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REPORT ON THE STATUTORY REVIEW OF SECTIONS 21.01 TO 21.19 OF THE *PATENT ACT*

Canada

This publication is available upon request in accessible formats. Contact:

Multimedia Services Section
Communications and Marketing Branch
Industry Canada
Room 264D, West Tower
235 Queen Street
Ottawa ON K1A 0H5

Tel.: 613-948-1554
Fax: 613-947-7155
Email: multimedia.production@ic.gc.ca

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MINISTER'S PREFACE

I am pleased to table this report on the review of sections 21.01 to 21.19 of the *Patent Act*, in accordance with section 21.2 of that Act.

On May 14, 2005, Canada's Access to Medicines Regime ("CAMR") came into force, implementing the August 30, 2003, decision of the General Council of the World Trade Organization ("WTO") which waived two provisions of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPS") thought to be a barrier to developing and least-developed countries' access to lower-cost medicines. The implementing legislation amended the *Patent Act* to enable a Canadian pharmaceutical manufacturer to apply to the Commissioner of Patents ("Commissioner") for a compulsory licence to export a lower cost, generic version of a patented pharmaceutical product to a developing or least-developed country unable to manufacture its own. It also amended the *Food and Drugs Act* to require that pharmaceutical products exported under CAMR be reviewed by Health Canada according to the same safety, efficacy and quality standards as those destined for the Canadian market.

Canada was the first country to announce its intention to implement the WTO waiver and is also the first to review its amending legislation. That review was initiated in November 2006, with the release of a consultation paper seeking public input on key aspects of CAMR. In April 2007, the House of Commons Standing Committee on Industry, Science and Technology undertook a parallel study of CAMR's operational provisions. That same month, a developing countries workshop on CAMR was organized by non-governmental organizations ("NGO"). The Government completed its review of all of the information which came to light through these multiple sources in May 2007, the results of which are set forth in this report.

In tabling the present report in both Houses of Parliament, I would like to thank the many Canadians who participated in the review. The Government benefited from extensive public feedback in response to its consultation paper, including from the

pharmaceutical industry, NGOs, academia and Parliamentarians. This was complemented by the testimony of various experts who appeared before Parliamentary committee and took part in the above mentioned workshop. I would also like to express my appreciation for the countless letters from many concerned citizens who took the time to express their views on both CAMR and the broader issue of access to medicines in the developing world.

Before pharmaceutical products may be exported under the waiver, WTO rules require that an eligible importing country publicly notify of its intention to import them. On July 19, 2007, Rwanda became the first country to provide such a notification, with a letter to TRIPS Council indicating that it wishes to use the waiver to import a fixed-dose, triple combination HIV/AIDS drug manufactured by the Canadian generic pharmaceutical manufacturer, Apotex Inc. ("Apotex"). On September 4, 2007, Apotex filed the first compulsory licence application under CAMR and on September 19, 2007, it was granted by the Commissioner.

Although, as noted above, the review of public input on CAMR came to a close in May 2007, an exception has been made for information relating to the Commissioner's recent granting of an export licence to Apotex. The rationale for doing so is that the Apotex licence is the first one of its kind to be granted in any country that has implemented the waiver and lessons learned from that experience are key to a properly informed assessment of CAMR.

On that note, I would like to close these introductory remarks by commending the many individuals who played a role in this important milestone in the international community's efforts to improve access to medicines in the developing world. While the scale of global public health issues is such that no single event can reverse the scourge of HIV/AIDS, tuberculosis, malaria and other epidemics, this latest development is a small but very positive step in that direction. It is hoped that other developing countries will follow Rwanda's lead and notify the WTO of the drugs they wish to import under the waiver, and that other pharmaceutical companies, both innovative and generic, will

continue to pursue opportunities to supply them. It is only through the concerted and sustained efforts of all relevant actors, developed and developing country governments, the NGO community, international trade bodies and the private sector, that real and meaningful progress can be made.

Original signed by

Jim Prentice
Minister of Industry

INTRODUCTION

Section 21.2 of the *Patent Act*[1] requires the Minister of Industry to complete a review of the provisions related to Canada's Access to Medicines Regime (CAMR) within two years of the regime's coming into force,[2] and to cause a report of the results of that review to be laid before each House of Parliament within 15 sitting days of the report's completion. The review of CAMR was completed in May 2007, and the present document reports on its results, thus fulfilling the requirements of the aforementioned section.

Background

The World Trade Organization's ("WTO") *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPS") requires that all Members provide protection for intellectual property ("IP") rights consistent with certain minimum norms and standards.[3] As regards patents, this entails providing inventions that are new, involve an inventive step and are capable of industrial application, 20 years of protection from the date the patent application is filed.

Article 31 of TRIPS provides an exception to these minimal norms and standards by allowing for compulsory licensing or governmental use of a patented invention, without the consent of the patent holder, under prescribed circumstances. In 2001, the WTO Doha Declaration on the TRIPS Agreement and Public Health recognized that certain provisions in Article 31 could make it difficult for Members with little or no pharmaceutical manufacturing capacity to access needed, patented medicines.[4] In particular, Article 31(f) which requires that the use of a patented invention authorized under a compulsory licence be "predominantly for the supply of the domestic market" was thought to be barrier to the export of needed medicines from developed countries with pharmaceutical manufacturing capacity to countries with little or no such capacity.

Council for TRIPS was thus instructed to find an expeditious solution to this problem and on August 30, 2003, WTO Members agreed to waive both Articles 31(f) and

(h) of TRIPS, subject to certain terms and conditions.[5] All other patent related obligations in TRIPS remain in effect. The waiver's stated purpose is to facilitate developing and least-developed countries' access to lower-cost versions of patented medicines needed to treat HIV/AIDS, tuberculosis, malaria and other epidemics. On December 6, 2005, WTO General Council approved changes to transform the waiver into a permanent amendment to TRIPS, upon ratification by two-thirds of WTO Members. To date, 11 Members have accepted the changes, with the remainder having until December 1, 2009 to do so.[6]

In keeping with its longstanding commitment to improve access to medicines in the developing world, in September 2003, Canada became the first country to announce its intention to implement the WTO waiver. On May 14, 2004, CAMR's legislative framework received Royal Assent and exactly one year later, following passage of supporting regulations, the regime came into force.[7] CAMR implemented the underlying WTO waiver by enabling a Canadian generic pharmaceutical manufacturer to apply to the Commissioner of Patents ("Commissioner") for authorization to manufacture and export a lower-priced version of a patented pharmaceutical product to treat HIV/AIDS, tuberculosis, malaria or some other public health epidemic to a developing or least-developed country unable to manufacture its own. Products exported under this regime must meet the same safety, efficacy and quality standards as those destined for the Canadian market.[8] In developing the framework for CAMR, Canada faced the unique challenge of fashioning an unprecedented compulsory licensing for export regime which would advance the waiver's humanitarian objectives, while respecting international trade rules and maintaining the integrity of the domestic patent system.

Statutory Review

In light of the groundbreaking nature of this initiative, CAMR's enabling legislation included a clause calling upon the Minister of Industry to review the relevant provisions of the *Patent Act* (sections 21.01 to 21.19) within two years of its coming into force, and to table a report of that review in Parliament within 15 sitting days of the report's completion.[9] In November 2006, the Government initiated the review with the

release of a consultation paper seeking public input on CAMR. During the subsequent 60-day comment period, approximately thirty submissions were received, primarily from the pharmaceutical industry, non-governmental organizations ("NGO"), academia, and Parliamentarians.[10] These submissions, which have been posted online at the CAMR website (http://camr-rcam.hc-sc.gc.ca), are cited frequently throughout this report.

As the Government proceeded with its examination of submissions received in response to the consultation paper, public concern over access to medicines issues prompted the House of Commons Standing Committee on Industry, Science and Technology ("INDU") to undertake a parallel study of CAMR.[11] In April 2007, INDU held hearings on the effectiveness of the regime, with appearances from government officials, representatives from the NGO community and from both the innovative and generic sectors of the pharmaceutical industry. That same month, the Government participated in a workshop organized by the North-South Institute and the Canadian HIV/AIDS Legal Network designed to provide a forum for developing and least-developed countries to speak to some of the challenges they face in seeking to import pharmaceutical products under the WTO waiver.[12] In May, the Chair of INDU wrote to the Minister of Industry to advise that its study of CAMR was completed and to request that a number of key issues raised during testimony be addressed in the statutory review.[13]

Report

All of the above input was carefully considered and in May 2007, the statutory review of CAMR was closed. The present document reports on the results of that review by briefly describing the key features of CAMR, as described in the consultation paper and discussed at the INDU hearings, and summarizing any relevant public input. To place CAMR in its broader context, this is followed by a discussion of the disease burden in the developing world, recent international and country-based initiatives to address that burden, and some economic considerations affecting the supply of antiretroviral drugs used to treat HIV/AIDS. An analysis of CAMR, taking into account all of the aforementioned, as well as relevant international trade rules and circumstances

surrounding the Commissioner's recent granting of the first ever export licence to Apotex,[14] forms the penultimate portion of the report, followed by an account of the Government's various other initiatives to improve access to medicines in the developing world. The report concludes with the finding that insufficient time has passed and insufficient evidence has accumulated since the coming into force of CAMR to warrant legislative changes to the regime, and that the Government should focus on non-legislative measures to improve access to medicines in the developing world, until a more definitive assessment can be made.

I. Eligible Importers

Overview of Relevant Aspects of CAMR

Although the August 30, 2003, decision of the WTO General Council only waives the application of certain intellectual property obligations as between Members, for humanitarian reasons, Canada chose to implement the waiver in a manner that allows generic versions of patented pharmaceutical products to be exported to developing and least-developed countries regardless of WTO membership. The countries eligible to import under CAMR are listed in Schedules 2, 3, and 4 of the *Patent Act*. Third parties may also act as purchasers of licenced product under CAMR, with the permission of an eligible importing country's government.[15]

These schedules are organized according to level of development and WTO membership status, and may be amended as required by the Governor-in-Council.[16] Schedule 2 is composed of least-developed WTO and non-WTO Members, Schedule 3 is composed of developing country WTO Members and Schedule 4 is composed of WTO Members that have signalled their intention to use the waiver only in cases of national emergency or extreme urgency.[17] Non-WTO Members that have been identified by the Organization of Economic Cooperation and Development ("OECD") as eligible for official development assistance may also be added to Schedule 4 on a case-by-case basis,

upon request. As will be explained in detail below, all eligible importing countries are required to make the appropriate notifications to either the WTO, in the case of WTO Members, or the Government of Canada for non-WTO countries, before they may import a product under CAMR.

Summary of Input from Review

Three main issues emerged in relation to this aspect of CAMR.

