

# Canadian Experience with Compulsory Licensing under the Canadian Access to Medicines Regime

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### Introduction

The Canadian Access to Medicines Regime (“CAMR”) is a national implementation of paragraph 6 of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). CAMR (Bill C-9 originally numbered Bill C-56) was introduced in 2003 and received royal assent in May 2004. The object and purpose of CAMR is to enable pharmaceutical manufacturers in Canada to apply for a compulsory license from the Commissioner of Patents (hereafter Commissioner) to “export a lower-prices version of the patented pharmaceutical product to a developing or least-developed country unable to manufacture on its own”.<sup>1</sup> CAMR amended the *Patent Act*, the *Food and Drugs Act* and the *Food and Drugs Regulations*.

At the time of CAMR’s inception, Canada was the first country to implement the 2003 TRIPS Paragraph 6 system. It was thus conceived without any comparative legislation. CAMR faced the possibility of revision through Bill C-393. The object of Bill C-393 was to make amendments to the *Patent Act* and *Food and Drugs Act*, to enable an easier system for generic manufacturers to produce and export products to countries affected by public health problems.<sup>2</sup> Bill C-393 was passed in the House, but died in the second reading in the Senate as of March 2011.<sup>3</sup> There have been numerous attempts to use CAMR since its inception in 2004. This briefing note will provide a chronological description of attempts to use CAMR to date. The note will first begin by providing an overview of the application procedure and requirements for a compulsory license authorisation as set out in CAMR. Subsequently, this briefing note will detail the five attempts to use CAMR, from 2004 until 2021. Thereafter, the note will conclude with a brief evaluation considering all attempts together.

### CAMR Domestic Application Requirements

In order for the Commissioner to issue a compulsory license pursuant to CAMR, a number of requirements must be met. This section will limit its scope to the application requirements of domestic generic manufacturers. As such, additional requirements relevant for importing

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<sup>1</sup> *Patent Act*, R.S.C. 1985, P-4, s. 21.01.

<sup>2</sup> Bill C-393 (Historical), *openparliament.ca*, available at: <https://openparliament.ca/bills/40-3/C-393/>

<sup>3</sup> <https://www.parl.ca/LegisInfo/BillDetails.aspx?Bill=C393&Language=E&Mode=1&Parl=40&Ses=3>

countries will not be discussed in detail. Many of the steps towards the issuance of a compulsory license according to CAMR do not need to be fulfilled in any particular order. However, some steps are naturally more convenient to pursue before others.

Pursuant to section 21.04(3)(c) of the *Patent Act*, the applicant must inform the pharmaceutical product patent holder(s) of their request for a voluntary license. This offers the opportunity for patent holders to enter into a voluntary licensing agreement. Upon unsuccessfully seeking a voluntary license from the patent holder(s) on reasonable terms and conditions<sup>4</sup>, the applicant may proceed with their CAMR compulsory license application. The voluntary license request, made by certified or registered mail, must be done at least thirty days prior to submitting the compulsory license application to the Commissioner.

Before any product can be manufactured for export, it must be approved by Health Canada. The approval process, however, is incumbent on the applicant successfully amending Schedule 1 of the *Patent Act*. Schedule 1 is a list of pharmaceutical products that are under patent in Canada. Only the products listed on Schedule 1 are eligible for Health Canada review and export pursuant to CAMR. Schedule 1 can be amended through an order by Governor-in-Council, on the recommendation of the Minister of Industry and of Health.<sup>5</sup> The amendment of Schedule 1 and subsequent Health Canada review can be completed before or after submitting the compulsory license application to the Commissioner. The purpose of Health Canada's review is to ensure that the quality of the product intended for export is at the same safety, efficacy and quality standards applicable to drugs destined for the Canadian Market.<sup>6</sup>

