# Revisiting Canada's Access to Medicines Regime in Response to COVID-19: A Review of the Legislation and its Underlying Objectives

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## Abstract

The current COVID-19 pandemic has highlighted the significance of the export-oriented compulsory licensing mechanism for countries lacking domestic manufacturing capacity. Article 31bis, the first amendment to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), is aimed at giving effect to the WTO General Council Decision 2003, which waived the domestic market requirement of compulsory licensing. In 2005, Canada became the first country to amend its patent laws to provide for Canada's Access to Medicines Regime (CAMR) as enabling legislation to implement the WTO General Council Decision 2003. Canada clearly described its regime as a humanitarian initiative aimed at helping least-developed countries and many developing countries that lack sufficient drug and/or vaccine manufacturing capacity of their own and rely upon imports to address their public health problems. The legislation got compromised by the conflicting goals of protecting the corporate interests of patentee corporations. This research paper argues that the CAMR system is not capable of delivering what was promised. This research paper maintains that Canada unnecessarily added extra layers of complication, restrictions, and regulatory requirements on top of what was required under Article 31bis, which is itself too onerous to invoke for resource-poor countries. This research paper also evaluates Canada's efforts to reform CAMR and suggests overhauling of export-oriented compulsory licensing mechanism to provide a functional and expeditious one-licence solution workable for importing countries and acceptable to generic drug companies.

**Keywords**

Patent Law, Compulsory Licensing, Access to Essential Medicines, World Trade Organization, TRIPS Agreement, Article 31bis, Canada, Canada's Access to Medicines Regime', Biolyse, Bolivia, Coronavirus, COVID-19

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## I. Introduction

The current health emergency highlights the importance of the TRIPS Agreement's Article 31bis mechanism or export-oriented compulsory licensing mechanism. Lack of sufficient domestic capacity to manufacture medical treatments is a considerable barrier in meeting higher demand for these treatments in a health emergency like the COVID-19 pandemic. Most of the countries eligible to use this system are struggling to combat acute shortages of COVID-19 vaccines, treatments, and diagnostics. Patents[1] protecting these critically needed health technologies pose formidable barriers to access. To effectively deal with the current pandemic situation, it is important for the most vulnerable countries that the Article 31bis mechanism functions to enable importing of critically needed generic treatments. This mechanism provides a legal basis for a cooperative strategy to save human lives through the effective use of compulsory licensing.[2] The workability and sustainability of this mechanism are important in

[1] 'A patent is a government grant of a time-limited legal monopoly given to an inventor in exchange for the public disclosure of an invention. It can be thought of as a veto over the activities of others in respect of making, using, selling or importing an invention'. See Lori Sheremeta and E Richard Gold, "Creating a Patent Clearinghouse in Canada: A Solution to Problems of Equity and Access," *Health Law Review* 11, no. 3 (2003): 17.

[2] Bassam Peter Wu, Xiaoping; Khazin, "Patent-Related Actions Taken in WTO Members in Response to the COVID-19 Pandemic," *World Trade Organization (WTO), Geneva*, (2020) 28.

supporting a system of multilateral coordination and solidarity to suppress the pandemic through a cooperative strategy.[3]

In February 2021, Bolivia, a developing country lacking vaccine manufacturing capacity, made a general notification to the WTO to notify its intent to use the Article 31bis mechanism to purchase COVID-19 vaccines from a Canadian generic manufacturer Biolyse Pharma.[4] Subject to the grant of a voluntary licence by Johnson & Johnson or the grant of a compulsory licence by Canada, Bolivia intends to import 15 million doses of vaccines to address supply shortages. Johnson & Johnson refused to negotiate a voluntary licence. Since March 2021, Biolyse Pharma has been trying to initiate the CAMR process to seek a compulsory licence. Amending Schedule 1 is the first step in using the Canadian regime. For more than six months, Biolyse Pharma, a fully certified current Good Manufacturing Practices/ Good Laboratory Practices (cGMP/GLP) biologics manufacturing facility eager to help bridge the supply gap, has been hamstrung by this preliminary step in using CAMR.[5]

In this context, this study argues that Canada's Access to Medicines Regime (CAMR) is not capable of delivering what was promised. Part II provides historical background of Article 31bis mechanism and legislative history of the Canadian regime which was legislated to implement this mechanism. Part III argues that the Canadian regime unnecessarily exceeds the requirements of Article 31bis. The Article 31bis system itself is too onerous and too complicated to invoke, especially in a time-sensitive health emergency. Limitations of this

[3] Thana C De Campos-Rudinsky, "Intellectual Property and Essential Medicines in the COVID-19 Pandemic," *International Affairs* 97, no. 2 (2021): 523–37, https://doi.org/10.1093/ia/iiaa232.
[4] Helen Lock, "Bolivia Could Unlock New Access to Life-Saving COVID-19 Vaccines — But Needs Canada to Grant a License." *Global Citizen,* 2 August 2021. Available from https://www.globalcitizen.org/en/content/bolivia-canada-patents-covid-19-vaccines-trips/ (accessed 4 September 2021).
[5] Muhammad Zaheer Abbas, "Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case," *South Centre*, no. 136 (2021): 9–16.

defective system have been repeatedly identified.[6] The Canadian regime is even more cumbersome and administratively demanding as it goes well beyond the requirements of Article 31bis in contrast with its stated purpose of providing a humanitarian aid strategy. The regime is not acceptable to generic manufacturers because of the lack of financial incentives and the absence of certainty or finality provided by this regime. Part IV evaluates Canada's efforts to reform CAMR. Several failed attempts indicate that the political will to reform and simplify the regime is lacking. The conclusion in Part V suggests overhauling of export-oriented compulsory licensing mechanism and supports the one-licence solution as proposed by the Canadian HIV/AIDS Legal Network. The system needs to be reformed without further delay as the limited supply of the COVID-19 vaccines has been a formidable barrier in ending the current pandemic. Having a functional export mechanism is key to suppressing this pandemic as many parts of the world, including some wealthy countries, have no or insufficient local biomanufacturing capability.

## II. Historical Background

In 1994, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) imposed limits on the use of compulsory licensing.[7] The original text of Article 31(f) of the TRIPS Agreement - which confined the use of compulsory licensing to manufacture generic products 'predominantly for the supply of the domestic market' - did not allow export of generic products manufactured under a compulsory

[6] See, for instance, Carlos M. Correa, "Supplying pharmaceuticals to countries without manufacturing capacity: Examining the solution agreed upon by the WTO on 30th August," *Journal of Generic Medicines* 1, no 2 (2004): 117; Matthew Rimmer, "Race Against Time: The Export of Essential Medicines to Rwanda" *Public Health Ethics* 1, no (2008); Muhammad Zaheer Abbas and Shamreeza Riaz, "WTO 'Paragraph 6' System for Affordable Access to Medicines: Relief or Regulatory Ritualism?," *Journal of World Intellectual Property* 21, no. 1–2 (2018): 32–51, https://doi.org/10.1111/jwip.12083; Alexandra Nightingale, "WTO 'Paragraph 6' System for Affordable Medicine: Time for Change?," *Intellectual Property Watch* (November 11, 2016).

[7] World Trade Organization (WTO), *The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1995,* Art. 31.

licensing arrangement.[8] Because of this limitation, poorer countries lacking drug manufacturing capabilities were unable to benefit from this public health flexibility.

This shortcoming of the Article 31 flexibility was highlighted during the HIV/AIDS crisis. Paragraph 6 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health recognized that 'WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use compulsory licensing under the TRIPS Agreement' and instructed 'the Council for TRIPS to find an expeditious solution to this problem and report to the General Council before the end of 2002'.[9]

On August 30, 2003, after two years of difficult negotiations among WTO Members, the General Council of the WTO decided to waive the 'domestic market' condition to resolve this issue.[10] On December 6, 2005, just before the Hong Kong Ministerial Conference, this Decision was translated into a permanent amendment to the TRIPS Agreement.[11] This Decision was codified in Article 31bis of the TRIPS Agreement. It waived 'the obligations of an exporting Member under Article 31(f) … with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)' provided certain provisions are met.[12] The system set out in Article 31bis provided a legitimate export-oriented compulsory licensing

[8] *Ibid,* Art. 31(f).
[9] *The Doha Ministerial Declaration on the TRIPS Agreement and Public Health 2001*, Para 6. (WT/MIN(01)/DEC/2).
[10] World Trade Organization General Council, "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" *Decision of the General Council of 30* (2003); See more Carlos Correa, *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement* (Oxford University Press, 2020).
[11] World Trade Organization, "Members OK amendment to make health flexibility permanent" *World Trade Organization*, 2005. https://www.wto.org/english/news_e/pres05_e/pr426_e.htm . The amendment entered into force on January 23, 2017, after attaining the two-thirds threshold for formal adoption. See World Trade Organization ,"WTO IP rules amended to ease poor countries' access to affordable medicines", *World Trade Organization*, 2017, https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm
[12] World Trade Organization, "WTO Analytical Index TRIPS Agreement – Article 31bis (Practice)" *World Trade Organization,* 1.

mechanism to export generic pharmaceutical drugs to eligible countries facing public health problems.