The first was with respect to the rationale and purpose of the Schedules themselves. The innovative pharmaceutical industry[18] expressed support for the concept of having pre-approved lists of eligible importing countries as a measure which they believe ensures that products exported under CAMR only go to countries with genuine public health needs and little or no pharmaceutical manufacturing capacity. NGOs and the generic pharmaceutical industry took the opposing view, and requested that either CAMR be amended so that all developing countries are automatically eligible to import and subject to the same notification requirements, regardless of WTO membership or level of development,[19] or, at a minimum, that all eligible importers be listed on one Schedule only.[20]

The second issue was whether and to what extent CAMR should allow for the re-exportation of pharmaceutical products from one eligible importing country to another. Currently, CAMR only authorizes a licence holder to export pharmaceutical products to the country named in the licence, in keeping with paragraph 2 of the WTO waiver. To the extent this prevents an importing country from re-exporting licenced products to another country in the same regional trade group and suffering the same public health problem, NGOs and the generic pharmaceutical industry argued it is contrary to paragraph 6 of the WTO waiver.[21] Allowing for re-exportation, they insisted, would also enable developing and least-developed countries to pool their limited purchasing power, leading to greater economies of scale and more potential for uptake of the regime by generic drug manufacturers.[22] The generic pharmaceutical industry further submitted that a single licence under CAMR should allow for the direct export to multiple countries, regardless of membership in any regional trade group.[23] For its part, the

innovative pharmaceutical industry appeared to recognize the limitations of the *status quo* in terms of harnessing economies of scale,[24] but cautioned that allowing re-exportation could compromise the anti-diversion safeguards in CAMR.[25]

The third issue was with respect to the requirement that non-state actors must have the permission of the designated importing country's government in order to purchase drugs under CAMR. While the innovative pharmaceutical industry[26] expressed support for this feature, NGOs argued for its elimination on the ground that it compromised their operational autonomy in developing countries and is not explicitly required by the WTO waiver.[27] Both sectors of the Canadian pharmaceutical industry questioned what, if any, evidence is required in order to establish that a third party has the permission of an importing country's government, as CAMR provides no explicit guidance in this respect.[28]

II. Eligible Pharmaceutical Products

Overview of Relevant Aspects of CAMR

The WTO waiver defines "pharmaceutical product" as "any patented product, or product manufactured through a patented process, needed to address the public health problems afflicting many developing and least-developed countries, such as HIV/AIDS, tuberculosis, malaria and other epidemics."[29] This definition extends to active pharmaceutical ingredients (APIs) and diagnostic kits. The stated purpose of CAMR is to facilitate access to these very same products.[30] To this end, a pre-approved list of products eligible to be exported under CAMR appears at Schedule 1 to the *Patent Act*.[31] Schedule 1 was initially composed of the pharmaceutical products on the World Health Organization's ("WHO") Model List of Essential Medicines ("EML") that are patented in Canada. Medicines on the EML are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.[32]

Schedule 1 may be amended by Order-in-Council to remain current with the evolving public health needs of developing countries. To ensure this process takes place in an informed and transparent manner, CAMR calls upon the Ministers of Industry and Health to establish an expert committee by May of 2008, to advise them on what drugs should be eligible for export under the regime. Since the coming into force of CAMR, Schedule 1 has been amended twice. The first amendment was in response to a request from an NGO and Apotex to add the same fixed-dose triple combination ("FDC") drug used in the treatment of HIV/AIDS that Apotex is now authorized to export to Rwanda. The second amendment added an antiviral drug used for the prevention and treatment of the influenza virus, also at the request of a Canadian pharmaceutical manufacturer and an NGO.

Summary of Input from Review

Three main issues emerged in relation to this aspect of CAMR.

The first issue was whether Schedule 1 is an appropriate mechanism for defining the products that can be exported under CAMR. The innovative pharmaceutical industry supported having a list of pre-approved pharmaceutical products eligible for export on the ground that it prevents the system from being used for commercial, non-humanitarian purposes.[33] However, NGOs and the majority of the generic pharmaceutical industry claimed that Schedule 1 unduly limits CAMR's ability to respond to the needs of developing countries and should be eliminated or substantially broadened.[34] One generic pharmaceutical manufacturer took a slightly more nuanced view of the issue, arguing that Schedule 1 should be maintained in its current form because an open-ended regime would put pressure on the generic industry to manufacture and export pharmaceutical products that hold little or no prospect of financial return.[35]

The second issue related to the definition of "pharmaceutical product" in CAMR.[36] NGOs submitted that at a minimum, Schedule 1 needed to be amended to make explicit reference to APIs, paediatric drugs and diagnostic kits.[37] Members of both the innovative and generic sectors of the pharmaceutical industry[38] observed that APIs are

generally not manufactured in Canada, are not currently reviewed for safety, efficacy and quality by Health Canada and thus should not be covered by CAMR.

The third issue concerned the process for amending Schedule 1. The innovative pharmaceutical industry requested that the expert advisory committee be established immediately with a mandate to review Schedule 1 at regular intervals in an open and transparent manner.[39] It likewise requested that patent holding companies be given the right to make representations to the committee when their products are being considered for addition to Schedule 1,[40] although individual companies differed slightly on the criteria that should be looked at by the committee when considering whether to recommend amendments to Schedule 1. As mentioned above, although the preferred option of NGOs is for the outright elimination of the Schedule, if it is retained and the committee established, they would like eligible importing countries to have the right to make representations to the committee to the same extent as patentees.[41]

III. Health Canada's Drug Review

Overview of Relevant Aspects of CAMR

Although not specifically required by the WTO waiver, CAMR provides that pharmaceutical products intended for export under the regime be reviewed by Health Canada according to the same safety, efficacy and quality standards applicable to drugs destined for the Canadian market.[42]

Health Canada reviews product submissions under CAMR on a priority basis. A Canadian pharmaceutical manufacturer may file its regulatory submission with Health Canada at any time, and is not required to await the negotiation of a supply agreement with an importing country or for the country to send the required notification to the WTO or the Government of Canada.[43]

In July 2006, the WHO accepted the results of Health Canada's review of the Apotex product for the purposes of listing it under its Procurement, Quality and Sourcing Project (also known as the Prequalification Project (PQP).[44] The objective of this WHO project is to facilitate the procurement by United Nations (UN) Agencies of acceptable pharmaceutical products for the treatment of HIV/AIDS, malaria and tuberculosis. It does this by identifying those that meet WHO standards. Although the PQP's purpose is to assist UN Agencies with drug procurement, low-income countries with limited capacity to review pharmaceutical products often reference it as an assurance of product quality when making purchasing decisions.

Summary of Input from Review

The innovative and generic sectors of the pharmaceutical industry were in agreement that this aspect of CAMR should be retained to ensure that importing countries receive high quality drugs consistent with Canadian standards.[45] The generic pharmaceutical industry further remarked that the fast-tracking of the review process by Health Canada and the lower regulatory fees applicable to CAMR-related regulatory submissions serve as an incentive to participate in the regime as they facilitate the entry of generic products onto the Canadian market once relevant patents expire.[46]

However, this view was not shared by members of the NGO community, many of whom argued that Health Canada's review was time-consuming, potentially duplicative of other international regulatory review processes, and should be eliminated.[47] Some suggested that CAMR should allow for products intended for export to be reviewed by either Health Canada, WHO PQP, the drug regulatory authority in the named importing country or any other drug regulator deemed sufficiently stringent by Health Canada.[48]

IV. Application Process

Overview of Relevant Aspects of CAMR

CAMR requires that a Canadian pharmaceutical manufacturer's application to the Commissioner for an authorization to export a generic version of a patented pharmaceutical product include, among other things, the name of the pharmaceutical product for which the licence is sought, the quantity to be manufactured, the patents which protect the product, the name of the importing country and the identity of the purchaser.[49] A copy of the notification the importing country provided to the WTO or the Government of Canada, as the case may be, must also accompany the application, as well as a number of statutory declarations.[50]

Summary of Input from Review

Whereas the innovative pharmaceutical industry considered the informational requirements of the application process to be the minimum required to ensure the objectives and conditions of the waiver are met,[51] the generic pharmaceutical industry and NGOs insisted that many of these requirements are either duplicative of what must take place at the WTO or are not required by the waiver at all and should be eliminated.[52] They therefore asked that the application process be replaced by one of several alternatives.

The first such alternative would entail amending the *Patent Act* to provide for a standing statutory authorization which would allow for the export of a generic version of any Canadian patented pharmaceutical product that meets the definition in the waiver to any country, regardless of its development status or membership in the WTO.[53] The second would consist of a simplified application process which would permit the grant of an open-ended licence upon request, provided the importing country duly notified the WTO or the Government of Canada of its intention to make use of CAMR.[54] The third would retain parts of the existing process but not the requirement that the applicant provide a certified copy of the importing country's notification to the WTO or to Government of Canada.[55]

V. Voluntary Licence Requirement

Overview of Relevant Aspects of CAMR

Pursuant to Article 31(b) of the TRIPS Agreement, which was not waived by the August 2003 Decision, a Member may only grant a compulsory licence if the applicant first requests a voluntary licence from the patent holder(s) on reasonable commercial terms and where such efforts are not successful in a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use.[56] Some have construed this to mean that the requirement can be waived in the exporting country when there is a national emergency or extreme urgency in the importing country.[57]

CAMR requires that the applicant include with its application for a compulsory licence a declaration stating that it had, at least 30 days prior, unsuccessfully sought a voluntary licence on reasonable terms and conditions from the patentee[58]. The voluntary licence request must include the name of the pharmaceutical product intended for export, the expected quantity of exports and the name of the importing country, among other information.[59] The request for a voluntary licence may be made at any time prior to that 30 day interval, as an applicant is not required to await an eligible importing country's notification to the WTO or the Government of Canada. However, the request cannot proceed if an applicant is unable to identify the intended recipient country.

Summary of Input from Review

The innovative pharmaceutical industry insisted that the duty to request a voluntary licence is an absolute requirement of TRIPS, and further observed that by making the patent holder aware of the need for the drug, it can also have the salutary effect of it being supplied to the importing country much faster than would be the case under a compulsory licence.[60] In contrast, NGOs and the generic pharmaceutical industry were of the view that the voluntary licence requirement is the single greatest

obstacle to uptake of the regime by developing countries and that it should be waived if a national emergency or extreme urgency exists in either the exporting or importing country.[61]

Generic manufacturers and NGOs took particular exception to the requirement that the applicant disclose the name of the eligible importing country to the patent holder in its request for a voluntary licence, claiming that it was hindering the use of CAMR because importing countries are reluctant to notify their desire to import pharmaceutical products under the WTO waiver for fear of having legal or other action taken against them by the patent holder(s) or trade sanctions brought against them by developed countries.[62] The reaction of some innovative pharmaceutical companies to the recent granting of compulsory licences for certain patented pharmaceutical products in Thailand was cited as corroborating this assertion.[63]

VI. Duration of Licence

Overview of Relevant Aspects of CAMR

According to Article 31(c) of TRIPS, which was not waived by the August 2003 Decision, the scope and duration of a compulsory licence must be limited to the purposes for which it was authorized. CAMR provides that a compulsory licence is valid for two years[64] but is renewable for an additional two year period where the licence holder does not export the entirety of the licenced product within that initial time frame.[65] In applying for renewal, the licence holder must certify that a portion of the originally authorized quantity remains to be exported and that it has otherwise complied with the terms and conditions of the licence.

Summary of Input from Review

Two main issues emerged in relation to this aspect of CAMR.

The first was the consistency of CAMR's two-year, once-renewable licence with the humanitarian objectives of the waiver. Most members of the innovative pharmaceutical industry believed that a fixed and finite licence is necessary to guard against diversion, although one innovative company took the position that an export licence should be granted indefinitely, or for as long as it is needed by the importing country.[66] The innovative industry was unanimous in holding that the current mechanism does not prevent a Canadian pharmaceutical manufacturer from using the regime to address the evolving public health needs of an importing country since additional applications for licences can be filed with the Commissioner of Patents at any point during the original term.[67] The industry also maintained that a lengthier term could disadvantage low-income countries if it results in binding obligations to lengthy supply contracts which cannot be adjusted downward to reflect ongoing price reductions.[68]

In contrast, NGOs and the generic pharmaceutical industry argued that a longer term would enable prospective applicants to take greater advantage of economies of scale and to better respond to the long-term public health needs of developing and least-developed countries.[69] They insisted that the term of a licence should run to expiry of all relevant patents.

