

Why Canada must Support a Temporary Waiver of IP during the COVID-19 Crisis

Submission to the Standing Committee on International Trade

This brief will focus on the first point proposed by the Committee: “(i) Canada’s position with respect to a proposal at the World Trade Organization (WTO) to provide “a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19”.

Recommendations:

1. That Canada immediately signify its support for a temporary waiver of patent provisions, such that COVID-19 related patents need not be granted or enforced during the pandemic, as originally sought by South Africa and India.
2. That Canada encourage its trade partners, including the US, Australian, and the UK governments, to immediately support this waiver.

Submitted in partnership by: Partners In Health Canada & Results Canada

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How an Intellectual Property (IP) waiver is essential to accelerating the production of tools urgently needed to end the pandemic

The current advances in vaccinology represent the most salient recent technological innovations derived from research and development (R&D). Billions of dollars are invested in R&D, and it is understandable that in normal times, those who invest in the research that leads to a breakthrough receive a protection to be able to market their innovation. However, in a global pandemic when manufacturing of critical COVID-19 diagnostics, therapeutics and vaccines is limited, supply is woefully insufficient to meet global demand, and countries around the world are struggling to vaccinate their citizens, patent protections should be temporarily waived as a matter of sound public policy and protection of fundamental human rights.

Provisions within today's international trade regime underscore the need to provide safeguards that can be invoked in public health emergencies. These include rights to issue compulsory licenses to override a medical patent, the right to introduce pre-grant patent opposition systems and strict patentability criteria, and the discretion to not allow exclusivity over test data. Unfortunately, existing provisions are inadequate to meet the demands of COVID-19 and global health security.

Many vaccine producers have already been ensnared in patent disputes in the past year. COVID-19 vaccines are protected by a thicket of patents on all aspects of development, production, and use: reagents, host cells, vectors, RNA sequences, compositions, process tech, and even age groups and methodological usages. There is also a large portfolio of IP, such as hundreds of patents on mRNA technology, owned by different entities. Under the current system of compulsory licenses, each country that seeks to produce vaccines must negotiate licensing terms for each IP protection for each technology with every firm that has monopoly rights over any aspect of it. This is a time intensive process and legal claims by holders of any of these rights can result in injunctions and delays. Beyond patents, other IP rights, including trade secrets, industrial designs, copyrights, etc. also pose barriers, with even more limited options to overcome them.

From a practical perspective, operating within the current system means that each country is obligated to use its stretched human resources to identify which of the patents are relevant and in effect nationally, and thus should become the object of a compulsory license. The ensuing protracted administrative delays are unacceptable in an emergency, which is why South Africa and India proposed a waiver from the delaying procedures and are petitioning the WTO to be dispensed from enforcing or granting patents related to COVID-19.

A TRIPS waiver would alleviate liabilities that currently deter public and private investments in local/regional biopharmaceutical manufacturing in Africa, Asia, and elsewhere. Countries in these regions are seeking certainty that if they adjust their domestic laws and practices to support investment in COVID-19 vaccine manufacturing, they will not get dragged into expansive litigation or face retaliatory sanctions from countries claiming WTO violations.

Because mRNA capacity doesn't yet exist in much of the world, it's true that an IP waiver would have to be accompanied by tech transfer, know-how, and training to kick-start production. But for other types of vaccines that use more traditional platforms (e.g. viral vector and protein subunit), this capacity transfer would be much more straightforward. Provided they're free of patent infringement

liability, generic manufacturers could begin producing vaccines relatively easily and with less intensive technical assistance from current manufacturers.

About Canada's current position on the TRIPS waiver petition at WTO

Canada's official position is that it is undecided on the TRIPS waiver petition. In the seven months since the petition was submitted, Canada has stalled by asking for examples of where the current system does not work, despite answers being repeatedly provided by waiver proponents and publicly available in WTO documents IP/C/W/670¹, IP/C/W/672², and IP/C/W/673³. In a domestic context, Canada enacted sweeping federal legislation in March 2020 allowing the production of any product related to the fight against the pandemic, regardless of patent protection⁴. It is this same type of comprehensive flexibility, urgently needed at a global level that is being debated and blocked by high-income countries within the WTO.

