

## Canada, Global Vaccine Supply, and the TRIPS Waiver

Ronald Labonté, Professor and Distinguished Research Chair, University of Ottawa

On behalf of Canadian Coalition for Global Health Research

---

The CCGHR is a non-profit organization committed to global health equity. It has over 500 individual and 20 university members. Our present interest is with improving rapid scale-up and equity in the distribution of COVID-19 vaccines and related medical products, and the role a TRIPS waiver might play in this. Canada is one of a small number of WTO member states that is not supporting the waiver largely on the grounds that existing TRIPS flexibilities are sufficient or that the proposed waiver would not make any difference in vaccine supply. We disagree with these statements, as does the DG of the World Health Organization, the DG of UNAIDS, many EU parliamentarians, over 110 WTO member states, and hundreds of health research and development organizations worldwide. We call on Canada to state publicly its support for the TRIPS waiver.

### *The Vaccine Context*

There is a critical undersupply of approved vaccines. At the same time there is slack vaccine manufacturing capacity worldwide that could be used to produce more vaccines, more rapidly. The TRIPS waiver is an important first step in scaling up vaccine production and distribution.

Inequity in the global distribution of vaccines is largely due to a small number of wealthier countries, including Canada, having made bilateral advance purchase agreements with PHARMA manufacturers of the (then) main vaccine candidates. As of mid-April, the WHO estimates that 87 percent of available approved vaccines have gone to high- and upper-middle-income countries while low-income countries have received just 0.2%<sup>1</sup>. This inequitable distribution, and the health and economic losses it brings, will persist throughout 2021 and well into 2022.

COVAX, the global initiative created to coordinate vaccine development and manufacturing to achieve an equitable distribution of vaccines intends to deliver 2 billion vaccine doses to participating countries by the end of 2021, including 92 funded low- and middle-income nations. It may be unable to meet even this modest target due to financial constraints; it needs an additional \$2 billion in 2021 to purchase the required doses. If successful, in the acute phase of the pandemic, COVAX vaccines will reach only 20% of the high-risk (essential) population in these countries. Even if parallel efforts by the IMF, the World Bank, and the African Union to increase financial resources allowing low-income countries to purchase their own vaccine supplies through bilateral agreements (outside of the COVAX facility), there remains an acute and substantial supply shortage. Vaccine supply projections outline that most low-income and lower-middle income countries will be unable to widely immunize their populations before the end of 2022 and extending into 2023, while most high-income countries like Canada are likely to do so well before fall 2021.

---

<sup>1</sup> <https://www.sunstar.com.ph/article/1891270/Manila/Local-News/Less-than-1-of-vaccines-went-to-low-income-countries-WHO-says>

### *Why Global Vaccine Inequity Should Matter to Canadians*

Human and economic impacts of vaccine shortage are staggering, both globally and for Canadians. Early in the pandemic, Prime Minister Trudeau publicly joined most political leaders in declaring that no one is safe until everyone is safe. The rise of more infectious and potentially dangerous variants is adding urgency to this claim. This has led to calls to scale up vaccine access as rapidly as possible, otherwise fully immunized Canadians may find themselves still at risk of new variant infections.

The longer it takes for the world's population to reach vaccine herd immunity, the worse the global recession and the greater the estimated economic losses across all countries. Economic modelling suggests that each Canadian could lose as much as \$2,000 annually as a result of a COVID-19 induced recession worsened by unequal vaccine allocation<sup>2</sup>. Global poverty rates will continue to surge, increasing the numbers of people fleeing unsafe and unhealthy countries for refuge elsewhere.

The economic fallout of a protracted pandemic will increase instability in many countries, posing conflict risks that could persist for many years and fomenting geopolitical tensions (China, the USA, Russia) that will eventually impact Canadians<sup>3</sup>.