In November 2003, Canada - having a highly developed generic drug industry - announced its intention to amend its patent laws in order to implement the WTO General Council Decision 2003.[13] Stephen Lewis, the UN Special Envoy on HIV/AIDS in Africa, played an instrumental role in triggering the legislative changes.[14] Moreover, Jean Chretien, then Prime Minister of Canada, wanted to leave a legacy.[15] To accommodate competing perspectives, five departments – Industry Canada, Health Canada, the Department of Foreign Affairs, the Canadian International Development Agency, and International Trade Canada - fully engaged in the drafting process.[16] In May 2004, Canada passed Bill C-9 (originally numbered Bill C-56) with the input of brand-name pharmaceutical industry, civil society organizations and the generic drug industry.[17] The Jean Chretien Pledge to Africa Act[18] received royal assent in May 2004.[19] This Act provided the legislative framework for Canada's Access to Medicines Regime (CAMR) which came into force in May 2005.[20]

[13] Laura C Esmail and Jillian Clare Kohler, "The politics behind the implementation of the WTO Paragraph 6 Decision in Canada to increase global drug access" *Globalization and Health* 8.1 (2012): 4.
[14] Paige E. Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime," *American Journal of Law and Medicine* 34, no. 4 (2008): 567–84, https://doi.org/10.1177/009885880803400404.
[15] Joel Lexchin, "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First," *Globalization and Health* 9, no. 1 (2013): 1–8, https://doi.org/10.1186/1744-8603-9-42.
[16] Tania Bubela, Richard E. Gold, and Jean-Frédéric Morin, "Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence," *McGill Journal of Law and Health* 4, no. 2 (2011): 3–41, www.mdpi.com/1999-4915/5/11/2881/pdf.
[17] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 572.
[18] After realizing that the legislation would fail, the Martin administration named the Act after Jean Chretien, the former Prime Minister with whom Paul Martin had a tense relationship. See Jean Frédéric Morin and E. Richard Gold, "Consensus-Seeking, Distrust and Rhetorical Entrapment: The WTO Decision on Access to Medicines," *European Journal of International Relations* 16, no. 4 (2010): 563–87, https://doi.org/10.1177/1354066110366054.
[19] Final Report, "Canada's Access to Medicines Regime (CAMR) Implementation - Focused Evaluation of Health Canada's Responsibilities Final Report Approved by Departmental Executive Committee on," *Departmental Executive Committee on Finance, Evaluation and Accountability (DEC-FEA) Health Canad*, 2008, iii.
[20] Ibid.

This legislation added a section to the Canada Patent Act entitled 'Use of Patents for International Humanitarian Purposes to Address Public Health Problems'.[21] Canada clearly described CAMR as a 'humanitarian' initiative aimed at addressing 'public health problems afflicting many developing and least developed countries'.[22] The humanitarian purpose of this legislation was to extend support to underprivileged patients in poorer countries: 'All those who have the privilege of living in a healthy environment should turn to those in need and help them. The people have a right to the same human respect, they need our help and they need to live'.[23]

The legislation, described as a humanitarian aid initiative, got compromised by the conflicting goals of ensuring good trade relations with the U.S. by protecting corporate interests of brand-name pharmaceutical industry. 'While the idea of CAMR was laudable, the complex set of rules adopted in its implementation makes it among the most bureaucratically complex pieces of legislation administered by the Canadian Intellectual Property Office'.[24] The compromises in the legislation, resulting from prioritising intellectual property rules and corporate interests over public health, made CAMR largely unworkable losing sight of its humanitarian aid or human rights goals.[25] As noted by *Médecins Sans Frontières* (*MSF*):

[21] Canadian Intellectual Property Office, "Canada's Access to Medicines Regime." Government of Canada (2015), https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00116.html (accessed September 4, 2021).
[22] Canadian HV/AIDS Legal Network, "Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers," *Canadian HV/AIDS Legal Network*, 2005, 1–10.(3). See more Derek McKee, "Globalisation, Legal Ideas, and the Creation of Canada's Access to Medicines Regime," *Transnational Legal Theory* 4, no. 4 (2013): 607–26, https://doi.org/10.5235/20414005.4.4.607.
[23] Canada, Parliament, House of Commons, *Debates, 37th Parliament, 2nd Session, Vol. 138 (November 7, 2003) pp9323.* See more Laura Caroline Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark," *ProQuest Dissertations and Theses*, 2010, 340, http://search.proquest.com/docview/1347620365?accountid=10673%5Cnhttp://openurl.ac.uk/athens:_edu?url_ver=Z39.88-2004&rft_val_fmt=info:ofi/fmt:kev:mtx:book&genre=unknown&sid=ProQ:ProQuest+Dissertations+%2526+Theses+Global&atitle=&title=The+Politics+of+Can. (accessed September 4, 2021).
[24] Bubela, Gold, and Morin, "Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence." 14.
[25] Lexchin, "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First." 3.

> We've tied our regime into so many knots of red tape that our capacity to break through this has in fact been completely stymied. Yet again, the will of Parliament and the will of Canadians has been thwarted by legislation that is far too timid and far too deferential to issues that have nothing to do with humanity, nothing to do with human rights, and nothing to do with getting people access to health care, and everything to do with protecting privilege and protecting profit.[26]

The Martin government actors tactfully used 'balance of interests' discourse to prioritise the corporate interests of patentee companies over the right to life and the right to health. In their press releases and speeches, they repeated 'their goal of striking a necessary balance between competing objectives of facilitating the flow of drugs to developing countries, complying with international obligations, and maintaining the integrity of the domestic patent regime'.[27] For instance, Lucienne Robillard, while speaking to a House of Commons committee, stated that 'we have tried to strike a sound balance between sometimes competing interests in order to have a workable regime'.[28] Likewise, Aileen Carroll, then Minister of International Cooperation, stated while speaking to the House of Commons, 'Bill C-9 is based on a balance of interests. On one side, there are the greatest humanitarian objectives, to send vital pharmaceuticals to developing countries. On the other side, we must protect the integrity of our intellectual property system'.[29] Even if CAMR had achieved such a balance, the approach

[26] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 226.
[27] Bubela, Gold, and Morin, "Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence." 13.
[28] House of Commons, *Standing Committee on Industry, Science and Technology: Evidence*, 002 (24 February 2004) (Hon Lucienne Robillard). See more McKee, "Globalisation, Legal Ideas, and the Creation of Canada's Access to Medicines Regime." 623.
[29] House of Commons Debates, 044 (29 April 2004) at 2567 (Hon Aileen Carroll). See more McKee, 62.

of balancing profits of corporations against fundamental human rights is questionable in the first place.