The second issue that emerged was in relation to the renewal process. The innovative pharmaceutical industry maintained that the *status quo* was simple and required no modification.[70] For their part, generic pharmaceutical manufacturers and NGOs contended that if a fixed and finite term was retained, the renewal process should be largely automatic.[71]

VII. Royalties Paid to Patent Holders

Overview of Relevant Aspects of CAMR

The WTO waiver requires that "adequate remuneration" be paid to the patentee on a case-by-case basis, taking into account the economic value to the importing Member of

the use authorized in the exporting Member.[72] In addition, Article 31(j) of TRIPS, which was not waived by the August 2003 Decision, requires that decisions relating to remuneration be reviewable judicially or independently by a distinct higher authority.[73]

Under CAMR, the remuneration, or royalty fee, to be paid by the licence holder to the patent holder is calculated according to a formula which multiplies the monetary value of the supply contract by an amount that fluctuates on the basis of the importing country's rank on the UN Human Development Index.[74] Under this formula, the lowest country on the index would pay a royalty of approximately 0.02 percent, and the highest 3.5 percent. Where a patent holder is of the view that the royalty resulting from the application of the formula is inadequate, it may apply to the Federal Court for an order setting a higher amount. In considering the merits of such an application, the Court must take into account the economic value of the use of the licenced product by the importing country and the humanitarian and non-commercial reasons underlying the issuance of the licence.

Summary of Input from Review

Although stakeholders were unanimous in their support for the current royalty formula,[75] one NGO suggested the regime be amended to clarify how royalties would be calculated when re-exportation occurs from one importing country to another in the same regional trade group.[76]

The only issue that emerged in relation to this aspect of CAMR concerned the right of the patent holder to challenge the royalty rate in Court, with innovative companies supporting it as a safeguard against the improper, commercial use of the waiver, and NGOs and generic manufacturers considering it an unnecessary litigation right which discouraged uptake of CAMR.[77]

VIII. The Good Faith Clause

Overview of Relevant Aspects of CAMR

The WTO waiver was adopted by the WTO General Council in light of the Chairperson's Statement that it must be used in good faith in order to deal with public health problems and not for commercial policy objectives. CAMR gives effect to this statement by providing the patentee with the right to challenge a licence in court where there is reason to believe that it is commercial in nature.[78] To do so, the patentee must first establish that the average price of the licenced drug is twenty-five percent or more of the average price of the equivalent patented brand name drug in Canada. If this test is met, the Court may look to the merits of the application and determine, based on a number of statutory considerations, whether the licence is commercial in nature.

Notwithstanding the relative price of the licenced drug and the Court's assessment of the merits, an application will be dismissed where the licencee can establish that the drug's price remains less than its cost of production plus fifteen percent.[79] However, if the patentee prevails on its application, the Court can either terminate the licence or allow it to continue on the payment of compensation by the licencee for the commercial use of the patent. A termination order can also be accompanied by either an order requiring the licencee to deliver any remaining licenced product in its possession to the patentee, or, with the consent of the patentee, an order requiring the licencee to export any remaining product to the purchasing country.

Summary of Input from Review

Three main issues emerged in relation to this aspect of CAMR.

The first concerned the prospective impact of litigation under the good faith clause on participation in the regime. The innovative pharmaceutical industry claimed that this should not discourage Canadian pharmaceutical manufacturers from seeking export licences under CAMR, provided they are consistent with the non-commercial,

humanitarian objectives of the waiver, particularly in light of the "cost of production" defence mentioned above.[80] The generic pharmaceutical industry and NGOs took the opposing view, insisting the good faith clause was a further "extra-litigation right" for patent holders and that the prospect of engaging in costly and time-consuming litigation with innovative pharmaceutical companies was discouraging some generic manufacturers from pursuing opportunities under CAMR.[81]

The second issue concerned the extent to which the good faith clause was necessary to implement the Chairperson's Statement. Whereas the innovative pharmaceutical industry suggested that the clause helps to ensure that the non-commercial objectives of the waiver are met, [82] the generic industry and NGOs argued that is unnecessary because prices on the world market will be kept low by competition from manufacturers in countries with lower labour and regulatory costs than Canada. The latter group also maintained that the clause was not explicitly required by the waiver.[83]

The third issue was whether alternative measures could be adopted to ensure that CAMR is not used for commercial purposes. Generic pharmaceutical manufacturers and one NGO suggested that the Chairperson's Statement was a generally worded exhortation to all affected parties to act in good faith, and that obligations under the good faith clause should not be limited to generic manufacturers but extend to patentees as well as exporting and importing countries.[84] One generic manufacturer stated that the licence holder should only have to provide costing information to the Commissioner after the licence is granted in order to eliminate the opportunity for the patentee to challenge the commercial character of the licence.[85] The innovative pharmaceutical industry disagreed with this suggestion and argued that the anti-diversion safeguards in CAMR should be strengthened further by imposing a good faith duty on the licence holder to ensure its goods are not used for commercial purposes or diverted back to Canada.[86]

IX. Quantities Exported

Overview of Relevant Aspects of CAMR

The WTO waiver requires an eligible importing country to notify the WTO of both the name and the quantity of the pharmaceutical product it wishes to import.[87] Compulsory licences granted under the terms of the WTO waiver must be limited to the quantity so indicated.[88]

To give effect to these provisions, CAMR requires that the quantity of product authorized to be manufactured and exported under compulsory licence not exceed the lesser of either the quantity set out in the manufacturer's licence application, or the quantity indicated in the importing country's notification to the WTO or to the Government of Canada.[89]

Summary of Input from Review

Two main issues emerged with respect to this aspect of CAMR.

The first was in relation to the requirement that the authorization granted under CAMR be for a fixed amount that was no greater than the amount stated by the named importing country in its notification. The majority of the innovative pharmaceutical industry was of the view that this requirement is a necessary safeguard against diversion. However, one innovative company acknowledged that it was difficult for developing and least-developed countries to forecast future demand for certain pharmaceutical products and recommended the requirement be eliminated.[90] NGOs argued that the requirement is inconsistent with the terms of the waiver, which only require an importing country to notify the Council for TRIPS of "expected quantities of the product(s) needed".[91]

The second issue was with respect to the process for amending the originally authorized quantity of exported products. Generic pharmaceutical manufacturers and NGOs believed CAMR should allow for a more simplified licence modification process

to better accommodate evolving public health needs in the developing world and post-grant requests to the same Canadian pharmaceutical manufacturer for greater amounts of the same product.[92] They also claimed that a simplified amendment process would facilitate compliance since patent holders would have legal recourse under the *Patent Act*.[93]

X. Anti-Diversion Measures

Overview of Relevant Aspects of CAMR

CAMR contains a number of measures to prevent the diversion of licenced pharmaceutical products to unintended markets. The WTO waiver requires that products produced under compulsory licence be distinguishable through special packaging and/or special colouring/shaping provided that such distinction is feasible and does not have a significant impact on price.[94] It also requires the licence holder to post information on a website describing these distinguishing features, as well as information on the quantities being shipped to each destination.[95]

In keeping with the above, CAMR requires that products exported under licence bear the mark "XCL" (for solid oral dosage forms), and sport distinguishing colours and labelling information from the patented versions available on the Canadian market.[96] Products are also issued an export tracking number by Health Canada which must be printed on the product label.[97]

Before a pharmaceutical product may be exported under CAMR, the licence holder must establish a website disclosing the name of the licenced product, its distinguishing characteristics, the identity of the importing country and the amount to be manufactured and sold for export, as well as information identifying every known party that will be handling the product while it is in transit from Canada to the importing country.[98] It must also provide to the patent holder(s), the importing country and the purchaser (within 15-days before the product is exported) a notice specifying the quantity

to be exported and the identity of every known party that will be handling the product while in transit.[99]

Under CAMR, countries that are not members of the WTO may be removed from the corresponding schedule if they fail to take reasonable steps to adopt anti-diversion 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".[100]

Summary of Input from Review

The innovative pharmaceutical industry argued that the retention of the anti-diversion measures in CAMR is critical to the overall integrity of the pharmaceutical supply chain, and suggested measures which would further strengthen them.[101] The latter included a requirement to place the name of the exporting country on product labels,[102] audits of the licencee's records (as is done in the European Union),[103] allowing Health Canada or the patentee to track all exported products[104] and requiring that licenced products be distinguishable from all other versions in the developed world.[105]

In contrast, the generic pharmaceutical industry, citing a lack of evidence indicating diversion is a common occurrence,[106] suggested eliminating all current anti-diversion measures on the ground that this the responsibility of the importing country.[107] In the alternative, the industry proposed relaxing the labelling/marking provisions of CAMR to reflect the minimal requirements of the WTO waiver. Some NGOs recommended eliminating the anti-diversion measures of CAMR altogether,[108] or were in favour of tighter border-control agreements.[109] Still others submitted that only the measures explicitly required by the WTO waiver should be retained.[110]

XI. Termination of Licence

Overview of Relevant Aspects of CAMR

As mentioned, the WTO waiver was adopted in light of the Chairperson's Statement that it must be used in good faith. In keeping with this, CAMR gives the patentee the right to apply to the Federal Court for an order terminating a compulsory licence where it can establish, *inter alia*, that the application contained materially incorrect information, that the licencee has not complied with the requisite anti-diversionary measures or has failed to pay royalties, that the product has been re-exported in a manner contrary to the WTO waiver, or that one of the prescribed terms of the licence has not been respected.[111]

Summary of Input from Review

The innovative pharmaceutical industry was of the view that the termination provisions of CAMR should be retained or amended to result in stronger penalties. However, they also criticized the high evidentiary burden on the patentee to prove that the licence holder had knowledge of the diversion and suggested this be eliminated.[112]

NGOs and the generic pharmaceutical industry submitted that certain anti-diversion provisions should be repealed, as they merely reproduce rights already available to patentees under the *Patent Act*.[113] NGOs argued that the language surrounding termination encourages litigation and discourages uptake of CAMR.[114] In the alternative, some NGOs suggested that the termination provisions be amended to accommodate re-exportation to regional trade groups and to authorize the Federal Court to grant discretionary remedies proportionate to the breach, avoiding outright licence termination.[115] They further suggested that "clear and direct knowledge" of the diversion be required, in order to avoid termination based on material errors or "honest mistakes".[116]

OTHER CONSIDERATIONS

Global Burden of HIV/AIDS, Tuberculosis and Malaria

Every year, 6 million people die as a result of HIV/AIDS, tuberculosis and malaria.[117] In 2006, 40 million people worldwide were living with HIV/AIDS and only 28 percent of HIV/AIDS sufferers who could benefit from treatment received it. This latter figure drops to a mere 15 percent in the case of women and children under 15 years of age.[118]

It is estimated that over 3 billion people reside in 1 of 107 malaria prone countries. 350 to 500 million people in these countries are infected with malaria annually, resulting in 1.5-2.7 million deaths. The demand for new, highly efficacious Artemisinin-based combination therapies ("ACT") has risen from a few 100,000s in 2001, to 10s of millions in 2005.[119] The WHO forecast for 2006 suggested that approximately 120 million ACT treatment regimes will be required globally.

