPS Agreement.⁴³ According to the TRIPS Agreement, the patentee's exclusive rights can be waived in certain circumstances where it is in the public's interest, often involving non-commercial government authorization or use.

Article 31 sets forth the preconditions and procedural requirements for issuing a compulsory licence.⁴⁴ Although the TRIPS Agreement does not explicitly use the term 'government use', many domestic laws – mainly in Commonwealth countries⁴⁵ – distinguish between a compulsory license and the English common law regime, the Crown's privilege, or the public non-commercial use of Article 31(b). The compulsory license procedure can be initiated either by a government entity or upon a third party request. A compulsory licence is issued only after an applicant has attempted to negotiate a voluntary licensing agreement on reasonable commercial terms with the patent holder, and was unsuccessful within a reasonable period of time, with the exception of cases of

³⁸ In 1474, the Venetian Patent Act reserved a compulsory license to the state to manufacture, use, and distribute the patent when needed. The compulsory assignment of patents that failed to be used by the patentee was also codified in Venetian law. See Mandich G, 'Venetian Patents (1450-1550)' (1948) 30 J Pat Off Soc'y 166, 194 and 206-07; Ulf Anderfelt, *International-Patent Legislation and Developing Countries* (Martinus Nijhoff 1971). Beginning in 1919, UK "licences of right" provisions gave patentees the ability to voluntarily endorse their patents or required patentee endorsement by law (remedying abuse), as being available for third party exploitation. The terms were either pre-fixed by the patentee or determined by the Comptroller-General of Patents. See Brennan DJ, 'The First Compulsory Licensing of Patents and Copyright' (2017) 17 Legal History 1, 2; Yang CC, 'Crown Use and Government Use' in Hilty RM, Liu KC (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (22 MPI Studies on IP and Competition Law, Springer Berlin 2015).

³⁹ According to Article 5A(2), Paris Union Members with the right to take legislative measures for granting compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by the patent. Paris Convention (as amended on 28 September 1979), 20 March 1883, Article 5A(2) <<https://wipo.int/en/treaties/textdetails/12633>> accessed 26 June 2021; Brennan DJ (n 38) 3, citing Ricketson S, *The Paris Convention for the Protection of Industrial Property: A Commentary* (Oxford University Press 2015) 82.

⁴⁰ Such a compulsory license shall be non-exclusive and shall not be transferable. See Paris Convention, Article 5A(4).

⁴¹ Reichman JH, Hasenzahl C, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an*

Overview of the Practice in Canada and the USA (UNCTAD and ICTSD 2003) <https://unctad.org/system/files/official-document/ictsd2003ipd5_en.pdf> accessed 26 June 2021; Reichman JH, 'Compulsory licensing of patented pharmaceutical inventions: evaluating the options' (2009) 37(2) J Law Med Ethics 247.

⁴² *ibid.*

⁴³ *ibid.*; Marrakesh Agreement, 15 April 1994 (entered into force 1 January 1995), 1867 UNTS 154 <www.wto.org/english/docs_e/legal_e/04-wto_e.htm> accessed 26 June 2021.

⁴⁴ These conditions begin by requiring that prior to the use of the patented technology, the applicant must have made some effort to obtain consent from the patent holder on reasonable commercial terms and was not successful in obtaining voluntary authorization of a licence within a reasonable time period. These requirements may be waived in cases of public non-commercial use, situations of extreme urgency or national emergency, or remedying anti-competitive practices. Regardless, the patent holder should be notified as soon as reasonably possible and should be paid equitable remuneration, considering the economic value of the compulsory licence authorization. The duration and scope of the uses are limited to the authorized purpose and are non-exclusive and non-assignable.

⁴⁵ For US Patent Law, see Governmental authorization: 28 USC § 1498 (2011); Compulsory licensing: *Bayh-Dole Act*, 35 USC § 200-12 (2011). See also Patents Act 1977, ss 55-59 (United Kingdom); Patents Act 1990, ss 163-69 (Australia); *Patent Act*, RSC 1985, c P-4, ss 19 - 19.4 and 21.02-21.2.

extreme urgency or a national emergency. On the other hand, a government use is a form of compulsory licence that can only be initiated by the government or its entities. This form of licensing is issued to acquire a patented drug or process to be made available for public interest reasons through domestic productions and importations.⁴⁶ This is referred to as ‘public non-commercial use’. Under the government use license, prior consent or negotiations with the patent holder are not required, however, adequate compensation to the patent holder is still required, regardless of the reason for the compulsory licence (Article 31(b), (h)).