### *Are TRIPS Flexibilities Sufficient?*

No. While countries with vaccine manufacturing facilities could issue a compulsory license, the process to do so is cumbersome and applies on a case-by-case basis; if this was straightforward, then it would have been done by this point in the pandemic. Countries must have an appropriate legal framework, attempt first to negotiate a licensing agreement with the patentee, and risk pressure from drug companies and their parent countries just for initiating the process. The Canadian example from the 2001 anthrax scare, where Bayer threatened legal action against the Government of Canada for violating its patent rights on ciprofloxacin, is a clear example where companies and governments, particularly lower-income countries, would be reluctant to invoke this strategy. Rules for compulsory licensing to export are well known to be so complex that there has been only one attempt to invoke this flexibility (the Canadian generic firm, Apotex). Recently another Canadian company (Biolyse) unsuccessfully sought a licensing arrangement to produce the Johnson & Johnson vaccine and then requested approval for compulsory licensing for export to lower-income countries<sup>4</sup>. After several months of facing bureaucratic obstacles its president in early April complained that "I don't really see how we can get anything done."<sup>5</sup>

TRIPS flexibilities never anticipated a global pandemic. It is not surprising that few countries have tried to issue compulsory licenses for COVID-related patented products and, apart from Biolyse's efforts, none have done so for vaccines. Meanwhile, current approved vaccines are surrounding themselves with patent 'thickets' making future compulsory licensing under existing flexibilities more difficult.

---

<sup>2</sup> <https://www.oxfam.org/en/press-releases/failure-vaccinate-globally-could-cost-2000-person-year-rich-nations>

<sup>3</sup> [https://www.vox.com/2021/4/14/22383514/covid-vaccines-india-africa-china?campaign\\_id=154&emc=edit\\_cb\\_20210414&instance\\_id=29239&nl=coronavirus-briefing&regi\\_id=46525520&segment\\_id=55584&te=1&user\\_id=b42060dfbc3ae790fc753fab07a45842](https://www.vox.com/2021/4/14/22383514/covid-vaccines-india-africa-china?campaign_id=154&emc=edit_cb_20210414&instance_id=29239&nl=coronavirus-briefing&regi_id=46525520&segment_id=55584&te=1&user_id=b42060dfbc3ae790fc753fab07a45842)

<sup>4</sup> <https://www.theglobeandmail.com/world/article-canadian-firm-seeks-mandatory-licence-to-produce-covid-19-vaccines-for/>

<sup>5</sup> <https://globalnews.ca/news/7743371/biolyse-covid-19-vaccines-health-canada-johnson-and-johnson/>

The temporary waiver is also more ambitious than current flexibilities, which apply only to patents. The waiver would remove obligations on WTO members to implement, apply, or enforce certain obligations related to COVID-19 products and technologies with respect to copyrights, industrial design, and protection of undisclosed information, in addition to patents. The waiver would be in force until the WHO declared the global pandemic over, i.e., that global herd immunity had been reached. It would not apply to any other aspects of the TRIPS Agreement, or to any other medical products not directly pertinent to COVID-19. The waiver would remove the threat of potential disputes facing capable generic manufacturers producing some of the new vaccines or other patented COVID-19 related medicines, diagnostic technology, or medical equipment.

#### *What About Voluntary Licensing?*

Decisions about vaccine manufacturing and supply rest with the patent-holding vaccine companies. Although these companies can negotiate licenses with other manufacturers to produce all or parts of their vaccines (and many have), the terms of these licenses are generally secret and often designed to maximize revenue for the patentee. AstraZeneca's license with the Serum Institute of India (SII) to produce 1 billion doses of its vaccine stipulates that these cannot go to high- or upper-middle-income countries, markets it appears to want for itself<sup>6</sup> (although Canada has bypassed this aspect of the agreement in being one of only a few higher-income countries to secure supply from SII). Johnson & Johnson's terms under which Aspen (a South African Pharma company) will produce elements of its vaccine requires that 91% of the doses be sent for sale in Europe rather than remain in the pandemic-afflicted country producing them.<sup>7</sup> Moderna refused to partner with a qualified Bangladeshi vaccine manufacturer, while qualified producers in other African countries have not had any responses to their licensing inquiries. As a synopsis of the present state-of-play concluded:

“...the originators’ unwillingness to partner is a huge gap between needed global supply and the production levels that vaccine developers deem useful for their business strategy, which is focused mostly on selling at higher prices to rich and upper-middle-income countries.”<sup>8</sup>

With the likelihood that mRNA vaccine boosters will be required one can envision a scenario where the wealthier vaccine hoarders of the recent past will also scoop this new supply. Current manufacturing (licensed or otherwise) will go to provide for these paying customer-nations while countries still awaiting a first ‘jab’ risk facing further shortage-induced delays.