Although tuberculosis rates have been on the decline in recent years, the total number of new cases is rising. Approximately 2 billion people are infected with the microbe that causes the disease and 2 million people die as a result of it annually. In 2004, 8.8 million new cases (including 3.9 million new smear positive cases) were reported, with 46 percent of all smear positive cases treated successfully by the Directly Observed Treatment, Short-course ("DOTS") program.[120]

International Initiatives and Partnerships

There are a number of international initiatives and partnerships that seek to increase access to medicines required to combat the global burden of disease. UNITAID, the Global Fund to Fight AIDS, Tuberculosis and Malaria ("GFATM"), the work of the WHO Commission on Intellectual Property Rights, Innovation and Public Health ("CIPIH"), the United States President's Emergency Plan for AIDS Relief ("PEPFAR"), the William J. Clinton Foundation, the Bill & Melinda Gates Foundation, the Stop TB Partnership, the Global Drug Facility ("GDF") and the Global Alliance for Vaccines and

Immunization (the "GAVI Alliance") use various procurement mechanisms to increase access to affordable medicines in low-income countries.

Established in 2006, UNITAID is an international drug purchase facility designed to accelerate access to medicines against HIV/AIDS, malaria and tuberculosis. More than 85% of UNITAID funds, which are secured through an innovative airline tax levy, are directed towards providing low-income countries with access to affordable and high quality medicines. A total of 34 countries have joined UNITAID, with funding expected to reach $300 million USD by 2007. UNITAID funds are allocated to its partners, and increased purchasing power is established through pooled procurement and central purchasing at a global level.[121] UNITAID also purchases medicines from countries that permit the exportation of drugs which are not necessarily bioequivalent to their reference products.[122]

The GFATM is a partnership between governments, civil society, the private sector and affected communities aimed at increasing resources for both prevention and treatment initiatives in countries of greatest need. Since 2001, the GFATM has attracted $4.7 billion USD in financing through 2008. GFTAM places full management and procurement responsibilities on the grant recipients where a number of variables can be considered by the latter, such as the status of country making the purchase, cooperative or group purchasing mechanisms and country of manufacture.[123]

The WHO founded an initiative to help 3 million people in low-income countries access HIV/AIDS treatment by December 2005 (the "3 by 5" initiative). While the target was not fully met, the progress gave much-needed momentum as the global community now works towards greater access.

Launched in 2003, PEPFAR is a five-year, $15 billion USD initiative to combating HIV/AIDS. PEPFAR will focus new resources in 15 of the most afflicted countries in the world. PEPFAR funds are used to purchase high quality products at the lowest possible price. This could entail bioequivalent versions of innovative,

antiretrovirals ("ARV") and other drugs.[124] According to PEPFAR, major innovative pharmaceutical companies are beating generic manufacturers' prices for ARVs in some low-income countries.

Innovative pharmaceutical companies have also been active in donating their products to improve treatment for HIV/AIDS patients in the developing world. Similarly, public-private partnerships are providing drugs at minimal or no cost to certain populations in many low-income countries. Established in 2002, the Clinton Foundation HIV/AIDS Initiative ("CHAI") has assisted countries in implementing large-scale, integrated care, treatment and prevention programs. CHAI partners with 25 countries in Africa, the Caribbean and Asia and supports governments to expand high-quality care and treatment to people living with HIV/AIDS. CHAI also has agreements with 7 pharmaceutical manufacturers of ARV formulations, active pharmaceutical ingredients and intermediates.[125] Products are purchased directly from partner suppliers or through procurement agents representing the manufacturers. For paediatric formulations, some products are available on the basis of CHAI acting as the procurement or sourcing agent. In May 2007, CHAI announced new agreements with generic drug manufacturers that will generate an average savings of 45% ($339 USD per person per year) in low-income countries for the next generation of first line treatments and 25% for second line treatments for HIV/AIDS.[126]

Established in 2000, the Stop TB Partnership involves organizations and individuals committed to eliminating tuberculosis as a public health problem. The global movement to increase social and political action is focused on DOTS treatment, new tuberculosis drugs, vaccines and diagnostics, as well as advocacy, communications and social mobilization. The Global Drug Facility ("GDF") was established in 2001 as a Stop TB Partnership project to increase access and availability to high quality tuberculosis drugs. GDF links the demand for drugs to supply and monitoring, while competitively outsourcing all services to partners. Grants to partners are tied to programme performance. Technical assistance in drug management and monitoring and the procurement of drugs at low costs are among the services GDF provides to partners.

The GAVI Alliance is a unique, multi-dimensional partnership of public and private sector resources with a single, shared focus of improving child health in the poorest countries by extending the reach and quality of immunization coverage within strengthened health services. The GAVI Alliance aims to delivers predictable, long-term financial and material support to the world's poorest countries to extend the reach and effectiveness of their immunization programs. Its key objectives are to increase access to new and underused vaccines and to help ensure the long-term sustainability of national efforts to control or eradicate diseases that cause high child mortality.

Country Based Initiatives

Countries use a variety of mechanisms to increase access to affordable medicines, including through compulsory licensing and the production of generic drugs. In 1997, South Africa adopted legislation that allowed it to produce generic versions of patented drugs through compulsory licensing and parallel importing. As mentioned, the Thai government recently issued compulsory licences for the production of 3 HIV/AIDS drugs. In 2007, the Brazilian government announced its intention to issue a compulsory licence for the HIV/AIDS drug, Efavirenz, if prices are not reduced by the patent holder.[127] Until recently, India was able to produce massive quantities of generic versions of innovative drugs, due to an absence of product patent protection for medicines.[128] However, in 2005, India implemented its TRIPS obligations and now provides product patents for medicines, with the result that new and recent pharmaceutical products will likely be exclusively sold by patent holders.[129] This may result in an increase in drug prices and greater global demand as new generations of patented drugs displace existing generic therapies.[130]

ARV Therapies as a Model to Treat HIV/AIDS

The use of ARV therapies to treat HIV/AIDS is often showcased as a model that has significantly increased access to medicines in low-income countries. HIV/AIDS treatment can be categorized into first, second and third line regimes. The WHO recommends a certain combination of drugs be used for individuals beginning treatment,

referred to as first line treatment. Second and third line treatment regimes are used when first line drugs fail, are toxic to the individual or other unique circumstances are presented. Since 2000, there has been a drastic reduction in the cost of first line HIV/AIDS treatment from $10,000 USD to an average of $219 USD per person per year in 2006.[131] The costs of paediatric versions of many antiretroviral drugs have also decreased substantially to $100 USD per child per year.[132] The fall in first line drug prices has increased access to treatment in low-income countries and is attributed to the scale-up of treatment programmes, an increase in the number of products that meet WHO standards leading to greater competition, and negotiations by international partners and major generic manufacturers.

The average price paid for second line treatment is significantly more expensive and remains unaffordable in many low- and middle-income countries.[133] In 2006, the most commonly used second line treatment cost an average of $1698 USD in low-income countries and $4735 USD in middle-income countries.[134] The increased price for second line treatment is said to be due to the lesser number of generic versions of these drugs available on the market.[135]

New generation ARVs for first, second and third line treatments have recently appeared in developed country markets and offer greater convenience, fewer side effects and improved treatment outcomes.[136] Some manufacturers have not sought marketing approval for these new treatment regimes in Asia, Africa or Latin America, making it difficult for low-income countries to access them.[137]

ANALYSIS

In September 2003, when Canada began developing a legislative framework with a view to implementing the WTO waiver, there were no international precedents upon which to rely. Since then, seven WTO Members have amended their domestic laws in

order to become potential exporting countries under the waiver. As explained in the November 2006 consultation paper, there are many commonalities between these other implementing regimes and CAMR, including, for example, provisions requiring the licencee to pay reasonable royalties to the patent holder(s), and to establish a web site disclosing certain basic information about the licenced product prior to its export.[138]

At the same time, no two regimes are perfectly aligned and CAMR contains a number of measures that have not been emulated elsewhere. These include its reliance on pre-approved lists of products eligible for export and countries eligible to import them and making the grant of an export licence contingent upon the health and safety review of the product by the exporting country's regulatory authority. In addition, whereas many other regimes waive the requirement that a pharmaceutical manufacturer request a voluntary licence from the patent holder(s) prior to applying for a compulsory licence, in cases of a national emergency or circumstances of extreme urgency, CAMR does not.[139]

Over the course of the review, certain stakeholders seized on these differences as evidence that other countries had succeeded in implementing more permissive regimes, while remaining compliant with the terms of the waiver and the obligations in the TRIPS Agreement. Prior to the granting of the Apotex licence, proponents for amending CAMR insisted it was unlikely to result in the issuance of an export authorization until the underlying measures were eliminated or substantially relaxed.[140]

While it is not within the purview of the present document to address questions of consistency between the measures adopted in these other countries and the waiver, the possibility that divergent approaches toward implementing a particular trade rule can be equally compliant with the obligations in the TRIPS Agreement is not disputed. This concept is reflected in Paragraph 1, Article 1 of the TRIPS Agreement itself, which provides that "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."

In so far as the scheduling of eligible pharmaceutical products and importing countries is concerned, although they may make CAMR appear more mechanistic than the regimes in place in these other countries, they also hold certain operational advantages. In particular, the existence of pre-approved products and importing countries provide prospective users of CAMR with greater assurance that, assuming all other statutory requirements are met, an application for a licence to export a product on Schedule 1 to a country on Schedules 2, 3 or 4, will be granted by the Commissioner almost as of right. In addition, by minimizing the discretionary elements of the Commissioner's decision to grant an export licence under CAMR, the Schedules help clarify and expedite the decision-making process, making its outcome far less vulnerable to legal challenge should a party seek to oppose it.[141] This perspective would appear to be borne out by the Apotex licence, which the Commissioner granted less than three weeks after the initial paperwork was filed and in respect of which the time for filing a judicial review application has now elapsed without any court proceedings being commenced.[142]

While the Schedules serve an important purpose in the overall functioning of CAMR, they do require regular upkeep to remain current with the evolving public health needs of developing countries and an ever-changing geopolitical environment. As mentioned, the Government has received two requests for additions to Schedule 1 to date, both of which were accepted and led to amendments being made in a relatively timely manner. It remains to be seen, however, whether the intended operational advantages which flow from the use of Schedules outweigh the drawback in time and resources required to maintain them.

Similar reasoning applies to Health Canada's mandatory health and safety review of products to be exported under CAMR, a feature which drew many comments from stakeholders, despite being technically outside the scope of the statutory review.[143] Most other WTO Members that implemented the waiver do not provide for such a review,[144] or make it optional at the behest of the pharmaceutical manufacturer,[145] leading some to

argue that this feature is unnecessary, unduly time consuming and should be eliminated from the regime or substantially revised.[146]

While there may be some merit to following the Swiss example by making Health Canada's review process optional, given that generic manufacturers view it as a potential incentive to participation in CAMR, and their clearly articulated preference that it remain in place, there is no evidence to demonstrate it would have any impact on how CAMR functions in practice. Furthermore, the perspective that this review is unduly time consuming is not supported by the evidence to date in respect of Apotex's product, which was approved by Health Canada approximately six months after it was submitted,[147] less time than the normal performance target for a similar submission type.[148]

The considerations surrounding the requirement in CAMR that a generic pharmaceutical manufacturer request a voluntary licence from the patent holder(s) at least 30 days prior to applying for a compulsory licence are more complex. As mentioned in the consultation paper, while Canada believes this measure was necessary to implement Article 31(b) of the TRIPS Agreement, some other countries have waived it where emergent circumstances are said to exist.[149] Although it is not clear from the domestic law in these countries whether such circumstances must reside in the country granting the licence or in the one importing the product so-licenced, a contextual reading would suggest the latter. Since neither the waiver nor the subsequent December 6, 2005 decision of Members to transform it into a permanent amendment address the matter, the extent to which this would be consistent with Article 31(b) remains the subject of debate.[150] It is noted, however, that all other obligations in that provision speak to circumstances in the Member granting the export licence.[151]

Even though the waiver of Article 31(b) requirement in the above mentioned countries has not led to the granting of compulsory licence to export, critics of this measure claim it should be eliminated from CAMR because it is representative of the "red tape" that is said to plague the regime and the principal reason for the lack of uptake at the time of the review.[152] Some critics also contend that the obligation on the

applicant to request a voluntary licence prior to applying for a compulsory licence, and to name a prospective importing country as part of the request, provides the patent holder(s) with an opportunity to control and drag out the application process.[153]

Proponents of this view cite difficulties encountered by Apotex in a previous attempt to obtain a compulsory licence under CAMR in respect of the same HIV/AIDS drug it is now authorized to export to Rwanda. In testimony before INDU, representatives of the company indicated they had been prepared to seek an export licence as early as July of 2006, but were unable to proceed to the application stage of this process because of the requirement that they identify an eligible importing country in the voluntary licence request to the patent holder.[154]

However, even if this aspect of CAMR were to be eliminated, notification by an importing country remains the operational *sine qua non* of the waiver and the disclosure of this information would still be required at the compulsory licence application stage. In either case, any delay resulting from an inability to identify the importing country would be the same.

