

RESEARCH ARTICLE

# Compulsory licensing: an effective tool for securing access to Covid-19 vaccines for developing states?

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(Accepted 30 April 2022)

## Abstract

A significant issue in combatting the Covid-19 pandemic is the need to enhance developing states' access to Covid-19 vaccines. The present paper considers the request for a temporary waiver of intellectual property rights in relation to Covid-19 technologies and treatments submitted to the World Trade Organization and analyses a key argument against the proposed waiver: that the compulsory licensing provisions set out in the TRIPS Agreement are sufficiently flexible to help states get access to vaccines. The compulsory licensing flexibilities set out in TRIPS, including the amendment to TRIPS in Article 31bis, are evaluated, to explore whether compulsory licensing could be an effective tool in helping developing states to access Covid-19 vaccines. Key issues are explored from a human rights perspective to examine whether a rights-based approach to the compulsory licensing provisions could offer further insights as to how the provisions could be more workable, to enhance access to medicines and vaccines for developing states.

**Keywords:** intellectual property; TRIPS; compulsory licensing; vaccines; access to medicines; human rights

## Introduction

The development of several Covid-19 vaccines within a year of the declaration of the pandemic is a huge accomplishment for scientific research. Pfizer, AstraZeneca, and Moderna have all produced and are now distributing vaccines which are effective against Covid-19, with others in development and expected to join the market.<sup>1</sup> While the development of these vaccines is a crucial part of the global response to the pandemic, an emerging issue is how to ensure that the vaccines are accessible to developing states. This echoes the wider access to medicines debate, where much of the literature has focused on the role of intellectual property (IP) rights as monopoly rights, which can create barriers to accessing medicines for developing states.<sup>2</sup> In October 2020, a proposal was submitted to the World Trade Organization (WTO) by India and South Africa to request a temporary waiver on certain IP rules set out in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) so as to allow more access to all Covid-related medicines, technologies and treatments. This proposal

<sup>1</sup>D Desierto 'Equitable COVID vaccine distribution and access: enforcing international legal obligations under economic, social, and cultural rights and the right to development' *EJIL: Talk!* (2 February 2021), available at <https://www.ejiltalk.org/equitable-covid-vaccine-distribution-and-access-enforcing-international-legal-obligations-under-economic-social-and-cultural-rights-and-the-right-to-development/>.

<sup>2</sup>Examples include F Abbott 'The TRIPS Agreement, access to medicines, and the WTO Doha Ministerial Conference' (2002) 5(1) *Journal of World Intellectual Property* 15; L Helfer and G Austin *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge: Cambridge University Press, 2011); H Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford: Oxford University Press, 2007).

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has faced resistance from some states, including the UK and the US. A key argument against the proposal is that existing TRIPS flexibilities allowing countries experiencing a public health emergency to issue compulsory licences are adequate to overcome issues relating to access to Covid-19 medicines and vaccines.

This paper explores the proposed waiver of IP rights and evaluates the adequacy of the current system of compulsory licensing system intended to assist developing states in furthering public health objectives, set out in Article 31*bis* of TRIPS. There is a tendency to look at the issue from a TRIPS perspective, but this paper proposes that it should also be considered from an international human rights law perspective. The right of access to medicines is part of the right to health set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)<sup>3</sup> and the 171 States that have ratified the ICESCR, including UK, Canada, and EU Member States, have international legal obligations in relation to the right to health.<sup>4</sup> Therefore this paper will consider the perspectives of both international legal regimes.

The present paper examines key challenges facing developing states in procuring sufficient quantities of Covid-19 vaccines in light of states' obligations under TRIPS and the ICESCR. Some of the key criticisms of the compulsory licensing provisions in Article 31 of TRIPS are analysed. The paper evaluates the sole use of the Article 31*bis* mechanism in Canada and why the mechanism may not be effective in achieving its objective of making it easier for developing countries to utilise compulsory licensing to address public health needs. The paper proposes that while, in principle, compulsory licensing can be a powerful tool in responding to some health emergencies, the existing criticisms of the Article 31*bis* mechanism need to be addressed in order for the provision to work as intended in public health emergencies. Examining these issues through a human rights lens offers scope for states to revisit some of the challenges in using the compulsory licensing provisions and could ensure that compulsory licensing offers a more significant contribution to enhancing access to medicines and vaccines for developing states.

## 1. Access to Covid-19 vaccines: key challenges for developing states

Pharmaceutical manufacturers of Covid-19 vaccines are trying to meet unprecedented global demand for vaccines, and a key challenge of access to Covid-19 vaccines is ensuring that the production of vaccines can meet demand. Expanding production capacity to meet global demand is a huge task.<sup>5</sup> This problem is compounded by 'vaccine nationalism' in relation to Covid-19 vaccines, where states are buying up supplies for domestic needs. Currently, acquisition and distribution of vaccines is largely through bilateral agreements and advance purchase agreements, which provide challenges to developing states in terms of access to adequate supplies. In February 2021, it was reported that high-income countries, with 16% of the global population, had purchased 60% of the vaccine supply.<sup>6</sup> Some developed countries, including the UK and Canada, reportedly purchased enough doses to vaccinate their populations multiple times by the end of 2021.<sup>7</sup> Some developed states such as the US have pledged to share their surplus vaccines, but will not export them until their domestic needs are met.<sup>8</sup> While it is

<sup>3</sup>International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) UNGA res 2200A (XXI).

<sup>4</sup>By comparison 164 states are members of the WTO (as at January 2022).

<sup>5</sup>O Wouters et al 'Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment' *The Lancet, Health Policy* (12 February 2021), available at [https://doi.org/10.1016/S0140-6736\(21\)00306-8](https://doi.org/10.1016/S0140-6736(21)00306-8).

<sup>6</sup>BBC News 'Covax: How will Covid vaccines be shared with poorer countries?' (15 February 2021), available at <https://www.bbc.com/news/world-55795297>.

<sup>7</sup>This data was produced by the People's Vaccine Alliance. See website available at <https://www.amnesty.org/en/latest/news/2020/12/campaigners-warn-that-9-out-of-10-people-in-poor-countries-are-set-to-miss-out-on-covid-19-vaccine-next-year/>.

<sup>8</sup>Reuters 'Vaccine surplus to be shared with "world": Biden' (11 March 2021), available at <https://www.reuters.com/video/watch/idPR4y?now=true>; 'UK falling behind most G7 countries in sharing Covid vaccines, figures show' (*The Guardian*, 24 October 2021), available at <https://www.theguardian.com/world/2021/oct/24/uk-falling-behind-most-g7-countries-in-sharing-covid-vaccines-figures-show>.

reasonable for these states to want to ensure protection for their own populations, by acquiring vaccinations for the state's entire population before the vulnerable in developing states have been vaccinated presents a significant inequity.

Wide-ranging intellectual property protections mean production of vaccines is limited to the right-holder, unless they agree to license the vaccine to another manufacturer. Rapid global distribution of vaccines is necessary to effectively combat the pandemic, but there is grave concern that developing countries are being left behind in the vaccine rollout. The Economist Intelligence Unit forecasts that around 84 developing countries will not receive widespread access to Covid-19 vaccines until 2023.<sup>9</sup> The proposed IP waiver submitted to the WTO in October 2020 would temporarily suspend the obligations of members to implement, apply, and enforce IP rights in TRIPS,<sup>10</sup> including wide-ranging patent protection for medicines and vaccines under Article 28, on Covid-related medicines<sup>11</sup> and technologies until widespread vaccination had occurred globally. The objective of the proposed waiver is to remove legal barriers and offer freedom to operate to manufacturers to scale up manufacturing and distribution of Covid-19 vaccines.<sup>12</sup> The waiver proposal has been opposed by several states, including the UK, Switzerland and the United States.<sup>13</sup> It remains to be seen whether this proposal will be agreed. A draft text, made public in March 2022, of a compromise purportedly negotiated by EU, US, India and South Africa has been widely criticised due to its much narrower scope than the original waiver proposed in October 2020.<sup>14</sup> A key argument against the original proposal is that patents would not be problematic, as states can utilise the flexibilities in TRIPS in the form of the compulsory licensing provisions in Article 31. Given the critical importance of distributing Covid-19 vaccines in developing states, the merit of this argument is evaluated in this research.

Global vaccination is in every state's interests, not just in terms of population health, and combatting the emergence of new variants of the virus, but also economically, with much publicised harms to businesses and economies from continued lockdowns. More importantly, WTO members who are parties to the ICESCR have specific legal obligations in their own territory with regard to the right to health in Article 12, of which access to essential medicines is a core component.<sup>15</sup> Further, in line with states' core obligations under Article 2, states have extraterritorial obligations to realise the right to health including through international assistance. The significance of offering a human rights perspective in relation to this issue is that the challenges can be addressed in the context of states' obligations to promote and protect the rights of individuals, regardless of the level of development of the state. Also, states parties to the ICESCR have committed to legally binding obligations under the treaty.

