

WTO COVID-19 TRIPS Waiver

Doctors Without Borders Canada Briefing Note



Introduction

In July of 2020, Justin Trudeau was the first of eight national leaders to put his name to an op-ed that closed with the following call to action: “We call on global leaders to commit to contributing to an equitable distribution of the COVID-19 vaccine, based on the spirit of a greater freedom for all.”¹

Doctors Without Borders / Médecins Sans Frontières (MSF) is responding to this call by asking Canada act upon this commitment at the World Trade Organization (WTO) and support the proposal originally put forth by India and South Africa² to allow all countries to choose to neither grant nor enforce patents and other intellectual property (IP) related to COVID-19 drugs, vaccines, diagnostics, and other health technologies for the duration of the pandemic, until global herd immunity is achieved. Canada has so far maintained that it “has not rejected this proposal”.³ At the same time, it has not supported text-based negotiations, and has continually emphasized the need to first hear about specific, concrete IP challenges rather than act on implementing solutions, most notably in document IP/C/W/671⁴ where Australia, Canada, Chile and Mexico raised eight questions asking for additional information on the necessity of the proposed TRIPS Waiver.

These eight questions have been answered in detail elsewhere, most notably in document IP/C/W/673s. MSF has repeatedly witnessed how exclusive rights and monopolies granted to pharmaceutical corporations, resulting in high prices and blocking generic competition, have had a negative impact on our medical actions in different countries, for example in accessing antiretrovirals for HIV/AIDS, tuberculosis, and hepatitis C. In IP/C/W/673, several countries provide a detailed overview of why the current system does not facilitate rapid, affordable access to health technologies, including problems with the use of compulsory licenses. We agree that the cumulation of decades of experience and evidence of intellectual property being a barrier and having a chilling effect on competition, scaling-up manufacturing, and ensuring affordable access to medicines, vaccines, and other health technologies is a solid argument for supporting the proposed TRIPS waiver.

Moreover, based on our experience and observations in Canada, MSF would like to draw particular attention to Canada’s arguments related to domestic compulsory licensing for

¹ <https://healthydebate.ca/opinions/trudeau-joins-call-for-global-access-to-vaccine-in-open-letter>

² As of Feb 24/2021, 58 countries had officially joined as co-sponsors.

³ https://www.international.gc.ca/world-monde/international_relations-relations_internationales/wto-omc/2021-02-23-trips-adpic.aspx?lang=eng

⁴ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W671.pdf&Open=True>

government use, and to compulsory licensing for export in the context of the pandemic in accordance with TRIPS Article 31bis (which Canada's Access to Medicines Regime – CAMR – is intended to implement). While MSF supports the use of compulsory licenses by all governments as a critical public health safeguard for access to medicines, MSF does not believe that either domestic compulsory licensing or compulsory licensing for export mechanisms are appropriate or equally effective alternatives to the proposed waiver as a response to the pandemic.

Domestic Compulsory Licensing under Article 31 of TRIPS agreement

Canada was very quick to give itself new legal tools to ease the issuance of domestic compulsory licensing at the start of the COVID-19 pandemic. In March 2020, as part of the *COVID-19 Emergency Response Act*, Canada amended its *Patent Act* to make this process simpler and faster.⁵⁶ As of the morning of March 25⁷, the day the amendment received assent, less than three thousand cases of COVID-19 had been detected in Canada, resulting in fewer than thirty deaths. According to this amendment:

19.4 (1) The Commissioner shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application.

It is worth noting this obligatory issuance upon the application of the Minister of Health does not require consultation with the patent holder beforehand, in compliance with the provision of Article 31 (b) of the TRIPS agreement. Considering that Canada had only turned to its existing compulsory licensing powers on one occasion in the 21st Century, this was a major step to take to protect public health, particularly in the absence of a specific barrier necessitating a compulsory license.

The crucial message here is not simply that Canada was willing to quickly ensure that this simplified pathway to a compulsory license for government use was in its toolbox very early in the pandemic, but that it did so without waiting for patent barriers to arise. This demonstrates that Canada was not responding to a specific, concrete IP barrier that required this intervention, but was instead preparing for potential barriers it might face. As such, at the WTO, other countries are being asked to supply evidence of specific barriers that Canada itself never waited for. Furthermore, the expiry date included in its compulsory licensing measure further demonstrates Canada was willing to enact measures to respond to emergency situations that were temporary, rather than permanent, in nature. Such is the case with the proposed waiver. Canada should permit a similarly temporary measure intended to proactively overcome potential barriers at the international level via the waiver.

⁵ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/C/W673.pdf&Open=True>

⁶ *COVID-19 Emergency Response Act*, Canada amended its *Patent Act* to make it simpler to issue a compulsory licence. https://laws-lois.justice.gc.ca/eng/AnnualStatutes/2020_5/page-8.html#h-33

⁷ <https://toronto.citynews.ca/2020/03/25/the-latest-numbers-of-covid-19-cases-in-canada-7/>

Canada's compulsory licensing measures have been remarked upon by other states at the WTO during this discussion, together with similar measures in a few other countries such as Australia, Germany and Hungary. While Canada may argue that both the amendment and the existing framework for compulsory licensing are a matter of domestic regulation permitted under TRIPS, it is not clear this distinction is as important as Canada suggests; temporary waivers are allowed within the WTO framework, and indeed several have been used in the past in relation to TRIPS⁸. Some such waivers have been in place for years and are authorized to continue for over a decade, considerably longer than the waiver currently under discussion.