Furthermore, once the identity of the eligible importing country is known, there is nothing in CAMR that enables a patent holder to delay a generic manufacturer from applying to the Commissioner for a compulsory licence to export 30 days after it requests a voluntary one. This was made clear in the events leading up to the granting of Apotex's licence. As widely reported in the media, Apotex's more recent request for a voluntary licence took place in late July 2007, the same month Rwanda made its notification to the WTO,[155] and the company's application for a compulsory licence was filed with the Commissioner less than two months later, in early September. To the extent that one can assert that there was delay between these two steps, it was relatively insignificant.

Some commentators contend that the general reluctance of developing countries to come forward and identify a need for a product under the waiver can be explained by intimidation tactics on the part of patent holding, innovative pharmaceutical companies,

or a fear of recrimination at the hands of the developed countries that are said to champion them.[156] During the review, no direct evidence was offered to this effect in the context of CAMR but commentators suggested it could be inferred from the public response of one innovative pharmaceutical company to Thailand's recent issuance of three compulsory licences for the domestic production of a patented drug,[157] as well as from earlier such incidents in South Africa and Kenya[158].

A less polemical explanation may be a continued lack of awareness in developing and least-developed countries about CAMR and what is required of them to import products in compliance with the waiver. During meetings with government officials as part of Canada's outreach activities on CAMR, a number of representatives of developing countries inquired about the process their health authorities would need to undertake to ascertain the domestic patent status of a particular product, which is a complicated and resource intensive undertaking in even the most advanced regulatory environment[159].

Another possible explanation is that despite the multitude of international and country-based initiatives to procure greater volumes of lower cost pharmaceutical products for developing and least-developed countries, many of these countries continue to lack the resources to pay for needed drugs, even at the lowest available price.[160] Despite recent increases in official development assistance,[161] global funding for the treatment of public health epidemics remains far lower than what is required to meet the health-related Millennium Development Goals by 2015, with some experts estimating the current gap at $50 billion USD per year.[162] In addition, although Canada boasts a world-class generic pharmaceutical industry with the highest possible manufacturing standards and an acknowledged commitment to supporting access to medicines initiatives in the developing world, there is evidence to suggest it may have difficulty competing on price with its Indian, South African and Chinese counterparts, particularly for the supply of low-cost HIV/AIDS products to sub-Saharan Africa.[163] Generic manufacturers in these latter countries are able to sell their products for less because they have the advantage of lower overhead and labour costs, as well as cheaper access to the raw materials needed for pharmaceutical production. Given these resource limitations, current international

procurement efforts for the developing world are focussed almost exclusively on developing country sources.[164]

This perspective is reinforced to some degree by events following the Commissioner's granting of an export licence to Apotex. Rwanda recently indicated its intention to open a public tender for a contract to supply this FDC HIV/AIDS drug to its Ministry of Health.[165] Despite the fact that Apotex is said to be offering its product at cost,[166] five major Indian generic pharmaceutical companies are listed on the Clinton Foundation Website as having lower-priced versions of the same product available for sale to African countries,[167] the lowest of which is roughly half the price specified by Apotex in its application to the Commissioner.[168] The director of the Rwandan health authority responsible for procurement recently indicated that his country has no legal obligation toward Apotex, notwithstanding its having identified the company's drug in its notification to the WTO, and that the purpose of the tender is to purchase the drug from whichever manufacturer offered the best quality and the lowest price.[169]

At the same time, it is recognized that the economic divide between developed and developing country generic drug prices may shrink in the coming years, as the impact of the January 1, 2005, obligation on WTO developing country Members to fully implement patent provisions of the TRIPS Agreement becomes manifest,[170] at least in so far as the latest generation of pharmaceutical products to treat HIV/AIDS, tuberculosis, malaria are concerned.[171]

Those who advocate amending CAMR also suggest that one way of levelling the playing field in this respect is for Canada to abandon the current one drug, one country model embodied in the regime, and in the regimes of other countries that have implemented the waiver, in favour of a standing statutory authorization in the *Patent Act* which would allow for the manufacture of generic versions of any drug patented in Canada for export to any eligible country specified in the legislation. Alternatively, it was suggested that CAMR should be modified to permit the grant of a single, open-ended

licence on a given drug that authorizes the licence holder to export it to any eligible country specified in the legislation.[172]

Either approach, it was argued, would be more consistent with international procurement practices and could be justified as a set of "limited exceptions" to exclusive patent rights, within the meaning of Article 30 of the TRIPS Agreement, particularly when that provision is read in conjunction with the above quoted language from Paragraph 1, Article 1 of the TRIPS Agreement, which allows members to determine the appropriate method of implementing TRIPS within their own legal system. It is also said that these alternatives would be consistent with Canada's "ethical duty" and "legal obligation under international human rights treaties" to take steps in order to prevent, treat and control epidemics and other diseases in least-developed countries.

While these arguments are compellingly advanced, they would appear to conflict with commonly understood interpretations of TRIPS. Canada has very direct experience in this regard, having attempted to defend certain measures in its *Patent Act* in a WTO dispute settlement proceeding on the basis of a large and liberal interpretation of Article 30 of TRIPS.[173] In that case, the WTO Panel did not accept Canada's argument that the curtailment of the patent owner's legal rights should be considered "limited" if the exception preserves the exclusive right to sell to the ultimate consumer during the patent term. Instead, it found that the rights to exclude "making" and "using" the patented product during the term of the patent are equally important and that a measure with no limitations at all upon the quantity of production and without regard to other, subsequent, consequences it might have, constitutes a substantial curtailment of this dimension and cannot be considered a "limited exception" within the meaning of Article 30. The Panel's reasoning aside, it would be logical to conclude that if Article 30 provided a basis for the type of legal mechanisms contemplated above, there would have been no need for WTO Members to agree to the waiver in the first place.

In light of all of the above, the view that certain unique features of CAMR make it less permissive or operationally sound than the legislation subsequently adopted in other

countries to have implemented the waiver does not appear to be substantiated by the available evidence at this juncture. While there may be room to improve CAMR, as there is with any legal framework, more time, evidence and analysis is needed to determine if changes to these features, along the lines of the amendments proposed by various stakeholder groups, would make a meaningful difference in the volume and frequency of exports. That insufficient evidence has accumulated to draw definitive conclusions in this regard is not surprising, given that CAMR only came into force in 2005, and that, according to the Canadian Generic Pharmaceutical Association, it can take three to five years for a generic manufacturer to develop and obtain regulatory approval for a generic version of a patented, innovative drug.[174]

Furthermore, for the moment at least, 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. To date, the dearth of developing country notifications to the WTO or Canada of an intention to import drugs under the waiver appears to have more to do with above mentioned economic factors, the obligations imposed on importing countries by the August 2003 Decision, as well as a general lack of awareness among developing countries about CAMR and the regimes in place in other countries that have implemented the waiver. The Canadian generic pharmaceutical industry appears to be aware of these more practical impediments, noting in testimony before INDU that it had neither the ability, nor the inclination to become the "generic breadbasket to the developing world."[175]

CONCLUSION

While the Government is of the view the case for making legislative or regulatory changes to CAMR has not yet been made out, it recognizes that the regime could do more to address the underlying economic barriers and will undertake further analysis of this

issue as greater experience in using the WTO waiver and other international mechanisms to improve access to medicines is gained. In particular, it appears that CAMR could be more explicit in allowing for the harnessing of economies of scale through the pooling of purchasing power by multiple developing countries suffering from the same public health problem. This approach finds support in the August 2003 Decision, which encourages the re-exportation of products imported under the waiver between similarly afflicted countries that are part of the same regional trade group.[176] While CAMR does not prohibit this,[177] it does reflect the overarching "one licence per product/country" architecture of the waiver, as do the regimes in other countries.[178] At the same time, it should be noted that there is nothing to prevent a generic manufacturer wishing to export the same product to multiple countries from filing multiple, simultaneous applications with the Commissioner, all of them further to the same underlying voluntary licence requests. The actual process for applying for a compulsory licence is relatively simple and consists of filling out certain basic information in a number of forms, with the cost of filing those forms assumed by Industry Canada pursuant to a memorandum of understanding between the department and the Commissioner.

Since CAMR came into force in 2005, the Government has engaged in extensive outreach activities to raise awareness of the regime in the developing world.[179] While the primary objective of these activities is to inform pharmaceutical regulatory authorities in developing and least-developed countries about the CAMR framework, they also serve to inform eligible importers about their own obligations under the terms of the WTO waiver. These efforts are generally well-received but it is clear that more time and resources are required before developing and least-developed countries benefit from the same comfort level with the intricacies of the global patent system and of the underlying WTO waiver as their developed country partners. In this regard, Canada intends to expand and intensify its outreach activities, the most recent of which involved the distribution of an electronic user's guide on CAMR and a questionnaire to select African countries by Department of Foreign Affairs and International Trade missions, in order to obtain a better sense of the future challenges they face in importing products under the

waiver. Lessons learned from the Apotex case will inform this ongoing dialogue with developing countries.

The Government will also move to establish the expert committee, as provided for in the *Patent Act*, to advise Ministers on what products should be eligible for export under CAMR. A system of checks and balances will be put into place to ensure the committee process is procedurally fair, properly informed and gives rise to regularly scheduled updates of Schedule 1 so that it can remain current with the evolving public health needs of the developing world.

CAMR-related activities aside, Canada will continue to support a multitude of international and domestic initiatives designed to improve access to medicines in the developing world, several of which are described below.

In Budget 2007, the Government introduced a new tax incentive to encourage greater pharmaceutical donations to the developing world. It is also supporting the University of Toronto in its collaborative work with Ghana and other West African countries to develop new strategies to improve access to medicines and take advantage of the flexibilities available in the TRIPS Agreement. Canada has contributed over $100,000 to this initiative.