### III. The Canadian Regime Unnecessarily Exceeds the Requirements of Article 31bis

Canada's legislative scheme, which was described as a humanitarian aid initiative, could actually deliver next to nothing because it is overly loaded with bureaucratic hurdles and protectionist provisions exceeding what was required under Article 31bis. In the last sixteen years, since coming into force of this regime in 2005, only a single export-oriented compulsory licence has been granted under CAMR. In 2007, Canada authorised Apotex Inc. to manufacture HIV/AIDS medication TriAvir for export to Rwanda.[30] There were substantial delays throughout the process. It took eight months to add Apo-TriAvir to Schedule 1.[31] Even the initial requirement of negotiating a voluntary licence took much more than the anticipated time. The protracted negotiations with the relevant patent holders – Shire BioChemical, Inc., the Wellcome Foundation Ltd., GlaxoSmithKline, and Boehringer Ingelheim Canada – took more than six months.[32] Overall, it took Apotex Inc. nearly four years to make its first shipment of the generic drug to Rwanda.[33] As noted by Nicholas Vincent:

> The time lost in waiting for the deliveries of drugs could almost certainly wipe out the possibility of using this in particular circumstances of national emergencies … This timing would be unacceptable and almost certainly unworkable under any conceived definition of 'national emergency'.[34]

[30] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 569.
[31] Schouten, "Canadian Experience with Compulsory Licensing under the Canadian Access to Medicines Regime," 5.
[32] Ibid.
[33] Ibid, 6.
[34] Nicholas G. Vincent, "TRIP-Ing up: The Failure of TRIPS Article 31Bis," *Gonzaga Journal of International Law* 24, no. 1 (2020) 20-21.

The Canadian regime, in its current form, is unacceptable to generic manufacturers. Mr. Jack Kay, Former President and Chief Operating Officer of Apotex Inc., noted that 'the real problem for Apotex is the legislation, as the CAMR requirements are impossible to navigate'.[35] He further stated that 'if other critical medicines are to go to Africa in a reasonable timeframe, the federal government must change the CAMR legislation significantly. CAMR is unworkable as it now stands'.[36] There are problems with how the Article 31bis mechanism was set up by the WTO. The practical implications of enforcing this regime in the real world were not adequately considered. As noted by the Canadian HIV/AIDS Legal Network:

> The problem is that the WTO decision itself is unnecessarily complicated, time-consuming, and risky. It sets out a process for obtaining a compulsory licence that is unrealistic, is user-unfriendly, and does not speak to the needs and the realities of developing countries and the practical considerations that face generic pharmaceutical manufacturers, which are primarily commercially motivated actors, as we all know, just as the brand name companies are.[37]

The Article 31bis mechanism does not consider the interests of generic companies whose participation is critical for the functioning of this system. For instance, generic manufacturers may be dissuaded by the preliminary condition to enter into a sales agreement with the identified importing country. The participating generic manufacturing company, which is yet to hold the license to manufacture the generic drug, must first 'enter into a sales agreement with an eligible importing country for the purchase of a specified amount of a patented product.[38] This approach is not in line with normal procurement practices. Governments

[35] Standing Committee on Industry, Science and Technology (April 23, 2007) 2.
[36] Jillian Clare Kohler et al., "Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?," *Healthcare Policy* 5, no. 3 (2010): 40–48, https://doi.org/10.12927/hcpol.2013.21638.
[37] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 230.
[38] Health Canada, "Company requirements under Canada's Access to Medicines Regime." (Accessed September 4, 2021).

looking to purchase medicines 'put out a tender calling for bids from potential suppliers of medicines before awarding such a contract'.[39] In the case of Apotex Inc., 'Rwanda had to issue the tender and wait for interested pharmaceutical companies to respond with a bid to fill the order. Rwanda had to review the bids and decide which was successful and award the contract'.[40] Apotex Inc. was disadvantaged in the tendering process as it had to ensure a competitive price to outbid its competitors without the certainty of being granted a compulsory license to fill the order.[41] A generic manufacturer entering into the tendering process without having a license to manufacture is disadvantaged as it may not be considered as a serious bidder.

Canada needlessly added several extra layers of complication which are not even required under Article 31bis. The unduly restrictive additional conditions of the Canadian regime exacerbate the difficulty in using the Article 31bis mechanism, which is itself fraught with difficulties. This section briefly touches upon each of these additional onerous requirements which Canada included in its regime to satisfy the demands of the brand-name pharmaceutical industry. It is hard to find a justification for exceeding the already cumbersome Article 31bis framework without any obligation to go above and beyond what is required under the WTO TRIPS regime.

**A. Information about the Legal and Regulatory Status of Purchasers**

Before lodging an application for an export-oriented compulsory licence, preliminary hurdles need to be jumped.[42] The very first barrier to using CAMR is the preliminary condition of

[39] Network, "Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers." 5.
[40] Ibid.
[41] Apotex Inc. had to slash the cost per unit to beat Indian generic manufacturers in the bidding process. It is estimated that Apotex Inc. lost US$ 3-4 million by offering a lower price (US$0.195 per tablet) to win the tender. See Vincent, "TRIP-Ing up: The Failure of TRIPS Article 31Bis." 31.. See more Alexandra Nightingale, "WTO 'Paragraph 6' System for Affordable Medicine: Time for Change?" *Intellectual Property Watch* (November 11, 2016).
[42] Network, "Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers." 4.

identifying and disclosing an eligible importing country, as required under Article 31bis.[43] In order for the compulsory licensing process to proceed, a would-be importer must be named. An interested generic manufacturer must first negotiate with a potential recipient country. The Canadian regime requires the applicant to provide a statutory declaration that the identified importing country has 'granted or intends to grant a compulsory licence to use the invention pertaining to the product'.[44]

The identified importing country may be pressured by brand-name pharmaceutical corporations and economically advanced countries not to use the export-oriented compulsory licensing option.[45] As noted by the Canadian HIV/AIDS Legal Network, 'This information (the name of the importing country) must be shared with the brand-name company and will certainly end up being shared with other governments, including those that have pressured developing countries to avoid using compulsory licensing'.[46] As noted by Mr. Jack Kay, 'the impediment in this [Apotex Inc.] case was the fact that the country that wanted the product did not want to be identified'.[47]

Brand-name pharmaceutical corporations may try to influence the would-be importer. The patent holder may go to its home country government and say 'You know, I have some generic producers here talking with X government in Africa and I'm really disturbed about that; I don't want them to buy generic. I want you to send the ambassador to talk to the public procurement authority'.[48] Country notification is, therefore, an impeding factor. An eligible country in need of generic drugs may be reluctant to stick its neck out and self-identify to the WTO exposing

[43] The WTO Secretariat makes the country notification available publicly through a page on the WTO website. See World Trade Organization, "WTO Analytical Index TRIPS Agreement – Article 31bis (Practice), 2.
[44] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.04(3)(d)).
[45] Kohler et al., "Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?" 42.
[46] Network, "Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers." 4.
[47] Standing Committee on Industry, Science and Technology (April 23, 2007) 8.
[48] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 115.

itself to the risk of backlash, victimisation, and intimidation. It is hard for a participating generic manufacturer to find a country willing to use CAMR as most of the poorer countries prefer avoiding the threat of trade sanctions from the U.S.[49] Considering this barrier, generic manufacturers should have been allowed to initiate the compulsory licensing process before convincing and naming a would-be importing country.

Country notification is a requirement under Article 31bis,[50] but Canada went one step ahead by requiring in the application form 'the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity'.[51] This condition is needless because nothing in the WTO General Council Decision 2003 'requires the exporting country to evaluate the legal and regulatory status of purchasers in the importing country. It is impractical and pointless to attempt to do so, and merely creates delays'.[52]

**B. Enumeration of Scheduled Countries**

The Canadian regime differentiates between WTO Member and non-Member countries. It provides the following three categories of Scheduled countries. First, a Schedule 2 country is 'any country recognized by the United Nations as being least-developed country'.[53] Second, any WTO Member country, that is not listed in Schedule 2, may be added to Schedule 3 if it 'has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision'.[54] Third, any WTO Member or non-Member

[49] Ibid, 75.
[50] World Trade Organization, "WTO Analytical Index TRIPS Agreement – Article 31bis (Practice), Section 2(a).
[51] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.04(2)(f).
[52] Douglas Clark and Brigitte Zirger, "Canada's Access to Medicines Regime- General Comments," *Canadian Generic Pharmaceutical Association*, no. 613 (2007).
[53] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.03(1)).
[54] Ibid.

country, not listed in Schedule 2 or 3 but named on the Organization for Economic Co-operation and Development's list of countries eligible for development assistance, may be added to Schedule 4 if it has provided the Government of Canada with a notice in writing, specifying the name and quantity of the pharmaceutical product needed, 'stating that it is faced with a national emergency or other circumstances of extreme urgency' but 'it has no, or insufficient, pharmaceutical capacity to manufacture that product' and 'it agrees that product will not be used for commercial purposes'.[55]

The Canadian regime is criticised for creating 'a double standard between those developing countries that were WTO members and those that were not'.[56] It adds further requirements for non-Member countries making it hard or unlikely for them to make use of the regime. To qualify for a compulsory licence, non-Member countries 'are required to declare a national emergency or circumstance of extreme urgency'.[57] Enumeration of scheduled countries also leads to potential delays. If a non-Member country not listed in any of the three Schedules faces a health emergency, the response under CAMR may be delayed because of the additional listing requirements. The provisions related to the enumeration of scheduled countries should be eliminated because Article 31bis does not require differentiation between Member and non-Member countries. This additional burden is unnecessary and undermines the purpose of the regime.[58]

### C. Negotiations for a Voluntary Licence

[55] Ibid.
[56]Mark D. Penner and Peter G. Armstrong, "Removing Barriers? An Overview of the Canadian Access to Medicines Regime," *Intellectual Property Journal* 21, no. 3 (2009): 357–78.
[57] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 581.
[58] Ibid, 581.

