Prepared Testimony before House of Commons Standing Committee on Industry, Science and Technology, Parliament of Canada,
regarding Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*

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1. Introduction and previous testimony regarding CAMR

I appreciate the opportunity to appear before the Committee regarding a bill proposed to enact changes to Canada's Access to Medicines Regime (CAMR). I appeared before this Committee on March 10, 2004 during consideration of what was then Bill C-9 that, as amended, was ultimately enacted as the CAMR. In the course of dialogue with House Committee members in 2004, I raised several concerns regarding the terms of the then draft legislation. I was of the view that a number of the restrictions and limitations under consideration would hamper effective use of the legislative mechanism as then proposed. Though some improvements were made in the legislation prior to its adoption, it was clear that Canada decided not to take full -- or effective -- advantage of the flexibilities in the WTO TRIPS Agreement, the 2001 Doha Declaration on the TRIPS Agreement and Public Health, and the August 30, 2003 Waiver Decision. It was foreseeable that the limitations in the CAMR would significantly restrict its utility in addressing the very serious public health problems confronting developing countries with limited or no capacity to give effect to compulsory licenses. It is not therefore surprising that this Committee is revisiting the CAMR with the objective of making it a more effective and useful mechanism.

2. Qualification to address subject matter of Bill C-393

I should spend a few moments explaining why I might reasonably be considered to have expertise on the subject of legislation to implement the WTO August 30, 2003 Waiver Decision. I have written and published extensively on the subjects of the WTO TRIPS Agreement, trade and intellectual property rights, and on the relationship between that subject matter and public

health, including access to medicines. I have regularly served as an expert consultant to the World Health Organization, but I am not appearing before you in that capacity), the World Bank, the WTO, the UN Conference on Trade and Development (UNCTAD) and other multilateral organizations regarding trade, intellectual property and public health matters. I served as legal consultant to the group of developing countries that formulated the proposal for the 2001 Doha Declaration, worked with those countries throughout the process in which the Doha Declaration was negotiated and adopted, and subsequently advised the core group of developing countries that was primarily responsible for negotiating the August 30, 2003 Waiver Decision at the WTO from the inception to the completion of that process. I have written and published about those negotiations in the Journal of International Economic Law, the American Journal of International Law and elsewhere. For the World Bank, I co-authored a detailed guide to implementation of the August 30, 2003 Waiver Decision, including model notifications and implementing legislation. I co-authored for the International Trade Committee of the European Parliament a report addressing whether the Parliament should approve acceptance by the European Union of the Article 31*bis* amendment to the TRIPS Agreement that would embed the August 30, 2003 Waiver Decision in the agreement. I participated in the international experts meeting convened in Ottawa in April 2007 to review the CAMR, and I prepared a report on the issuance by Canada of the first compulsory license for export (on September 19, 2007) for International Legal Materials (published by the American Society of International Law) (attached hereto as Annex 1). (Each of the aforementioned publications is available at <http://frederickabbott.com>.) I also participated in an expert consultation convened earlier this year at the offices of the UN Development Programme to review Bill C-393 and assess its compliance with Canada's obligations as a WTO Member. (Finally, I should note that I am presently advising the Government of India in dispute settlement consultations at the WTO, as India and Brazil have initiated consultations with the European Union and the Netherlands regarding seizures of legitimate generic drugs in transit through the EU *en route* to developing countries. Canada has participated as a third-party observer in these consultations.)

3. Effectiveness of the August 30, 2003 Waiver Decision

The August 30, 2003 Waiver Decision has been criticized by NGOs promoting access to medicines, by some academics, by some groups representing generic producers, as well as by some developing countries, for establishing an overly cumbersome set of rules that make it difficult to give effect to the basic objective of permitting export of low-priced generic pharmaceutical products to developing countries that do not have the capacity to manufacture those products under compulsory license. I have consistently observed that the August 30 Decision was the result of a long and intensive negotiation involving stakeholders with

decidedly different perspectives concerning the appropriate implementing mechanism, and that the August 30 Decision reflects a compromise between stakeholders seeking the most straightforward and efficient method for addressing public health needs, on one hand, and stakeholders seeking to protect perceived industrial interests, on the other. Neither NGOs seeking to provide the easiest mechanism for facilitating access to medicines, nor the originator pharmaceutical industry, found or find the August 30 Decision to reflect an ideal world of either access to medicines or industrial protection. But the critical question, and one on which the jury still seems to be out, is whether this negotiated solution can be made to work given an appropriate implementing framework. My own view has been that the system can be made to work, and that the obstacles presented by the regulatory or bureaucratic requirements of the WTO mechanism can be adequately dealt with by pharmaceutical industry business managers, skilled lawyers and medicines procurement specialists; although a mechanism that requires such labor may not be the friendliest for assuring access to medicines for those in need. But making this WTO mechanism work requires a serious effort to design national implementation mechanisms that seek to take advantage of the opportunities inherent in the WTO legal framework. The CAMR took a different approach, introducing regulatory and bureaucratic requirements beyond those incorporated in the August 30 Decision. For whatever reason, the CAMR was designed to add obstacles to effective use of the August 30 Decision. The question before this Committee is whether it should recommend that the CAMR be redesigned with the objective of seriously promoting exports of low-priced generic medicines to where they are very much needed.