The Office of the High Commissioner for Human Rights has stated that '[a]ffordable, non-discriminatory access to the vaccine is a human right',<sup>16</sup> and the availability of vaccines is an essential

<sup>9</sup>The Economist Intelligence Unit 'More than 85 poor countries will not have widespread access to coronavirus vaccines before 2023' (27 January 2021), available at <https://www.eiu.com/n/85-poor-countries-will-not-have-access-to-coronavirus-vaccines/>.

<sup>10</sup>TRIPS Council *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19* (IP/C/W/669, 2020).

<sup>11</sup>While access to vaccines is a specific issue, vaccines are recognised as biologic medicines by the World Trade Organization. World Trade Organization, World Health Organization and World Intellectual Property Organization *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (WTO, WHO, WIPO, 2012) p 100.

<sup>12</sup>B Thiru '22 April 2021: South Africa raises the banner for text-based work on a WTO TRIPS waiver' *Knowledge Ecology International* (23 April 2021), available at <https://www.keionline.org/35988>.

<sup>13</sup>Desierto, above n 1.

<sup>14</sup>E 't Hoen 'Proposed TRIPS waiver a hollow diplomatic compromise with little practical impact' *Medicines Law & Policy* (12 April 2022), available at <https://medicineslawandpolicy.org/2022/04/proposed-trips-waiver-a-hollow-diplomatic-compromise-with-little-practical-impact/>; J Zarocostas 'Mixed response to COVID-19 intellectual property waiver' *The Lancet: World Report Vol 399* (2 April 2022) DOI: [https://doi.org/10.1016/S0140-6736\(22\)00610-9](https://doi.org/10.1016/S0140-6736(22)00610-9).

<sup>15</sup>UNCESCR *General Comment No 14: The Right to the Highest Attainable Standard of Health (Art 12)* (E/C.12/2000/4, 2000) pp 34–37.

<sup>16</sup>OHCHR 'Human rights and access to COVID-19 vaccines' (17 December 2020) p 1, available at [https://www.ohchr.org/Documents/Events/COVID-19\\_AccessVaccines\\_Guidance.pdf](https://www.ohchr.org/Documents/Events/COVID-19_AccessVaccines_Guidance.pdf).

dimension of the right to health under Article 12 of the ICESCR.<sup>17</sup> The specific legal obligations on Member States under Article 12 include obligations to respect, protect and fulfil the right to health.<sup>18</sup> The obligation to respect includes an obligation on Member States to refrain from marketing unsafe medicines.<sup>19</sup> Obligations to protect involve duties on Member States to enact legislation or national policies to secure equal access to health care and services provided by third parties, including to control the marketing of medicines and ensuring that third parties do not limit access to health-related services.<sup>20</sup> General Comment No 14, issued by the Committee on Economic, Social and Cultural Rights (CESCR) in 2000 to provide guidance on interpreting Article 12,<sup>21</sup> clarifies that availability of affordable essential medicines is a critical component of the right to the highest attainable standard of health, by outlining that access to essential medicines is a core obligation of states.<sup>22</sup> A state has to show that they have made every effort to use all available resources to satisfy those minimum core obligations.<sup>23</sup>

Article 12(2) states that ‘the steps to be taken by the States Parties to achieve the full realization of this right shall include those necessary for “(c) the prevention, treatment, and control of epidemic ... and other diseases”’.<sup>24</sup> The control of epidemic diseases refers to states’ individual and joint efforts to ‘make available relevant technologies, implementation or enhancement of immunization programmes and other strategies of infectious disease control’.<sup>25</sup> General Comment No 14 defines the actions under Article 12(2)(c) regarding control of diseases as states parties’ individual and joint efforts to make available relevant technologies,<sup>26</sup> which may be relevant in terms of new medicines under patent and generic production, and highlights the extraterritorial responsibility to cooperate with other states. Therefore, states parties have specific legal obligations to take actions necessary for the control of global pandemics such as Covid-19, and global vaccination is crucial to control the pandemic.

‘Vaccine nationalism’ and access to vaccines is a state-to-state issue, and states parties to the ICESCR are also under distinct extraterritorial obligations under Article 2(1), including a collective responsibility to address the problem of diseases which are easily transmissible beyond state borders, and developed states have particular obligations to assist developing states. Article 2(1) outlines that without international cooperation and assistance the full realisation of the ICESCR rights will not be attainable for all Member States.<sup>27</sup> Therefore, Article 2 requires that cooperation must include that which is necessary to prevent, treat, and control epidemics, including global pandemics such as Covid-19. This is in line with the provisions in TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health<sup>28</sup> to take measures necessary to protect public health. A criticism of the scope of the rights in the ICESCR is that the CESCR has not provided an in-depth clarification of the international obligations of states, and this has led to the use of different terms and weak language on the nature of states’ commitments.<sup>29</sup> In relation to the Covid-19 pandemic specifically, such international assistance to control global pandemics can be secured through ensuring vaccines supplies

<sup>17</sup>UNCESCR *General Comment No 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the Covenant* (E/C.12/GC/25, 2020) p 70.

<sup>18</sup>General Comment No 14, above n 15, p 34.

<sup>19</sup>*Ibid*, p 34.

<sup>20</sup>*Ibid*, p 35.

<sup>21</sup>*Ibid*.

<sup>22</sup>*Ibid*, p 43.

<sup>23</sup>UNCESCR *General Comment No 3: The Nature of States Parties’ Obligations (Art 2, Para 1 of the Covenant)* (E/1991/23, 1990) p 10.

<sup>24</sup>ICESCR, above n 3.

<sup>25</sup>General Comment No 14, above n 15, p 16.

<sup>26</sup>*Ibid*, p 13.

<sup>27</sup>General Comment No 3, above n 23, p 14.

<sup>28</sup>WTO *Declaration on the TRIPS Agreement and Public Health* (WT/MIN(01)/DEC/2, 2001).

<sup>29</sup>F Coomans ‘The extraterritorial scope of the International Covenant on Economic, Social and Cultural Rights in the work of the United Nations Committee on Economic, Social and Cultural Rights’ (2011) 11 *Human Rights Law Review* 1, at 34.

are shared equitably. The commitments of developed states to share the vaccine after their domestic populations have been vaccinated are not enough to meet those extraterritorial obligations.

Securing access to vaccines for developing countries to achieve public health goals is not incompatible with the obligations of WTO members under TRIPS. While there are extensive intellectual property protections for creators, Articles 7 and 8 of TRIPS set out the object and purpose of the Agreement and recognise that a balancing of interests is required when interpreting TRIPS and that members may adopt measures necessary to protect public health, so limited exceptions should be permitted if they pursue purposes set out in Articles 7 and 8.<sup>30</sup> Article 7 set out that the protection of intellectual property rights should be in a manner conducive to social and economic welfare, and Article 8 set out that the members may adopt measures necessary to protect public health, when implementing the Agreement nationally.<sup>31</sup> The Preamble of the WTO Agreement also stresses the importance of the objective of sustainable development, and of the integration of developing countries.<sup>32</sup> This is not incompatible with the obligations of states parties to the ICESCR. Therefore states have obligations to promote public health objectives under both legal regimes and it is questionable whether they are doing enough to meet these obligations, particularly in relation to assisting developing states.

Using the compulsory licensing provision, where a licence to use the rights of the patent is granted without the patent holder's authorisation, is a legitimate tool under TRIPS. It could be a way to leverage TRIPS to achieve greater access to vaccines, and is also a discharge of obligations of states parties under the ICESCR. However, although a powerful tool, the current compulsory licensing provisions in TRIPS are not sufficient to effectively enhance access to Covid-19 vaccines for developing states.