Through Canada's African Health Systems Initiative, the Government will contribute $450 million over the next decade to support country-led efforts to strengthen health systems, improve health outcomes and make progress towards the Millennium Development Goals in Africa. This new 10-year funding will also help to reinforce other Canadian commitments to address disease-specific health challenges in Africa, such as HIV/AIDS. Through bilateral support in Africa**,** Canada provided approximately $130 million in the fiscal year 2006/2007 in support of efforts to improve health outcomes in 24 African Countries. Most recently, on November 26, 2007, the Government announced that Canada is on track to double its aid to Africa by 2008-2009 and will contribute $105 million over 5 years to train over 40,000 health workers and provide life-saving treatment

for mothers and children with diseases such as malaria, measles and malnutrition in Africa and Asia. This leading initiative is in partnership with UNICEF, the Bill & Melinda Gates Foundation, the WHO, the World Bank and other donor countries.[180]

The Government also supports a number of initiatives that directly target the provision of medicines and/or vaccines to developing countries. Most notably, Canada is the seventh largest donor to the GFATM, with a total contribution of more than $530 million since inception, 60 percent of which goes to combating HIV/AIDS. Through current GFTAM support, it is projected that 1.8 million people will receive treatment for HIV/AIDS, 3 million people will be cured through DOTS treatment, and 264 million ACT treatments for resistant malaria will be provided. Canada participated in the second replenishment exercise of the GFATM in September 2007, and has signalled its ongoing support for this important initiative.

Canada has long been a champion of vaccinating children against preventable diseases. Since 2001, Canada has contributed $182 million to the GAVI Alliance**,** which provides new and underused vaccines to developing countries. This represents the highest ever grant from a donor country. Since 1998, Canada has been a major funding contributor to the Canadian International Immunization Initiative ("CIII"), providing $130 million to this important initiative. In its first five years the CIII grant has played a part in saving the lives of over 500,000 children through immunization.

Canada contributes approximately $29 million annually to the Micronutrient Initiative, a global program dedicated to eliminating micronutrient deficiencies in children and women in developing countries. UNICEF estimates that more than 1.5 million child lives have been saved through the provision of vitamin A. Canada has also been a substantial supporter of polio eradication efforts, with a particular focus on delivery of vaccines, providing more than $165 million to the Global Polio Eradication Initiative since the 1990s.

With an initial contribution of $100 million, Canada was one of the first and largest donors to the WHO's 3 by 5 initiative. Canada is also providing significant support towards the development of new prophylactic technologies to combat HIV/AIDS, such as a vaccine and microbicide. On 20 February 2007, the Prime Minister announced the establishment of the Canadian HIV Vaccine Initiative ("CHVI"), a collaborative project funded by Canada (up to $111 million) and the Bill & Melinda Gates Foundation (up to $28 million). The CHVI will contribute to global efforts to develop a safe, effective, affordable and universally accessible HIV vaccine. The CHVI complements Canada's support for the International AIDS Vaccine Initiative ($82 million since 2000) the African AIDS Vaccine Program ($5 million from 2003 to 2008) and the International Partnership for Microbicides ($30 million over 5 years).

Canada has also committed $200 million to Advance Market Commitments to accelerate the development of an effective pneumococcal vaccine for developing countries. Canada will provide $20 million over 2 years to the Canadian Red Cross to support programming in malaria prevention and control in Africa.

The above initiatives aside, Canada will continue to look for new and innovative ways to contribute to the global effort to improve public health conditions in the developing world. As regards CAMR, the Government will continue to closely monitor developments, both domestically and in other countries that have implemented the WTO waiver, in the hopes that further eligible importing countries will come forward to request pharmaceutical products. Should sufficient evidence eventually accrue to demonstrate that specific amendments would make a meaningful difference in the effectiveness of CAMR, the Government will work closely with all interested stakeholders to ensure a result that is fair, functional and fully compliant with Canada's international trade obligations.

[1] R.S.C. 1985, c. P-4.
[2] *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, R.S.C. 2004, c. 23.
[3] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994 [TRIPS]. Least-developed countries have been given an extension until January 1, 2016, to provide protection for patents.
[4] WTO, General Council, *Ministerial Declaration on TRIPS and Public Health* (4 November 2001), WTO Doc. WT/MIN(01)/DEC/21.
[5] WTO, General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health* (30 August 2003), WTO Doc. WT/L/540 and Corr. 1 [WTO waiver]. In instances where importation of licensed product also requires the issuance of a compulsory licence in the importing country, the WTO waiver also waived the article 31(h) requirement that remuneration be paid by the importing country to the patent holder. Under the waiver, it is only in the exporting country that remuneration must be paid, taking into account the economic value of the authorization to the importing country.
[6] "Countries Accepting Amendments of the TRIPS Agreement" (28 September 2007), online: WTO, <http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm>. On October 23, 2007, the Council for TRIPS agreed to recommend to the WTO General Council to extend the deadline by two years (i.e. December 1, 2009).
[7] *Supra*, note 2.
[8] See: *Food and Drugs Act*, R.S.C. 1985, c. F-27, s. 37.2.
[9] *Supra* note 1. Subsection 21.2(1) states: "A review of sections 21.01 to 21.19 and their application must be completed by the Minister two years after this section comes into force." Subsection (2) adds: "The Minister must cause a report of the results of the review to be laid before each House of Parliament on any of the first fifteen days on which the House is still sitting after the report has been completed."
[10] "Canada's Access to Medicines Regime- Consultation Paper" (24 November 2006), online: CAMR, <http://camr-rcam.hc-sc.gc.ca/review-reviser/index_e.html> [CAMR consultation paper]. See also Representations in response to the CAMR consultation paper, online: CAMR, <http://camr-rcam.hc-sc.gc.ca/review-reviser/index_e.html> [Representations].
[11] Canada, Standing Committee on Industry, Science and Technology [INDU], "Canada's Access to Medicine Regime", 39th Legislature, 1st Session (18 April – 14 May 2007) online: House of Commons, <http://cmte.parl.gc.ca/cmte/CommitteeHome.aspx?Lang=1&PARLSES=391&JNT=0&SELID=e22_.1&COM=10476&STAC=1956890> (Chair: Hon. James Rajotte).
[12] "Access to Medicines and Intellectual Property: An International Expert Consultation on Canada's Access to Medicines Regime, Global Developments and New Strategies", (Ottawa, April 2007), online: The North-South Institute <http://www.nsi-ins.ca/english/pdf/Agenda%20AccessToMeds.pdf> North-South Workshop].
[13] Letter from the Honourable James Rajotte, M.P. to the Honourable Maxime Bernier, P.C., M.P. (14 May 2007), online: INDU <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=211186> [Rajotte Letter].
[14] "Commissioner of Patents authorizes the manufacture of an anti-viral drug to Rwanda", Canadian Intellectual Property Office (CIPO) (September 19, 2007), online: <http://strategis.gc.ca/sc_mrksv/cipo/new/new-e.html#sep19>.
[15] *Supra* note 1, s. 21.04(2)(f).
[16] *Ibid.*, s. 21.03(1)(b), (c) and (d).
[17] Hong Kong, China; Israel; Korea; Kuwait; Macao, China; Mexico; Qatar; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu; Turkey; and the United Arab Emirates.
[18] Representations, *supra* note 10, from BIOTECanada, p. 3; Canada's Research-Based Pharmaceutical Companies [Rx&D], p. 11; Bayer Inc. [Bayer]; GlaxoSmithKline [GSK]; Hoffman-La Roche [Roche], pp. 14-15; Eli Lilly Canada Inc [Eli Lilly], p. 2; Janssen-Ortho; and Wyeth, p. 2.
[19] Representations, *ibid.*, from Oxfam, p. 7; McGill Human Rights Working Group on HIV/AIDS and Public Health [McGill], p. 4; Global Treatment Access Group/Interagency Coalition on AIDS and Development [GTAG], p. 1; and Canadian Generic Pharmaceutical Association [CGPA], p. 4. See also

Robert Fox (Oxfam Canada) and Richard Elliott (HIV/AIDS Legal Network), appearances before INDU (18 April 2007), *supra* note 11; North-South Workshop, *supra* note 12, from HIV/AIDS Legal Network, Professor Fred Abbott (Florida State University).

[20] Representations, *ibid*., from Oxfam, p. 7; McGill, p. 4; World Vision//Save the Children/Plan Canada, p. 4.

[21] WTO waiver, *supra* note 5, at para. 6.

[22] Representations, *supra* note 10, from HIV/AIDS Legal Network, p. 7. See also Richard Elliott (HIV/AIDS Legal Network) and Sarah Perkins (International Human Rights Program, University of Toronto), appearance before INDU (18 April 2007), *supra* note 11.

[23] Representations, *ibid*., from CGPA. See also Jim Keon (CGPA), appearance before INDU (23 April 2007), *ibid*.

[24] Representations, *ibid*., from Rx&D, p. 11; Pfizer, p. 11; Roche, p. 14; Bayer; and GSK, p. 3.

[25] Representations, *ibid*., from Eli Lilly, p. 2; and Roche, p. 14.

[26] Representations, *ibid*., from Rx&D, p. 11; Bayer; BIOTECanada, p. 3; Roche, p. 14; Pfizer, p. 11; and GSK, p. 2. See also Gregg Alton (Gilead Sciences), appearance before INDU (23 April 2007), *supra* note 11.

[27] Representations, *ibid*., from McGill, p. 4; Oxfam, p. 7; HIV/AIDS Legal Network, p. 9; GTAG, p. 3; Access to Drugs Initiative (University of Toronto), pp. 6-7; Canadian Crossroads International, p. 2; CGPA, p. 4. See also Richard Elliott (HIV/AIDS Legal Network) and Robert Fox (Oxfam), appearances before INDU (18 April 2007), *ibid.*; North-South Workshop, *supra* note 12, from HIV/AIDS Legal Network.

[28] Representations, *ibid*., from CGPA, p. 4; Apotex, p. 2; Rx&D, p. 11; Bayer; BIOTECanada, p. 3; Roche, p. 14; Pfizer, p. 11; and GSK, pp. 2-3.

[29] *Supra* note 5, para. 1(a).

[30] S*upra* note 1, s. 21.01.

[31] *Ibid*., s. 21.02. CAMR defines pharmaceutical products as "any patented product listed in Schedule 1, in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product."

[32] "WHO Model List of Essential Medicines", *World Health Organization* [WHO] (March 2007), online: <http://www.who.int/medicines/publications/essential medicines/en/>. See also: "The Selection of Essential Medicines", WHO Perspectives on Medicine (June 2002), online: <http://whqlibdoc.who.int/hq/2002/WHO_EDM_2002.2.pdf>.

[33] Representations, *supra* note 10, from BIOTECanada, p. 3; Roche, p. 15; Eli Lilly, p. 3; Janssen-Ortho; Rx&D, p. 12; Wyeth, p. 2; Bayer; Pfizer, p. 12; and GSK, pp. 2-3. See also Terry McCool (Eli Lilly), appearance before INDU (23 April 2007), *supra* note 11.

[34] Representations, *ibid*., from Oxfam, p. 7; Médecins Sans Frontières [MSF]; McGill, p. 5; Access to Drugs Initiative (University of Toronto), p. 8; GTAG, pp. 2-3; HIV/AIDS Legal Network, p. 12; Canadian Crossroads International, p. 2; and CGPA. See also Carol Devine (MSF), appearance before INDU (18 April 2007), *ibid*.; Jim Keon (CGPA), appearance before INDU (23 April 2007), *ibid*.; North-South Workshop, *supra* note 12, CGPA.

[35] Representations, *ibid*., from Apotex, p. 2.

[36] *Supra* note 1, s. 21.02, which states: "pharmaceutical product" means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product.

