Brief to Standing Committee on International Trade and Investment Policy: Selected Consideration Concerning COVID-19 Vaccines

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This brief will discuss (1) the scope and purpose of the proposed World Trade Organization TRIPS waiver ("the waiver"), (2) comment on arguments put forth by opponents, (3) discuss the government of Canada's statements to the WTO TRIPS Council about its Canadian Access to Medicines Regime (CAMR) as a "system [that] has worked as intended," despite the government failing to include COVID-19 vaccines as eligible products, and (4) make recommendations.

The TRIPS Waiver proposal

In October 2020, South Africa and India proposed a waiver of certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 (IP/C/W/669). Specifically, they called for a waiver from the implementation, application and enforcement of Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or the provisions in Part III of the TRIPS which enforce those Sections.

The waiver would not get rid of patents or any other intellectual property type, and it would not change national laws. The waiver would only suspend obligations to abide by the WTO TRIPS rules, and even then, be limited to one virus, COVID-19, limited to a specified number of years, and subject to annual reviews by WTO Members.

The primary benefits of the waiver would be the suspension of TRIPS Article 31(f) and Article 31*bis,* both relating to exports under a compulsory license, and Article 39, on the protection of undisclosed information. Although, there may also be additional benefits in waiving Articles 30 and certain copyright and design provisions.

Articles 30 of the TRIPS Agreement places a set of restrictions on the exceptions to patent rights. The boundaries of Article 30 were explored by the WTO in WT/DS114/13, regarding Canada's early working exception for pharmaceutical drugs. Thereafter, Canada was required to make a regulatory amendment to make the pre-marketing stockpiling of patented medicines an infringement.

Article 31 of the TRIPS provides for (other) uses of a patent without the authorization of the right holder. These other uses are frequently referred to as compulsory licenses, although the specific terms in national laws vary.

Within Article 31 is subparagraph f, which limits exports under a compulsory license to less than 50 percent of would could be produced nationally. This provision, 31(f), is designed to limit the use of compulsory licenses by preventing manufacturers from achieving an efficient scale of production. It has a discriminatory impact against countries with smaller national markets, is protectionist, inefficient by design, and massively inappropriate for a pandemic, where exports and expanded scale of manufacturing are both desperately needed.

Following negotiations conducted in 2003, the WTO adopted an exception to 31(f) for "pharmaceutical products," which were defined to include active ingredients and related diagnostic kits (but not items like respirators or N95 masks). This was later adopted by the WTO as Article 31*bis*, which itself has been criticized as protectionist and inefficient.

Article 31*bis* permits exports under a compulsory license that exceed the 50 percent threshold of national production, but only when several measures are taken that require considerable foresight, coordination between governments and manufacturers, and the involvement of the WTO TRIPS Council; forcing both importing and exporting governments to coordinate with multiple departments or agencies. The provisions of Article 31*bis* are set out in more than 1800 words, compared to the 643 words used for Article 31, or the mere 20 words in Article 31(f), which Article 31*bis* was intended to fix. Canada, despite having experienced shortages of some products, including vaccines today, has elected to be ineligible to import products under Article 31*bis* but is eligible to export.

Overall, both Article 31(f) (plainly) and 31*bis* (practically) are toxic measures designed to limit exports and would be lifted by a TRIPS waiver.

Article 39 of the TRIPS Agreement deals with undisclosed information including, for example, secret manufacturing know-how, and information given to regulators of pharmaceutical products. The TRIPS waiver would reduce risks to countries that undertake measures to force the sharing of manufacturing know-how.

The references to copyrights and designs in the waiver were motivated, in part, by reports of threatened litigation over attempts to use 3D printers to make emergency ventilators.

Opposition to the waiver

Drug companies (and allies, like the Center for Global Development) have offered a number of arguments in defense of the WTO TRIPS rules. Rightsholders have hired more than 100 registered lobbyists to oppose the waiver in the United States, making contradictory claims that the waiver would not work, and yet work too well for countries like China or India.

As both a legal and a political measure, the waiver can be seen as a weakening of intellectual property norms for the pandemic. With massive government subsidies for R&D, and manufacturing companies unable to meet demand, the case against the waiver has come down to claims that the waiver is particularly ineffective for scaling up vaccine manufacturing. This

remains to be seen, of course, and many of the narratives about the futility of inducing entry into vaccine manufacturing are awkward given the surprisingly short term entirely new vaccines to have reached the market, the widespread use of emergency regulatory authorizations, and the roughly six months it has taken for the steady stream of new outsourcing contracts to enter into production (See: https://www.keionline.org/covid-19-vaccine-manufacturing-capacity).