## 2. Compulsory licensing and Article 31 of TRIPS

Article 31 of TRIPS details the circumstances where other use of a patented product can be permitted without the authorisation of the patent holder, provided that the conditions in Article 31(a)–(l) are satisfied. Compulsory licensing under TRIPS has been utilised in relation to medicines where a WTO member that has implemented TRIPS into national legislation, grants a licence to a generic manufacturer to produce a medicine that is under patent in that member state at cheaper cost. This licence is granted without the patent holder's authorisation irrespective of the holder's exclusive rights over the patented medicine. The construction of Article 31 indicates that the provision does not explicitly set limitations on the grounds upon which compulsory licences can be granted but merely states the conditions that WTO members should observe, although all conditions are mandatory.<sup>33</sup> Therefore, WTO members have flexibility as to how to utilise this provision, in theory assisting WTO members in developing better access to essential medicines by allowing WTO members to circumvent a patent in order to make available medicines to treat public health crises. This flexibility gives members scope to use this provision for public health purposes. UN Special Rapporteurs on the right to health have also made recommendations that states need to take advantage of the compulsory licensing flexibilities within TRIPS and incorporate the TRIPS flexibilities into national legislation, and that states should ensure that national patent law standards were flexible to allow exceptions to further promote compulsory licensing and access to medicines.<sup>34</sup> These

<sup>30</sup>R Howse and A Eliason *The Regulation of International Trade* (Oxford: Routledge, 4<sup>th</sup> edn, 2013) pp 536–538; A Slade 'Good faith and the Trips Agreement: putting flesh on the bones of the Trips "objectives"' (2014) 63(2) *International and Comparative Law Quarterly* 353, at 367.

<sup>31</sup>WTO *Agreement on Trade-Related Aspects of Intellectual Property Rights* (LT/UR/A-1C/IP/1, 1994).

<sup>32</sup>WTO *Agreement Establishing the World Trade Organization* (LT/UR/A/2, 1994) Preamble.

<sup>33</sup>T Cottier 'TRIPS, the Doha Declaration and public health' (2003) 6(2) *Journal of World Intellectual Property* 373, at 386; K-J Ni 'Legal aspects (barriers) of granting compulsory licenses for clean technologies in light of WTO/TRIPS rules: promise or mirage?' (2015) 14(4) *World Trade Review* 701, at 710; F Abbott 'WTO TRIPS Agreement and its implications for access to medicines in developing countries' *Commission on Intellectual Property Rights (UK)* (Study Paper 2a, 2002) p 13.

<sup>34</sup>UNCHR *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health Report of the Special Rapporteur, Paul Hunt, Addendum, Mission to the World Trade Organization* (E/CN.4/2004/49/Add.1, 2004) p 81;

recommendations highlight that there is no zero-sum conflict between trade law and the right to health, and reflect how states could address potential tensions between their human rights obligations and their obligations under TRIPS. However, WTO members, in particular developing countries, have faced challenges in using this provision to enhance access to medicines.

### (a) Problems in utilising Article 31

Compulsory licensing has tended to work most effectively where there is manufacturing capacity within the state to produce the required medicines. However, not all developing states have domestic manufacturing capacity.<sup>35</sup> A particular problem with the provisions under Article 31 has related to Article 31(f), which required that the medicines for which a compulsory licence was issued had to be predominantly for the domestic use of the WTO member which issued that licence. The Doha Declaration<sup>36</sup> sought to address the challenges of members lacking manufacturing capacity to make use of the compulsory licensing provision under Article 31. The Declaration affirmed 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’.<sup>37</sup> The Declaration provided explicit clarification that TRIPS can and should be interpreted by WTO members in such manner as necessary to promote public health and to combat public health crises, and is a significant statement on the interpretation of TRIPS. This also supports the objective set out in Article 8, adding further clarity to the existing interpretative framework of TRIPS, and is compatible with states parties’ obligations under Article 12 of the ICESCR.

Paragraph 6 of the Doha Declaration was also significant as it led to a waiver of the obligation on exporting WTO members under Article 31(f) to allow export of medicines to countries without sufficient manufacturing capacity. The reference to ‘pharmaceutical products’ also demonstrates that the Decision was not limited to medicines only, permitting a wider scope for the type of products which may be imported, such as vaccines. This provision was intended to make the compulsory licensing provision in TRIPS more effective, as developing and least developed countries with the inability to manufacture the medicines domestically were unable to utilise this TRIPS provision. The General Council Ministerial Decision on 6 December 2005<sup>38</sup> provided for an amendment to TRIPS to insert Article 31*bis*. This amendment incorporates the TRIPS Council Decision on the implementation of paragraph 6 of the Doha Declaration into TRIPS, ensuring that the waiver of the domestic use requirement under Article 31(f) is permanent.<sup>39</sup> An objective of the paragraph 6 system was to ensure that newer medicines reached individuals in need more rapidly,<sup>40</sup> by clarifying that WTO members had the freedom to realise national public health objectives by using the harmonised IP provisions under TRIPS. However, it is a widely held view that the Doha Declaration and the paragraph 6 system did not eliminate all of the problems generated by TRIPS.<sup>41</sup> This raises the question of how effective

UNHRC *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (A/HRC/11/12, 2009) pp 102–104.

<sup>35</sup>R Beall and R Kuhn ‘Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis’ (2012) 9(1) *PLoS Med* 1, at 4.

<sup>36</sup>WTO *Declaration on the TRIPS Agreement and Public Health* (WT/MIN(01)/DEC/2, 2001).

<sup>37</sup>*Ibid*, p 4.

<sup>38</sup>WTO *Decision on Amendment of the TRIPS Agreement* (WT/L/641, 2005).

<sup>39</sup>The amendment was approved by the requisite number of WTO members on 23 January 2017. WTO ‘2017 news items: WTO IP rules amended to ease poor countries’ access to affordable medicines’ (23 January 2017), available at [https://www.wto.org/english/news\\_e/news17\\_e/trip\\_23jan17\\_e.htm](https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm).

<sup>40</sup>Above n 38, Preamble.

<sup>41</sup>Hestermeyer, above n 2, p 271; P Vandoren and JC Van Eeckhaute ‘The WTO Decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: making it work’ (2003) 6(6) *Journal of World Intellectual Property* 779, at 780; H Sun ‘The road to Doha and beyond: some reflections on the TRIPS Agreement and public health’ (2004) 15(1) *European Journal of International Law* 123, at 125.

the paragraph 6 system has been in improving access to medicines, and whether it can effectively enhance access to Covid-19 vaccines for developing states.

An overriding criticism of the ineffectiveness of the Doha Declaration is that the compulsory licensing process resulting from the paragraph 6 system and Article 31*bis* is burdensome and arduous to use.<sup>42</sup> In 2009, the then Special Rapporteur on the right to health, Anand Grover, also criticised the implementation of paragraph 6 of the Doha Declaration and a call for a simpler mechanism to be devised,<sup>43</sup> indicating the current provisions posed challenges in relation to the right to health. Both the importing and exporting countries have to issue compulsory licences and the importing country has to demonstrate insufficient manufacturing capacity. A specific method of establishing insufficient manufacturing capacity is not prescribed,<sup>44</sup> which may cause uncertainty as to which countries may rely on this provision. Administrative requirements must also be complied with, including issuing notice to the WTO. The information needed includes the quantities required by the importing country, and the use for the drug and requires detailed information from the importing country at the outset. Information on the specific labelling and marking of the drug is required to counteract the risk of parallel importation. These requirements can be costly for the exporting country, and as a result this may act as a disincentive to generic manufacturers to engage in exporting medicines to developing and least developed countries.

Some of the requirements for making the product distinguishable from the patented version may also be more difficult to apply to a vaccine. The requirements that the exported product must be clearly labelled and distinguishable from the patented version in terms of shape, colour and packaging demonstrates a compromise between ensuring that compulsory licensing could be used effectively for the furtherance of global public health aims, and the developed members' concerns over trade diversion of the exported product. This could be described as a compromise between the competing interests of the needs of developing and least developed countries seeking greater clarity on the flexibilities of TRIPS in respect of manufacturing patented medicines to treat health emergencies, and those WTO members with large pharmaceutical manufacturing industries that wanted to preserve strict IP protection.

Another criticism of the paragraph 6 system and Article 31*bis* is that these onerous requirements must be satisfied before the compulsory licence can be issued, and the process 'fails to take into account that flexibility and rapidity of response to ever-changing circumstances are vital'.<sup>45</sup> This also reflects that access to medicines in emergencies during public health crises requires immediate action, which may be difficult to respond to under the current compulsory licensing requirements. This is particularly problematic in relation to Covid-19 vaccines, where the public health situation is quickly evolving and there is an urgent, global, need to vaccinate vulnerable people. Difficulties in the application of this mechanism can be evidenced by the fact that between 2003, when the paragraph 6 waiver was first implemented, and as of January 2022 there has been only one case where this mechanism has been used to conclusion. This indicates that, although a potentially powerful tool, the paragraph 6 system has not worked well in practice.

### **(b) The sole completed use of the paragraph 6 system**

Canada was one of the first countries<sup>46</sup> to amend its patent law following the decision to implement paragraph 6 of the Doha Declaration, resulting in Canada's Access to Medicines Regime

<sup>42</sup>D Matthews 'TRIPS flexibilities and access to medicines in developing countries: the problem with technical assistance and free trade agreements' (2005) 27(11) *European Intellectual Property Review* 420, at 422.