The post-TRIPS period witnessed considerable challenges related to the implementation of Article 31 in countries with insufficient or no capacity to manufacture the drugs in question. The TRIPS provisions initially restricted the use of compulsory licenses to serve predominantly for domestic market supply. Furthermore, countries with manufacturing capacity could not assist other countries by issuing a compulsory license with the view to export the drug.

For several years, this restriction presented a barrier to facilitating access to essential medicines and technology for developing countries and least developed (LDCs) that lacked the means of domestically producing these much-needed medications.⁴⁷ In the 2001 WTO Ministerial Conference, the Doha Declaration on TRIPS and Public

Health reaffirmed the rights of Members to utilize TRIPS flexibilities to promote access to medicines for all.⁴⁸

The Doha Declaration opened a pathway for WTO Members with insufficient domestic manufacturing capabilities to produce medicines.⁴⁹ Paragraph 5 of the Doha Declaration reaffirmed the right of each Member to ‘determine what constitutes a national emergency or other circumstances of extreme urgency.’ Paragraph 5(c) specifically mentions that ‘public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.’ Since the COVID-19 pandemic is, in fact, a public health crisis, the use of compulsory licensing will therefore be justified.

The Declaration also addressed the constraint on exports set out in Article 31(f). The TRIPS Council adopted a waiver in August 2003, which became permanent in December 2005, allowing compulsory licensing for the purpose of producing and exporting generic versions of pharmaceutical products to Members with insufficient domestic manufacturing capacity.⁵⁰ This led to the insertion of Article 31*bis* into the TRIPS Agreement, which entered into force on 23 January 2017.⁵¹

⁴⁶ Love JP, ‘Recent examples of the use of compulsory licenses on patents’ (2007) Knowledge Ecology International Research Note 2007:2 <www.keionline.org/book/kei-rn-2007-2-recent-examples-of-compulsory-licensing-of-patents> accessed 26 June 2021; Khor M, *Compulsory License and “Government Use” to Promote Access to Medicines: Some Examples* (Third World Network 2014) 3.

⁴⁷ Kumar S, ‘Compulsory Licensing of Patents During Pandemics’ (2021) <<https://dx.doi.org/10.2139/ssrn.3636456>> accessed 26 June 2021.

⁴⁸ In the context of public health, clause 4 reads ‘We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.’ See WTO, ‘Declaration on the TRIPS agreement and public health’ (Ministerial Conference, Fourth Session, Doha, 20 November 2001), WTO Doc WT/MIN(01)/DEC/2

<www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 26 June 2021 (Doha Declaration).

⁴⁹ See Abbott FM, Reichman JH, ‘The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions’ (2007) 10 *Journal of International Economic Law* 921; Wong H, ‘The case for compulsory licensing during COVID-19’ (2020) 10(1) *J Glob Health* 010358-1.

⁵⁰ WTO, *Amendment of the TRIPS Agreement*, Decision of 6 December 2005, WT/L/641; WTO, ‘TRIPS and public health: notifications’ <www.wto.org/english/tratop_e/trips_e/public_health_e.htm> accessed 26 June 2021.

⁵¹ Article 31*bis* states that the obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

B. PAST EXPERIENCES WITH PATENT COMPULSORY LICENSING

Following the TRIPS Agreement and the Doha Declaration, the non-voluntary authorization to use patents has been invoked in both developed and developing economies, with a majority of licenses issued in relation to HIV/AIDS treatments.⁵² In doing so, countries have been able to significantly lower costs for critical healthcare and medicine access.

Between 1969 and 1992, Canada made extensive use of non-voluntary licensing of patented inventions to import or manufacture medicines.⁵³ Canada largely relied on statutory regulation for both abuse of patent rights (failure to exploit patents locally) and public interest objectives.

In the 2000s, compulsory licensing and government use licenses were used in the HIV/AIDS epidemic to improve access to antiretroviral drugs. Brazil (2003), Ecuador, Ghana (2005), Guinea (2005), Indonesia (2004), Malaysia (2004), Mozambique (2004), Thailand (2006), Swaziland (2004), Zambia (2004), and Zimbabwe (2004) each issued at least one compulsory or government use license for one or more antiretroviral drugs to respond to the spread of HIV/AIDS in their respective countries.⁵⁴ In 2007, Rwanda made use of paragraph 6 of the Doha

Declaration and issued a compulsory license for the HIV/AIDS drug TriAvir that it could not produce locally. A few months later, Canada issued a compulsory license allowing Apotex, a Canadian pharmaceutical company, to use nine patented inventions for manufacturing TriAvir for Rwanda.⁵⁵ More recently, the German Federal Court of Justice in 2017 confirmed a compulsory license granted in preliminary proceedings as a defence against alleged patent infringement⁵⁶ for an antiretroviral drug for people living with HIV/AIDS.⁵⁷ These past experiences can be leveraged to respond to COVID-19 on a global scale to provide access to affordable treatment options through compulsory licensing.

