INTRODUCTORY NOTE TO WORLD TRADE ORGANIZATION CANADA FIRST NOTICE TO MANUFACTURE GENERIC DRUG FOR EXPORT

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The Canadian Commissioner of Patents issued the first compulsory license for export to Apotex, Inc., a Canadian manufacturer of pharmaceutical products, pursuant to Canada's Access to Medicines Regime (CAMR) on September 19, 2007.[1] The license covers export to Rwanda, a least-developed African country, of a fixed dose combination of antiretroviral medicines used in the treatment of HIV-AIDS. The Apotex formulation, referred to as Apo-Triaver, combines 300mg Zidovudine (AZT), 150mg Lamivudine (3TC) and 200mg Nevirapine. Canadian patents on the separate antiretroviral components are held by the Glaxo Group, Shire Biochem and Boehringer Engelheim, respectively.[2] The license authorizes the manufacture of 15,600,000 Triaver tablets, and is valid for two years from the date of issuance.

This regulatory action is of some historical note because it represents the first issuance of a compulsory license for export within the framework established by the WTO Decision of August 30, 2003 on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the ''August 30 Decision'').[3] The issuance by Canada of this compulsory license appears to be a positive step toward providing low-cost access to necessary medicines for individuals in developing countries. However, the terms of the CAMR were the subject of substantial controversy during the period leading up to its adoption, and the legislation has remained controversial during its implementation.[4] A key question remains whether the perceived deficiencies in the CAMR make it too problematic for practically contributing to solving the access to medicines problem.

Soon after adoption of the August 30 Decision, Stephen Lewis, then UN Special Envoy on HIV-AIDS in Africa, urged Canada's government to take advantage of it. Jean Chrétien, Canada's Prime Minister, endorsed the idea. Almost immediately, the government's initiative was attacked by the originator pharmaceutical industry. Harvey Bale, Director-General of the International Federation of Pharmaceutical Manufacturer Associations (IFPMA), said publicly, ''It will be a 'negative black eye for Canada' that will 'very well affect the investment climate'.''[5] The multinational originator industry thereafter lobbied intensively in favor of restricting the government's scope of action during the period in which the legislation was drafted. NGOs promoting access to medicines and Canadian generics producers lobbied for a less restrictive regime. Canada's Parliament ultimately incorporated in the Jean Chrétien Pledge to Africa Act[6] (now generally referred to as the CAMR) a set of conditions on the issuance of compulsory licenses for export not found in the August 30 Decision. It may be that the difficulties encountered so far in use of the CAMR — as illustrated by the Apotex experience — represent ordinary 'start up' inefficiencies, and once stakeholders have become familiar with the intricacies of the Canadian system it will be possible to use it effectively. On the other hand, most of the difficulties were foreseeable and involved requirements over which generic producers and NGOs in Canada voiced concern during the legislative process. In that light, the CAMR may need amendment before it becomes a truly useful addition to the arsenal of weapons used to address disease burdens.

First, though not called for by the August 30 Decision (or reflected in the legislation of other implementing countries) the CAMR incorporates a limited list of pharmaceutical products covered by the system.[7] An application to export a medicine not included on the list must be proceeded by a petition for such listing. The combination antiretroviral product for which Apotex sought a license in the instant case was not on the pre-approved list, and Apotex successfully petitioned the government to add it.[8] Second, the CAMR requires an applicant for a compulsory license to have unsuccessfully conducted voluntary negotiations with the patent holder(s). Canada has so far refused to acknowledge that the August 30 Decision permits use of the waiver of voluntary negotiations provided for in Article 31(b) of the TRIPS Agreement. Canada is alone among the countries implementing the August 30 Decision to suggest that the various circumstances justifying such a waiver (including public health emergency and public non-commercial use) must exist in Canada, the exporting country, as opposed to the importing country which needs the medicine. Canada's position effectively turns the object and purpose of the August 30 Decision on its head. The Canadian government has taken tentative steps toward acknowledging the illogic of this stance, but it has not yet accepted this as a reason to amend the CAMR.[9] Apotex has indicated that uncertainty regarding the time periods required for voluntary negotiation, and uncertainty as to what constitutes adequate evidence of a reasonable effort, are impediments to using the system. None of the three patent holding companies involved in the Triaver combination were willing to grant a satisfactory voluntary license.[10] Other drawbacks to the CAMR

system have been identified by NGOs, generic producers and developing country public health officials expressing interest in making it work,[11] including an initial two-year period for execution of the license.