<sup>43</sup>UNHRC, above n 34, p 102.

<sup>44</sup>B Mercurio 'Trips, patents, and access to life-saving drugs in the developing world' (2004) 8 *Marquette Intellectual Property Law Review* 211, at 240.

<sup>45</sup>K Paas 'Compulsory licensing under the TRIPS Agreement – a cruel taunt for developing countries?' (2009) 31(12) *European Intellectual Property Review* 609, at 613.

<sup>46</sup>R Kampf *World Trade Organization Economic Research and Statistics Division, 'Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation* (ERSD-2015-07, 2015) p 6.

(CAMR).<sup>47</sup> Under this regime, in 2007 the Canadian and Rwandan governments issued compulsory licences for Canadian generic manufacturer Apotex to supply Rwanda with antiretroviral drug Apo-Triavir to treat HIV/AIDS. This transaction was only completed on one occasion, with a single supply of the required medicines being provided to the importing country. Apotex was critical of the process, arguing that the ‘fact that countries cannot place a simple order or extend a tender for a specific product but have to initiate what is perceived to be a “political” or legal process is in itself intimidating’.<sup>48</sup> This response supports the assertion that the administrative requirements are demanding, particularly as the need is a public health need which should be managed expeditiously. Apotex, as of January 2022 the only pharmaceutical manufacturer to have been through the complete process of using the paragraph 6 system to supply generic antiretroviral drugs, has not repeated the process. The company’s experience highlights why developing countries are unlikely to rely on the paragraph 6 system to import generic medicines. If the manufacturing industries within developed WTO member countries considered that it was difficult to satisfy the export requirements under the mechanism then it is unlikely that they would continue to use it. If developing WTO members cannot engage a developed member with sufficient manufacturing capacity with the process then the problem of providing an adequate supply of medicines to the population is not resolved.

Apotex also commented that the ‘process is, for the most part, invisible to most agencies in countries that would access it’.<sup>49</sup> This suggests that developing WTO members are not taking advantage of the paragraph 6 system because the relevant governments are unaware or uninformed of the availability of this process. It may be contended that greater support from developed WTO members is needed for importing members during the application process, instead of a focus on protection of the patent holder’s product. Developed members which have sufficient expertise could provide technical assistance, and this may help to make the mechanism more effective. Therefore, greater support from developed WTO members could be valuable in apprising developing members of the process, and is consistent with states parties’ obligations to provide international assistance under Article 2 of the ICESCR.

The criticisms of the paragraph 6 system have been widely discussed in the literature, but as states have a degree of flexibility in implementing the paragraph 6 system into national law, it is also important to explore the experience of implementing and utilising the system at national level, in order to understand what can be learned from the Canadian experience and how this could inform the practice of other states seeking to utilise the paragraph 6 system more effectively. This evaluation is of particular relevance to the issue of access to Covid-19 vaccines as in March 2021, Biolyse Pharma announced its intention to rely upon CAMR to seek a compulsory licence to manufacture a generic version of the Johnson & Johnson Covid-19 vaccine to be supplied to developing countries.<sup>50</sup> Already, Biolyse has experienced difficulties in seeking a compulsory licence through CAMR, as the company anticipates that the process will be lengthy,<sup>51</sup> in spite of the urgent need for Covid-19 vaccines. Some of the more practical aspects, such as accessing the necessary documents and administrative support, do

<sup>47</sup>J Cohen-Kohler et al ‘Canada’s implementation of the paragraph 6 decision: is it sustainable public policy?’ (2007) 3 *Global Health* 12, at 1.

<sup>48</sup>Apotex Inc ‘Submission to the Standing Committee on Industry, Science and Technology; Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act’ (26 October 2010) p 3.

<sup>49</sup>*Ibid*, p 4.

<sup>50</sup>National Post ‘Ontario company seeks licence to make generic Johnson and Johnson COVID vaccine for developing countries’ (24 March 2021), available at <https://nationalpost.com/news/politics/ontario-company-wants-to-make-johnson-and-johnson-vaccine-with-government-license>.

<sup>51</sup>J LeBel ‘Biolyse suggests Health Canada lacks urgency over its ask to produce COVID-19 vaccines for export’ *Global News* (8 April 2021), available at <https://globalnews.ca/news/7743371/biolyse-covid-19-vaccines-health-canada-johnson-and-johnson/>.

not appear to be a straightforward process for the company.<sup>52</sup> This attempt to rely on CAMR will test the commitment of the Canadian Government to assist developing countries access to vaccines in line with its human rights obligations to provide international assistance, particularly as Canada is currently one of the WTO members not supporting the proposed temporary IP waiver for Covid-19-related treatments.<sup>53</sup>

*(c) Canada's access to medicines regime: why it hasn't worked*

The Government of Canada passed An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa),<sup>54</sup> in May 2004. The Act, along with a supporting set of regulations, established the legal framework for CAMR, which aimed to make it easier to provide essential medicines to developing states. This could be seen as the State trying to uphold its obligations under the international trade rules and its human rights obligations under the ICESCR, including its extra-territorial obligations. It is important to see a developed state taking this action for the purpose of improving access to medicines in developing states. However, the fact that this provision has only been used once shows that it is not achieving its intended objectives.

Criticisms of CAMR include the limited list of pharmaceutical products that were subject to compulsory licensing for export<sup>55</sup> and the limit of two years on the term of the compulsory licence.<sup>56</sup> CAMR contains schedules setting out eligibility for a compulsory licence, and Schedule 1 sets out the list of patented products that can be used to address public health issues affecting developing and least developed states.<sup>57</sup> Since the enactment of this legislation, more medicines have been added to the list, although this process was fairly lengthy, taking up to seven months rather than a matter of days as anticipated.<sup>58</sup> Therefore although it is possible to update the list to include medicines to meet the specific needs of developing countries that wish to acquire a compulsory licence under this regime, it appears to be a protracted and inefficient process, which could deter the utilisation of this regime to acquire medicines that do not already appear on the list. Reports suggest that Biolyse anticipates that amending the Schedule 1 list to include Covid-19 vaccines will be a significant hurdle.<sup>59</sup> It had been suggested that pressure from branded pharmaceutical companies was a factor in retaining such a list, because of their view that it would provide a way of ensuring that compulsory licences were not used for commercial purposes.<sup>60</sup> However, this goes beyond what was agreed within the WTO, where there was no requirement for a list included under the paragraph 6 system.<sup>61</sup>

The reasoning for imposing a two-year limit was so that the purchasers were not committed to a long-term contract for a particular medicine and should have the flexibility to take advantage of obtaining newer, more effective medicines.<sup>62</sup> However, it has been argued that the limit has the effect

<sup>52</sup>Knowledge Ecology International 'Canada based Biolyse Pharma seeks to manufacture COVID-19 vaccines for low-income countries, may test Canada's compulsory licensing for export law' (12 March 2021), available at <https://www.keionline.org/35587>.

<sup>53</sup>WTO 'Members to continue discussion on proposal for temporary IP waiver in response to COVID-19' (10 December 2020), available at [https://www.wto.org/english/news\\_e/news20\\_e/trip\\_10dec20\\_e.htm](https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm); G York 'Canada criticized for refusing to support COVID-19 vaccine patent waiver at WTO meeting' (11 March 2021), available at [https://www.theglobeandmail.com/world/article-canada-criticized-for-refusing-to-support-covid-19-vaccine-patent/?utm\\_medium=Referrer:+Social+Network+/+Media&utm\\_campaign=Shared+Web+Article+Links](https://www.theglobeandmail.com/world/article-canada-criticized-for-refusing-to-support-covid-19-vaccine-patent/?utm_medium=Referrer:+Social+Network+/+Media&utm_campaign=Shared+Web+Article+Links).

<sup>54</sup>An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa) (SC 2004, c 23).

<sup>55</sup>R Elliott 'Pledges and pitfalls: Canada's legislation on compulsory licensing of pharmaceuticals for export' (2006) 1 International Journal of Intellectual Property Management 94, at 100.

<sup>56</sup>Ibid, at 107.

<sup>57</sup>Above n 54, Schedule 1.

<sup>58</sup>P Goodwin 'Right idea, wrong result – Canada's access to medicines regime' (2008) 34 American Journal of Law & Medicine 567, at 579.

<sup>59</sup>LeBel, above n 51.

<sup>60</sup>Goodwin, above n 58, at 580.

<sup>61</sup>WTO *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (WT/L/540, 2003).