C. CURRENT USE OF COMPULSORY LICENSING FOR COVID-19

With the spread of COVID-19 around the globe, countries have taken various legislative and regulatory measures to facilitate access to patented medicines and equipment or to ensure the possibility of issuing compulsory licenses.⁵⁸ In March 2020, Israel was the first country to issue a coronavirus-related compulsory license as part of their COVID-19 response.⁵⁹ This government intervention came as a result of insufficient supplies of an HIV drug, initially viewed as a possible treatment for COVID-19, from the American pharmaceutical company AbbVie. The government obtained the right to import generic versions

⁵² Approximately 20 countries have either issued or publicly entertained issuing a compulsory license for one or more pharmaceutical products since the founding of the WTO. See Reed Beall, Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis' (2012) 9(1) PLoS Med e1001154 <<https://doi.org/10.1371/journal.pmed.1001154>> accessed 26 June 2021; Wong (n 56).

⁵³ The Canadian government amended the *Patent Act* in 1969 to allow for compulsory licensing to import pharmaceuticals. See Joel Lexch in, 'Pharmaceuticals, Patents, and Politics: Canada and Bill C-22' (1993) 23 Int J Health Serv 147. See also Reichman, *Non-voluntary Licensing of Patented Inventions* (n 46) 20.

⁵⁴ See Beall (n 60), Wong (n 56), Hilty (n 43) 64.

⁵⁵ WTO, 'Canada is first to notify compulsory licence to export generic drug' (4 October 2007) <www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm> accessed 26 June 2021.

⁵⁶ The German Federal Patent Court is a specialized IP court composed of judges with both legal and technical training and dealing with industrial property rights, such as patents, trademarks and designs. It is also the competent court to issue compulsory licenses. The Federal Patent Court's decisions can be appealed to the Federal Court of Justice. See Patent Act

(Patentgesetz, PatG) as published on 16 December 1980 (1981 Federal Law Gazette I, 1), as amended by Article 4 of the Act of 8 October 2017 (2017 Federal Law Gazette I, 3546), s 24 (Germany).

⁵⁷ Bundesgerichtshof [BGH] [Federal Court of Justice] 11 July 2017, X ZB 2/17 Entscheidungen des Bundesgerichtshofes in Zivilsachen [BGHZ] 215, 214 (Germany) (Merck Sharp and Dohme Ltd v Shionogi and Co Ltd). See also Christoph Spennemann, Clara Warriner, 'Compulsory license in Germany: Analysis of a landmark judicial decision' (2021) South Centre Policy Brief No. 91 <www.southcentre.int/policy-brief-91-april-2021> accessed 26 June 2021.

⁵⁸ Domestic and regional IP offices have also taken administrative measures in response to the COVID-19 pandemic such as deadline extensions, remote work, fee relief, etc. This paper does not cover these administrative measures and focuses only on the legislative and regulatory measures. The operational changes and measures taken by national and regional IP offices can be viewed on WIPO, 'COVID-19 IP policy tracker' <www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/ipo-operations> accessed 28 June 2021.

⁵⁹ Kass D, 'Israel Defies AbbVie IP To Import Generic Drugs For COVID-19' (Law360, 19 March 2020) <www.law360.com/articles/1255079/israel-defies-abbvie-ip-to-import-generic-drugs-for-covid-19> accessed 26 June 2021.

of Ritonavir/Lopinavir, branded as Kaletra, from India for the sole purpose of treating COVID-19 patients. While most of the vaccination in Israel was carried out with vaccines from leading pharmaceutical companies (Pfizer, Moderna, etc.), this move has created a significant pressure on vaccine producers to provide an early access and to guarantee the supply of COVID-19 treatments in the country.