4. The approach of Bill C-393

a. Practical aspects of medicines procurement

Bill C-393 seeks to streamline CAMR and take advantage of the flexibilities inherent in the August 30 Decision by providing a pharmaceutical producer with the opportunity to obtain a "single license" from the Commissioner of Patents that will authorize it to make and use a patented pharmaceutical invention or inventions for purposes of export to eligible countries that identify public health needs. A principal reason for proposal of this single license mechanism is to solve a significant problem reflecting the way the international pharmaceutical market works in practice. Many or most pharmaceutical procurement authorities acquire medicines by publishing a request for bids or proposals for supply of medicines, soliciting responses from industry. (Competitive bidding is not always practiced when, for example, a medicine is known to be "single source" on the international market.) It is extremely difficult in practice for a producer, for example a prospective Canadian supplier, to respond to a bid request conditionally, indicating that supply is predicated upon obtaining a compulsory license,

and that obtaining a compulsory license may be a lengthy process that involves (a) modifying a government list to add the subject medicine as a potential licensed product, (b) opening negotiations with a patent holder or patent holders for a voluntary license and (c) awaiting an ultimate determination by the Commissioner of Patents regarding whether a license should be issued. A public health procurement authority in a developing country would and should be understandably reluctant to award a supply contract based upon the fulfillment of an uncertain set of contingencies on the part of the producer-supplier.

Requiring a Canadian producer to seek a compulsory license for export on a case-to-case, country-to-country basis, presents obvious difficulties. The present CAMR system presumes that a producer can and should develop a pharmaceutical production line to fulfill a single contract to be negotiated and put into effect over a protracted time period. Then, the individual license is set to terminate after two years. Simply put, and you have undoubtedly heard or will hear this from the Canadian generic producers, this is a non-economic proposition. The process is almost certain to drain business and personnel resources without justification. It is counterproductive if the intention of the CAMR is to make Canadian producers a source of low-priced generic products needed by developing countries to meet public health requirements.

b. The single license mechanism

The single license mechanism would allow Canadian producers to submit proposals or bids in response to requests from developing countries requiring medicines to meet public health needs. Canadian producers would be in a position to commit to supplying the medicines in the event they are the successful bidder. Similarly, the single license mechanism would permit Canadian producers to respond to direct purchase requests from developing countries, or to seek contracts from developing countries (so as to allow the producers to realize production efficiencies), without fear that ultimately they would not be able to meet their contract commitments.

i. Consistency with WTO rules

A. Multiple destinations and purchasers

The proposal for a single license mechanism is consistent with the August 30 Decision and with Article 31 of the WTO TRIPS Agreement. Paragraph 2 of the Decision sets out the obligations of importing and exporting Members with respect to the grant of a compulsory license. The express terms of the obligations refer to exporting to "eligible importing Member(s)", "pharmaceutical product(s)" and the "names" and expected "quantity(ies)" of products. It is clear from the express terms of the Decision that a license may be granted for more than one product and for export to more than one destination. There is nothing in the Decision that indicates that the destination eligible importing Members must notify their intention to

purchase and import at the same time, or as a single group. The obligation on the importing Members is to provide certain notifications to the WTO TRIPS Council before products are shipped. The exporting Member (e.g., Canada) is required to notify the TRIPS Council of the grant of the license, including the conditions of the license. Those conditions include the products, quantities, destinations, and duration of the license. But, that notification requirement does not limit the exporting Member in terms of the stated conditions of the licence; it is a reporting requirement. (Footnote 8 to the August 30 Decision clarifies that the notification requirement does not involve approval by any WTO body.) There is nothing in the text of the reporting requirement that precludes the exporting Member (e.g., Canada) from stating in a licence (or even in a statute) that destination countries may include all eligible importing Members that notify their requirements to the TRIPS Council prior to importation of any medicines, or that the quantities to be supplied by the generic producer under the compulsory licence will depend upon the requirements of the notifying importing Members. Likewise, there is nothing in the reporting requirement to preclude that it be updated by the exporting Member as the license is executed.