[37] Representations, *supra* note 10, from GTAG, pp. 2-3; Oxfam, p. 7; HIV/AIDS Legal Network, p. 12. See also Sarah Perkins (International Human Rights Program, Faculty of Law, University of Toronto), appearance before INDU (18 April 2007), *supra* note 11.

[38] Representations, *ibid.*, from Roche, p. 16; Wyeth, p. 2; and CGPA, p.5.

[39] *Supra* note 1, s. 21.18. See also: Representations, *ibid*., from Roche, p. 16; Rx&D, p. 13; Pfizer, p. 13; Bayer; Bristol-Myers Squibb [BMS], pp. 2-3; GSK, pp. 2-3; BIOTECanada, p. 3; Eli Lilly, p. 3; and GTAG.

[40] Representations, *ibid*., from BIOTECanada, p. 3; Rx&D, p. 13; BMS, pp. 2-3; Bayer; Janssen-Ortho; Eli Lilly, p. 3; GSK, pp. 2-3; and Wyeth, p. 3.

[41] Representations, *ibid*., from McGill, pp. 5-6; and HIV/AIDS Legal Network, pp. 13-14.

[42] *Food and Drugs Act*, *supra* note 8; *Food and Drug Regulations*, C.R.C., c. 870, C.07.004 [*Food and Drug Regulations*].
[43] *Ibid*.
[44] The assessment teams evaluating the products and manufacturers include experts from some of the national regulatory authorities of the European Union as well as Canada and Switzerland; online: <http://mednet3.who.int/prequal/>
[45] Representations, *supra* note 10, from Rx&D, p. 14; International Federation of Pharmaceutical Manufacturers and Associations [IFPMA], p. 3; BIOTECanada, p. 3; Bayer; Pfizer, p. 14; Roche, p. 17; Janssen-Ortho; Gilead, p. 6; Abbott, pp. 2-3; Eli Lilly, p. 3; GSK, pp. 2-3; Wyeth, p. 2; Canadian Chamber of Commerce; CGPA, p. 6; Apotex, p. 2; and Access to Drugs Initiative (University of Toronto), pp. 12-13. See also Gregg Alton (Gilead Sciences) and Jim Keon (CGPA) appearances before INDU (23 April 2007), *supra* note 11; North-South Workshop, *supra* note 12, from CGPA.
[46] Representations, *ibid*., from CGPA, p. 6; and Apotex, p. 2. See also Jim Keon (CGPA) and Jack Kay (Apotex), appearances before INDU (23 April 2007), *ibid*.
[47] Representations, *ibid*., from GTAG, pp. 2-3; Canadian Crossroads International, p. 2; MSF; and McGill, p. 6.
[48] Representations, *ibid*., from Access to Drugs Initiative (University of Toronto), p. 9; HIV/AIDS Legal Network, pp. 14-15; GTAG, pp. 2-3. See also Richard Elliott (HIV/AIDS Legal Network), appearance before INDU (18 April 2007), *supra* note 11; North-South Workshop, *supra* note 12, from HIV/AIDS Legal Network.
[49] *Patent Act*, s*upra* note 1, s. 21.04(2).
[50] *Ibid*, s. 21.04(3).
[51] Representations, *supra* note 10, from Roche, p. 18.
[52] Representations, *ibid*., from Apotex, p. 2; CGPA, pp. 7-8; MSF; Faculty of Pharmacy (University of Toronto), p. 3; Canadian Crossroads International, p. 2; and GTAG, pp. 2-3.
[53] Representations, *ibid*., from Oxfam, p. 5; GTAG, p. 2; Canadian Crossroads International, p. 2; and HIV/AIDS Legal Network, pp. 15-17.
[54] *Ibid*.
[55] *Ibid*.
[56] TRIPS, *supra* note 3, article 31(b).
[57] See North-South Workshop, *supra* note 12, Fredrick M. Abbott (Florida State University).
[58] See *Patent Act*, *supra* note 1, s. 21.04(3)(c)(i).
[59] Ibid. s. 21.04(3)(c)(ii).
[60] Representations, *supra* note 10, from Rx&D, p. 15; Pfizer, p. 15; Bayer; BIOTECanada, p. 3; GSK, pp. 2-3; Eli Lilly, p. 3; Wyeth, p. 5; and Roche, p. 18. See also Terry McCool (Eli Lilly), appearance before INDU (23 April 2007), *supra* note 11.
[61] Representations, *ibid*., from Oxfam, p. 5; Access to Drugs Initiative (University of Toronto), pp. 12-13; HIV/AIDS Legal Network, pp. 15-17; GTAG, p. 2; Canadian Crossroads International, p. 2; McGill, pp. 6-7; CPGA, pp. 7-8. See also Richard Elliott (HIV/AIDS Legal Network) and Robert Fox (Oxfam), appearances before INDU (18 April 2007), *supra* note 11.
[62] See Jack Kay (Apotex), appearance before INDU (23 April 2007), *supra* note 11; North-South Workshop, *supra* note 12, Jack Kay.
[63] See Stephen Lewis (Former United Nations Special Envoy for HIV/AIDS in Africa), appearance before INDU (18 April 2007), *ibid*.
[64] *Patent* Act, *supra* note 1, s. 21.09.
[65] *Ibid.,* s. 21.12.
[66] Representations, *supra* note 10, from Gilead Sciences, p. 7; Rajotte Letter, *supra* note 13.
[67] Representations, *ibid.*, from Rx&D, p. 16.
[68] Representations, *ibid*., from Roche, p. 18. See also Terry McCool (Eli Lilly), appearance before INDU (23 April 2007), *supra* note 11.
[69] Representations, *ibid*., from Access to Drugs Initiative (University of Toronto), pp. 9-10; Apotex, p. 2; Canadian Crossroads International, p. 2; CGPA, p. 9; Faculty of Pharmacy (University of Toronto), p. 3; GATG, p. 2; Canadian HIV/AIDS Legal Network, pp. 17-18; McGill, pp. 7-8; MSF; Oxfam, pp. 5-6; World Vision/ Plan Canada/ Save the Children Canada/ Canada, p. 5; Rajotte Letter, *supra* note 13; North-South Workshop, *supra* note 12.

[70] Representations, *ibid.*, from Rx&D, p.16.
[71] Representations, *ibid*., from CGPA, p. 9, Access to Drugs Initiative (University of Toronto), p. 9; Canadian HIV/AIDS Legal Network, p. 17.
[72] WTO waiver, *supra* note 5, para. 3.
[73] TRIPS, *supra* note 3, s.31(j).
[74] *Use of Patented Products for International Humanitarian Purposes Regulations*, SOR/2005-143, s. 8.
[75] Representations, *supra* note 10, from Rx&D, p. 16; CGPA, p. 9; Eli Lilly, p. 3; Roche, p. 19; and Wyeth, p. 5; Rajotte Letter, *supra* note 13, pp. 15-16.
[76] Representations, *ibid*., from the HIV/AIDS Legal Network, p. 11.
[77] Representations, *ibid*., from Canadian Crossroads International, p. 2; GTAG, p. 3; HIV/AIDS Legal Network, p. 19; Oxfam, p. 6; James Moore, P.C., M.P., p. 3; Rajotte Letter, *supra* note 13.
[78] *Patent Act*, *supra* note 1, s. 21.17. This provision has come to be known as the "good faith clause".
[79] There is an international precedent for both figures. Under the European Union's Access to Medicines Program, pharmaceutical companies who sell tiered-price products to developing countries enjoy special protection from reimportation on the condition that their medicines are made available either at a price cut of 75 percent off the average ex factory price in OECD countries, or at less than the cost of production plus 15 percent. See Council Regulation (EC) No. 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines.
[80] Representations, *supra* note 10, from Eli Lilly, p. 3; Roche, p. 19; Wyeth, p. 5; and Rx&D, p. 17.
[81] Representations, *ibid*., from Apotex Inc., p. 3; CGPA, pp. 9-10; Faculty of Pharmacy (University of Toronto), p. 3; GTAG, p. 3; HIV/AIDS Legal Network, p. 19; McGill, pp. 8-9; Oxfam, pp. 6-7; World Vision/ Canada/Save the Children/Plan Canada, p. 3; and James Moore, P.C., M.P., p. 3; Rajotte Letter, *supra* note 13, pp. 16-17.
[82] Representations, *supra* note 10, from Eli Lilly, p.3; Roche, p.19; Wyeth, p.5; and Rx&D, p.17.
[83] Representations, *ibid*., from CGPA, p. 10.
[84] Representations, *ibid*., from CGPA, p. 10; Apotex, p. 3; HIV/AIDS Legal Network, pp. 18-19.
[85] Representations, *ibid*., from Apotex, p. 3.
[86] Representations, *ibid*., from Roche, p. 17.
[87] WTO waiver, *supra* note 5, para 2(a).
[88] *Ibid*., para 2(b)(i).
[89] *Patent Act*, *supra* note 1, s. 21.05(2).
[90] Representations, *ibid*., from Gilead, p. 7. See also Gregg Alton (Gilead Sciences), appearance before INDU (23 April 2007), *supra* note 11.
[91] See Carol Devine (MSF), appearance before INDU (18 April 2007), *ibid*.
[92] Representations, *supra* note 10, from Oxfam, pp. 6-7; CGPA, p. 11; McGill, p. 9.
[93] Representations, *ibid*., from CGPA, p. 11.
[94] WTO waiver, *supra* note 5, para 2(b)(ii).
[95] *Ibid*., para 2(b)(iii).
[96] *Food and Drug Regulations*, *supra* note 42, C.07.008.
[97] *Ibid.* C.07.009.
[98] *Patent Act*, *supra* note 1, s. 21.06.
[99] *Ibid*., s. 21.07.
[100] WTO Waiver, *supra* note 5, s. 4; see also *supra* note 1, s.21.03(3)(a).
[101] See Terry McCool (Eli Lilly), appearance before INDU (23 April 2007), *supra* note 11.
[102] Representations, *supra* note 10, from Rx&D, p. 18; Roche, pp. 20-21.
[103] Representations, *ibid* from Rx&D, p. 18.
[104] Representations, *ibid*., from Roche, pp. 20-21, Eli Lilly, p. 3.
[105] Representations, *ibid*., from Roche, pp. 20-21.
[106] Representations, *ibid*., from Faculty of Pharmacy (University of Toronto), p. 4.
[107] Representations, *ibid*., from CGPA, pp. 11-12.
[108] *Ibid*.
[109] Representations, *ibid*., from Oxfam, pp. 6-7; CGPA, p. 11; McGill, p. 10.
[110] Representations, *ibid*., from Oxfam, pp. 6-7.
[111] *Patent Act*, *supra* note 1, s. 21.14.