Many governments have introduced emergency legislation in relation to IP rights to ensure the opportunity to issue compulsory licenses in response to the COVID-19 pandemic. The goal of these regulatory interventions is to clarify the current regulatory framework in the country, reiterate the opportunities for research and experimental use, and facilitate the process of obtaining a compulsory license to protect public health. In collaboration with the European Medicines Agency and the European Medicines Regulatory Network, the European Commission developed guidelines for stakeholders on adaptations to regulatory frameworks to address challenges arising from the COVID-19 pandemic, with a particular focus on crucial medicines for treating COVID-19 patients.⁶⁰

Canada was among the first movers to amend its domestic compulsory licensing system through emergency legislation titled the *COVID-19 Emergency Response Act*.⁶¹ Part 12 of the emergency legislation amended the Patent Act by adding section 19.4 to the compulsory license and government use regime, accelerating and simplifying the application process. Under the new section, the government and any person specified by the government in the application can obtain a one year licence to ‘make, construct, use, and sell a

patented invention to the extent necessary to respond to the public health emergency’.⁶² The license issued is non-transferable and will be valid for one year from the granting date or once the Minister of Health notifies the Commissioner that the authorization is no longer necessary, whichever comes first.⁶³ According to the new measures, the Canadian government can issue compulsory licenses without protracted negotiations over the terms of access to vaccines or other related technologies.⁶⁴ DeBeer and Gold raised two main concerns with the Canadian measures. First, the one year authorization is restrictive and can be uneconomical for companies to start production on generics.⁶⁵ Second, Canada’s compulsory licensing provisions are likely more useful for existing devices or the new use of known drugs rather than for new vaccines or antivirals.⁶⁶ In other words, the measures can be used to facilitate access to equipment and tools already in the market but likely may not apply to any new vaccine(s) that might emerge from ongoing R&D as patent applications generally take years to be examined and granted by the patent office. Regardless of the potential benefits or drawbacks, the amendment included a sunset clause that expired at the end of September 2020 and was not renewed or extended.

In Europe, France enacted the Emergency Law No. 2020-290 dated 23 March 2020, introducing Article L3131-15 into the Public Health Code to combat the COVID-19 pandemic. This gave extraordinary powers to the French Prime Minister, enabling him to, amongst other things, bypass the general provisions in the IP Code to impose compulsory licences where necessary.⁶⁷ Germany adopted similar provisions in the Act on the Protection of the Population in the Event of an Epidemic Situation of

⁶⁰ European Medicines Agency, ‘Notice to Stakeholders: Questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic’ (European Commission, Heads of Medicines Agencies and European Medicines Agency, 10 April 2020) <www.ema.europa.eu/en/news/guidance-regulatory-requirements-context-covid-19-pandemic> accessed 26 June 2021.

⁶¹ *COVID-19 Emergency Response Act*, SC 2020, c 5 (Canada).

⁶² *Patent Act*, RSC 1985, c P-4, s 19.4, as amended by SC 2020, c 5, s 15.

⁶³ *ibid* s 19.4(3).

⁶⁴ Clavette C, de Beer J, ‘Patents Cannot Impede Canada’s Response to COVID-19 Crisis’ (*Centre for International Governance Innovation*,

6 April 2020) <www.cigionline.org/articles/patents-cannot-impede-canadas-response-covid-19-crisis> accessed 26 June 2021.

⁶⁵ de Beer J, Gold ER, ‘International Trade, Intellectual Property, and Innovation Policy: Long-Term Lessons from the COVID-19 Crisis’ in Flood CM, *et al.* (eds), *Vulnerable: The Law, Policy and Ethics of COVID-19* (University of Ottawa Press 2020) 582.

⁶⁶ *ibid*.

⁶⁷ Loi No. 2020-290 du 23 mars 2020 d’urgence pour faire face à l’épidémie de COVID-19 (France, Emergency Law No. 2020-290 of 23 March 2020).

National Importance on 27 March 2020, which gave the Federal Ministry of Health additional powers to invoke Section 13(1) of the German Patent Act and limit patent rights for certain inventions to be used in the interest of public welfare or national security.⁶⁸

Both public welfare and security concerns can be cited during a pandemic to justify the issue of a compulsory license. For example, the Russian Federation issued an ordinance for a compulsory license for inventions related to the production of remdesivir on 31 December 2020.⁶⁹ According to Decree 3718-r, Pharmasintez JSC, a Russian generic company, was granted a compulsory one year license to use Gilead's patents, subject to fair compensation.⁷⁰ The Russian generic manufacturer filed a request with the government for a compulsory license after a few unsuccessful attempts to obtain a voluntary license from Gilead. In Latin America, the National Assemblies of both Chile and Ecuador requested their respective governments to grant compulsory licenses and facilitate access to vaccines, drugs, diagnostics, and other technologies related to the prevention and treatment of COVID-19.⁷¹

The COVID-19 pandemic has led to increased demand for therapeutics, vaccines, and diagnostics worldwide, especially among developing countries and LDCs. As a result, Article 31*bis* made the use of compulsory licenses more accessible and opened the door to using them for exporting pharmaceutical products to countries that lack domestic manufacturing capacity. However, with the

perceived need for compulsory licenses comes the problem of accessibility to undisclosed information necessary to manufacture the licensed technologies.