The Canadian regime requires the applicant for a compulsory licence to provide a statutory declaration that, at least 30 days before filing the application, they sought a voluntary licence[59] from the patent holder on 'reasonable terms and conditions' and that such efforts were unsuccessful.[60] It requires this negotiation for a voluntary licence even in the event of a national emergency.[61] Canada once again exceeded the WTO TRIPS regime which waives the requirement of negotiating a voluntary licence in instances of national emergency or other circumstances of extreme urgency.[62]

What constitutes 'reasonable terms and conditions' is not specified.[63] This ambiguous provision allows patent holders to cause delays 'by disputing details of the application, and demanding further information'. The Canadian Generic Pharmaceutical Association raised this concern that 'the patentee can delay the issuance of a compulsory licence indefinitely by demanding ever more information and claiming it does not have enough information to decide if a proposed licence is on reasonable terms and conditions'.[64]

The 30-day time window stipulated under CAMR to seek a voluntary licence starts once a would-be importer country is identified. This time window 'creates a 30-day period during which the patent holder and others, such as the United States Trade Representative, could try to pressure the importing country not to use the compulsory licence route'.[65] This unwarranted requirement, resulting in preventable delays and obstructions, is against the very purpose of

[59] The government of Canada initially wanted to include the 'the right of first refusal' in CAMR meaning that 'after a generic drug company had negotiated a contract to supply medicines under a compulsory licence, the patentee would have had the option of stepping in and taking over the contract, filling the order on the same terms'. Civil society organizations opposed this proposal as it would have thwarted the operation of the mechanism by disincentivising generic manufacturers. In response to strong resistance, the government of Canada replaced this proposal with a requirement to negotiate a voluntary licence. See McKee, "Globalisation, Legal Ideas, and the Creation of Canada's Access to Medicines Regime." 617.
[60] Patent Act R.S.C., 1985, c. P-4 (Canada) Section 21.04(3)(c).
[61] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 578.
[62] *WTO, TRIPS Agreement*, Art. 31(b). See more MSF Canada, *Neither Expeditious, nor a solution: The WTO August 30th Decision is unworkable*: An illustration through Canada's Jean Chrétien Pledge to Africa', 2.
[63] Kohler et al., "Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?", 42.
[64] Douglas Clark and Brigitte Zirger, "Canada's Access to Medicines Regime- General Comments." 7.
[65] Kohler et al., "Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?" 42.

Article 31bis which was primarily aimed at providing an expeditious solution to the problem. To allow generic manufacturers to respond quickly to public health needs of eligible countries, the requirement to negotiate a voluntary licence should be eliminated. The CAMR process should start with the generic manufacturer automatically applying for a compulsory licence.

**D. Enumeration of Eligible Drugs in Schedule 1**

Canada chose to limit the WTO General Council Decision 2003 to a list of medicines. Canada restricted the use of its regime to the export of medications listed in Schedule 1 - the pre-approved list of medicines. Schedule 1 is completely unnecessary as enumeration of eligible drugs is not required under Article 31bis. As noted by John Fulton, 'Canada is the only country in the world that has this trap door in front of the compulsory licensing application process … It's like a full-time job for a team of people to just get the process started. What company is going to spend that kind of time and effort'?[66] Richard Elliott confirmed that 'there is nothing in the WTO law - including in the instruments that were negotiated and agreed to try to set parameters for a mechanism like CAMR to compulsory license drugs – that requires that you limit the list of products that can be the subject of such a mechanism'.[67]

The U.S. and the EU insisted, during negotiations for the Decision 2003, that the export-oriented compulsory licensing mechanism be limited to a list of infectious diseases. This position was flawed and unreasonable. As noted by Amir Attaran, 'If the TRIPS Agreement already lets countries with manufacturing capacity issue compulsory licenses for any medicine and any disease, and if the purpose of Paragraph 6 is to lift countries without manufacturing capacity to an equal footing, then how does one possibly justify an "equality" limited to two

[66] Policy Alternatives, "Global Vaccine Inequity: COVID-19 and Canada's Access to Medicines Regime."
[67] Ibid.

dozen infectious diseases'?[68] Frederick Abbott and Jerome Reichman also questioned the proposal to restrict the scope of the Decision 2003 to specific diseases: 'There is no public health justification for denying patients access to treatments for certain diseases because trade officials have decided that some diseases should be on (or off) an official list'.[69] The U.S. and EU proposal was rejected as it failed to garner much support.

For the purposes of Article 31bis, 'pharmaceutical product means any patented product, or product manufactured through a patented process of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health'.[70] The eligible importing country decides which pharmaceutical product is needed.[71] The importing country can notify the WTO of whichever patented products it needs.[72] It is not up to Canada, an exporting country, to decide which products are eligible for a compulsory licence. It is not Canada's responsibility to decide which medications are needed by developing and least developed countries to address their public health problems.

At the time of legislating CAMR, civil society organizations and interest groups had raised concerns over the scope of the list and requested to remove the list. To assuage these concerns, the Martin government 'emphasized that the schedule can be readily amended to include drugs not on the list through the governor in Council, implying flexibility'.[73]

[68] Amir Attaran, "Assessing and Answering Paragraph 6 of the DOHA Declaration on the Trips Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution," *Emory International Law Review* 17, no. 2 (2003): 754.
[69] Frederick M. Abbott and Jerome H. Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions," *Journal of International Economic Law* 10, no. 4 (2007): 937, https://doi.org/10.1093/jiel/jgm040.
[70] World Trade Organization, "WTO Analytical Index TRIPS Agreement – Article 31bis (Practice)" 2, Section 1(a).
[71] Ibid, Section 2(a)(i).
[72] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 578.
[73] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 126.

> … in terms of schedule 1, it can be amended 'by adding the name of any patented product that may be used to address public health problems … if the Governor in Council considers it appropriate to do so'. Maybe I'm misreading this, but this seems to me to be fairly simple way to add medicines.[74]

Civil society also raised concerns about vulnerability of this process to political pressure and subsequent delays in amending the list. The Martin government downplayed these concerns:

> Yes, it's theoretically possible, … that someone could go off on some wild tangent for days and days and days when there's a health emergency breaking out. I think we saw with the anthrax threat that we were able pretty quickly to break patents. I'm not sure that's really feasible when there is an identifiable need. So let's be clear that a governor in council change takes minutes.[75]

These claims of the Martin government were far from being realistic. Practically, it has proven to be time-consuming to add a drug to Schedule 1. Instead of taking minutes or days, it has taken as long as fifteen months to add a new drug to this Schedule. [76] In addition to causing potential delays, Schedule 1 makes the regime unviable for generic manufacturers. As noted by Paige Goodwin, 'the Schedule must be amended for not only new drugs, but new combinations and dosages as well. Given the dynamic nature of HIV/AIDS treatment, requiring generic manufacturers to seek formal amendment of Schedule 1 in all of these circumstances is incredibly burdensome'.[77] Schedule 1 should be abolished in its entirety as it is unnecessarily hindering the effectiveness of the Canadian regime.

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[74] Ibid, 148.
[75] Ibid, 143.
[76] In 2014, Teva Canada Limited attempted to use CAMR to export tenofovir disproxil. Nearly fifteen months after Teva's letter to Health Canada and Industry Canada, the order amending Schedule 1 came into force. See Schouten, "Canadian Experience with Compulsory Licensing under the Canadian Access to Medicines Regime," 7.
[77] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 579.