The CAMR effectively requires that an applicant for a compulsory license have identified a prospective developing country purchaser before it can pursue the application process.[12] NGOs, public health officials from developing countries and generic producers have stressed that a large part of government pharmaceutical purchasing is conducted through public bidding, making the requirement to have identified a purchaser in the application incompatible with customary procurement practices. The CAMR in this context generally reflects a requirement of the August 30 Decision that an export license identify the eligible importing Member(s) that has notified its requirements to the TRIPS Council.[13] There may, however, be mechanisms that could facilitate tentative completion of the CAMR licensing process pending formal notification of the intended destination of the subject exports.[14]

On the positive side, the CAMR's approach to the setting of royalties is widely supported by prospective users of the system, providing a transparent mechanism for differentiating royalty rates depending upon the level of economic development of the importing country.[15] Moreover, if the amount of effort expended in drafting government regulations is indication of serious interest in developing a workable system, Canadian regulators have certainly done their part. The websites operated by the various responsible agencies of the Canadian government provide an extensive array of forms and regulatory directions, presumably intended to allow interested parties to make effective use of the system.[16]

As of the date of this Introductory Note, Apotex has not exported Triaver to Rwanda, and it is not clear whether this will ultimately happen. Since Apotex began development of the combination, Indian generic producers have developed similar products and are offering at them at somewhat lower prices than Apotex, without the complications of the CAMR. Apotex is a successful privately held global supplier of generic medicines. It has prospered in competition with low-cost suppliers from other geographic regions. Given an appropriate compulsory licensing for export mechanism, there is no reason why this Canadian company could not make a substantial contribution to improving developing country access to medicines.

ENDNOTES

1 Canadian Intellectual Property Office (CIPO), Use of Patents for International Humanitarian Purposes to Address Public Health Problems (Canada's Access to Medicines Regime), Applications for Authorizations Received by CIPO, Apotex, Inc., Authorization under Section 21.04 of the Patent Act, Sept. 19, 2007, at <http://strategis.ic.gc.ca/sc_mrksv/cipo/jcpa/p4-e.html>.

2 The Glaxo patents, as identified by the authorization, are numbers CA 2311988, CA 2070230, CA 2068790, CA 2286126 and CA 2105487. The Shire patents are numbers CA 2059263 and CA 2009637. The Boehringer Ingelheim patent is number CA 2030056. *See* Authorization, *id.* Glaxo's basic patent on AZT for use in the treatment of HIV-AIDS has been the subject of significant controversy in the United States and Canada because, *inter alia*, the claimed invention substantially relied on research conducted at the U.S. National Institutes of Health. *See Burroughs Wellcome v. Barr Laboratories*, 40 F. 3d 1223 (Fed. Cir. 1994) and *Apotex v. Wellcome*, 2002 SCC File No. 28287 (Supt Ct. Can. 2002.

3 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), Doc. WT/L/540 (Sept. 1, 2003). The August 30 Decision will be transformed into the first formal amendment of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (''TRIPS Agreement'') upon acceptance by two-thirds of the WTO's Members of a Protocol of Amendment adopted on December 6, 2005. *See generally* Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2004), Frederick M. Abbott and Rudolph V. Van Puymbroeck, *Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Paper No. 61 (2005), and 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*, 10 J. INT'L ECON L. 921 (2007).

4 Canada's Minister of Industry has recently laid before Parliament a report on his review of the CAMR as provided for in Section 21.2 of the Patent Act. *See* Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act, Dec. 14, 2007, available at <http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_report_rapport_e.html> (hereinafter ''Minister's Review''). The Minister's Review includes discussion of the results of a meeting convened by Canadian NGOs, attended by a range of government representatives, to consider potential amendments to the CAMR. *See* North-South Institute and Canadian HIV/AIDS Legal Network, Meeting Report, *Access to Medicines and Intellectual Property: An International Expert Meeting on Canada's Access to Medicines Regime, Global Developments, and New Strategies for Improving Access*, 19-21 April 2007, Ottawa, Canada, available at <http://www.aidslaw.ca/publications/interfaces/

downloadFile.php?ref=1205> (hereinafter "NSI Meeting Report").

5 Steven Chase and Drew Fagan, *Drug companies balk at Ottawa's AIDS plan*, GLOBE AND MAIL, Sept. 27, 2003.

6 Bill C–9, An Act to Amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), R.S.C., c. P–4 (2004).

7 R.S.C., c. P-4, s. 21.02. See Minister's Review, *inter alia*, at 9-11; NSI Meeting Report, *inter alia*, at 28-32.

8 NSI Meeting Report, e.g., at 36.

9 *See* NSI Meeting Report, at 28; Minister's Review, at 31.