D. COMPULSORY TRADE SECRETS LICENSING

While the use of compulsory licensing might allow access to vaccine technologies and provide a solution to the exclusive rights provided to the patent holder, undisclosed information that encompasses the information needed to manufacture and distribute medical treatments remains another significant obstacle to access COVID-19 medical treatments.⁷²

Undisclosed information, including both trade secrets and test data submitted to government agencies, covers information that can range from genomic data and results of clinical trials,⁷³ to manufacturing know-how and research dead-ends.⁷⁴ Unless a trade secrets owner licenses the information, the secret remains locked up by the owner.

The current system of compulsory licensing is limited to granted patents that protect COVID-19 medical treatments against fulfilling certain conditions, and there is no equivalent mechanism in IP laws to oblige trade secrets owners to share their technology.⁷⁵ Therefore, there is a need for compulsory trade secrets licensing in the interest of global public health crises that allows researchers and governments to access the protected information.⁷⁶ Meanwhile, trade secrets owners will be

⁶⁸ WIPO, 'Germany: Act on the Protection of the Population in the Event of an Epidemic Situation of National Importance' (27 March 2020) <www.wipo.int/news/en/wipolex/2020/article_0008.html> accessed 28 June 2021.

⁶⁹ WIPO, 'COVID-19 IP Policy Tracker' (n 66).

⁷⁰ Gowling WLG, 'Russia, February 2021: Update on Pharma Regulatory Issues' (26 February 2021) <<https://gowlingwlg.com/en/insights-resources/articles/2021/update-on-pharma-regulatory-russia-2021>> accessed 28 June 2021.

⁷¹ WIPO, 'COVID-19 IP Policy Tracker' (n 66); Avelina Ponce, 'Ecuador: patents, compulsory licences and the COVID-19' (*International Bar Association*) <www.ibanet.org/article/7c9b53ca-3240-4d6e-9e5c-61bcde61b0ce> accessed 28 June 2021.

⁷² Undisclosed information provides an economic or competitive advantage to their owner and are unlimited in time as long as the conditions for its protection continue to be met.

⁷³ According to Article 39(3): "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use".

⁷⁴ Levine DS, 'COVID-19 Trade secrets and information access: an overview', (*Infojustice.org*, 10 July 2020), <www.infojustice.org/archives/42493> accessed 26 June 2021.

⁷⁵ Abbas MZ, 'Treatment of the novel COVID-19: why Costa Rica's proposal for the creation of a global pooling mechanism deserves serious consideration?' (2020) 7 *Journal of Law and the Biosciences* 1.

⁷⁶ Gurgula O, Hull J, 'Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer' (2021) *Journal of IP Law & Practice*.

compensated for the investments conducted to develop and compile this undisclosed information.⁷⁷ The compulsory trade secrets license can find grounds in paragraph 4 of the Doha Declaration which states that ‘the TRIPS Agreement does not and should not prevent members from taking measures to protect public health’. Unlike trademarks, there is no specific exclusion of a compulsory trade secrets license in the TRIPS Agreement.⁷⁸

Governments can then grant a hybrid compulsory licence for patents and associated undisclosed information required to manufacture the critical and lifesaving technology. Independent discovery and reverse engineering can also complement the government efforts to obtain access to information and data needed to manufacture the vaccines and other medical technologies.

Like with compulsory patent licensing, the implementation of compulsory trade secrets licensing could find grounds in the ‘public interest’ concept to justify the disclosure of undisclosed information. A sufficient public interest has been recognized by courts in the US to grant access to trade secrets. In *Detroit Medical Center v GEAC Computer Systems*,⁷⁹ the court found that a general interest in confidentiality agreements was outweighed by the public interest of receiving adequate medical care and ordered the trade secret holder to provide access to the confidential information. In Europe, the 2016 Trade Secrets Directive exempted the national rules requiring trade secret holders to disclose for reasons of public interest from the protection against the unlawful acquisition, use and disclosure of trade secrets.⁸⁰

This public interest factor may be relevant in terms of the urgency of COVID-19 and the global interest in vaccine

production. A public interest consideration for compulsory trade secrets licensing does not conflict with the TRIPS flexibilities to protect public health and can be used as a ground to justify the grant of a compulsory license similar to the government use of patents.