B. Individual merits

Article 31 of the TRIPS Agreement remains generally applicable to exports under compulsory license except as specifically waived or changed by the August 30 Decision. Regarding "other use" of the subject matter of a patent without the consent of the right holder (i.e., a compulsory or government use license), Article 31(a) of the TRIPS Agreement provides that "authorization of such use shall be considered on its individual merits". That subparagraph of Article 31 does not in any way, express or implied, indicate that the recipient of a compulsory license (i.e., a compulsory licensee) should be limited to supplying a single or designated recipient of products produced under the license. Since manufacturers of products would rarely supply a single buyer, a compulsory licensee should ordinarily be expected to supply multiple buyers. There is nothing unusual about a compulsory licensing system in which the licensee is supplying multiple buyers over a period of time.

In that regard, it may be useful for the Committee to consider the legal framework under which the United States of America authorizes its federal government to make use of any third-party patent by precluding the issuance of injunctions against such use (28 USC §1428). This mechanism is effectively acknowledged in Article 31(b) of the TRIPS Agreement, as well as in Article 44.2 of the TRIPS Agreement. There is no requirement of prior notification to the patent holder, and no transaction by transaction, or license by license, authorization required under this United States well-known statutory mechanism. It is not considered inconsistent with the TRIPS Agreement.

Bill C-393 would establish a framework under which any number of Canadian pharmaceutical producers may submit applications to the Commissioner of Patents for the grant of compulsory

licenses for export. Under the terms of the draft legislation, the Commissioner is instructed to grant a license when the applicant has complied with the relevant conditions. The Commissioner is instructed to reject applications that do not comply with the relevant conditions, or when the Commissioner under a broad grant of authority determines that the license would not fulfil the objectives of the legislation. The Canadian Parliament will have established the basis upon which the individual merits of applications are assessed by the Commissioner, consistent with Article 31(a), and with the letter and spirit of the August 30 Decision and the Doha Declaration.

C. Expected quantities

Bill C-393 provides that the compulsory licensee will be authorized to meet the needs of eligible importing Members that enter into contract with that Canadian supplier. There is nothing in the August 30 Decision requiring that the quantities to be supplied under a compulsory license for export be fixed in advance to a "maximum quantity", as is currently the case under the CAMR. Indeed, the Decision limits exports to those necessary to meet the needs of eligible importing Members (Paragraph 2(b)(i)), but it is not expected that importing Members should be able to predict the quantities of product needed over time with specificity; in the August 30 Decision, WTO Members expressly refer to the "expected" quantities of products needed. The World Bank model notifications, for example, suggest that a formula such as "'a quantity of pharmaceutical product "x" sufficient to treat "y" patients over "z" period'" might be employed to provide adequate flexibility for eligible importing Members.

D. Duration

Bill C-393 does not expressly limit the duration of each license. This is sensible because eligible importing Members may be notifying their public health needs over a period of time. Article 31(c) of the TRIPS Agreement provides that the "duration of such use shall be limited to the purpose for which it was authorized". Article 31(g) further provides that "such use shall be liable ... to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances." Bill C-393 authorizes the patent holder to apply to the Federal Court for termination of the compulsory license if the licensee does not perform properly, including if diversion takes place with the consent of the licensee. Otherwise, it is foreseeable that licenses would terminate upon the expiration of the relevant Canadian patents as to which the licenses have been granted. A patent holder might presumably apply to the Federal Court to terminate a license if the circumstances giving rise to the adoption of the amended CAMR change such that the reasons for its adoption so substantially change that the legislation no longer serves its public health purpose, though that eventuality does not appear to be one that requires immediate legislative attention.

c. Fast-track option

During legislative consideration of the CAMR in 2004, I expressed strong reservations regarding the decision not to take advantage of the terms of Article 31(b) of the TRIPS Agreement that allow the grant of "fast-track" licenses in situations of national emergency, extreme urgency or for public noncommercial use. Article 31(b) expressly contemplates that governments may waive the requirement of prior negotiation with the patent holder when such circumstances dictate. The Doha Declaration expressly affirms (in paragraph 5) that WTO Members have the freedom to determine the grounds upon which compulsory licenses are granted and expressly acknowledges that public health crises relating to HIV/AIDS, tuberculosis, malaria and other epidemics may be determined to represent a national emergency or circumstance of extreme urgency. Moreover, many of the purchases by eligible importing Members are likely to be undertaken by public health authorities using the relevant pharmaceutical products for "public noncommercial use". In these cases, the TRIPS Agreement explicitly provides that a WTO Member may waive the prior negotiation requirement. Negotiation with the patent holder is likely to lead only to delay, and not to the grant of a voluntary license on reasonable terms and conditions under the circumstances. This was the experience of the only Canadian generic producer that so far used the CAMR mechanism – not least because of an inability, for many months, to identify to the patent holders the specific country for which the generic producer was seeking a voluntary licence. I again strongly urge you to include an option within the new legislative framework for compulsory licenses for export to be granted without prior negotiation with the patent holder, which flexibility is expressly incorporated in the TRIPS Agreement for a significant portion of essential cases.

