The IP Waiver for COVID-19: Bad Policy, Bad Precedent

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The role of intellectual property rights (IPRs) and access to medicines is contentious. On the one hand, IPRs encourage investment, innovation and the advancement of health science. On the other hand, the limited-term monopoly rights can result in artificially high prices and become a barrier to access to medicines. While the wisdom of the IPRs system has at times been tested, it has proven its value in the current COVID-19 pandemic as IPRs played a large role in the rapid (and unprecedented) development and availability of multiple vaccines. Despite the success, India and South Africa proposed that the World Trade Organization (WTO) waive IPRs under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in order to increase access to vaccines and other COVID-19-related technologies.¹

The proposal, tabled at a meeting of the TRIPS Council in October 2020, calls on Members to waive IPRs relating to and having an impact on the “prevention, containment or treatment of COVID-19”.² The proposal attracted support from the majority of developing country Members,³ but was opposed by a handful of

¹ See the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994), para. IX:3 (“In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the Members unless otherwise provided for in this paragraph.”)

² WTO, “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa,” WTO Doc. IP/C/W/669, (2 October 2020), para. 12.

³ “Members to continue discussion on proposal for temporary IP waiver in response to COVID-19”, WTO News Item, (10 December 2020), https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

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Members including the United States (US).⁴ Given that consensus could not be reached within the deadline of 90 days as set out in Art. IX:3 of the Agreement Establishing the WTO, Members agreed to keep the waiver proposal on the agenda of the TRIPS Council in 2021.⁵

On 5 May 2021, the US reversed its position and announced that it would support a waiver for COVID-19 vaccines.⁶ To be clear, this does not mean that the US supported the waiver as proposed by India and South Africa. Instead, the US has simply agreed to negotiate the perimeters of a waiver. Others, including the European Union (EU), Canada, Australia, Norway, Switzerland, the United Kingdom (UK) and even leading developing countries such as Brazil, Chile and Mexico remain opposed or lukewarm on the waiver.⁷ The US dropping opposition does not mean the concerns of other Members will simply disappear – one would hope that these nations opposed the waiver for valid reasons and did not simply blindly follow the US. Indeed, many of the above-listed Members remain unconvinced that even such a draconian step as a waiver of IPRs would accomplish the goal of increased vaccine production.⁸ For its part, the EU continues to favour an approach which makes better use of existing flexibilities available in the TRIPS Agreement.⁹

Thus, those expecting quick agreement on the waiver will be disappointed. Negotiations at the WTO are always difficult and lengthy, and US Trade Representative Katherine Tai acknowledged that the “negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved”.¹⁰ Issues of negotiation will include the scope of the waiver. Whereas the

⁴ Under what is referred to as “consensus decision-making”, every Member of the WTO essentially has a veto over all organisational decisions. For background, see Simon Lester, Bryan Mercurio and Arwel Davies (2018) *World Trade Law* (Bloomsbury) pp. 74–77.

⁵ Importantly, while the WTO rules would allow for Members to vote on the proposal (on the basis of one value, one vote), with a three-fourths majority needed in order for the waiver to be adopted, in practice the WTO has never abandoned “consensus decision-making” in favour of a vote. See *id.* at 82–83.

⁶ Office of the United States Trade Representative, “Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver” 5 May 2021, <https://ustr.gov/node/10649>. The timing of the announcement is curious, given that the United States Trade Representative (USTR) had recently released its annual “Special 301 Report” on IP protection and enforcement reiterating the traditional US position: “USTR continues to seek adequate and effective protection for pharmaceutical and other health-related IP around the world to ensure robust American innovation in these critical industries to fight not only the current, but also future pandemics.” See Office of the USTR, “2021 Special 301 Report”, 30 April 2021, p. 27, [https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20\(final\).pdf](https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf).

⁷ See e.g. “Covid: Germany rejects US-backed proposal to waive vaccine patents” BBC News, 6 May 2021, <https://www.bbc.com/news/world-europe-57013096>.

⁸ Andrew Green, “TRIPS waiver tripped up in WTO by ‘third way’” Devex, 5 March 2021, <https://www.devex.com/news/trips-waiver-tripped-up-in-wto-by-third-way-99329>.