Disturbingly, what is being replicated through the TRIPS waiver debate is a neocolonial zNorth–South divide, where high-income countries decide what health care tools low-and-middle-income countries (LMICs) can have at their disposal to care for their citizens, and under what conditions. Countries opposing the waiver are clustered in Europe, along with the United States and a small number of others; countries now co-sponsoring or in support of the waiver, nearing or exceeding 100 in total, cover Africa and much of Asia and South America.

The neo-colonial approach is pervasive and far-reaching. Denied the ability to manufacture vaccines and assuming adequate supplies were available, and pricing was open and transparent (of which, neither is the case) most low-income countries and even middle-income countries could not afford to purchase vaccines from existing manufacturers. The largely Northern pharmaceutical industry continues to make billions of dollars in profits knowing limited vaccine access will be made available for a small percentage of low-income country populations through private and public sector philanthropy, which reinforces colonial power structures. The pharmaceutical industry is getting richer on the back of donor countries' taxpayers, and underutilized industrial potential and structural impoverishment of lower income countries is being perpetuated. This model has no place in 21st century international trade architecture, and much less in the management of the most severe health and economic crisis of our lifetimes.

So far, Canada has chosen to stand on the side of pharmaceutical profits and international trade lobbyists rather than on the side of human lives. It is important to emphasize that Canada's praiseworthy commitment to COVAX and the ACT-Accelerator do not change the fact that **rapidly scaled-up global supply of vaccines is part of the solution to ending the pandemic for all.**

¹ See Council for Trade-Related Aspects of Intellectual Property Rights, "Examples of IP Issues and Barriers in COVID-19 Pandemic", (WTO: 2020, November, 23) <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W670.pdf&Open=True>

² See Council for Trade-Related Aspects of Intellectual Property Rights, "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Responses to Questions", (WTO: 2021, January 15), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W672.pdf&Open=True>

³ See Council for Trade-Related Aspects of Intellectual Property Rights, "Response to Questions on Intellectual-Property Challenges Experienced Members in relation to COVID-19 in Document IP/C/W/671", (WTO: 2021, January 15), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W673.pdf&Open=True>

⁴ Doctors Without Border "WTO COVID-19 TRIPS Waiver Briefing Note" https://www.doctorswithoutborders.ca/sites/default/files/msf_canada_briefer_on_trips_waiver.pdf

Voluntary IP contribution and technology transfer from existing patent-holders have been encouraged for months, and clearly have not risen to the demands of the moment. Firms in many developing countries have asked for licenses or contract manufacturing arrangements and have been denied, while monopoly control on vaccine production has artificially segmented the global market at the expense of widespread access and regional manufacturing. To date, not a single vaccine manufacturer has opted to engage with the World Health Organization's COVID-19 Technology Access Pool (C-TAP), which encourages the voluntary contribution of IP, technology, and data to support scale-up of manufacturing. The problem is not a failure to connect existing manufacturers with prospective ones; it's to give the latter the legal, political, and technical assurance they need to move forward.

Given these realities, Canada's position is inconsistent with values, discourse on global health equity and solidarity, and domestic practice. It is equally difficult to justify from a policy perspective, as the Canadian public is at greater risk of variants that will continue to spread if the majority of the world remains unvaccinated.

How Waiving IP will Save Lives

Currently, populations based in high-income countries are being vaccinated twenty-five times faster than people living in low-income countries.⁵ At current levels of production, the developing world will largely be unvaccinated in 2021 and will remain so at least for a great portion of 2022, and likely well into 2023. And yet we know that global equitable vaccine distribution (i.e. distributing vaccines as proportion of global population) would avert twice as many deaths than if high-income countries were fully vaccinated first.⁶

The tragic situation in India right now underscores that we desperately need more producers that are both legally and technically capable of producing vaccines, whether mRNA or non-mRNA. However, only the Serum Institute of India and SKBio in South Korea⁷ can manufacture AstraZeneca's vaccine under the types of voluntary licensing approaches currently available. The Serum Institute is at a breaking point with COVID-19 cases skyrocketing in India. As doses that were initially reserved for export are now being retained for use in India, the rest of the world, including Canada, is being affected⁸, further showing that we cannot rely on a small handful of manufacturers to supply the entire world. Concerningly, African governments likewise have no certainty from COVAX on when they will receive their next AstraZeneca doses.