### E. Publicly Identifying the Parties Handling the Product in Transit

The anti-diversion requirements under CAMR exceed what is required under Article 31bis. The licensee or generic manufacturer is required under Article 31bis to post on a website 'the quantities being supplied to each destination … and the distinguishing features of the product(s)'.[78] Article 31bis included cumbersome anti-diversion provisions to address the overstated concerns of brand-name pharmaceutical industry about the risk generic medications potentially diverted to Western markets. These concerns of brand-name pharmaceutical industry are hypothetical as there is little evidence of actual trade diversion or re-exportation. As noted by the Canadian HIV/AIDS Legal Network, 'there has been no evidence that diversion of lower-priced generic medicines is a significant problem'.[79] For instance, 'India has been producing generic medications for decades and these drugs do not seem to have made their way into Western markets'.[80]

Unique identifying features, in terms of labelling and packaging, of the product are required. Article 31bis is ambiguous in terms of who should be able to distinguish the products manufactured under the scheme. There is a lack of clarity on whether it be customs authorities, medical doctors, distributors and retailers, or patients. According to generic manufacturers, anti-diversion measures required under Article 31bis are too onerous and disincentivise their participation.[81] They have expressed concerns that the distinguishability requirements can negatively impact the cost and quality of medications.[82] They particularly consider the requirement for each generic company to maintain a website as burdensome.[83]

[78] World Trade Organization, "WTO Analytical Index TRIPS Agreement – Article 31bis (Practice), Section 2(b)(iii).
[79] Network, "Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers." 8.
[80] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 576.
[81] Report, "Canada's Access to Medicines Regime (CAMR) Implementation - Focused Evaluation of Health Canada's Responsibilities Final Report Approved by Departmental Executive Committee on." 14.
[82] Ibid, 26.
[83] Ibid, 14.

The Canadian regime creates an additional obligation to post on the website 'information identifying every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported'.[84] The additional requirement of publicly identifying the parties responsible for the transportation and distribution of the drugs manufactured under CAMR negatively impacts participation in this regime. Article 31bis 'does not impose an obligation on an exporting country such as Canada to police or prevent diversion of exported pharmaceutical products in other countries, because it is impractical to do so, and will lead to delays'.[85] Under Article 31bis, it is the responsibility of the importing country to take such measures. It clearly stipulates that 'eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system'.[86]

**F. Time Limit on the Duration of Compulsory Licence**

Under the Canadian regime, an authorization granted for a compulsory licence is valid for a period of two years.[87] An authorization may be renewed only once for a period of two years.[88] The compulsory licence can be renewed only if 'the quantities of the pharmaceutical product authorized to be exported were not exported before the authorization ceases to be valid'.[89] Generic manufacturers cannot use this renewal if additional quantities of the authorized pharmaceutical product need to be shipped.

This time limit, which introduces costly uncertainty into CAMR, is problematic for generic manufacturers as they 'may need to set a production schedule ahead of time (up to three years

[84] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.06(1).
[85] Douglas Clark and Brigitte Zirger, "Canada's Access to Medicines Regime- General Comments." 11.
[86] World Trade Organization, "WTO Analytical Index TRIPS Agreement – Article 31bis (Practice) Section 3.
[87] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.09.
[88] Ibid, Section 21.12(2 and 4).
[89] Ibid, Section 21.12(1).

in advance)'.[90] This condition disincentivises generic manufacturers because after the expiry of the stipulated timeframe of four years, they 'must start the application procedure from the beginning, including an attempt to negotiate a voluntary licence with the patent holder'.[91] Generic companies should be expected to consider these potential transaction costs and bureaucratic constraints while making their decision to use the process having a restrictive time limit. As noted by Jillian Cohen-Kohler and others:

> Given the heavy front-end investment demanded from generic companies, these limits do not provide any prospect for a large or long-term market and give these companies little incentive to engage in this legislation. This is particularly the case if a company would need to adjust and/or increase their manufacturing infrastructure for products which are not normally part of their product portfolio.[92]

This condition is also problematic for the importing country because the needs of the authorized pharmaceutical product often cannot be precisely identified at the time of placing the initial order.[93] Nevertheless, the Canadian regime requires the application for a compulsory licence to provide 'the maximum quantity of the drug to be manufactured and sold for export under the authorization'.[94] The requirement to start the process from the beginning for any additional supplies can lead to costly delays and preventable suffering especially if a national emergency develops after the grant of a compulsory licence and more quantities of the medication are needed over an indefinite period. The Canadian regime places an unnecessary administrative

[90] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 582.
[91] Ibid 582.
[92] Thomas R. Frieden and Marine Buissonnière, "Will a Global Preparedness Treaty Help or Hinder Pandemic Preparedness?," *BMJ Global Health* 6, no. 5 (2021): 10–12, https://doi.org/10.1136/bmjgh-2021-006297.
[93] Network, "Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers." 6.
[94] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.05(2).

burden on the importing country and fails to consider the consequences of waiting for cumbersome bureaucracies in a health emergency.

Article 31bis did not require any such time limit on a compulsory licence. Without requiring a finite time limit on compulsory licences, the TRIPS Agreement stipulates that 'the scope and duration of such use shall be limited to the purpose for which it was authorized'.[95] Canada's restrictive approach, exceeding Article 31bis, is questionable because 'low-cost drugs may still be needed for humanitarian purposes after for years'.[96] The importing country may still lack the capability to manufacture pharmaceutical drugs and its people may still be sick and in need of the medication.

It would be a more flexible and reasonable approach if the importing country is allowed to decide the duration of the licence keeping in view its public health needs. It is not Canada's responsibility to determine for how long the importing country will need the product. It is rather irresponsible and unreasonable for an exporting country to presume that a product manufactured under the scheme will be needed by the importing country for a certain limited period.

**G. Patentee's Additional Litigation Rights**

Under the Canadian regime, the Federal Court may terminate the authorization for a compulsory licence under the enumerated conditions including that the patentee establishes that the holder of the authorization - generic manufacturer - provided inaccurate information; failed to establish and maintain a website or failed to disclose information that was required to be disclosed on that website; failed to provide the Export Notice; exported the product in a quantity greater than the authorized quantity; allowed re-export of the product in a manner

[95] *WTO, TRIPS Agreement*, Art. 31(c).
[96] Douglas Clark and Brigitte Zirger, "Canada's Access to Medicines Regime- General Comments." 3.

contrary to the General Council Decision; or allowed export of the product manufactured under the authorization to a country other than a country named in the authorization.[97] The authorization may also be terminated if the importing 'country has permitted the product to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision'.[98]

Another ground for termination of the authorization is that 'the essence of the agreement under which the product is to be sold is commercial in nature'.[99] If this ground is established, the Federal Court may either terminate the authorization or require the holder of authorization 'to pay, in addition to the royalty otherwise required to be paid, an amount that the Federal Court considers adequate to compensate the patentee for the commercial use of the patent'.[100] The Federal Court may also require the holder of authorization 'to deliver to the patentee any of the product to which the authorization relates remaining in the holder's possession …'.[101] There is no objective test to determine what constitutes 'commercial in nature'. While making this determination subjectively, the Federal Court is required to consider 'the need for the holder of the authorization to make a reasonable return sufficient to sustain a continued participation in humanitarian initiatives'[102] and 'the ordinary levels of profitability, in Canada, of commercial agreements involving pharmaceutical products'[103] as well as 'international trends in prices as reported by the United Nations for the supply of such products for humanitarian purposes'.[104]

[97] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.14.
[98] Ibid, Section 21.14)
[99] Ibid, Section 21.17)
[100] Ibid, Section 21.17(3)).
[101] Ibid, Section 21.17(4)).
[102] Ibid, Section 21.17(2)).
[103] Ibid, Section 21.17(2).
[104] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.17(2).

Vague terms like ‘commercial purposes’, ‘inaccurate information’, and ‘reasonable return’ are used in these provisions which add to the complexity of the regime. These ambiguously worded extra litigation rights are counterproductive. As noted by Mark Penner and others, ‘even if an applicant should obtain a licence under the CAMR there was no certainty under the regime that the licence would be effective or result in medicines actually being provided’.[105] These extra litigation rights are unnecessary as they are not required under Article 31bis. Let alone termination of an authorization once granted, Article 31bis does not require even review and/ or amendment of the terms of an authorized compulsory licence.