As to the question of why other countries have not done the same domestically, bilateral pressures by trading partners have historically dissuaded many countries from putting compulsory licensing measures in place, or from amending them with the same speed that Canada has now done in response to COVID-19. Even in the midst of the covid-19 pandemic, the office of the United States Trade Representative [USTR] issued its Special 301 Report criticizing actions of trading partners for using or threatening to use TRIPS flexibilities.⁹ In addition, simply to attempt the use of compulsory licenses requires resources that may pose serious obstacles for many countries even in the absence of political barriers, particularly in overburdened health ministries who have little capacity to spare to search the patent status of each product to request compulsory licenses to be issued for government use, and who face protracted litigation from patent holders.¹⁰ As such, some countries with laws that permit compulsory licensing have never operationalized them.

Furthermore, when it comes to products like vaccines, patents may exist at many stages of the development, production and delivery process. The COVID-19 vaccine portfolio involves numerous novel platforms and technologies, such as mRNA. Patents may cover specific strains, adjuvants, antigen production and other such elements.¹¹ . These background patents are frequently owned by different entities in different countries, adding great complexity, as well as potential legal risks, even where compulsory licensing tools are available. Finally, the typical domestic compulsory license at national level often only covers patents, while other types of IP, such as undisclosed information concerning test data and manufacturing know-how may not be covered. As a result, additional legal tools, covering a range of IP, are needed for such measures to be effective.

Finally, Canada offers its own clear example of the failure of relying upon voluntary actions by the pharmaceutical industry. As a recent Canadian headline states, "Every COVID-19 vaccine maker was asked to make their doses in Canada and all said no".¹² Canada lacks effective tools to respond to this refusal. This is the case even where Canada does possess capacity for

⁸ See e.g., <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/971.pdf&Open=True>

⁹ https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf

¹⁰ Natco Pharma v Bayer Corp. (Sorafenib Tosylate Compulsory License, India) [Bayer Corp. had taken the matter up to the Supreme Court of India after the Compulsory License was granted by the patent office]; Pat Sidley. Drug companies sue South African government over generics. BMJ (2001) available at <https://www.bmj.com/content/322/7284/447> [More than 40 pharmaceutical companies, many of them the world's largest and most powerful companies, will be taking the South African government to court to try to stop it enacting legislation aimed at reducing the price of medicines for South Africans.]

¹¹ <https://msfaccess.org/fair-shot-vaccine-affordability>

¹² <https://www.cp24.com/news/every-vaccine-maker-was-asked-to-make-their-doses-in-canada-and-all-said-no-anand-1.5296162>

limited domestic production.¹³ The result is that Canada has been reliant on production in other countries, leaving it vulnerable to export restrictions in the United States, and more recently the European Union. A subsequent arrangement with Novavax for potential production to begin late in 2021 does not resolve these underlying concerns.

To summarize, Canada's question in IP/C/W/671 asking countries to demonstrate the difficulties of using compulsory license under Article 31 of TRIPS is ultimately unhelpful, and indeed obstructive. First, as Canada itself has demonstrated, proactive tools to address barriers even before they arise are preferable to reactive tools. Second, a history of political pressures and insufficient legal and legislative resources mean many countries lack such domestic tools, let alone the ability to rapidly develop and deploy them during a pandemic. Third, national compulsory licensing tools, even where available, are not well-equipped to cope with the volume and variety of intellectual property involved in the COVID-19 response. Finally, Canada itself demonstrates the consequences of reliance on voluntary measures by pharmaceutical companies without additional tools in reserve.

Compulsory Licensing for Export

Canada's current conservative approach also stands in marked contrast to previous actions it has taken in support of improving global access to novel medicines in the face of a pandemic. It previously did so in response to circumstances in other countries that are now faced by Canada itself when it comes to COVID-19 vaccines: the inability to produce such products domestically.

In 2004, Canada passed the *Pledge to Africa Act*, making it the first country in the world to enact legislation to enable a special TRIPS flexibility outlined in the *Doha Declaration*. It created **Canada's Access to Medicines Regime (CAMR)** to enable the Paragraph 6 mechanism (now codified in Article 31bis of TRIPS). Article 31bis addresses the issue of states that do not have domestic manufacturing capacity to exercise compulsory licenses; to fill this gap, it permits countries with domestic capacity to issue compulsory licenses for export to countries that do not. CAMR thus permitted compulsory licenses to be issued in Canada for production for export, without that license being granted for domestic use.