Due to the complex nature of trade secrets, the non-voluntary license of trade secrets should be exclusive to the licensee, non-transferable to third parties, limited in time, bounded by the same requirements for protection, and must include a precise definition of the licensed subject matter. The confidential information should be destroyed at the end of the license term and the government could be liable to the trade secrets owner against any breach of the confidential information even after the license term.

With demonstrated success of using compulsory licenses in the past, countries have seen the direct connection between the need for finding affordable and timely access to medical resources and the overall societal impact against the rights of patent owners. Some may argue that having these types of provisions within international agreements could lead towards a slippery slope in devaluing IP protection and disincentivizing research and innovation. However, the supporting provisions in the Doha Declaration and use of compulsory licensing are clearly intended to be used sparingly and only when necessary to protect public health. The novel COVID-19 pandemic exemplifies the type of emergency that would warrant the use of compulsory licensing for global knowledge transfer. Ultimately, while the ability of governments to determine the grounds upon which they may grant compulsory licensing is domestically driven, the TRIPS Agreement should be revised to include provisions authorizing the issue of a compulsory licensing of trade secrets.

⁷⁷ Levine DS, ‘Trade secrets and the battle against COVID’ (2020) 15 Journal of IP Law & Practice, No. 11, pp. 849.

⁷⁸ Article 21 states that it is ‘understood that the compulsory licensing of trademarks shall not be permitted’.

⁷⁹ *Detroit Medical Center v GEAC Computer Systems Inc*, 103 F. Supp. 2d 1019 (E.D. Mich. 2000).

⁸⁰ Article 1(2)(b) of the Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016L0943>> accessed 26 June 2021.

4. TRIPS WAIVER

Globally, there has been increasing concern over affordable, equitable access to treatments, diagnostics, and especially vaccines for COVID-19. Accordingly, on 2 October 2020, India and South Africa submitted a proposal to the WTO for a temporary waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19 (the Waiver).⁸¹ The proposal allows WTO Members to not enforce or implement obligations pertaining to four sections of the TRIPS Agreement, with a view to facilitating greater access to COVID-19 related technologies: Section 1 on copyright; Section 4 on industrial designs; Section 5 on patents; and Section 7 on the protection of undisclosed information.⁸² The Waiver is meant to be a temporary measure until widespread vaccination is implemented worldwide and global herd immunity has been achieved.⁸³

Since its introduction, the proposal gained widespread support from WTO Members and non-governmental organizations (NGO).⁸⁴ The prospect of a waiver has once again thrown the international norms of the patent system and its impacts on health and technological

development to center stage. The current proposal created two different camps: on the one hand, those opposed to the Waiver who prioritize the importance of preserving incentives for research and innovation, and on the other hand, those in favor of granting the Waiver to meet global needs and secure equitable access to affordable health products and technology. The following section will first explore the arguments raised in support of the Waiver, followed by those in opposition.

The primary justification behind the Waiver proposal is that it would be an effective response to the global need for affordable medical products and technology transfer during the pandemic, given the limitations in the TRIPS Agreement that hamper and prohibit developing countries from taking advantage of existing flexibilities. The goal of the Waiver, therefore, is to 'ensure that complications arising from IP rights protection do not delay response or lead to a suboptimal response from the countries around the world affecting lives of all people'.⁸⁵ Past experiences demonstrated that patent rules impeded developing countries' access to affordable vaccines, such as pneumococcal conjugate vaccines (PCV), and human papillomavirus (HPV) vaccines, which delayed generic alternatives.⁸⁶ These

⁸¹ WTO, *Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19* (October 2020), IP/C/W/669

<<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>> accessed 26 June 2021 (TRIPS Waiver proposal).

⁸² The initial proposal submitted on 2 October 2020 included reference to related rights. However, the revised decision text submitted to the TRIPS Council on 25 May 2021 excluded the protection of performers, producers of phonograms and broadcasting organizations from being waived. The revised decision text was submitted at the request of the delegations of the African Group, Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, Venezuela and Zimbabwe. See WTO, *Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, Revised Decision Text (May 2021), IP/C/W/669/Rev.1

<<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>> accessed 26 June 2021.

⁸³ The revised text added a paragraph on the duration of the Waiver and proposed that the General Council assesses the existence of the exceptional circumstances justifying the Waiver after a minimum period to determine the date of termination. Paragraph 2 of the revised text states that 'this waiver shall be in force for at least three years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver'.