<sup>62</sup>Elliott, above n 55, at 107.

of restricting the generic pharmaceutical manufacturers' ability to compete in the market,<sup>63</sup> as the relatively short term of the licence may limit the ability of the manufacturers to recoup the initial costs of producing the generic medicine.<sup>64</sup> The reasoning behind paragraph 6 is to find an efficient solution to the problem of access to available, affordable medicines in developing countries, particularly in emergency situations.<sup>65</sup> Therefore, this raises the question of whether there is a need for generic manufacturers to build a commercial market, and whether this is a relevant consideration where the compulsory licence is issued to address an emergency need for a specific medicine or vaccine to combat a global pandemic. The primary goal of CAMR is to promote access to medicines in developing countries.<sup>66</sup> The objective of this legislation was to enhance effective access to medicines for developing states in Africa,<sup>67</sup> so the purpose was not primarily to ensure that generic manufacturers derive a profit as a result of their participation. However, in realistic terms if there is little incentive in participating then it could be difficult to attract the interest of pharmaceutical companies in taking part in the scheme. The lack of commercial incentives for generic manufacturers has been identified as an issue with CAMR, as it is difficult for the generic manufacturer to recoup the investment for producing the generic version of the medicine where it is produced for one country for a limited period.<sup>68</sup> Therefore, to make CAMR more functional as part of the wider objective of enhancing access to essential medicines and to play a major role in exporting essential medicines, the commercial motivations of generic manufacturers need to be taken into account in order to encourage them to engage with the regime.

Another criticism of CAMR is the inclusion of additional conditions imposed on non-WTO member developing countries that wish to be added to the schedule of eligible importing countries.<sup>69</sup> The additional conditions on non-WTO members include a declaration of the adoption of measures to prevent diversion of the products to unintended markets and the requirement that the pharmaceutical products under the compulsory licence are not used for commercial purposes.<sup>70</sup> The schedules of countries eligible to import medicines under CAMR are organised according to level of development and WTO membership, with non-WTO members able to be added upon request and subject to satisfaction of these additional conditions.<sup>71</sup> The Canadian government's review of CAMR noted that the branded pharmaceutical industry supported such specifications with the view that this would ensure that medicines were only exported to countries with genuine public health needs.<sup>72</sup> However, it has been suggested that these conditions were included with the aim of restricting potential competition for such medicines being generated within the importing country's market.<sup>73</sup> Such competition could contribute to reducing prices and improving access in that country, and therefore the conditions appear contrary to the spirit and purpose of the legislation. Such conditions may also be difficult to satisfy for non-WTO members without comprehensive public healthcare schemes and where

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<sup>63</sup>Ibid.

<sup>64</sup>Ibid.

<sup>65</sup>M Abbas and S Riaz 'WTO "paragraph 6" system for affordable access to medicines: relief or regulatory ritualism?' (2018) 21 *Journal of World Intellectual Property* 32, at 45.

<sup>66</sup>A Houston and R Beall 'Could the paragraph 6 compulsory license system be revised to increase participation by the generics industry: lessons learned from an unheralded and unsuccessful attempt to use Canada's access to medicines regime?' (2018) 12 *McGill Journal of Law and Health* 227, at 242.

<sup>67</sup>G Tsai 'Canada's access to medicines regime: lessons for compulsory licensing schemes under the WTO Doha Declaration' (2009) 49 *Virginia Journal of International Law* 1063, at 1089.

<sup>68</sup>Abbas and Riaz, above n 65, at 41; H Mathur 'Compulsory licensing under section 92A: issues and concerns' (2008) 13 (5) *Journal of Intellectual Property Rights* 464, at 467; Cohen-Kohler et al, above n 47, at 3–4; Houston and Beall, above n 66, at 242–243.

<sup>69</sup>Goodwin, above n 58, at 581.

<sup>70</sup>Ibid.

<sup>71</sup>Government of Canada *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act* (Ottawa: Industry Canada, 2007) pp 7–8.

<sup>72</sup>Ibid, p 8.

<sup>73</sup>Elliott, above n 55, at 105.

medicines are predominantly accessed through private pharmacies,<sup>74</sup> and so could limit the number of non-WTO states that can satisfy the eligibility conditions under CAMR. Therefore it appears difficult to justify why non-WTO members should be subject to conditions that WTO members do not have to satisfy, particularly as this distinction is not a requirement of the WTO.

It is notable that the cost of the medicines imported by Rwanda was still higher than the cost of comparable Indian generic medicines.<sup>75</sup> This suggests that in addition to the process being burdensome, it was also not cost-effective and does not achieve the purpose of promoting the use of compulsory licensing for pharmaceuticals to treat pandemics and life limiting diseases. A further issue is that the waiver fails to allow developing countries to take advantage of cheaper generic medicines through economies of scale.<sup>76</sup> This is problematic in terms of encouraging generic manufacturers to invest in producing medicines under the Canadian regime, as the limitations on the quantities of medicines would make it difficult to recoup the development costs. It is a significant challenge as although the Canadian regime was implemented for the purpose of promoting access to medicines, it is the pharmaceutical companies which manufacture the generic medicines to be ordered under the regime, and as commercial enterprises they are unlikely to enter into a commercial arrangement where they stand to make a loss. The experience of Canada shows that there needs to be effective legal infrastructure at national level to implement the system.<sup>77</sup>

In spite of the criticism of CAMR, and the fact that the regime has not been utilised since 2008, there appears to be little appetite to reform the Canadian regime. In 2009 a Bill<sup>78</sup> was presented in the House of Commons proposing several amendments to CAMR. However the Bill did not pass a second reading in the Senate,<sup>79</sup> with the dissolution of the government following a no-confidence vote in March 2011,<sup>80</sup> and the Bill was not proceeded with by the new government.<sup>81</sup> As at January 2022, there has been no further action taken by the government to make CAMR more workable. Critics of the regime argue that legislative reform of CAMR is needed, and for it to be a workable provision it needs to be combined with other initiatives.<sup>82</sup> Another view is that further input from the developing countries may lead to improved policies to achieve affordable access to medicines.<sup>83</sup> This view conveys that for such a scheme to work there needs to be a multilateral approach to ensure that the needs of all stakeholders are considered, so that there is a less unbalanced outcome. There appears to be little evidence from the Canadian government that the above proposals would gain sufficient support to ensure their adoption, and therefore it is difficult to assess whether such proposals would be workable for other states who are considering implementing a similar model. The significant administrative obstacles also mean it is unlikely that the current model will work efficiently to secure Covid-19 vaccines for developing states.

<sup>74</sup>Ibid, at 105–106.

<sup>75</sup>S Lee 'Can incentives to generic manufacturers save the Doha Declaration's paragraph 6?' (2013) 44 *Georgetown Journal of International Law* 1387, at 1404; Beall and Kuhn, above n 35, at 4; Tsai, above n 67, at 1081.

<sup>76</sup>J Wakely 'Compulsory licensing under TRIPs: an effective tool to increase access to medicines in developing and least developed countries?' (2011) 33(5) *European Intellectual Property Review* 299, at 307.

<sup>77</sup>E Ng and J Kohler 'Finding flaws: the limitations of compulsory licensing for improving access to medicines – an international comparison' (2008) 16 *Health Law Journal* 143, at 171–172.

<sup>78</sup>Parliament of Canada, House of Commons *Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act* 40th Parliament, 3rd Session (3 March 2010–26 March 2011).

<sup>79</sup>Ibid.

<sup>80</sup>BBC News (US and Canada) 'Canadian government falls after no-confidence vote' (25 March 2011), available at <https://www.bbc.com/news/world-us-canada-12865339>.

<sup>81</sup>Parliament of Canada, Senate Public Bill S-208, *An Act to amend the Patent Act and the Food and Drugs Act (drugs for international humanitarian purposes)* 41st Parliament, 1st Session (2 June 2011 – 13 September 2013).

<sup>82</sup>J Kohler et al 'Canada's access to medicines regime: promise or failure of humanitarian effort?' (2010) 5(3) *Healthcare Policy* 40, at 46; Tsai, above n 67, at 1081–1083.

<sup>83</sup>L Esmail and J Kohler 'The politics behind the implementation of the WTO paragraph 6 decision in Canada to increase global drug access' (2012) 8(7) *Global Health* 11–12.