#### *Will the TRIPS Waiver Increase Vaccine Supply?*

Yes. But only if patentees are also willing to share the technology and know-how associated with their vaccines. In that respect, as has been noted:

---

<sup>6</sup> <http://www.ipsnews.net/2021/03/end-vaccine-apartheid-millions-die/>

<sup>7</sup> <https://www.commondreams.org/newswire/2021/04/13/eve-wto-covid-meeting-director-generals-third-way-same-old-way-big-pharma>

<sup>8</sup> <https://www.commondreams.org/newswire/2021/04/13/eve-wto-covid-meeting-director-generals-third-way-same-old-way-big-pharma>

“...knowledge-sharing and tech transfer are the crux of the IP issue—not patents and legal strictures per se.”<sup>9</sup>

But such sharing is not occurring. The proposed COVID-19 Technology Access Pool (C-TAP) was intended to promote this, but no PHARMA manufacturer has joined, and its open-access intention was ridiculed by senior PHARMA officials for undermining their business model. There is now a proposal to create a ‘technology transfer hub’ through the ACT-Accelerator, with the promise to pressure and incentivize voluntary licensing agreements. More specifically, WHO is calling for an mRNA technology transfer hub since those vaccines show the most efficacy, the greatest likelihood of adaptation to variants, and a relative ease in scaling up production capacities. To be successful, “owners...of technology and/or intellectual property rights” must be “willing to contribute” their “know-how and technology”.<sup>10</sup>

The proposed TRIPS waiver becomes leverage to incentivize such sharing. Without it there would be little compulsion for current vaccine patentees to voluntarily share given their reluctance to do so since the race for COVID-19 vaccine discovery began. It would allow governments that presently oppose (or nominally do not support) the waiver to recognize the waiver’s role less as denial of IPRs (the waiver is only temporary) than acknowledgement that the ‘warp speed’ development of COVID-19 vaccines was almost entirely funded or underwritten by public funds. It will also require governments that are home countries to PHARMA to persuade patentees to share, which could include some modest royalty but not the multi-billion profits some of them anticipate.<sup>11</sup>

### *The Moral Question*

Ultimately the question facing this committee is less about the legal nuances of the TRIPS agreement and more about whether COVID-19 vaccines should be treated as publicly financed private business commodities or as global public goods. Some rewards for the efforts of the private businesses involved are due, but the human, health, and even economic costs of failing to compel ‘warp speed’ vaccine production globally by any and all means (including approval of the TRIPS waiver) constitute a profound moral failure. As Canadians, we are privileged to have the opportunity to transform this injustice.

### **Background**

We have been active on this issue since soon after the TRIPS waiver was announced. In November 2021 we issued A Joint Statement of the Canadian Coalition for Global Health Research and the Canadian Society for International Health, calling for improved equitable access to COVID-19 products and technologies through intellectual property waiver (<https://www.ccghr.ca/improving-equitable-access-intellectual-property-waiver-covid-19-products-technologies-deserves-global-support/>).

Experts and leading global health researchers, through these same organizations, issued another open letter to the Government of Canada in December 2020 (<https://www.ccghr.ca/open-letter-government-canada/>), expressing appreciation for contributions to the COVAX AMC facility and ACT Accelerator and

---

<sup>9</sup> <https://www.cgdev.org/debate/would-exempting-covid-19-vaccines-intellectual-property-rights-improve-global-access>

<sup>10</sup> <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>

<sup>11</sup> <https://qz.com/1997697/will-pfizer-and-moderna-profit-from-the-covid-19-booster-shot/>

urging the government to continue to focus on global recovery from this pandemic by supporting the TRIPS waiver and sharing surplus vaccines.

In March 2021, more than 120 leaders in global and public health from across Canada signed an open letter (<https://www.ccghr.ca/wp-content/uploads/2021/03/Open-Letter-Global-Vaccine-Distribution-March-2021.pdf>) to the government, providing an evidence-based argument for equitable global access to COVID-19 vaccines. This letter included endorsement from leadership of the Canadian Coalition for Global Health Research, the Canadian Society for International Health, the People's Health Movement Canada, and Grandmothers' Advocacy Network; and had Canada-wide representation.