In 2008, Canada racked up another global first when CAMR was used by the generics company Apotex to send two shipments of an antiretroviral triple therapy to Rwanda. However, this global first would also be a global last; this single use of CAMR is the only time that the Paragraph 6/Article 31bis flexibilities have ever been used, anywhere in the world. Apotex, the company that used the mechanism, stated publicly it would never use the process again unless the process were reformed.¹⁴ MSF, who was part of this effort to use CAMR shortly after its creation, also conveyed its concerns about the failings of the regime to Canada.¹⁵ It is thus evident that CAMR, and the broader Paragraph 6/Article 31bis mechanism, do not work in their current form.

¹³ <https://www.macleans.ca/politics/ottawa/ottawa-spent-millions-on-domestic-vaccine-production-where-is-it/>

¹⁴ See Apotex Inc, "CAMR Federal Law Needs to be Fixed if Life-Saving Drugs for Children are to be Developed", Newswire (14 May 2009). See also Tanya Talaga, "Hope for Cheap HIV Drugs Dims" The Star (19 September 2009), online: https://www.thestar.com/life/health_wellness/2009/09/19/hope_for_cheap_hiv_drugs_dims.html).

¹⁵ Marilyn McHarg & Médecins Sans Frontières Canada, "Review of the Canadian Access to Medicines Regime: Submission to the Government of Canada" (2007), online: <www.camr-rcam.gc.ca/review-reviser/camr_rcam_msf_11-eng.pdf>;

As such, Canada's position in the context of current discussions around the COVID-19 waiver is difficult to comprehend. On December 10, 2020, Canada stated:

Canada remains the only Member to have used the special compulsory licensing system under Article 31bis, and can thus observe, on the basis of concrete experience, that the system worked as intended. Canada has heard that the Article 31bis system having been used only once suggests that the system is inadequate. Rather, Canada believes that this suggests that the overall TRIPS regime works well, as part of the broader international framework, and provides Members with sufficient latitude and flexibility, such that there has been limited or no need to issue compulsory licenses under Article 31bis.

This is, to be blunt, a bizarre and unsupported conclusion. CAMR has been the subject of considerable criticism by the pharmaceutical industry, NGOs and academics since its inception. Indeed, the fact that CAMR does not work in its current form is one thing this disparate group can agree upon. In its CAMR submission, MSF also raised concerns¹⁶ about the broader Paragraph 6/Article 31bis mechanism, which has similarly been widely criticized as unworkable in its current form, including by the United Nations Secretary-General's High-Level Panel on Access to Medicines.¹⁷ While there is disagreement over how Article 31bis could be reformed to be more effective, or even whether such reform is possible, there is once again considerable agreement upon the fact that it does not work in its existing form. Article 31bis, instead of simplifying and accelerating the process, does quite the opposite, through requirements that range from adding unnecessary steps (mandatory differential packaging and colouring of products under the compulsory license), to actively impeding the flexibility needed in an evolving public health crisis (requiring importing countries to specify the quantity needed for each product in each compulsory license used under the notification made to the WTO). Such excessive procedural requirements create unnecessary barriers, particularly during the pandemic when all resources and every moment of time are precious. As such, Canada's assertions about the functionality of this mechanism do not reflect its own purported concern for evidence-based decision making.

Furthermore, the Canadian argument is circular. Even if it were true that, in general, the current global system works sufficiently well "*that there has been limited or no need to issue compulsory licenses under Article 31bis*", the WTO waiver is explicitly intended to address circumstances quite outside the normal state of affairs. As illustrated above, Article 31bis is quite inadequate to address these novel challenges. Thus, Canada's focus on whether countries have formally initiated Article 31bis proceedings miss the mark; there is no value in any country initiating use of the wrong tool for the job.

At the same time, Canada's approach to Article 31bis does offer one further applicable lesson. Despite its enthusiasm to make a *Pledge to Africa*, Canada has indicated it would not use the Paragraph 6/Art.31bis mechanism as an importing member.¹⁸ This is a further demonstration that it is entirely possible for Canada to support, or at the very least not interfere with, other countries' abilities to access medicines in the manner those countries see fit while simultaneously allowing Canada to maintain its own policy choices when it comes to intellectual property. It also highlights a particular irony of the current situation: Canada lacks sufficient domestic production capacity for COVID-19 vaccines, and as such is itself dependent on

¹⁶ <https://msfaccess.org/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable>

¹⁷ See e.g. High-Level Panel on Access to Health Technologies, Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, (September 2016) at 9, online: <http://www.unsgaccessmeds.org/final-report> [UN High-Level Panel Report].

¹⁸ https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

importation. Only expanding the global supply will ensure access. The waiver is one such measure to support this in the pandemic.

Conclusion

Both in its domestic response to COVID-19, and its global response to past pandemics, Canada has been quick to pass legislation creating tools to improve access to medicines not after careful, studied examination of evidence that these mechanisms are effective at resolving narrowly defined access problems, but on the premise that these novel tools might be of value in the response going forward. Its failure to adopt a similar approach to the WTO waiver proposal is not only unfortunate but undermines Canada's stated goal of ending COVID-19 everywhere. Rather than continuing to insist other countries attempt to apply inadequate existing tools to the novel problem of the COVID-19 pandemic, Canada's approach at the WTO should take a page from its domestic strategy of proactively anticipating new problems before they arise and creating new tools to address them.