### 3. Wider challenges of compulsory licensing and Covid-19 vaccines

In addition to the challenges for developing states to rely upon Article 31*bis*, there are also other potential barriers which arise, particularly in relation to making effective use of compulsory licensing to secure access to vaccines. Article 31*bis* is also closely linked to Article 39.3 of TRIPS, which covers the protection of undisclosed test data that is required to market a pharmaceutical product from unfair commercial use. This provision becomes problematic where it has the effect of preventing the generic manufacturers from using the original data of a patented medicine produced by the originator company to obtain regulatory approval for the generic copy.<sup>84</sup> Therefore generic manufacturers have to produce their own data on the safety and effectiveness of the generic copy, making the production of generics more costly and time consuming, which will have the effect of increasing the cost. Access and use of test data for regulatory approval is also a potential barrier to access to medicines if the pharmaceutical product has not been subject to regulatory approval in the importing state, as the need to generate new data presents an additional hurdle for the importing state, particularly where the pharmaceutical product is required to address a national health emergency.<sup>85</sup> This is of particular relevance in relation to upscaling manufacture of Covid-19 vaccines, as the complexities of the vaccine-making process also makes it more challenging to create generic versions.<sup>86</sup>

Generic manufacturers of small molecule medicines are not required to carry out clinical trials but only need to prove bioequivalence with the original product. However, this is not sufficient for vaccines. Vaccines contain combinations of various components which are more complex than chemical-based formulations of small molecule medicines. Any new vaccine is considered a new biological entity, regardless of whether it is manufactured through the same technology as any existing vaccines.<sup>87</sup> Full clinical safety and efficacy trials of the generic, or biosimilar, version of a vaccine need to be undertaken, which often requires complex and lengthy testing.<sup>88</sup> In addition to the time needed in order to carry out the necessary clinical trials, such trials also involve considerable additional cost. Clinical trials of vaccines are important to ensure safety, but this illustrates that there may be a distinction between the utility of compulsory licensing of Covid-19 vaccines and of medicines to treat Covid-19. There may also be multiple patents over the components which make up a vaccine.<sup>89</sup> Therefore, should states choose to rely on the compulsory licensing provision, it may be the case that several compulsory licences would have to be issued in relation to one vaccine, which could lead to further delays in access. This also highlights that differences between small molecule medicines and vaccines affects the utility of the compulsory licensing flexibilities in Article 31 of TRIPS.

Traditionally, compulsory licensing has been perceived as an exceptional measure.<sup>90</sup> Compulsory licences are issued on a case-by-case basis, and some compulsory licences require prior negotiations with rights holders, meaning that the process can be lengthy and cumbersome to use, so compulsory licensing does not offer a global solution to the issue of access to Covid-19 vaccines. It does not address the question of how new Covid-19 vaccines will be made available globally. Manufacturing capacity and the expansion of vaccine production is currently a key concern. While it is currently uncertain whether the temporary IP waiver on Covid-19 treatments and technologies will be agreed by WTO members, there is an urgent global need to increase vaccine production. Where there is only one manufacturer to produce the supply of a vaccine, it is essential that the vaccine is quickly available

<sup>84</sup>G O'Farrell 'One small step or one giant leap towards access to medicines for all?' (2008) 30(6) *European Intellectual Property Review* 211, at 214.

<sup>85</sup>N Vincent 'TRIP-ing up: the failure of TRIPS Article 31*Bis*' (2020) 24 *Gonzaga Journal of International Law* 1, at 28.

<sup>86</sup>S Bostyn 'Access to therapeutics and vaccines in times of health pandemics: how exclusivity rights can affect such access and what we can do about it' (2020) 4 *Intellectual Property Quarterly* 227, at 240–244.

<sup>87</sup>A Nguyen and N Schwalbe 'Apples and oranges? Can second generation vaccines become as low cost as generic medicines?' (2019) 37 *Vaccine* 2910, at 2911.

<sup>88</sup>Bostyn, above n 86, at 244.

<sup>89</sup>*Ibid.*, at 243.

<sup>90</sup>A McMahon 'Biotechnology, health and patents as private governance tools: the good, the bad and the potential for ugly?' (2020) 3 *Intellectual Property Quarterly* 161, at 177.

in significant quantities, but this is unlikely to be possible with only one supplier. If there are no alternatives to a patented medicine or vaccine, a compulsory licence will have little utility.<sup>91</sup> There is a need to promote domestic manufacturing capacity, and access to supply for those countries without sufficient capacity. Few developing countries have the domestic manufacturing capacity to produce the necessary volume of Covid-19 vaccines themselves and instead will need to rely on support from states and companies.<sup>92</sup> Therefore, sharing know-how and technology transfer with developing states is important so they can generate their own supplies of vaccines.<sup>93</sup> This will be particularly important should vaccine boosters be subject to patent protection.<sup>94</sup>

The technical knowledge and know-how for creating the vaccine is protected under Article 39.2 of TRIPS.<sup>95</sup> This form of protection is separate from the patent protection afforded under Article 28 of TRIPS, and is significant as the know-how as to the most effective manufacturing process to produce the vaccine could be protected even where a compulsory licence is issued in relation to the patented information. There may be a considerable amount of know-how related to the production of vaccines which manufacturers would not have access to. Therefore, it is not only the legal protection afforded by patents which may be a barrier to the vaccines, but it is the lack of technical know-how which is likely to be a barrier to upscaling manufacture of the vaccines.<sup>96</sup> A key objective is upscaling production and distribution of Covid-19 vaccines. Arguably, even where the states do have manufacturing capacity, people could be vaccinated more quickly if the patent-holding manufacturers shared the know-how.

Additional challenges relating to supply of vaccines include the need for cold storage and adequate transport to ensure safe delivery. While this specific issue is not directly related to IP protection, it highlights the importance of working collaboratively with states to ensure the necessary infrastructure is in place, and this cannot be facilitated solely by seeking to rely on compulsory licensing. The challenges in utilising the compulsory licensing provisions at a national level serve to illustrate why the temporary waiver has been proposed for the purpose of promoting global collaboration to upscale manufacturing and supply of vaccines. This indicates that the existing compulsory licensing system will not be an effective tool to secure access to vaccines in a global pandemic, and will not assist states to fully discharge their international legal obligations on accessing the vaccines under TRIPS and the ICESCR.

A key criticism of the draft compromise waiver made public in March 2022 is that the draft largely restates the existing flexibilities in Article 31 TRIPS, while parts of the text include TRIPS-plus provisions.<sup>97</sup> The draft only relates to Covid-19 vaccines and not medicines, therapeutics and diagnostics. Further, the draft only applies to developing WTO members that produced less than 10% of world exports in 2021,<sup>98</sup> so it does not cover all countries. The draft does propose minor modification to

<sup>91</sup>E Urias and S Ramani 'Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence' (2020) 3 *Journal of International Business Policy* 367, at 382.

<sup>92</sup>Wouters et al, above n 5, at 3.

<sup>93</sup>C Garrison 'What is the "know-how gap" problem and how might it impact scaling up production of Covid-19 related diagnostics, therapies and vaccines?' *Medicines Law and Policy* (16 December 2020) p 13, available at <https://medicineslawandpolicy.org/wp-content/uploads/2020/12/The-Know-how-gap-problem-Medicines-Law-Policy.pdf>.

<sup>94</sup>Bostyn, above n 86, at 243.

<sup>95</sup>Garrison, above n 93, p 1.

<sup>96</sup>It is important to note the transitional provisions for least developed countries under Art 66.1, who do not have to implement TRIPS standards of patent protection until 2033. However, the transitional provisions for least developed states do not help if the states do not have access to the technical know-how to create the vaccines.

<sup>97</sup>E 't Hoen 'Proposed TRIPS waiver a hollow diplomatic compromise with little practical impact' *Medicines Law & Policy* (12 April 2022), available at <https://medicineslawandpolicy.org/2022/04/proposed-trips-waiver-a-hollow-diplomatic-compromise-with-little-practical-impact/>; MSF 'MSF responds to potential compromise on the "TRIPS Waiver"' (16 March 2020), available at <https://msfaccess.org/msf-responds-potential-compromise-trips-waiver>; Zarocostas, above n 14.

<sup>98</sup>Draft text published in E Silverman 'A compromise is reached on an intellectual property waiver for Covid-19 vaccines, but does it go far enough?' *STAT* (15 March 2022), available at <https://www.statnews.com/pharmalot/2022/03/15/covid19-vaccine-patents-wto/>.

Article 31(f) by introducing a waiver of the domestic use requirement. This could potentially be useful in comparison to Article 31*bis*, but this provision would only apply to eligible states.<sup>99</sup> Further, the additional reporting requirements and the requirement that an authorisation to use the subject matter of patents issued by members in line with Article 31(a) must list all of the patents covered, would effectively make the changes to Article 31 more restrictive.<sup>100</sup> The draft text does not go far enough to meet the specific legal obligations of states to take actions necessary for the control of the pandemic outlined in Article 12(2)(c) of the ICESCR. It does not sufficiently promote public health objectives under TRIPs and the ICESCR and also makes it difficult to achieve the international cooperation needed to secure universal access to Covid-19 vaccines in line with states' obligations under Article 2 of the ICESCR. Therefore, the March 2022 draft is inadequate for states to comply with the human rights obligations to guarantee the right to health.