⁸⁴ On 16 October 2020, Kenya and Eswatini became official cosponsors of the proposal. Approximately 100 countries supported the Waiver in the following months in addition to several intergovernmental civil societies. More recently, Canada, US, Russia, China, and other developed countries that initially opposed the Waiver joined the proposal. Nevertheless, the EU submitted on 4 June 2021 a proposal seeking WTO Members to commit to a multilateral trade action plan to ensure fair and universal access by expanding the production of COVID-19 treatments and vaccines. The EU's proposal urges governments worldwide to achieve three goals: (1) Ensure that COVID-19 vaccines, treatments, and their components can cross borders freely; (2) encourage producers to expand their production, while ensuring that those countries most in need of vaccines receive them at an affordable price; and (3) facilitate the use of compulsory licensing within the TRIPS Agreement. The TRIPS Agreement already provides this flexibility, which is a legitimate tool that can be used swiftly where needed. See WTO, *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property* (4 June 2021), IP/C/W/680 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W680.pdf&Open=True>> accessed 24 June 2021.

⁸⁵ WTO, *Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19 in Document IP/C/W/671* (15 January 2021), IP/C/W/673 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W673.pdf&Open=True>> accessed 26 June 2021.

⁸⁶ Médecins Sans Frontières (MSF), 'A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer

study on the Oxford/AstraZeneca vaccine confirmed that the majority of the money to develop the vaccine came from UK government departments, British and American scientific institutes, the European Commission and charities including the Wellcome Trust.⁹⁷

WTO Members opposed to the Waiver have advanced several arguments. First, they argue that there is no concrete evidence indicating that IP rights have been a real barrier to accessing COVID-19 related technologies. There are various major factors hindering access to COVID-19 treatments and technologies, including the lack of manufacturing capacity (facilities, equipment, raw materials and storage) and researcher capability to implement the knowledge transferred, and these factors will not be resolved by waiving IP rights.⁹⁸ Certain technology related to COVID-19 can be easily replicated and produced for the urgent need of developing countries, but not the manufacturing of COVID-19 vaccines, which requires specialized knowledge and large investments. Given the low prices of generic vaccines, advanced generic manufacturers in a limited number of countries may be the primary beneficiaries of the Waiver, not the countries who rely on imported supplies due to inadequate manufacturing, storage, and transport capabilities.⁹⁹ In April 2021, Moderna announced that there is a shortfall in previously estimated doses, despite best efforts. The Company attributes this to supply chain issues and stated that, ‘vaccine manufacturing is a highly complex process and a number of elements, including

human and material resources, have factored into this volatility’.¹⁰⁰ Similar supply issues have occurred with the Johnson & Johnson vaccine in the US, and AstraZeneca production in India.¹⁰¹

Furthermore, suspending the enforcement of IP rights would hinder R&D and affect the spectrum of innovation. The rationale for IP rights is built around the idea that creativity and innovation are rewarded. The IP system provides innovators with a set of exclusive rights as incentives to taking risks and spending time and funds on R&D activities. While in the short-term, waiving IP rights may accelerate distribution for COVID-19 vaccines, technologies, and treatments, it may hinder the research of new technologies and treatments in the long-term.¹⁰² Waiving IP rights during this pandemic would impact preparedness for the next crisis. Venture capitalists would be less interested in investing in R&D and innovation without the prospect of a return on investment, guaranteed by exclusive rights for commercialization.¹⁰³ However, this argument does not consider the scale of the outbreak and economic impacts, or the public funding spent on R&D. Waiver sponsors argue that the pharmaceutical industry should not reap off all the benefits involved in inventing treatments given the significant public funding that has backed such efforts.¹⁰⁴ The financial incentive of manufacturers and the goals of globally fighting the pandemic are currently in conflict, especially as COVID-19 becomes an endemic. The IP system as it currently operates should not only

(*Institute for New Economic Thinking* 2020) <<https://www.ineteconomics.org/uploads/papers/Public-sector-contribution-to-drug-discovery-and-development.pdf>> accessed 28 June 2021.

⁹⁷ See Cross S, et al., ‘Who funded the research behind the Oxford-AstraZeneca COVID-19 Vaccine? Approximating the funding to Oxford University for R&D of the ChAdOx vaccine technology’ (2021) <<https://www.medrxiv.org/content/10.1101/2021.04.08.21255103v1.full.pdf>> accessed 26 June 2021.

⁹⁸ See Rutschman AS, Barnes-Weise J, ‘The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal’ (*Petrie-Flom Center*, 5 May 2021)

<<https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver>> accessed 28 June 2021; Bacchus J, ‘An Unnecessary Proposal: A WTO Waiver of IP Rights for COVID-19 Vaccines’ (*Cato Institute*, 16 December 2020) <www.cato.org/publications/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid> accessed 28 June 2021. See also Mercurio (n 105).