What opponents of the waiver want is for developers to fully privatize control over publicly subsidized vaccines in the middle of the pandemic and restrict the sharing of both intellectual property and know-how to arrangements that suit commercial objectives. The harm from hoarding intellectual property and know-how has been considerable, but the full dimensions of these policy failures will not be known for a while, and depend upon the duration of the pandemic, the durability of vaccine immunity, the risks of exposure to new variants, and the promised future hikes in vaccine prices.

The Canadian Access to Medicines Regime (CAMR)

At the WTO, Canada has asked for examples of where compulsory licensing was difficult to use, mentioning that Canada is the only country to have successfully used the special compulsory licensing mechanism. In their 20 December 2020 statement at the WTO TRIPS Council, Canada stated:

> *"Canada remains the only Member to have used this special compulsory licensing system under Article 31bis and can thus observe on the basis of concrete experience that this system has worked as intended. Article 31bis only used once does not suggest that the system is inadequate rather Canada believe that this suggests that the overall TRIPS regime works as part of a broader international framework that provides Member with sufficient latitude and flexibility such as there has been limited or no need to issues compulsory licenses under Article 31bis."*[1]

The object and purpose of the Canadian Access to Medicines Regime (CAMR) is to enable generic or biosimilar pharmaceutical manufacturers to obtain a compulsory license to manufacture a product and export it to a country that is unable to manufacture on its own.

Since CAMR's implementation nearly 17 years ago, there have been five separate attempts to use the special compulsory license regime to export patented pharmaceutical products to lower-income countries. Only one, by Apotex, was successful, and the process took nearly four years.[2] To date, Apotex's experience with the special compulsory license for export is the only time that Article 31*bis* flexibility has been used, not just in the Canadian context but also globally.

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[1] Intervention by Canada, Item 15 - Waiver from certain provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, *Government of Canada* (10 December 2020).
[2] Review of the Canadian Access to Medicines Regime Submission to the Government of Canada, *Médecins Sans Frontières* (24 January 2007).

Knowledge Ecology International has examined the five attempts to use the special compulsory licensing regime in Canada, each of which indicates that the system is laborious and has fundamental flaws limiting its feasibility of use and expeditiousness.[3] NGOs, experts and generic manufacturers have echoed the conclusion that the system, as it stands, is onerous and the government has discouraged its use.[4] The experiences of those attempting to use the regime stand in stark contrast to Canada's 20 December 2020 statement at the WTO that the system in question does work as intended.

Only products listed on Schedule 1 of the *Patent Act* are eligible for export pursuant to CAMR. At the moment, no COVID-19 therapeutic or vaccine is included in Schedule 1. Knowledge Ecology International is working alongside Biolyse Pharma in their efforts to amend Schedule 1 and can comment firsthand on the difficulty in pushing forth a simple amendment to a Schedule, whose purpose is to remain current with public and global health needs.

Products as Public Goods

It is not enough to lift the WTO TRIPS obligations during a pandemic. Governments need to collaborate to ensure that COVID-19 pandemic countermeasures, including but not limited to, therapeutics, vaccines and diagnostic tests can be developed so that the inventions, data, know-how and working cell lines are treated as global public goods. The public cannot rely upon for-profit corporations, who answer to shareholders, to make critical decisions that determine the speed of manufacturing and the prices of countermeasures.

Recommendations

1. Add 'COVID-19 Vaccines' to Schedule 1 of the *Patent Act*.
2. Support the WTO TRIPS waiver in its present form or engage in text-based negotiations to find a feasible version that, at a minimum, will suspend the toxic effects of Article 31(f) and 31*bis* and does not block government measures to expand access to manufacturing know-how.
3. Providing funding to support the WHO proposed technology transfer hub for vaccine manufacturing, as a global effort.
4. Ask the WHO C-TAP to create contractual agreements that enable vaccine manufacturers to share rights in regulatory filings.
5. Support proposals to create a WTO agreement for the supply of public goods.

[3] Schouten, A. Canadian Experience with Compulsory Licensing under the Canadian Access to Medicines Regime, *Knowledge Ecology International* (31 March 2021).

[4] Lexchin, J. Canada and access to medicines in developing countries: intellectual property rights first, *Globalization and Health* (3 September 2013); Kohler, J. C., Lexchin, J., Kuek, V., & Orbinski, J. Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort? *Healthcare Policy* (February 2010); Elliott, R. & Morrison, C. Making CAMR Work: Streamlining Canada's Access to Medicines Regime, *HIV/AIDS Legal Network* (21 October 2010); and Goodwin, E., P. Right Idea, Wrong Result - Canada's Access to Medicines Regime, *American Journal of Law & Medicine* (6 January 2021).

6. Propose or support provisions in the WHO negotiations on a pandemic treaty for cross border sharing of rights in inventions and know-how for publicly funded R&D.

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