#### 4. Evaluating the paragraph 6 system

Compulsory licensing is a powerful tool, and Article 31*bis* was specifically added to TRIPs for the purpose of helping developing states to access essential medicines in public health emergencies. The Covid-19 pandemic and challenges faced by developing states in acquiring vaccines has renewed attention on the inefficacies of Article 31*bis* and increased the urgency of the need to review this provision to make it fit for purpose. The Doha Declaration, and the subsequent incorporation of the paragraph 6 system in Article 31*bis*, was a positive development in terms of promoting public health as it was a response to addressing the immediate problem of access to medicines. However, the challenges experienced by the participants in the Canadian regime in utilising the paragraph 6 system, coupled with the fact that no other states have attempted to utilise the system, shows that this mechanism has not been effective in achieving its aim of promoting access to medicines.<sup>101</sup> The current focus on compulsory licensing and the suitability of the provisions for enhancing access to Covid-19 vaccines presents an opportunity to revisit this mechanism to address these challenges and to make compulsory licensing more workable for future health emergencies. Examining the problems from a human rights perspective can help to facilitate a deeper understanding of the legal and policy issues, and how they interact with the particular economic and social circumstances of states.<sup>102</sup> Member States have specific legal obligations to respect, protect and fulfil the right to health.<sup>103</sup> Embedding these obligations into national policy could offer a platform for states to maintain IP legislation, which includes compulsory licensing provisions, that is consistent with its human rights obligations.

Human rights bodies have recommended that developed and developing countries have compulsory licensing systems in national law<sup>104</sup> as safeguards to protect access to essential medicines as a

<sup>99</sup>J Love 'The Quad WTO proposal on COVID 19 and TRIPs proposal is tied for the 5th best option for exports' *Medium* (20 March 2022), available at <https://jamie-love.medium.com/the-quad-wto-proposal-on-covid-19-and-trips-proposal-is-tied-for-the-5th-best-option-for-exports-dd8f165efdee>.

<sup>100</sup>Human Rights Watch 'More effort needed for meaningful outcome at WTO on Covid-19' (18 March 2022), available at <https://www.hrw.org/news/2022/03/18/more-effort-needed-meaningful-outcome-wto-covid-19>; J Love 'Pandemic: needed by the rulebook' *Chatham House* (1 April 2022), available at [https://www.chathamhouse.org/publications/the-world-today/2022-04/pandemic-needed-rulebook?CMP=share\\_btn\\_tw](https://www.chathamhouse.org/publications/the-world-today/2022-04/pandemic-needed-rulebook?CMP=share_btn_tw); J Love 'The proposed TRIPs compromise risks setting several bad precedents' *Bill of Health: Harvard Law* (7 April 2022), available at <https://blog.petriefrom.law.harvard.edu/2022/04/07/trips-compromise-bad-precedents/>.

<sup>101</sup>R Elliott 'Delivering on the pledge: global access to medicine, WTO Rules, and reforming Canada's law on compulsory licensing for export' (2007) 3 *McGill International Journal of Sustainable Development Law and Policy* 23, at 56; O'Farrell, above n 84, at 212; O Owoye 'International patents law and public health: revisiting the TRIPs compulsory licensing regime and the Doha paragraph 6 system' (2015) 37(12) *European Intellectual Property Review* 782, at 789; M Mellino 'The TRIPs Agreement: helping or hurting least developed countries' access to essential pharmaceuticals' (2010) 20 *Fordham Intellectual Property, Media and Entertainment Law Journal* 1349, at 1376.

<sup>102</sup>P Yu 'Intellectual property and human rights 2.0' (2019) 53 *University of Richmond Law Review* 1375, at 1430.

<sup>103</sup>General Comment No 14, above n 15, pp 34–37.

<sup>104</sup>UNCHR *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health Report of the Special Rapporteur, Paul Hunt, Addendum, Mission to the World Trade Organization* (E/CN.4/2004/49/Add.1, 2004) p 81;

component of the right to health. However, it is evident from the Canadian experience that such provisions need to be extensive, efficient and easy to use. In 2015 a WTO working paper<sup>105</sup> surveyed the methods of implementation, finding that as of July 2015, 51 WTO members had adopted specific implementation provisions at varying levels of detail.<sup>106</sup> In evaluating the system, the paper proposed that there may be a need to simplify national measures, and also to encourage suppliers and industry to participate more actively by making the process more sustainable and cost effective.<sup>107</sup> This echoes the recommendation of the UN Secretary-General's High-Level Panel on Access to Medicines, to find a solution to make the objective of paragraph 6 more achievable in practice.<sup>108</sup> The recommendation also highlights that the paragraph 6 system is in principle compatible with the human rights obligations of states, although more needs to be done to make the system more workable. This proposal could go some way to addressing the challenges experienced by the participants under the Canadian regime, however it does not fully address the argument in academic literature that the waiver itself is too burdensome to be effective.<sup>109</sup>

The High-Level Panel also recommended that states should reinforce the current legal position by facilitating the use of compulsory licensing through legislation, and to support the use of TRIPS flexibilities by WTO member states.<sup>110</sup> It is noted that the Report concludes that the paragraph 6 system should be revised, but fails to provide specific guidance on steps that could be taken to increase the use of the system.<sup>111</sup> This suggests that the panel missed the opportunity to progress the discourse on how the paragraph 6 system might be improved, and highlights that employing human rights language could offer useful and persuasive guidance on enhancing the current legal provisions. This view also indicates that more practical guidance from the international law bodies on how states could effectively implement specific measures to enhance access to medicines could be helpful.

A suggested reason for the lack of use of the paragraph 6 system is that the lack of dedication in supporting developing countries to take the opportunity to utilise the paragraph 6 system demonstrates that developed WTO members are not willing to share in the transfer of technology to developing countries, which could assist them in developing production capacity to meet the needs of their own population.<sup>112</sup> Under Article 67 of TRIPS, developed members have an obligation to provide financial and technical cooperation to developing and least developed members for the purpose of implementing TRIPS. States parties to the ICESCR have obligations to offer international assistance, and not to restrict the ability of other states to use TRIPS flexibilities. This view suggests that TRIPS has not supported developing countries in their development because they are still reliant upon developed members for imports, and have not benefited from transfer of technology in order to develop domestic production. It also suggests that developed countries have focused on the protection of IP

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UNHRC *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (A/HRC/11/12, 2009) pp 102–104; UNCHR *The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner* (E/CN.4/Sub.2/2001/13, 2001) p 66.

<sup>105</sup>Kampf, above n 46.

<sup>106</sup>Ibid, p 6.

<sup>107</sup>Ibid, p 8.

<sup>108</sup>United Nations Secretary-General's High-Level Panel on Access to Medicines *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* (September 2016) p 9, available at <http://www.unsgaccessmeds.org/final-report>.

<sup>109</sup>F Abbott and J Reichman 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions' (2007) 10(4) *Journal of International Economic Law* 921, at 932; R Thapa 'Waiver solution in public health and pharmaceutical domain under TRIPS Agreement' (2011) 16 *Journal of Intellectual Property Rights* 470, at 473; W Guan 'IPRs, public health, and international trade: an international law perspective on the TRIPS amendment' (2016) 29 *Leiden Journal of International Law* 411, at 438–439.

<sup>110</sup>United Nations Secretary-General's High-Level Panel on Access to Medicines, final report (n 6) 27.

<sup>111</sup>Houston and Beall, above n 66, at 231.

<sup>112</sup>R Amollo 'Revisiting the TRIPS regime: Rwanda-Canadian ARV drug deal "tests" the WTO General Council decision' (2009) 17(2) *African Journal of International and Comparative Law* 240, at 269; Mellino, above n 101, at 1379–1380.

afforded by TRIPS rather than the dissemination of knowledge and technology transfer to developing countries which the agreement can support.