Upon successfully amending Schedule 1, the applicant may submit their drug submissions for Health Canada review. There are two distinct submissions required by the applicant, namely, the Domestic Submission and the Division 7 Submission. These can be done in parallel or consecutively. The Domestic Submission application needs to include all information required to obtain authorisation in the Canadian market. The Division 7 Submission application necessitates documentation to support differences in the labelling and marking of the product, requirements set out in C.07.008 of the Food and Drug Regulations (C.R.C., c. 870). The timelines for the Domestic Submission is 345 days for a New Drug Submission (NDS) or 180 days for an Abbreviated New Drug Submission (ANDS).<sup>7</sup> For a priority submission, the NDS timeline is reduced to a total of 205 days.<sup>8</sup> The timeline for the Division 7 Submission is a combined 75 days screening and review. The Commissioner and manufacturer are notified upon Health Canada's approval of both submissions. Consequently, only once the

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<sup>4</sup> *Patent Act*, *supra* note 1, s. 21.04(3)(c)(i).

<sup>5</sup> *Patent Act*, *supra* note 1, s. 21.03(1).

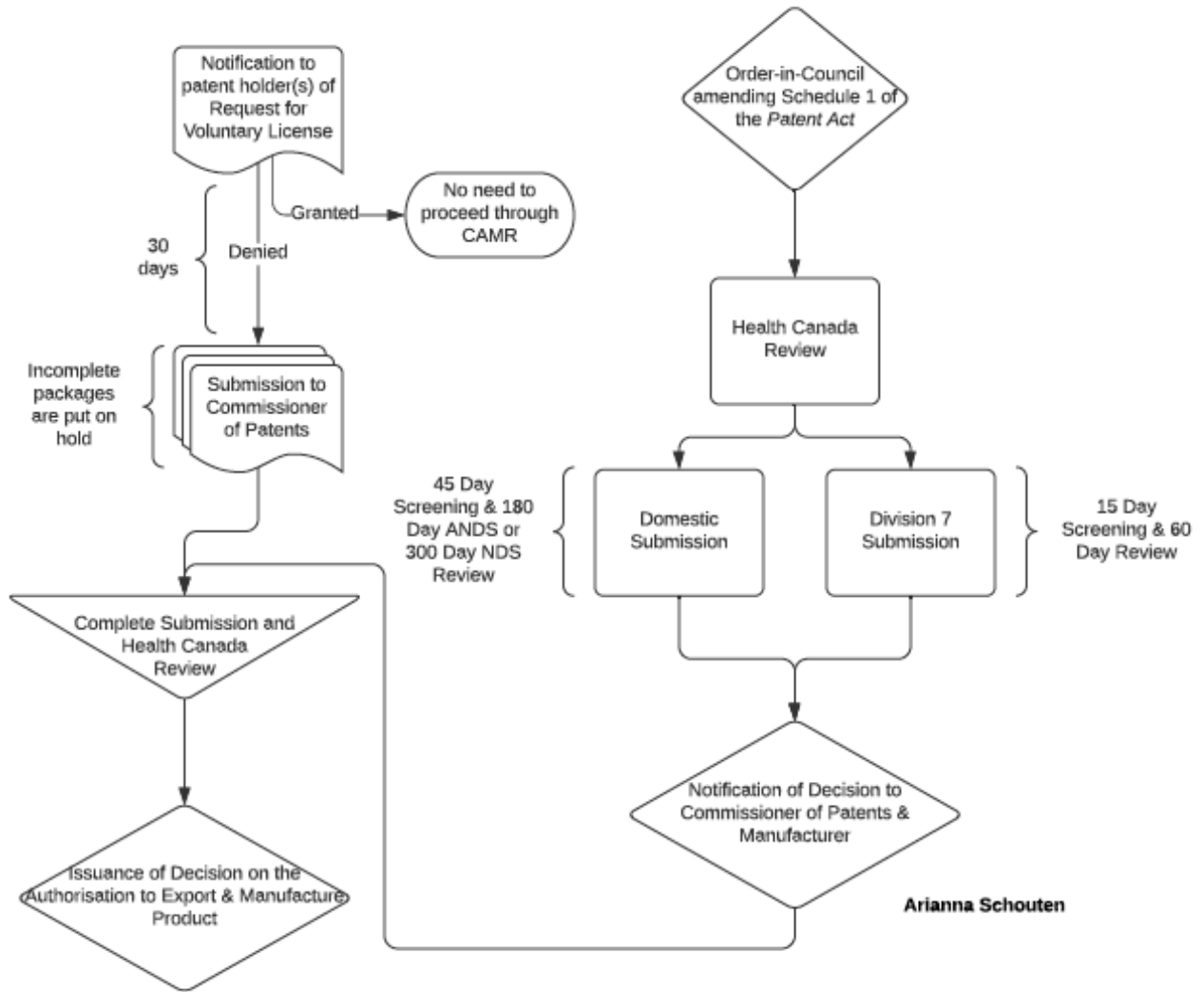
<sup>6</sup> *Food and Drug Act*, R.S.C. 1985, c. F-27, s. 37.2.; *Food and Drug Regulations*, C.R.C., c. 870, C.07.004.