While some have claimed the TRIPS waiver would not have impact on increasing supply because excess production capacity does not exist in LMICs, this is demonstrably false. In every region of the world, there are multiple producers that could begin supplying vaccines safely and affordably if IP protections were waived and technology and know-how were shared. Just in Africa, Biovac and Aspen in South Africa, Institut Pasteur in Senegal, and Vacsera in Egypt could rapidly retool factories

⁵ Bloomberg, "More Than 1.02 Billion Shots Given: COVID-19 Vaccine Tracker", (Bloomberg: 2021, April 29), <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>

⁶ See Bill & Melinda Gates Foundation, "COVID-19 A Global Perspective: 2020 Goalkeepers Report", (BMGF: 2020, September), https://www.gatesfoundation.org/goalkeepers/downloads/2020-report/report_letter_en.pdf

⁷ WHO, "WHO lists two additional COVID-19 vaccines for emergency use and COVAX roll-out", (WHO: 2021, February 15), <https://www.who.int/news/item/15-02-2021-who-lists-two-additional-covid-19-vaccines-for-emergency-use-and-covax-roll-out>

⁸ Ryan Tumilty, "India suspends vaccine exports as cases skyrocket, stalling Canadian deliveries", (National Post: 2021, April 22), <https://nationalpost.com/news/canada/india-suspends-vaccine-exports-as-cases-skyrocket-stalling-canadian-deliveries>

to make mRNA vaccines. In Latin America, existing facilities in Brazil, Argentina, and Mexico are under contract to monopoly holders and are already producing vials and other essential supplies.⁹ Several countries, including Rwanda, are already forging partnerships to invest in building new production capacity to boost vaccine supply for the African continent;¹⁰ and an Indian manufacturer is a frontrunner in developing a potential mRNA vaccine without the heavy cold-chain requirements typically needed for such COVID-19 vaccines.¹¹

The blanket dismissal of R&D and high-quality manufacturing capacity in LMICs is not a new phenomenon and has been proven wrong in the past. And yet, patent-holding pharmaceutical companies are refusing to work with or consider viable LMIC vaccine manufacturer requests to be brought into production. Overcoming such political and legal hurdles is one of the obstacles the TRIPS waiver is designed to address.

Conclusion

It has become a truism that no one is safe until everyone is safe from COVID-19. We know the world will not be able to return to normal unless all countries have access to the tools they need to control the virus. Unfortunately, the actions of global leaders have not yet reflected that sense of urgency. Canada has an opportunity to act now.

By supporting the TRIPS waiver, Canada can contribute to immediate acceleration of global vaccine manufacturing and distribution, which would save countless lives and reinforce Canada's commitment to essential health services as a human right. We urge Canada to act with courage and conviction on this moral and public policy imperative.

Submitted in partnership by:

Partners In Health is a non-profit, global health organization that fights social injustice by bringing the benefits of modern medical science first and foremost to the most vulnerable communities around the world. Our work is based on solidarity rather than charity alone and is driven by the belief that all human lives are equally valuable.



Results Canada is a non-profit, non-governmental advocacy organization, comprised of passionate everyday people committed to raising our voices for a world without extreme poverty. We leverage resources for programs and improved policies that give people living in extreme poverty the health, education, and opportunity they need to thrive.



⁹ Public Citizen, "Waiver of the WTO's Intellectual Property Rules (TRIPS): Facts vs. Common Myths" (citizen.org: 2021, March 29), <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-myths-vs-facts/>

¹⁰ Sara Jerving, "AU launches Partnership for African Vaccine Manufacturing", (Devex: 2021, April 14), <https://www.devex.com/news/au-launches-partnership-for-african-vaccine-manufacturing-99654>

¹¹ Médecins Sans Frontières, "WTO COVID-19 TRIPS Waiver Proposal", (Transcend Media: 2021, March 1), <https://www.transcend.org/tms/2021/03/wto-covid-19-trips-waiver-proposal/>