This stance is also out of step with the states parties' commitments on international cooperation and assistance under Article 2(1) of the ICESCR in furtherance of the Article 12 right to health, including states parties individual and joint efforts to make available relevant technologies.<sup>113</sup> States have a duty to take reasonable measures for the fulfilment of the right to health, including access to medicines. Therefore, states should encourage pooling of technology and open licensing to promote international cooperation and technology transfer. Promoting participation in global initiatives such as the Medicines Patent Pool and C-TAP,<sup>114</sup> and facilitating global partnerships to enhance access to medicines would be consistent with states' extraterritorial obligations.<sup>115</sup> In relation to making the existing compulsory licensing system more workable, it has been suggested that the UN human rights regime could do more to monitor state measures to comply with human rights obligations.<sup>116</sup> The issuing of concluding observations and recommendations by the CESCR to states parties offers guidance on implementation of their obligations under the ICESCR and can contribute to the scope and understanding of the treaty. The concluding observations could offer a form of monitoring of states' compulsory licensing policy and can also facilitate the sharing of best practice through an interactive dialogue. For example, the CESCR's concluding observations on Brazil's state report included welcoming measures the state party had taken to adopt compulsory licensing of HIV/AIDS antiretroviral drugs in order to make them affordable and enable the extension of treatment to all patients.<sup>117</sup> Although the recommendations and guidance are non-binding, they could have persuasive power, as the recognition of good practices at international level through the concluding observations can provide helpful models to other states in addressing similar concerns.

The WTO working paper also suggests that political pressures may explain the limited use of the system, and a definitive statement is needed to clarify that allowing compulsory licensing for the export of medicines under the paragraph 6 system is a positive advance.<sup>118</sup> Further, although the system was intended to clarify that TRIPS was to be interpreted in a manner supportive of public health interests, the fact that clarification is still required on this point suggests that members remain concerned about potential consequences if they were to issue compulsory licenses to export medicines. The restrictive administrative requirements of Article 31*bis* suggested that the provision resulted as a compromise with the pharmaceutical industry, and that it would be difficult to foresee further negotiations on the issue within the WTO.<sup>119</sup> As part of states' duty to respect the right to health in Article 12 of the ICESCR they should adopt policies relating to compulsory licensing which are consistent with access to medicines. States should assess the human rights impact when adopting policies relating to compulsory licensing, to ensure appropriate consideration of access to medicines. To utilise compulsory licensing under Article 31 would also be a legitimate use of an exception to patent protection under TRIPS that has been agreed by members. Therefore, states should not be subject to external pressure not to utilise Article 31, and should be able to seek recourse through the WTO DSB if subjected to such pressure by another member.

<sup>113</sup>General Comment No 14, above n 15, p 13.

<sup>114</sup>E 't Hoen, 'The elephant in the room at the WHO Executive Board' *Medicines Law & Policy* (22 January 2021), available at <https://medicineslawandpolicy.org/2021/01/the-elfphant-in-the-room-at-the-who-executive-board/>; Bostyn, above n 86, at 243; PK Yu 'Modalities, challenges, and possibilities: an introduction to the pharmaceutical innovation symposium' (2021) 7 *Texas A&M Journal of Property Law* 1, at 34.

<sup>115</sup>J-Y Lee *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Oxford: Routledge, 2015) p 230.

<sup>116</sup>Yu, above n 102, at 1405.

<sup>117</sup>UNCESCR 'Concluding observations of the Committee on Economic, Social and Cultural Rights: Brazil' (12 June 2009) UN Doc E/C.12/BRA/CO/2, p 3.

<sup>118</sup>Kampf, above n 46, p 8.

<sup>119</sup>Abbott and Reichman, above n 109, at 984.

In contrast, an argument advanced in support of the importance of strong IP right protection is that the Doha Declaration could lead to the erosion of patent protection of pharmaceuticals in developing countries.<sup>120</sup> Specific concern related to the compulsory licensing provision in Article 31(f), which provided that a country could issue a compulsory licence in a national emergency without notice to or negotiation with the patent holder.<sup>121</sup> This argument finds that strong patent rights for pharmaceuticals are necessary for international trade, which in turn will benefit developing countries in the long term as the strong patent rights will encourage innovation.<sup>122</sup> It is important to note that patent holders are entitled to challenge a compulsory licence on particular grounds, for example non-compliance with the legal requirements,<sup>123</sup> which may undermine this argument. While innovation is necessary to advance medical technologies in order to improve treatment for those in need, this position does not address the issue that developing countries are still reliant on the exporting country to issue a compulsory licence under the paragraph 6 system. This in turn demonstrates that the developing countries are dependent on other countries to provide the particular medicines needed. This position also does not support the development of developing and least developed countries in assisting them to establish the capabilities to increase and improve their own manufacturing capacities, to manufacture the medicines that are needed domestically.

Following the development of the UN Guiding Principles on Business and Human Rights,<sup>124</sup> General Comment No 24 highlights that states parties have a responsibility to regulate transnational corporations as part of their human rights obligations under the ICESCR.<sup>125</sup> General Comment No 24 also indicates that states parties have extraterritorial obligations founded in Article 2 of the ICESCR<sup>126</sup> to take steps to prevent and remedy infringements of ICESCR rights that occur outside their territories due to the activities of business entities over which they can exercise control.<sup>127</sup> Further, states parties' obligations to protect the right to health involve duties to enact legislation or policies to secure equal access to health services provided by pharmaceutical companies within that state, including taking steps to ensure that pharmaceutical companies respect the state's obligations in relation to access to medicines.<sup>128</sup> This could involve encouraging such companies to develop and sustain corporate social responsibility policies and undertake appraisals of their own IP policies. It is important to acknowledge that the issue of global access to essential medicines and vaccines requires a response which is much broader than simply amending intellectual property policy. Inadequate domestic health care systems, lack of infrastructure to distribute medicines in developing and least developed countries, and procedural and legislative problems involved in issuing compulsory licences are all contributing factors. The Doha Declaration and Article 31*bis* have provided clarification on the flexibilities in TRIPS, and provide an important interpretative tool in the analysis of Article 31(f) of TRIPS. Examining some of the existing challenges in using compulsory licensing from a human rights perspective could offer further insights on how the compulsory licensing provisions could be more workable, to enhance the accessibility and availability of essential medicines.

<sup>120</sup>A Sykes "TRIPS, pharmaceuticals, developing countries, and the Doha "solution"" (2002) 3(1) *Chicago Journal of International Law* 47, at 56.

<sup>121</sup>*Ibid.*

<sup>122</sup>*Ibid.*, at 57.

<sup>123</sup>E Beas Rodrigues Jr *The General Exception Clauses of the TRIPS Agreement* (Cambridge: Cambridge University Press, 2012) p 198.

<sup>124</sup>United Nations Office of the High Commissioner for Human Rights *Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework* (United Nations, New York and Geneva 2011) UN Doc HR/PUB/11/04 [https://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR\\_EN.pdf](https://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf).

<sup>125</sup>UNCESCR 'General Comment No 24 (2017) on State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities' (10 August 2017) UN Doc E/C.12/GC/24, p 16.

<sup>126</sup>*Ibid.*, p 36.

<sup>127</sup>*Ibid.*, p 30.

<sup>128</sup>General Comment No 14, above n 15, p 35.

## Conclusion

Concerns of 'vaccine nationalism' and the lack of consensus among WTO members to agree a temporary IP waiver has once again raised the question of the adequacy of compulsory licensing provisions to enhance access to Covid-19 vaccines for developing states. Compulsory licensing is a powerful tool, and is a way for states to discharge their human rights obligations as well as their obligations under TRIPS. Reform of compulsory licensing provisions would not provide an expeditious solution to address the problems of developing countries in acquiring Covid-19 vaccines, but the Covid-19 pandemic proves that it is time to look at making compulsory licensing better to use in public health emergencies, by revisiting the utility of Article 31 of TRIPS and the Article 31*bis* amendment.

The UN human rights bodies have done much work to clarify the content of the right to health under Article 12 of the ICESCR as including access to medicines. States can reconcile their competing obligations under TRIPS and Article 12 of the ICESCR at national level in a manner that enhances access to essential medicines by taking a rights-based approach. Recommendations emanating from the UN human rights framework, including the UN Secretary General's High-Level Panel on Access to Medicines highlight the importance of utilising the TRIPS flexibilities and promoting the use of compulsory licensing so that a balance between the IP system and the right to health can be successfully achieved. These developments also reflect the fact that compulsory licensing is viewed within the UN human rights framework and by the WTO as an important tool to enhance access to medicines. However, using compulsory licensing to facilitate entry of generic competitors into the market will only be effective if the process is simple and user-friendly.

Although the amendment in Article 31*bis* of TRIPS was intended to make it easier for states without manufacturing capacity to secure access to affordable medicines through the compulsory licensing mechanism, this has not been widely used. The experience in Canada, on the only occasion the paragraph 6 system has been used successfully to date, emphasises the importance of effective infrastructure at national level to implement this system. Simplified and efficient compulsory licensing systems in national law would be consistent with states' right to health obligations. Undertaking human rights impact assessments with regard to national policy on compulsory licensing could also offer a deeper understanding of the issues affecting access to medicines. International collaboration and cooperation is also crucial to ensure that states meet their legal obligations in TRIPS and their human rights obligations to effectively protect global public health.