To conclude, in my view, Bill C-393s core proposal of a straightforward mechanism for issuing a single license to supply eligible importing countries with needed pharmaceutical products is consistent with Canada's obligations under the TRIPS Agreement and the August 30, 2003 Waiver Decision. Thank you for your attention, and again for the opportunity to appear before you. I look forward to answering your questions.

Biographical Information for Frederick M. Abbott

Frederick Abbott is Edward Ball Eminent Scholar Professor of International Law at the Florida State University College of Law. He is Rapporteur for the Committee on International Trade Law of the International Law Association, consultant to the UNCTAD/ICTSD Project on Intellectual Property and Sustainable Development, and has served as consultant to the World Health Organization, the World Bank and other multilateral organizations. He is on the Panel of Experts of UNCTAD's Program on the Settlement of Disputes in International Trade, Investment and Intellectual Property. Professor Abbott serves as panelist for the World Intellectual Property Organization Arbitration and Mediation Center. He is on the editorial board of the Journal of International Economic Law (Oxford). He is former Chair of the American Society of Law Intellectual Property Interest Group and the International Law Section of the American Association of Law Schools, and former Director of the American Society of International Law Research Project on Human Rights and International Trade. He is Chair of the Intellectual Property Advisory Committee of the Foundation for Innovative New Diagnostics (FIND), and member of the Intellectual Property Advisory Committee of the Drugs for Neglected Diseases initiative (DNDi). Professor Abbott is the author of numerous books and articles in the fields of international economic law, international intellectual property rights law, public health regulation and public international law. His books include Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World (with Graham Dukes) (2009); International Intellectual Property in an Integrated World Economy (with Thomas Cottier and Francis Gurry) (2007), UNCTAD-ICTSD Resource Book on TRIPS and Development (Principal Consultant with Carlos Correa)(2005), The International Intellectual Property System: Commentary and Materials (with Thomas Cottier and Francis Gurry) (1999), China in the World Trading System: Defining the Principles of Engagement (1998), Public Policy and Global Technological Integration (1997), and Law and Policy of Regional Integration (1995). His book on treaty-making, Parliamentary Participation in the Making and Operation of Treaties, edited with Stefan Riesenfeld, was awarded the American Society of International Law Certificate of Merit. Prior to 1989 Professor Abbott was a partner at Pillsbury, Madison & Sutro (now Pillsbury Winthrop Shaw Pittman). He has served as Visiting Professor at University of California at Berkeley (Boalt Hall) School of Law, as Jean Monnet Professor at the University of Bonn, Visiting Professor and Weickert Fellow at the University of Berne, Visiting Professor at University of California, Hastings College of the Law and at Vanderbilt Law School, and was Professor at Chicago-Kent College of Law. Professor Abbott regularly teaches on the faculties of the World Trade Institute in Berne and the Central European University in Budapest. Professor Abbott holds BA and LLM degrees from UC Berkeley, and a JD from Yale Law School.

Annex 1

International Legal Materials

November, 2007

INTRODUCTORY NOTE TO WORLD TRADE ORGANIZATION CANADA FIRST NOTICE TO MANUFACTURE GENERIC DRUG FOR EXPORT BY FREDERICK M. ABBOTT

September 19, 2007

***1127** 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.[FN1] 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.[FN2] The license authorizes the manufacture of 15,600,000 Triaver tablets, and is valid for two years from the date of issuance.

FN1. 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>.

FN2. 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.

End of Footnote(s).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").[FN3] 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.[FN4] 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.

FN3. 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).

FN4. 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/reviewreviser/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").

End of Footnote(s).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'."[FN5] 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[FN6] (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.

FN5. Steven Chase and Drew Fagan, *Drug companies balk at Ottawa's AIDS plan*, GLOBE AND MAIL, Sept. 27, 2003.

FN6. 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).

End of Footnote(s).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.[FN7] 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.[FN8] 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.[FN9] 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.[FN10] Other drawbacks to the CAMR ***1128** system have been identified by NGOs, generic producers and developing country public health officials expressing interest in making it work,[FN11] including an initial two-year period for execution of the license.

FN7. 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.

FN8. NSI Meeting Report, e.g., at 36.

FN9. *See* NSI Meeting Report, at 28; Minister's Review, at 31.

FN10. *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.

FN11. *See generally,* NSI Meeting Report, and Minister's Review.

End of Footnote(s).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.[FN12] 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.[FN13] 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.[FN14]

FN12. *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.

FN13. August 30 Decision, *supra* note 3, at para. 2(b).

FN14. *See* NSI Meeting Report, *inter alia,* at 34-35.

End of Footnote(s).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.[FN15] 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.[FN16]

FN15. *See* Minister's Review, at 16-17.

FN16. *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>.

End of Footnote(s).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.