Providing the ground of ‘inaccurate information’ to terminate a compulsory licence is a risky approach. It can be used by patentee companies as a tool to undermine the process. For instance, the applicant for a compulsory licence is required to include ‘for each patent to which the application relates, the name of the patentee of the invention and the number, as recorded in the Patent Office, of the patent issued in respect of that invention’.[106] There can be hundreds of patents issued to multiple patentees in respect of an invention. As noted by the Canadian Generic Pharmaceutical Association, ‘no matter how many patents are included in the application, brands will argue there are others to which the application relates’.[107] Canada has needlessly chosen this approach as this information is not even required under Article 31bis.

These additional rights are inessential because ‘the patentee can pursue the existing remedies under the *Patent Act* if it wishes to argue the generic manufacturer is not entitled to the protection of the licence due to some alleged breach of the licence’.[108] Canada needs to understand that ‘the patentee, not the government of Canada, is the appropriate party to enforce

[105] Penner and Armstrong, “Removing Barriers? An Overview of the Canadian Access to Medicines Regime.” 372.
[106] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.04(2)(d).
[107] Douglas Clark and Brigitte Zirger, “Canada’s Access to Medicines Regime- General Comments.” 8.
[108] Ibid, 3.

its own patents'.[109] Undoubtedly, brand-name pharmaceutical corporations are fully capable of taking appropriate legal measures in the concerned jurisdiction under applicable laws of that jurisdiction if a product manufactured under an authorization is unlawfully diverted to an unintended country.

## IV. Reforming Canada's Access to Medicines Regime

The Canadian regime does not facilitate bulk purchasing and economies of scale. Generic manufacturers are disincentivised from using the CAMR system because of little or no prospects of making profits after going through the hassle of using an overly cumbersome and risky process. As noted by Mr. Jack Kay, 'it really comes down to the fact that Apotex is in the business of making money for its shareholders… I am not going to tie up my resources, our legal departments, in order to go through the process of trying to get a compulsory licence because it's just far too complicated'.[110] 'If we want to make these products available in an affordable manner to these countries in order to save lives, we have to come up with a policy that the generic industry can take advantage of', he added.[111] Likewise, John Fulton said that 'this [regime] has to be financially responsible. It has to make some money. We're not Bill Gates'.[112] In its current form, 'the mechanism offers no opportunity for profit'.[113]

A simple and streamlined mechanism is required to make the mechanism acceptable to generic manufacturers. The Canadian HIV/AIDS Legal Network maintains that 'the simpler it is for developing countries and generic manufacturers to use the CAMR system with greater

[109] Ibid, 2.
[110] Standing Committee on Industry, Science and Technology (April 23, 2007) 14.
[111] Ibid, 17.
[112]
Mike Zettel, "Approval means local pharm company may soon make generic bird flu drug" (July 14, 2006) *Niagara This Week*, https://www.niagarathisweek.com/news-story/3297855-approval-means-local-pharm-company-may-soon-make-generic-bird-flu-drug/
[113] Morin and Gold, "Consensus-Seeking, Distrust and Rhetorical Entrapment: The WTO Decision on Access to Medicines."

economies of scale, the lower the costs of production that can be achieved by generic manufacturers in Canada. This makes them more competitive in the global marketplace'.[114] As advocated by civil society:

> Our central recommendation … is to simplify this process by letting the generic manufacturer here in Canada get one compulsory licence at the beginning of the process, before there are any particular contracts negotiated with any particular country or countries. With that legal authorization in hand, the generic manufacturer can then bid through transparent international tendering processes that many developing countries will have. They can negotiate with multiple developing countries on the list of eligible countries and achieve a certain degree of economy of scale, because they can actually negotiate larger-sized contracts, which means they can negotiate with suppliers of active pharmaceutical ingredients to get the prices of producing the pill down even further, and they will not be required to go through the process every single time, for every single drug order from each particular country.[115]

Interest groups and civil society organizations campaign for amending the Canadian regime to make it workable. The International AIDS Conference 2006 highlighted the ineffectiveness of CAMR and the issue got considerable media attention. Facing the media pressure, then Health Minister Tony Clement publicly committed to initiating an immediate legislative review of the

[114] Network, "Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers." 7.
[115] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 229.

regime.[116] He pronounced that 'CAMR was a flawed piece of legislation'.[117] 'Obviously the legislation isn't working', he said publicly.[118]

The Parliamentary Standing Committee on Industry, Science and Technology carried out a government-wide level study of the Canadian regime in April and May 2007. This legislative review of the regime was led by Industry Canada, which issued a consultation paper inviting input in the form of written submissions from stakeholders.[119] The Committee received written consultations from a large scope of actors including domestic and international organizations, generic manufacturers, and brand-name pharmaceutical corporations. Some of these actors also testified before the Committee.[120] The Committee Chair submitted a summary of stakeholders' recommendations in the form of a letter to the Minister of Industry after completion of the review process in May 2007.[121] The Harper government had a chance to simplify the Canadian regime by amending the legislation. Instead, in July 2007, the Minister of Industry concluded in a report on the findings of the review that 'insufficient time has passed and insufficient evidence has accumulated since the coming into force of CAMR to warrant legislative changes to the regime'.[122]

The Harper government decided to do nothing to simplify the regime as it considered it too premature to amend the legislation. The Conservatives preferred to maintain the status quo as it 'had little incentive to improve the legislation since it was a Liberal initiative'.[123]

[116] Isabel, "Clement Vows to Get Cheap Drugs Flowing- Health Minister Decries Lack of Aid But Current Law Prevents Action," *Torstar Syndication Services, a Division of Toronto Star Newspapers Limited*, 2006, 1–4.
[117] Lexchin, "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First." 4.
[118] Isabel, "Clement Vows to Get Cheap Drugs Flowing- Health Minister Decries Lack of Aid But Current Law Prevents Action." 1.
[119] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 76.
[120] Laura C Esmail and Jillian Clare Kohler, "The politics behind the implementation of the WTO Paragraph 6 Decision in Canada to increase global drug access" *Globalization and Health* 8.1 (2012): 5.
[121] Report, "Canada's Access to Medicines Regime (CAMR) Implementation - Focused Evaluation of Health Canada's Responsibilities Final Report Approved by Departmental Executive Committee on." 9.
[122] Hon Ian Callinan AC QC, *Report on the Statutory Review of the Tribunals Amalgamation Act 2015, 7*.
[123] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 257.

Additionally, with the change in political leadership, the foreign policy of Canada 'took on a more aggressive approach with respect to intellectual property protection'.[124] In 2007, the Department of Foreign Affairs and International Trade stated that 'it was assessing its interests in protecting intellectual property as it initiated trade agreements in Peru, Colombia and the Dominican Republic'.[125] Considering the new policy position, amending CAMR, which was primarily meant to address non-domestic public health issues against the wishes of brand-name pharmaceutical industry, was clearly not a priority for Canada's new political leadership.

In March 2009, a Private Member's bill - Bill S-232 introduced by Senator Yoine Goldstein - aimed at streamlining the regulatory requirements in the Canadian regime, was introduced by Senator Goldstein.[126] The Senate referred this bill to the Senate Committee on Banking, Trade and Commerce. In October 2009, the Committee held hearings over this bill.[127] Bill S-232 could not become law as it lapsed in December 2009 upon the prorogation of the Canadian Parliament.[128] A parallel Private Member's bill, Bill C-393, was introduced in the House of Commons in May 2009 by Judy Wasylycia-Leis – the New Democratic Party Member for Winnipeg North.[129] This bill aimed at implementing the 'one-licence solution' proposed by the Canadian HIV/AIDS Legal Network.[130] In March 2011, Bill C-393 was passed by the House of Commons but the Conservatives delayed it in the Senate until it lapsed with the calling of a federal election.[131] Both these Bills were actively supported by the Stephen Lewis Foundation