⁹ European Commission, “Opening statement by Executive Vice-President Valdis Dombrovskis at the European Parliament plenary debate on the Global Covid-19 challenge” 21 May 2021, https://ec.europa.eu/commission/commissioners/2019-2024/dombrovskis/announcements/opening-statement-executive-vice-president-valdis-dombrovskis-european-parliament-plenary-debate_en.

¹⁰ Office of the United States Trade Representative, “Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver” 5 May 2021, <https://ustr.gov/node/10649>.

original proposal and its amended form extend the waiver beyond patents and vaccines to include nearly all forms of IP (i.e. copyright,¹¹ industrial designs and trade secrets) as well as to all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”¹² (with no requirement on how or the extent to which they are related to or useful in combatting COVID-19), the US and others seem to support a waiver limited to patents and vaccines.¹³ The length of the waiver will also be a contentious negotiating issue, with proponents seeking a virtual indefinite waiver lasting until the Membership agrees by consensus that it is no longer required – meaning even a single Member’s objection to ending the waiver would mean the waiver continues to remain in force¹⁴ – as will the request that any action claimed to be taken under the waiver is outside the scope of the WTO’s dispute settlement mechanism.¹⁵ These provisions will almost certainly be opposed by other Members, who would perhaps agree to a time-limited waiver which could be extended rather than an unchallengeable indefinite waiver which will be difficult to reverse. The proposal also fails to mention anything in relation to transparency and notification requirements and lacks safeguards against abuse or diversion. These points will likely also prove contentious in the negotiations.

With so many initial divergences and as yet undiscussed issues, the negotiations at best could be completed by the time of the next WTO Ministerial Conference, scheduled to begin on 20 November 2021. There is precedent in this regard, as previous TRIPS negotiations involving IP and pharmaceuticals were not fully resolved until the days before the Ministerial Conferences (in 2003 and 2005).¹⁶ There is also a chance that the negotiations will continue past the calendar year 2021.

The chance for a swift negotiation diminished with the release of a revised proposal by India and South Africa on 22 May 2021. As mentioned above, the proposal contains no limit as to product coverage, scope, notification requirements or safeguards and proposes that the waiver will remain in effect for what could be an

¹¹ With the exception of the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Art. 14 of the TRIPS Agreement. See “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Revised Decision Text”, Communication from the African Group, The Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, The LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, The Bolivarian Republic of Venezuela and Zimbabwe, P/C/W/669/Rev.1, 21 May 2021, para. 3.

¹² *Ibid* at para. 1.

¹³ New Zealand has also announced it supports a waiver limited to vaccines. Hon Damien O’Connor, “NZ backs moves to improve global access to COVID vaccines”, 6 May 2021, <https://www.beehive.govt.nz/release/nz-backs-moves-improve-global-access-covid-vaccines>.

¹⁴ Revised Waiver Proposal, *supra* note 11, para. 2: “This waiver shall be in force for at least 3 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.”

¹⁵ *Ibid* at para. 6.

¹⁶ See WTO, “Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)” TRIPS Factsheet, https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_e.htm.

indefinite period. This was not a proposal designed to engender quick negotiations and a solution. Instead, the proposal perhaps reveals India's and South Africa's true intent to use the COVID-19 pandemic as an excuse to roll-back IPRs rather than a good-faith effort to rapidly increase access to lifesaving vaccines and treatments around the world.

It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.¹⁷

The US announcement remains meaningful, however, for two reasons. First, it signals a departure from the longstanding and bipartisan support for the pharmaceutical industry, which for decades has been instrumental in setting the IP and trade agenda.¹⁸ Second, it sends a strong signal that the US does not oppose *others* from waiving patent protection for vaccines. This shift may also be part of a broader and alternative strategy to increase vaccine production and distribution, whereby the US is not viewing or supporting waiver negotiations as a legal tool but more so as a threat to encourage vaccine innovators to increase production. In essence, the desired reaction would be that the IP holders increase efforts to license, transfer technology and expand manufacturing – exactly what the world needs at this time.