<sup>7</sup> Canada's Access to Medicines Regime: Application Process for drugs for Export to Developing and Least Developed Countries, *Health Canada* (6 December 2006), available at: <https://www.canada.ca/en/health-canada/services/canada-access-medicines-regime/documentation/health-canada-guidance-documents/application-process-drugs-export-developing-least-developed-countries.html#a231>.

<sup>8</sup> *Id.*

pharmaceutical product in question has been approved by Health Canada can the Commissioner make a determination on the application and thereafter issue an authorisation to export and manufacture the patented pharmaceutical product.

Image A: Simplified Domestic CAMR Application Process



## Attempts to use CAMR

### *2004: Gleevec (imatinib mesylate)*

In December 2004, Essential Inventions, Inc. (hereafter Essential Inventions) sought a compulsory license to manufacture and export imatinib mesylate to Chile.<sup>9</sup> Imatinib mesylate is a treatment for various forms of cancer, such as leukemia (acute lymphoblastic, chronic eosinophilic and chronic myelogenous) and gastrointestinal stromal tumors. As required by CAMR, Essential Inventions had previously made a request for a voluntary license from Novartis - the patent holder. Upon no reply, they made a first step in the compulsory license application process under CAMR.

Essential Inventions proceeded to send a letter to the Minister of Health. In this letter, they stated their intention to seek a compulsory license for export in order to provide an affordable supply of imatinib mesylate to countries not defined as high-income by the World Bank.<sup>10</sup> Towards the end of their letter, Essential Inventions asks to whom and how to submit their request to add imatinib mesylate to Schedule 1 of the *Patent Act*.<sup>11</sup> Essential Inventions never received any response to their letter or request.

### *2004 - 2008: Apotex & Rwanda*

Soon after CAMR received royal assent in May 2004, Médecins Sans Frontières (MSF) publicly indicated their commitment to test this legislation.<sup>12</sup> Later that year, in December 2004, at the same time as Essential Inventions' letter to the Minister of Health, Apotex Inc. ("Apotex") agreed to produce a triple antiretroviral combination therapy Apo-TriAvir (lamivudine (150mg) + nevirapine (200mg) + zidovudine (300mg)) for export. Throughout the process beginning in 2004, Apotex worked in consultation with MSF.<sup>13</sup>

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<sup>9</sup> Request for compulsory license for Glivec patents in Chile, *Essential Inventions* (17 December 2004), available at: <http://www.essentialinventions.org/docs/chile/imatinib17dec04.html>; and Letter to Canadian Health Minister Ujjal Dosanjh requesting a compulsory license, *Essential Inventions* 14 December 2004), available at: <http://www.essentialinventions.org/drug/imatinibmesylate/ei12142004.pdf>.