[124] Ibid, 257.
[125] Laura C Esmail and Jillian Clare Kohler, "The politics behind the implementation of the WTO Paragraph 6 Decision in Canada to increase global drug access" *Globalization and Health* 8.1 (2012): 9.
[126] Kohler et al., "Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?" 44.
[127] See Senate of Canada, "The Standing Senate Committee on Banking Trade and Commerce- Evidence" (November 4, 2009) https://sencanada.ca/en/Content/Sen/committee/402/bank/47502-e (accessed September 4, 2021).
[128] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 288.
[129] Kohler et al., "Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?" 44.
[130] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 288. See more Richard Elliott, "Making CAMR Work: Streamlining Canada's Access to Medicines Regime Brief to the House of Commons Standing Committee on Industry, Science and Technology regarding Bill C-393" (October 21, 2010) 1-46.
[131] Lexchin, "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First." 4.

and the Canadian HIV/AIDS Legal Network.[132] On the contrary, the brand-name pharmaceutical industry supported CAMR in its current form and opposed any changes to the regime.[133]

In February 2012, a new bill, Bill C-398, was introduced in the Canadian parliament.[134] Another opportunity to simplify the regime by amending the legislation was missed. Bill C-398 was defeated in the House of Commons. Many of the Conservatives who had previously supported the passing of Bill C-393 in 2011 voted against amending the legislation.[135] Russ Hiebert, then parliamentary secretary to the Minister of National Defence, argued that 'there were better ways to help people suffering from disease in Africa and elsewhere'.[136] Previously, the Harper government had also maintained in its 2007 report on the statutory review of CAMR that 'the Government should focus on non-legislative measures to improve access to medicines in the developing world'.[137]

Canada's former Health Minister Tony Clement said in 2006, 'if we can put a man on the moon, we can solve this issue'.[138] On the contrary, there was no meaningful uptake and the reality on the ground did not change despite several attempts to change the law. These failed attempts indicate that the political will to reform and simplify the Canadian regime is lacking. A lot of political will and political capital is required to open up the Patent Act against the wishes and interests of the brand-name pharmaceutical industry.

[132] Bubela, Gold, and Morin, "Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence." 14.
[133] Bubela, Gold, and Morin.
[134] Network, "Fixing Canada's Access to Medicines Regime (CAMR): 20 Questions & Answers." 6.
[135] Lexchin, "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First." 4.
[136] Ibid.
[137] Hon Ian Callinan AC QC, *Report on the Statutory Review of the Tribunals Amalgamation Act 2015, 7*. See more Kohler et al., "Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?", 44.
[138] Isabel, "Clement Vows to Get Cheap Drugs Flowing- Health Minister Decries Lack of Aid But Current Law Prevents Action." 1.

The Canadian policymakers rather find it convenient to resort to 'non-legislative measures', which are costly as the government allocates substantial amounts from public funds. According to a 2006 press briefing of Canada's then Health Minister Tony Clement, Canada had committed $800 million to combat HIV/AIDS internationally.[139] More recently, a spokesperson for the Trudeau government's ISED program stated that the government has allocated $840 million in support of low- and middle-income countries to access COVID-related health technologies.[140] Canada needs to understand that donations and charitable contributions are not a sustainable solution to the problems which CAMR and Article 31bis seek to address. Fixing these regimes to achieve their intended results is arguably a better way to help people suffering from disease in poorer countries. A reformed, simplified, and functional compulsory licencing regime should be a preferred policy response if Canada is serious in showing solidarity and discharging its humanitarian duty by improving access to essential medicines and vaccines.

It is important to note here that Canada does not consider non-legislative measures, like donations and charity, for its own citizens. In response to COVID-19, Canada quickly resorted to legislative measures to protect health of Canada's own citizens. In the blink of an eye, Canada was able to make legislative changes to its compulsory licensing regime. On March 24, 2020, the Trudeau government amended Canada's Patent Act (Bill C-13) to make it faster and simpler for the government to utilize the compulsory licensing option.[141] Previously, in 2001, Canada was prepared to resort to compulsory licensing in response to the anthrax scare. As Bayer Inc., the owner of the ciprofloxacin-related patents, appeared unable to meet supply

[139] Ibid, 2. See more Lexchin, "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First." 6.
[140]Brennan, "How to manufacture Covid-19 vaccines without the help of J&J, Pfizer or Moderna? Biolyse sees the difficulties up close."
[141] Katrina Perehudoff, Ellen t' Hoen, and Pascale Boulet, "Overriding Drug and Medical Technology Patents for Pandemic Recovery: A Legitimate Move for High-Income Countries, Too," *BMJ Global Health* 6, no. 4 (2021): 10–13, https://doi.org/10.1136/bmjgh-2021-005518.

demands of the drug, Health Canada stated that it had the authority to compulsorily dissolve the patents.[142] Canada also considered issuing compulsory licences to enhance supply of Roche's drug Tamiflu in response to the avian flu outbreaks of 2005.[143]

It is important to bear in mind that the Canadian regime was meant to help underprivileged countries that are already strapped-for-resources. The regime has 19 sections and more than 100 clauses and sub-clauses. Just to understand the regime, the potential users may require legal assistance or professional training. Preparation and submission of extensive documentation are required to use the regime. An eligible importing country lacking the requisite knowledge and human resources may overlook the regime and consider alternate options. As noted by Jillian Cohen-Kohler and others, 'in crisis situations, government officials will not opt to deal with cumbersome administration in order to get drugs to those in need. They will seek expeditious and simple solutions to stop people from dying or being sick from lack of access to medicines'.[144] A resource-poor 'country that has got a huge death rate from AIDS, they don't have the time or resources to go through this with every single drug … a country like Tanzania, you have one person working on international intellectual property'.[145]

The CAMR system was set up, but it has not been funded. It appears that Canada considers that the regime will function and succeed without any logistic or financial support. It wrongfully assumes that eligible countries have the requisite knowledge and human resources to use this mechanism.[146] Eligible importing countries are more likely to need technical support to use this complicated regime. Many low- and middle-income countries may not be even aware that CAMR exists. Considering the lack of international awareness of the regime, the

[142] Bubela, Gold, and Morin, "Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence." 22.
[143] Bubela, Gold, and Morin.
[144] Frieden and Buissonnière, "Will a Global Preparedness Treaty Help or Hinder Pandemic Preparedness?" 7.
[145] Goodwin, "Right Idea, Wrong Result - Canada's Access to Medicines Regime." 583.
[146] Frieden and Buissonnière, "Will a Global Preparedness Treaty Help or Hinder Pandemic Preparedness?" 1.

Canadian government should allocate funds to undertake 'a full-scale education program to inform stakeholders – especially those in developing countries – of the legislation and its mechanisms'.[147]

Some of the problems with the Canadian regime are rooted in the 2003 WTO General Council Decision. WTO Members knew that the export-oriented compulsory licensing mechanism is not workable, but they consensually agreed to it to save their reputations.[148] They 'became trapped in a rhetoric of consensus-seeking that made it preferable for all to agree to a flawed mechanism rather than to keep negotiating'.[149] They might have considered that 'walking away with nothing in hand was worse than a mechanism that they knew was flawed'.[150]

There is a need to revisit this flawed mechanism. Perhaps, a minor surgical amendment was needed. It could have been a good idea to simply delete Article 31(f) from the TRIPS Agreement. A cumbersome framework was provided to address the hypothetical concerns of brand-name pharmaceutical industry as there is little evidence of actual trade diversion or re-exportation. Governments have mechanisms in place to curb any malpractices. As noted by Abbott and Reichman, 'Drug importation should ordinarily be subject to close supply chain management, and steps taken to ensure the integrity of supply are likely to prove useful from a public health perspective as well'.[151] Governments can further strengthen their existing mechanisms to deal with any abuse of the public health flexibility.