Alan Beattie, writing in the *Financial Times*, believes that even the proponents of the waiver desire this outcome: “having talked to the proponents, [the original proposal] was always a tactical position designed to start a debate, identify possible support and flush out opponents rather than a likely outcome. To that end, it seems to have worked rather well.”¹⁹ India's negotiator to the TRIPS Agreement and longtime WTO staffer, Jayashree Watal, agrees, stating the proposal is an “indirect attempt to put pressure on the original manufacturers to cooperate [and license production to companies in their countries]”.²⁰ This view makes sense, as the proponents (and their supporters) have not even pointed to one credible instance where IPRs have blocked the production of a COVID-19 vaccine. Moreover, it is

¹⁷ See e.g. William Bergmann, “COVID IP Waiver Doesn't Resolve Vaccine Production Barriers” Law360, 13 May 2021, <https://www.law360.com/articles/1383618>; Thomas J. Kowalski, Deborah L. Lu, Heidi Lunasin and Brandon A. Chan, “Considerations and Implications of the Proposed Temporary Waiver of COVID-19 Vaccine-Related Intellectual Property Rights” Duane Morris LLP, 6 May 2021, <https://www.lexology.com/library/detail.aspx?g=103174a5-5d3e-45cb-9812-f07263cc8e89>.

¹⁸ See generally, Iain Osgood and Yilang Feng (2018) “Intellectual property provisions and support for US trade agreements” *The Review of International Organizations* vol. 13 p. 421.

¹⁹ Alan Beattie, “Katherine Tai springs a surprise on Covid vaccine patents” *Financial Times*, 6 May 2021.

²⁰ “Three Crises and One Waiver” *Verfassungsblog*, 7 May 2021, <https://verfassungsblog.de/three-crises-and-one-waiver/>.

well known that the leading vaccines using mRNA are difficult to reproduce and having the “blueprints” does not guarantee safe and effective production. Simply stated, if a pastry chef provides instructions on how to bake a cake, the cake they bake is still going to be better than cakes baked by novices using the exact same recipe. The know-how and trade secrets are the key ingredient to the manufacture of quality, safe and effective pharmaceuticals or vaccines, and not only is it not transferred through compulsory licenses but it is hard to imagine how any government would force the transfer of such information even under a waiver. For this reason, instead of encouraging production everywhere – including in locations where safety and efficacy standards are virtually nonexistent – and accepting that there will be a flood of substandard vaccines coming onto the world market (with devastating effects) it is much more sensible to find out where potential manufacturing capabilities exist and find ways to exploit them and scale them up.

When asked if a waiver would improve vaccine availability and equity, Watal responded: “No. It won’t. That’s clear.”²¹ I share Watal’s view and do not support a TRIPS waiver for IPRs or even a limited waiver for patents. With evidence mounting that “what the proposal ... will definitely not achieve is speeding up the Covid-19 vaccination rate in India or other parts of the Global South”²² I refuse to sacrifice academic integrity by supporting a proposal simply because it is gaining traction in some circles.²³ IPRs played a key role in delivering vaccines within a year of the discovery of a new pathogen; it seems inexplicable that the world would abandon the system without any evidence that IPRs are limiting during the current crisis.²⁴ Moreover, innovators have been generous in licensing technology transfer and production and one would be hard-pressed to find credible reports of qualified generic producers being refused a license. This is not surprising, since multiple competing vaccines are on the market it simply does not make economic sense for innovators to refuse a license – the generic manufacturer would simply obtain a license (and market share) and pay royalties to a competitor.

Instead, I support efforts to enable prompt and effective use of existing flexibilities in the TRIPS Agreement and concerted and coordinated efforts involving governments and the private sector to ensure all qualified generic producers willing and capable of manufacturing vaccines are doing so and to create

²¹ *Ibid.*

²² *Ibid.*

²³ For more detailed arguments against the proposal, see Bryan Mercurio, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review” (forthcoming) Virginia Journal of International Law https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820. For other reasoned views against the waiver, see “Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021” https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_07_Position_statement_Covid_IP_waiver.pdf.

²⁴ See e.g. Anne Moore, “COVID vaccines: why waiving patents won’t fix global shortage – scientist explains” The Conversation, 4 May 2021, <https://theconversation.com/covid-vaccines-why-waiving-patents-wont-fix-global-shortage-scientist-explains-158643> (“Little (if any) evidence has been presented that suggests IP protection is blocking COVID-19 vaccine manufacture. Rather, technical and logistic issues are the biggest barriers currently standing in the way of increasing vaccine production and deployment. To boost vaccine availability right now, it would be better to address these.”)

supply by working to bring more facilities up to standard. Cooperation will not only lead us out of this pandemic but also put us in a better position to deal with the next one. Killing the goose that laid the golden egg may seem appealing to some in the short term but will only ensure that no eggs are delivered in the next pandemic.

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