<sup>10</sup> Letter to Canadian Health Minister Ujjal Dosanjh requesting a compulsory license, *Essential Inventions* 14 December 2004), available at: <http://www.essentialinventions.org/drug/imatinibmesylate/ei12142004.pdf>.

<sup>11</sup> *Id.*

<sup>12</sup> Neither Expeditious, nor a Solution: the WTO August 30 Decision is Unworkable, *MSF* (August 2006), available at: [https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr\\_rcam\\_msf\\_11-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr_rcam_msf_11-eng.pdf).

<sup>13</sup> Canada, Standing Committee on Industry, Science and Technology [INDU], "Canada's Access to Medicine Regime", 39 th Legislature, 1 st Session (18 April - 14 May 2007), available at: <https://www.ourcommons.ca/DocumentViewer/en/39-1/INDU/meeting-55/evidence>, (Chair: Hon. James Rajotte).

A few months after indicating their agreement to produce Apo-TriAvir, Apotex had a prototype of the triple combination therapy.<sup>14</sup> As a next step, pursuant to the requirements in CAMR, Apotex sought to amend Schedule 1 of the *Patent Act*. As a result, in August 2005, the order to amend Schedule 1 came into force and Apo-TriAvir (abacavir + lamivudine + zidovudine) was added to Schedule 1.<sup>15</sup> It took eight months from the moment Apotex agreed to produce the triple antiviral therapy to the amendment of Schedule 1.

In parallel to the efforts to amend Schedule 1, Apotex moved forward with the regulatory review by Health Canada. At this point, this was the first instance where the Canadian regulatory agency reviewed a product in connection with the CAMR compulsory license procedure. In response, Health Canada set up a unique reviewing stream for CAMR related submissions and now reviews CAMR submissions on a priority basis.<sup>16</sup> Apotex's product was approved by Health Canada approximately six months after their submission<sup>17</sup>, the full dossier was submitted in December 2005 and was approved in June 2006.<sup>18</sup> Next to Apotex's Health Canada approval, Apotex also submitted dossiers to World Health Organization (WHO) Prequalification Project<sup>19</sup>, whereafter the WHO accepted Health Canada's review in July 2006.<sup>20</sup>

In July of 2007, Apotex sent their notification to the relevant patent holders of their request for a voluntary license.<sup>21</sup> The relevant patent holders were Shire BioChemical, Inc., Boehringer Ingelheim Canada, GlaxoSmithKline and the Wellcome Foundation Ltd.<sup>22</sup> This step proved to be a major hurdle for Apotex in the process to obtain a compulsory license. The reason being that the informal negotiations, which involved a complex patent landscape, took upwards of six months to complete.<sup>23</sup>

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<sup>14</sup> Review of the Canadian Access to Medicines Regime Submission to the Government of Canada, *Médecins Sans Frontières* (24 January 2007), available at: [https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr\\_rcam\\_msf\\_11-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr_rcam_msf_11-eng.pdf).

<sup>15</sup> *Patent Act*, *supra* note 1, schedule 1 (version from 2005-08-31 to 2006-09-20)

<sup>16</sup> See Guidance Document: The Management of Drug Submissions and Applications, *Health Canada* (25 July 2019), available at:

[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands\\_gespd-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php).

<sup>17</sup> Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act - Canada's Access to Medicines Regime, *Health Canada* (12 December 2014), available at:

<https://www.canada.ca/en/health-canada/services/canada-access-medicines-regime/documentation/report-statutory-review-sections-21-01-21-19-patent-act.html#fnb168-ref>.

<sup>18</sup> Jack Kay Testimony, *supra* note 13.

<sup>19</sup> Letter from Apotex Inc., to Director Patent Policy Directorate and Director Therapeutic Products Directorate, Re: CAMR Consultation paper, (23 January 2007), available at:

[https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr\\_rcam\\_apotex\\_18-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr_rcam_apotex_18-eng.pdf).

<sup>20</sup> *Supra* note 17.