10 *See* Apotex Press Release, *Life Saving AIDS Drug for Africa Gets Final Clearance*, Sept. 20, 2007, available at <http://www.apotex.com/PressReleases/Default.asp?flash=Yes>; NSI Meeting Report, at 34.

11 *See generally*, NSI Meeting Report, and Minister's Review.

12 *See* Minister's Review, at 32; NSI Meeting Report, at 34-35. On July 17, 2007, Rwanda transmitted notification to the WTO, pursuant to paragraph 2(a) of the August 30 Decision, of its intention to import Triaver from Apotex in Canada. Council for Trade-Related Aspects of Intellectual Property Rights, 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 IP/N/9/RWA/1, 19 July 2007.

13 August 30 Decision, *supra* note 3, at para. 2(b).

14 *See* NSI Meeting Report, *inter alia*, at 34-35.

15 *See* Minister's Review, at 16-17.

16 *See*, e.g., Government of Canada, Canada's Access to Medicines Regime, available at <http://camr-rcam.hc-sc.gc.ca/doc/link-liens/index_e.html>; Canadian Intellectual Property Office, Use of Patents for International Humanitarian Purposes to Address Public Health Problems (Canada's Access to Medicines Regime), available at <http://strategis.ic.gc.ca/sc_mrksv/cipo/jcpa/content-e.html>.

WORLD TRADE ORGANIZATION: CANADA FIRST NOTICE TO MANUFACTURE GENERIC DRUG FOR EXPORT*
[October 4, 2007]
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WORLD TRADE ORGANIZATION

IP/N/10/CAN/1
5 October 2007

(07-0000)

Original: English

Council for Trade-Related Aspects of Intellectual Property Rights

NOTIFICATION UNDER PARAGRAPH 2(C) OF THE DECISION OF 30 AUGUST 2003 ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

CANADA

The following notification has been received from the delegation of Canada on 4 October 2007 for circulation to the Council for TRIPS.

In accordance with paragraph 2(c) of the WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, attached[1] is the authorization granted on 19 September 2007 by Canada's Commissioner of Patents to Apotex, Inc, pursuant to section 21.04 of the *Patent Act*.[2] Rwanda had previously filed a related notification, dated 17 July 2007, pursuant to paragraph 2(a) of the same Decision of the WTO General Council (IP/N/RWA/1).

Pursuant to paragraph 2(c) and 2(b)(iii) of the Decision of 30 August 2003 on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the information on the shipment (quantities and distinguishing features) will be posted on the licensee's website at: <www.apotex.com/apotriavir/abouttriavir.asp>.

Annex

AUTHORIZATION UNDER SECTION 21.04 OF THE PATENT ACT

In the matter of application for authorization number CAMR-1 by Apotex, Inc. for export to Rwanda of the following pharmaceutical product:

(a) if the pharmaceutical product is a drug as set out in section 2 of the *Food and Drugs Act*: A fixed dose combination tablet of lamivudine (150mg) + nevirapine (200mg) + zidovudine (300mg), as provided in Schedule 1 to the *Patent Act*

(b) if the pharmaceutical product is a medical device:

1. I hereby authorize Apotex, Inc. whose postal address is

150 Signet Drive
Toronto, Ontario
M9L 1T9

to make, construct and use, the patented inventions identified in patent numbers 2,311,988; 2,070,230; 2,068,790; 2,286,126; 2,216,634; 2,105,487; 2,059,263; 2,009,637 and 2,030,056 solely for purposes directly related to the manufacture of the above-mentioned pharmaceutical product, and to sell it for export to the above-mentioned country or WTO Member.

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2. The quantity of the pharmaceutical product authorized to be manufactured by this authorization is 15,600,000 tablets.

3. In accordance with section 21.09 of the Act, this authorization is valid for a period of two years, beginning on the date shown below.

Granted at Gatineau, Quebec, the 19th day of September, 2007-10-05

Mary Carman
Commissioner of Patents

ENDNOTES

1 Canada's Commissioner of Patents authorization can also be found at <http://strategis.gc.ca/sc_mrksv/cipo/new/CAMR_Authorization.pdf>

2 The WTO General Council Decision was implemented in Canada by an *Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa Act)*, of 2004. The text of Canada's Patent Act may be found at <http://laws.justice.gc.ca/en/showdoc/cs/P-4/bo-ga:s_21_01//en#anchorbo-ga:s_21_01>