⁹⁹ Mercurio (n 105) 10–11.

¹⁰⁰ Beaumont P, Walker P, ‘Moderna struggling to supply promised doses of Covid vaccine’ (*The Guardian*, 16 April 2021) <www.theguardian.com/world/2021/apr/16/moderna-struggling-to-supply-promised-doses-of-covid-vaccine> accessed 28 June 2021.

¹⁰¹ *ibid.*

¹⁰² In finding a balance between exclusivity and access in the TRIPS Agreement, James Bacchus asked, ‘If we unduly weaken protection for IP, then we need to ask ourselves: Where will the next innovation, the next new technology, the next life-saving medicine come from?’. See Bacchus J, ‘TRIPS-Past to TRIPS-Plus: Upholding the Balance between Exclusivity and Access’ (2021) CIGI Paper No. 254 <www.cigionline.org/publications/trips-past-to-trips-plus-upholding-the-balance-between-exclusivity-and-access> accessed 28 June 2021.

¹⁰³ See Mercurio (n 105) 7; Ezell S, Cory N, ‘The Way Forward for Intellectual Property Internationally’ (*Information Technology & Innovation Foundation*, 25 April 2019) <<https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally>> accessed 28 June 2021.

¹⁰⁴ Mercurio (n 105) 6.

promote profit-based incentives and monopolies but should also take into consideration public health and the overall societal good. Eventually, the main advantage of the Waiver proposal resides in the fact that patentee's exclusive rights can be postponed in time of crisis. However, the fundamental problem remains in how to obtain the know-how and data required to manufacture the products. Emergency laws such as the French law or the US Defense Production Act discussed earlier can facilitate access to undisclosed information, but an effective mechanism does not always exist in domestic legislation. The Waiver does not require developed countries to transfer technologies and know-how to developing countries.

5. CONCLUSIONS: MOVING FORWARD

International treaties are developed to proactively protect public interests during times of crisis and global emergencies, with the COVID-19 pandemic as a prime example of such a time. This pandemic has created an opportunity to test these measures and it has become evident that they are ill-designed to respond to the extent required to combat COVID-19 globally.

Protecting IP rights internationally is clearly an important priority as it incentivizes future R&D of innovative technologies and encourages researchers to publicize their inventions. However, against global needs for access to life-saving technologies, these IP rights should be limited for the purposes of societal good. The existing flexibilities as well as the proposed Waiver aim to limit the intrusion upon protected IP rights only to the extent necessary to respond to COVID-19. The use of compulsory licensing for patents granted, as outlined in Article 31*bis* and reinforced by Clause 5 of the Doha Declaration, is a mechanism available for States to respond to national emergencies at their discretion. This mechanism should be augmented by a compulsory trade secrets license ensuring access to information and data necessary to implement medical technologies. This paper suggests revisiting the international standards of the

TRIPS Agreement to include an additional mechanism of compulsory trade secrets licensing.

In the context of the COVID-19 pandemic, the urgent need to access COVID-19 treatments warrants an efficient mechanism to access IP, often from multiple rights holders in multiple countries. With growing international support, this TRIPS Waiver aims to mitigate delayed responses to combatting COVID-19 caused by IP protection complications. This Waiver recognizes the shortcomings of the current flexibilities in the TRIPS system and aims to provide a temporary solution to waive IP rights until widespread vaccination is implemented worldwide and global herd immunity has been achieved. Looking towards the future, however, the long-term solution for facilitating access to COVID-19 technologies, requires a compulsory licensing system for trade secrets. The current compulsory licensing regime may fall short to respond immediately to a global crisis but presents an option for governments to issue a license for domestic use related to the public's health. Compulsory licensing has garnered international validation through the TRIPS Agreement and Doha Declaration and has been implemented within several domestic legislations to respond to matters of emergency or public health. It is a feasible tool to limit the patentee's exclusive rights that need to be reinforced by a compulsory trade secrets license enabling access to undisclosed information.

Looking at the current situation, the Waiver presents an unparalleled opportunity to share knowledge and provide access to licenses to respond effectively to the severe supply shortage of global vaccines as a result of vaccine nationalism. The Waiver allows for an expedited process foregoing the bureaucratic burdens that compulsory licenses face and avoids the divisive nature of the use of a national security exception. The immediate need for vaccines is clear, and the Waiver is the tool that will provide the most affordable and most timely solution to the global problem of inequitable access to COVID-19 treatment. If the current pandemic does not justify the limitation of IP rights to provide equitable access to life-

saving technologies, it is hard to imagine a situation that could ever warrant a mechanism such as the one proposed. If not now, when?

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