<sup>21</sup> *Patent Act*, *supra* note 1, s. 21.04(3)(c)(i).

<sup>22</sup> Rimmer, M. (2008). Race against time: the export of essential medicines to Rwanda. *Public Health Ethics*, 1(2), 89-103.

<sup>23</sup> Weber, A., & Mills, L. (2010). A one-time-only combination: Emergency medicine exports under Canada's access to medicines regime. *Health & Hum. Rts.*, 12, 109; See also Jack Kay Testimony, *supra* note 13.

In July of 2007, with the help of the Clinton Foundation<sup>24</sup>, Rwanda became the first country to notify the World Trade Organization (WTO) of their intention to import a patented pharmaceutical product through a compulsory license in accordance with article 31bis of the TRIPS Agreement.<sup>25</sup> Canada's notification to the WTO came after Apotex's submission to the Commissioner. Once Apotex filed their compulsory license application to the Commissioner in September of 2007, it was granted 15 days later.<sup>26</sup> Soon after, in October of that year, Canada issued their notification to the WTO.<sup>27</sup> The WTO notifications and the issuance of a compulsory license pursuant to CAMR took place in 2007, years after Apotex's initial interest in manufacturing the triple antiviral therapy and of the amendment to Schedule 1. It was only in 2008, nearly four years later, that the first shipments were sent from Apotex in Canada to Rwanda.

The compulsory license issued to Apotex was limited to 15,600,000 tablets for a period of two years. The first shipment was sent out in September 2008 and the second shipment in September 2009.<sup>28</sup> Upon completion of the compulsory license application, Apotex declared that they would not go through the CAMR process again unless it were streamlined.<sup>29</sup>

#### *2006: Biolyse & Tamiflu*

In 2006, as a result of the spread of avian influenza A(H5N1), Biolyse Pharma ("Biolyse") sought a compulsory license to export Tamiflu (oseltamivir phosphate), an antiviral drug used for the prevention and treatment of the influenza. There was a large uptick in the spread of H5N1 in 2006, whereby it caused outbreaks throughout poultry and other birds in a large number of

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<sup>24</sup> The Clinton Foundation "coached Rwanda" in applying for assistance with CAMR. See Talaga, Tanya. AIDS drug fiasco a tale of red tape, *Toronto Star* (9 August 2007), available at:

[https://www.thestar.com/news/canada/2007/08/09/aids\\_drugs\\_fiasco\\_a\\_tale\\_of\\_red\\_tape.html](https://www.thestar.com/news/canada/2007/08/09/aids_drugs_fiasco_a_tale_of_red_tape.html).

<sup>25</sup> Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Doc. IP/N/9/RWA/1, *World Trade Organization* (19 July 2007).

<sup>26</sup> Annex from Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Doc. IP/C/57, *World Trade Organization* (10 December 2010).

<sup>27</sup> Notification Under Paragraph 2(c) of the Decision of 20 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Doc. IP/N/10/CAN/1 *World Trade Organization* (8 October 2007).

<sup>28</sup> Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), *World Trade Organization*, available at: [https://www.wto.org/english/tratop\\_e/trips\\_e/tripsfacsheet\\_e.html](https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.html).

<sup>29</sup> Talaga, Tanya. Hope for cheap HIV drugs dim, *Toronto Star* (19 September 2009), available at: [https://www.thestar.com/life/health\\_wellness/2009/09/19/hope\\_for\\_cheap\\_hiv\\_drugs\\_dims.html](https://www.thestar.com/life/health_wellness/2009/09/19/hope_for_cheap_hiv_drugs_dims.html).

countries.<sup>30</sup> The WHO believed at the time that this highly pathogenic variant of influenza A was a potential for a global pandemic.<sup>31</sup>

As a first step in the attempt to gain a compulsory license to export Tamiflu (oseltamivir phosphate), Biolyse sought to amend Schedule 1 of the *Patent Act*. In February of 2006, Biolyse requested the addition of oseltamivir phosphate to Schedule 1 and a month later received a reply from the Ministry of Health. In this reply, it stated that “Health Canada, in collaboration with Industry Canada, will review your request and will give it priority consideration in keeping with humanitarian principles of Canada’s Access to Medicines Regime”.<sup>32</sup> The Order-In-Council to amend Schedule 1 took place seven months after their request, in September 2006. Upon successfully amending Schedule 1, Biolyse no longer sought further action in their compulsory license application.