The COVID-19 pandemic provides an opportunity to rethink the wisdom and rationale of the Article 31bis mechanism. The underlying objective of this mechanism is 'to find an expeditious

[147] Esmail, "The Politics of Canada's Access to Medicines Regime: The Dogs That Didn't Bark." 218.
[148] Morin and Gold, "Consensus-Seeking, Distrust and Rhetorical Entrapment: The WTO Decision on Access to Medicines."
[149] Morin and Gold.
[150] Morin and Gold.
[151] Frederick M. Abbott and Jerome H. Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions," *Journal of International Economic Law* 10, no. 4 (2007): 944, https://doi.org/10.1093/jiel/jgm040.

solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement'.[152] This objective is completely eclipsed by the excessive formalities of this mechanism. As noted by MSF:

> 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 licence), 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 licence 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.[153]

The export-oriented compulsory licensing mechanism needs to be reformed without further delay. The reform should focus on two key issues. First, there is a critical need to reduce the number of compulsory licences that need to be granted to address a public health situation. A system should be designed for the grant of a single global compulsory licence to allow one or more generic manufacturers to produce and supply the needed pharmaceutical product(s) and vaccines to all countries in need. Second, there is a need to cut-down the formalities and restrictive requirements of this mechanism. The single compulsory licence should be granted without predetermined limits on the quantity of drugs and duration of such authorization. Such

[152] World Trade Organization General Council, "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" *Decision of the General Council of 30* (2003), Preamble.
[153]Médecins Sans Frontières, "WTO COVID-19 TRIPS Waiver Proposal," *Médecins Sans Frontières Access Campaign* 1, no. 2 (2020), https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access.

a single licence scheme would not only serve the purpose of providing an expeditious solution to the problem but also galvanize the generic drug industry to participate in the regime. Participating generic drug companies would be able to scale-up production of the authorized product for supply to whichever eligible country needs it, as long as needs it, and in whatever quantity needs it to address a public health situation.

Such a workable and fruitful regime would be beneficial not only when it is used practically but also in indirect ways even when it is not put into practice. Brand-name pharmaceutical corporations would be expected to reconsider their pricing strategies if such a functional scheme is designed and implemented. The mere existence of such a legislative mechanism can be pivotal in persuading the patentee corporations to act responsibly in terms of realizing the public health needs of less privileged countries, especially in a health emergency.

The workability of export-oriented compulsory licensing mechanism is critical not only for low- and middle-income countries but also for high-income or developed countries, with adequate manufacturing capability, to effectively deal with a health emergency. It is strange that Article 31bis speaks about manufacturing capacity but does not aim to address the access barriers faced by countries with large epidemics. As noted by Amir Attaran:

> Absolutely every country, regardless of income, faces the danger of acute public health emergencies. These can arise through natural causes, such as the SARS epidemic that recently affected Asia and Canada, or through acts of terrorism, such as the postal anthrax attacks on the United Sates in 2001. Either set of circumstances can briefly require a country in extremis to import medicines manufactured elsewhere under compulsory licence. This is true even if the

> country is rich or has manufacturing capacity, because that capacity can be overwhelmed by a large epidemic.[154]

Even the most advanced countries with exemplary manufacturing capacity may struggle to meet supply demands in a major health emergency. They may face situations where they need to import drugs or vaccines manufactured elsewhere under export-oriented compulsory licensing. As noted by Tania Bubela and others:

> [D]uring the 2005 bird flu crisis, the U.S. had supplies of TAMIFLU available for less than 1% of its population. It did not have the capacity to switch all of its domestic manufacturing capacity to produce the medicine quickly enough if the crisis had worsened. Without the mechanism for [export-oriented] compulsory licensing, the U.S. could not have imported the medicine from another country without the patent holder's consent, making it legally impermissible for the country to address its health crisis.[155]

For the collective benefit of all countries, the system needs to be reformed to address new challenges. For instance, the technologies in COVID-19 vaccines are complicated involving not only several patents but also trade secrets and know-how. Access to test data is also a considerable issue because some countries enforce data exclusivity rules. A compulsory licence does not provide access to undisclosed information and test data.[156] The grant of a compulsory licence may not achieve the desired or intended results if brand-name corporations are not willing to relax their grip on test data and trade secrets related to COVID-19 vaccine

[154] Attaran, "Assessing and Answering Paragraph 6 of the DOHA Declaration on the Trips Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution." 763.
[155] Bubela, Gold, and Morin, "Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence." 23.
[156] Anna Rothschild and Sinduja Srinivasan, "How Pharma's Lucrative Patent System Is Complicating the Pandemic." *FiveThirtyEight* (May 24, 2021) https://fivethirtyeight.com/features/how-pharmas-lucrative-patent-system-is-complicating-the-pandemic/ (accessed September 4, 2021).

manufacturing. An updated system of compulsory licencing needs to be designed to tackle not only patents but also other forms of protection.

It is important to consider how brand-name corporations can be made to reveal their trade secrets relevant to manufacturing COVID-19 vaccines and therapeutics. Olga Gurgula and John Hull suggest a means by which this could be done. They have advocated for a supplementary mechanism of compulsory licensing of trade secrets.[157] This approach can be promising as the concept of public interest can arguably be stretched to justify non-voluntary disclosure of relevant trade secrets during a health emergency. This approach is not established at the global level, but it is not novel or unprecedented. In June 2000, the US District Court for the Eastern District of Michigan held that 'the public's interest in receiving adequate medical care outweighs its general interest in the performance of such [confidentiality] agreements'.[158] This approach is consistent with Articles 7[159] and 8[160] of the TRIPS Agreement and paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health.[161]

Moreover, the Article 31bis framework does not take into account modern therapeutics like biologics which include products like gene-based therapies, cell-based therapies, and antibody-based therapies.[162] This framework was developed keeping in view chemical-based

[157] Olga Gurgula and John Hull, "Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer," *Journal of Intellectual Property Law & Practice*, forthcoming (2021): 1, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3872796.
[158] *Detroit Medical Center v. GEAC COMPUTER SYSTEMS*, 103 F. Supp. 2d 1019 (E.D. Mich. 2000). See more Olga Gurgula and John Hull, 13.
[159] Article 7 provides that '[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.
[160] Article 8 provides that 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest … Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'.
[161] Paragraph 4 of the Doha Declaration 2001 provides that 'the TRIPS Agreement does not and should not prevent members from taking measures to protect public health'.
[162] Vincent, "TRIP-Ing up: The Failure of TRIPS Article 31Bis." 24.

formulations which are identical from capsule to capsule or pill to pill and 'often consist of a single active ingredient that is formulated in a tablet, capsule, or liquid, combined with various inert components and fillers that are required for various reasons including stability, delivery, and administration purposes'.[163] There is a need to revisit this outpaced framework to cater for modern personalized therapies and complicated technologies which are increasingly becoming prevalent in contemporary healthcare.

## V. Conclusion

The Canadian regime was intended to be a humanitarian effort. The original policy rationale got compromised by the conflicting goals of ensuring good trade relations with the U.S. by protecting the corporate interests of patentee companies. The compromises in the legislation led to an unworkable regime that is overly protective of patentee companies' commercial interests while losing sight of its humanitarian aid objectives. To placate patentee corporations, Canada added extra layers of complication, restrictions, and regulatory requirements on top of what was required under Article 31bis. Transaction costs and unnecessary bureaucratic hurdles limit the effectiveness of CAMR not only for eligible importing countries but also for participating generic manufacturers. The regime in its current form is not in line with its stated purpose of providing a humanitarian solution to the problems faced by poorer countries in accessing essential medicines. There are too many ways and means in which patentee companies and governments can frustrate the use of this excessively cumbersome and complex framework.

Some of the problems with the CAMR system are rooted in the WTO General Council Decision 2003. It has been emphasized repeatedly for quite a long time that the Decision 2003/ Article 31 bis mechanism is defective. Even when we have a massive global pandemic, the Article

[163] Vincent. 23.

31bis mechanism has proved to be unworkable. It was designed to be too slow, complex and cumbersome to be of any use in a health emergency. The COVID-19 pandemic puts a fresh light on the ineffectiveness of this poorly designed mechanism. It should be a cause of concern that to date, not a single dose of any of the COVID-19 vaccines has been exported under the Article 31bis mechanism. If the regime is not functioning in these extraordinary times, then it is quite evident that this system is not capable of working as intended.

The WTO Members need to go back to the drawing board to come up with a better solution to the problem. A system should be designed for the grant of a single global compulsory licence to allow one or more generic manufacturers to produce and supply the needed pharmaceutical products and vaccines to all eligible countries without predetermined limits on the quantity of drugs and duration of such authorization. Such a one-licence solution would not only serve the purpose of providing an expeditious solution to the problem but also galvanize the generic drug industry to participate in the regime. The proposed framework is important not only for low- and middle-income countries but also for the multilateral WTO system itself in terms of managing trade as well as humanitarian concerns. It is in the long-term interest of many players - who back globalization, trade liberalization, and free market economy - to support this framework because the current pandemic tests the ability of the WTO system to respond to a global humanitarian crisis.