#### *2014-2015: Teva & Tenofovir Disoproxil*

In 2014, Teva Canada Limited (“Teva”) turned to CAMR. Their intention was to export tenofovir disoproxil, an antiretroviral medication for HIV and Hepatitis B. Much like the previous instances of using CAMR, Teva first sought to add tenofovir disoproxil to Schedule 1 of the *Patent Act*. In February of 2014, Teva sent a letter to Health Canada and Industry Canada asking for tenofovir disoproxil and certain combination drugs containing tenofovir disoproxil to be added to Schedule 1.<sup>33</sup>

As a result, Teva got three products added to Schedule 1, namely, efavirenz + emtricitabine + tenofovir disoproxil, emtricitabine + tenofovir disoproxil and tenofovir disoproxil.<sup>34</sup> As set out in the Regulatory Impact Analysis Statement of the aforementioned amendment, the addition of three antiviral medications was motivated by two points. Firstly, to ensure Schedule 1 “remains current, as the three listed products are listed on the current [Essential Medicines List]”. Secondly, to enable the Commissioner “to issue an immediate authorisation” if a manufacturer were to submit an application under CAMR.<sup>35</sup> The order amending Schedule 1 came into force

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<sup>30</sup> Avian and other zoonotic influenza, *World Health Organization*, available at: [https://www.who.int/influenza/human\\_animal\\_interface/en/](https://www.who.int/influenza/human_animal_interface/en/); and Kilpatrick, A. M., Chmura, A. A., Gibbons, D. W., Fleischer, R. C., Marra, P. P., & Daszak, P. (2006). Predicting the global spread of H5N1 avian influenza. *Proceedings of the National Academy of Sciences*, 103(51), 19368-19373, available at: <https://www.pnas.org/content/103/51/19368>.

<sup>31</sup> Avian influenza: assessing the pandemic threat, *World Health Organization* (2005), available at: [https://apps.who.int/iris/bitstream/handle/10665/68985/WHO\\_CDS\\_2005.29.pdf;jsessionid=5EE197CE27AC93620671297877BD0545?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/68985/WHO_CDS_2005.29.pdf;jsessionid=5EE197CE27AC93620671297877BD0545?sequence=1).

<sup>32</sup> Letter to John Fulton, Executive Vice President of Biolyse from Minister of Health, *CPTech* (9 March 2006), available at: <http://www.cptech.org/ip/health/tamiflu/canada-moh03092006.pdf>.

<sup>33</sup> Houston, A. R., & Beall, R. F. (2018). Could the Paragraph 6 Compulsory License System Be Revised to Increase Participation by the Generics Industry: Lessons Learned from a Unheralded and Unsuccessful Attempt to Use Canada's Access to Medicines Regime. *McGill JL & Health*, 12, 227.h.

<sup>34</sup> Order Amending Schedule 1 if the PATent Act (2014-1), *Canada Gazette* (17 June 2015), available at: <https://canadagazette.gc.ca/rp-pr/p2/2015/2015-07-01/html/sor-dors154-eng.html>.

<sup>35</sup> *Id.*

nearly 15 months after Teva's letter. Upon successfully amending Schedule 1, Teva did not continue with their compulsory license application.

### *2021: Biolyse & COVID-19 Vaccines*

In a second attempt to use CAMR, Biolyse is currently seeking to manufacture the Johnson & Johnson ("J&J") adenovirus vaccine candidate to help meet the growing COVID-19 vaccine demand. As of March 5th 2021, Biolyse has initiated this process by notifying the patent holder of their request for a voluntary license. In the meantime, Biolyse is seeking to amend Schedule 1 of the *Patent Act* in order to include Ad26.CVO2.S also known as JNJ-78436735.

Biolyse has been encountering a number of difficulties in their attempt to apply for a compulsory license.<sup>36</sup> From the lack of functional government phone numbers, inaccurate information and dysfunctional web-links, to intransparent and uninformed processes to amend Schedule 1. Besides the difficulties under CAMR, there has been a notable interest from low- and middle-income countries in importing Biolyse's potential production of COVID-19 vaccines. The critical step of finding a country to import and purchase the product is already in the process of being accomplished. To date, Biolyse's attempts to meet the requirements of a compulsory license application pursuant to CAMR are ongoing.

## Conclusion

This briefing note has laid out five attempts to apply for a compulsory license under CAMR. Of these five attempts, only three have successfully amended Schedule 1 of the *Patent Act*. In these three cases, it took between 7 to 15 months from initiating interest in an order to amend Schedule 1 until the order was established in law. The previous experience of Biolyse, Apotex & Teva substantiate that amending Schedule 1 takes a substantial time investment. Furthermore, with no established expert advisory committee, as provided for in the Statutory Review of CAMR (2007), there is still currently no transparent or informed process to recommend amendments to Schedule 1 to ensure it evolves with current public health needs.<sup>37</sup>

The singular success of Apotex's compulsory license experience with CAMR is still, to date, the only special export license granted under the TRIPS Paragraph 6 system. Apotex's experience from interest to issuance of a compulsory license took nearly 4 years. In evidence before INDU in 2007, which was tasked with studying CAMR at the time, Mr. Jack Kay (Former President & Chief Executive Officer of Apotex) provided testimony to the difficulties encountered with CAMR. Specifically stating that "the real problem for Apotex is the legislation, as the CAMR

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<sup>36</sup> Schouten, Arianna. Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low-Income Countries, may test Canada's compulsory licensing for export law, *Knowledge Ecology International* (12 March 2021), available at: <https://www.keionline.org/35587>.

<sup>37</sup> *Supra* note 17.



requirements are impossible to navigate”.<sup>38</sup> In response to Hon. Dan McTeague (Pickering-Scarborough East, Lib), Mr. Kay provided a poignant description on what it was like to use CAMR in its current state, namely, “to fight a battle in order to get the licence”.<sup>39</sup>

In the Report on The Statutory Review of Sections 21.01 to 21.19 of the Patent Act - Canada’s Access to Medicines Regime, published in 2007, it states that “the granting of the first and only export licence under the waiver to Apotex, and the circumstances surrounding it, suggest that CAMR works reasonably well and quickly, provided an importing country has made the requisite notification to the WTO”.<sup>40</sup> The rhetoric surrounding the functionality of CAMR mirrors Canada’s declaration at the WTO on December 10, 2020 that Canada “can thus observe, on the basis of concrete experience, that the system worked as intended”.<sup>41</sup> However, upon examining the attempts made to use CAMR, the Canadian manufacturers and NGOs experience dispute the Government’s conclusions. Instead, their experiences throughout the last 17 years point to fundamental flaws in CAMR and its lack of accessibility and timeliness.

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<sup>38</sup> Jack Kay Testimony, *supra* note 13.

<sup>39</sup> *Id.*

<sup>40</sup> *Supra* note 17.

<sup>41</sup> Intervention by Canada, Item 15 - Waiver from certain provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, *Government of Canada* (10 December 2020), available at:

[https://www.international.gc.ca/world-monde/international\\_relations-relations\\_internationales/wto-omc/2020-12-10-TRIPS-ADPIC.aspx?lang=eng](https://www.international.gc.ca/world-monde/international_relations-relations_internationales/wto-omc/2020-12-10-TRIPS-ADPIC.aspx?lang=eng).