[112] *Ibid.*, ss. 21.14(f) and (g). See also representations, supra note 10, from Roche, p. 21; Rx&D, pp. 18-19; Wyeth, p. 6; Bayer; and GSK, pp. 2-3.
[113] Provisions concerning termination in cases of incorrect or failure to disclose information; non-consensual diversion to unauthorized countries; exceeding the licence's quantity restriction; and, where a product has been exported to a non-WTO member, it has been used for commercial purposes or the country has not adopted appropriate anti-diversion measures. See: Representations, *ibid*., from CGPA, p. 12; MSF; Oxfam, pp. 6-7; HIV/AIDS Legal Network, pp. 19.
[114] See Richard Elliott (HIV/AIDS Legal Network), Robert Fox (Oxfam), appearances before INDU (18 April 2007), *supra* note 11; Jim Keon (CGPA), appearance before INDU (23 April 2007), *supra* note 11.
[115] Representations, *supra* note 10, from Access to Drugs Initiative (University of Toronto), p. 17.
[116] Representations, *ibid*., from McGill, p. 10; Access to Drugs Initiative (University of Toronto), p. 15.
[117] "TB Facts & Figures", *Global Drug Facility* (March 2006), online: Stop TB Partnership <http://www.stoptb.org/gdf/whatis/facts_and_figures.asp>.
[118] "Towards Universal access: Scaling up Priority HIV/AIDS Interventions in the Health Sector: Progress Report", WHO, UNAIDS, UNICEF (April 2007), online: WHO <http://www.who.int/hiv/mediacentre/univeral_access_progress_report_en.pdf>.
[119] "World Malaria Report 2005", WHO, UNICEF, UNDP, online: *Roll Back Malaria Partnership* <http://www.rollbackmalaria.org/wmr2005/>.
[120] "Global Tuberculosis Control – Surveillance, Planning and Financing", *WHO Reports* (2007), online: WHO <http://www.who.int/tb/publications/global_report/2007/en/index.html>.
[121] "UNITAID Mission", *UNITAID* (31 October 2007), online: <http://www.unitaid.eu/how-it-works.html>.
[122] Jeremiah Norris and S.J. Weicher, "UNITAID/IDPF: An Analysis of the International Drug Purchase Facility" (November 2006) Hudson Institute, online: <http://www.hudson.org>.
[123] "Guide to the Global Fund's Policies on Procurement and Supply Management", *The Global Fund to Fight AIDS, TB and Malaria* (2006), online: <http://www.theglobalfund.org/EN/about/procurement/>.
[124] "The President's Emergency Plan for AIDS Relief", Office of the United States Global AIDS Coordinator (23 February 2004), online: US Department of State <http://www.state.gov/s/gac/plan/c11652.htm>.
[125] "Antiretroviral (ARV) Price List", *Clinton Foundation* (8 May 2007), online: <http://www.clintonfoundation.org/pdf/chai-arv-price-list-050807.pdf>.
[126] *Ibid*.
[127] "Brazil Moves on Compulsory Licence after Failed Talks with Drug Company", *Third World Network* (1 May 2007), online: <http://www.twnside.org.sg/title2/wto.info/twninfo050703.htm>.
[128] "Are sources of affordable generic medicines drying up?", *MSF* (15 March 2005), online: <http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=4309CA5D-E018-0C72-09FA0FB6AAD81E55&method=full_html>.
[129] *Ibid*.
[130] *Ibid*.
[131] *Supra* note 118.
[132] "MSF Fact Sheet: Children and HIV/AIDS", *MSF* (July 2007), online: <http://www.doctorswithoutborders.org/news/hiv-aids/MSF-Children-and-AIDS-fact-sheet-July2007.pdf>.
[133] *Supra* note 118.
[134] *Ibid*.
[135] "The Second-Line AIDS Crisis: Condemned to Repeat?", *MSF* (11 April 2007), online: <http://www.doctorswithoutborders.org/news/access/thailand_briefingdoc_04-11-2007.cfm>.
[136] "Former President Clinton Announces Breakthrough on 'Next Generation' One-Pill, Once-Daily AIDS Treatment: $1 Per Day Price Reduces Cost By 45% or More in Developing Countries", *WHO* (8 May 2007), online: <http://www.who.int/hiv/Clinton_Announcement_8May.pdf>.
[137] *Supra* note 135.
[138] CAMR consultation paper, *supra,* note 10, Annex B.
[139] *Ibid*. See also: *supra*, note 1, s. 21.04(3)(c)(i).
[140] Representations, *supra* note 10, from CGPA, p. 3. See also: Stephen Lewis (Former United Nations Special Envoy for HIV/AIDS in Africa), Sarah Perkins (IHRP, University of Toronto), and Richard Elliott (HIV/AIDS Legal Network), appearances before INDU (18 April 2007), *supra* note 11.

[141] See Douglas Clark (Department of Industry), appearance before INDU (16 April 2007), *supra* note 11.
[142] *Federal Courts Act*, R.S.C. 1985, c. F-7, s. 18.1.
[143] Section 21.2 of the *Patent Act* requires the Minister of Industry to review the relevant patent provisions of CAMR (sections 21.01 to 21.19). It does not require a review of Section 30 of the *Food and Drugs Act* and C.07.004 of the Food and Drug Regulations which allow for pharmaceutical products intended for export under CAMR to be reviewed by Health Canada for safety, efficacy and quality.
[144] CAMR consultation paper, *supra* note 10, Annex B. See, in particular, the regimes of Norway, India, China, Korea and the Netherlands.
[145] *Ibid*. See EU and Swiss regimes.
[146] Representations, *supra* note 10, from HIV/AIDS Legal Network, p. 4; Oxfam, p. 6; GTAG, p. 3.
[147] "Life Saving AIDS Drug for Africa Gets Final Clearance" (20 September 20 2007), online: Apotex <http://www.apotex.com/ca/en/aboutapotex/pressreleases/20070920.asp>.
[148] The "Performance Target" for review of an NDS varies from 205 days for "priority" submissions, to 345 days for regular submissions. See: "Guidance for Industry: Management of Drug Submissions", Health Canada (30 November 2005), online: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd_e.html>.
[149] The EU, Switzerland, the Netherlands and Norway
[150] See: Frederick M. Abbott (Florida State University), appearance before INDU (10 March 2004). See also: Frederick M. Abbott & Rudolph V. Van Puymbroeck, "Compulsory Licensing for Public Health" (2005) World Bank Working Paper No. 61, p. 36; Amir Attaran, "A Tragically Naïve Canadian Law for Tragically Neglected Global Health" (2007) 176:12 CMAJ 1726.
[151] Attaran, *ibid*.
[152] See, for example: "Quick Fixes to Canada's Access to Medicines Regime Left Behind as MPs Close Commons", HIV/AIDS Legal Network, (21 June 2007), online: <www.aidslaw.ca/publications/interfaces/downloadDocumentFile.php?ref=724>; Tanya Talaga, "AIDS drugs fiasco a tale of red tape", *Toronto Star* (9 August 2007), online: <http://www.thestar.com/article/244582>.
[153] See comments from Richard Elliott in "Canada Issues Compulsory Licence for HIV/AIDS Drug Export to Rwanda, in First Test of WTO Procedure", *Bridges Weekly Trade News Digest* (26 September 2007), online: ICTSD <http://www.ictsd.org/weekly/07-09-26/story2.htm>. See also: "Life Saving AIDS Drug for Africa Gets Final Clearance" (20 September 20 2007), online: Apotex <http://www.apotex.com/ca/en/aboutapotex/pressreleases/20070920.asp>.
[154] See Jack Kay (Apotex), appearance before INDU (23 April 2007), *supra* note 11.
[155] "Rwanda Becomes First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs", *Bridges Weekly Trade News Digest* (25 July 2007), online: ICTSD <http://www.ictsd.org/weekly/07-07-25/story2.htm>.
[156] North-South Workshop, *supra* note 12.
[157] See: Tove Iren S. Gerhardsen, "Thailand Presents Report on Compulsory Licensing Experience", Intellectual Property Watch (12 March 2007), online: IP Watch <http://www.ip-watch.org/weblog/index.php?p=563&res=800&print=0>. See also: "Thailand Issues Three Compulsory Licences on Drug Patents - Abbott Retaliates", *The Program on Information Justice and Intellectual Property*, (23 October 2007), online: Washington College of Law at American University <http://www.wcl.american.edu/pijip/thai_comp_licences.cfm>.
[158] North-South Workshop, *supra* note 12, Tenu Avafia (Intellectual Property Policy Advisor with the UN Development Programme, South Africa) and Edward Buluma (Procurement Manager with the Kenya Medical Supplies Agency).
[159] See Annex A below.
[160] North-South Workshop, *supra* note 12, Edward Buluma.
[161] Canada's Official Development Assistance in 2004-2005 increased by 52.4% from the previous year, to $4.14 billion. See: "Statistical Report on Official Development Assistance - Fiscal Year 2004-2005," *Canadian International Development Agency* (January 2007), online: <http://www.acdi-cida.gc.ca/CIDAWEB/acdicida.nsf/En/JUD-4128122-G4W>.

[162] "Pledges and Contributions" (15 October 2007), online: The Global Fund <http://www.theglobalfund.org/en/funds_raised/pledges>. See also: "Funding Global Health Needs" (15 October 2007), online: Brookings <http://www.brookings.edu/comm/events/20070228globalhealth.htm>.
[163] Colleen V. Chien, "HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?" *Public Library of Science* (14 March 2007), online: PLoS One <http://www.plosone.org/article/info:doi%2F10.1371%2Fjournal.pone.0000278>. This report analyzes all purchasing orders to supply Sub-Saharan Africa with HIV/AIDS drugs that were reported to the WHO Global Price Reporting Mechanism from January 2004 to March 2006 and concludes that Indian Generics supplied 53% of the total volume, while South African Generics supplied 10% and Canadian generics supplied 0%.
[164] *Supra* note 125. See also "Pledges and Contributions", *supra* note 162.
[165] Romeo St. Martin: "Rwanda will only accept Canadian generics if price is right", *Politics Watch* (26 September 2007), online: Politics Watch <http://www.politicswatch.com/drugs-september26-2007.htm>. See also Rwanda Ministry of Health (15 October 2007), online: <http://www.moh.gov.rw>.
[166] "Applications for Authorization Received by CIPO" Canadian Intellectual Property Office (4 September 2007), online: CIPO <http://strategis.ic.gc.ca/sc_mrksv/cipo/jcpa/GoodmansCAMR.pdf>. See also Jack Kay (Apotex), appearance before INDU (23 April 2007), *supra* note 11; "Canada Issues Compulsory Licence for HIV/AIDS Drug Export to Rwanda, in First Test of WTO Procedure", *Bridges Weekly Trade News Digest* (26 September 2007), online: ICTSD <http://www.ictsd.org/weekly/07-09-26/story2.htm>.
[167] See "Clinton Foundation HIV/AIDS Initiative" (15 October 2007), online: William J. Clinton Foundation <http://www.clintonfoundation.org/cf-pgm-hs-ai-home.htm>.
[168] *Supra* note 14.
[169] See remarks of Anita Asiimwe in "Canadian WTO Notification Clears Path for Rwanda to Import Generic HIV/AIDS Drug", *Bridges Weekly Trade News Digest* (10 October 2007), online: ICTSD <http://www.ictsd.org/weekly/07-10-10/story4.htm>.
[170] India and China amended their respective Patent Acts to comply with the WTO waiver. These amendments came into force January 1, 2005, and January 1, 2006, respectively.
[171] See: "WHO sticks head in sand over high cost of newer AIDS drugs" MSF (14 August 2006), online: <http://www.accessmed-msf.org/prod/publications.asp?scntid=14820061728498&contenttype=PARA&>.
[172] Representations, *supra* note 10, from HIV/AIDS Legal Network, p. 19; Access to Drugs Initiative (University of Toronto), p. 15.
[173] WTO, Dispute Settlement: *Canada – Patent Protection of Pharmaceutical Products* (Complainant: European Community), Dispute DS 114, (17 March 2000) online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm>.
[174] "WTO ruling on generic drugs means cost savings for Canadians: The defense of Early Working Provisions a victory for generic drug manufacturers", *CGPA* (17 March 2000), online: <http://www.canadiangenerics.ca/en/news/mar_17_00.shtml>.
[175] See Jim Keon (CGPA), appearance before INDU (23 April 2007), *supra* note 11.
[176] WTO waiver, *supra* note 5, para. 6.
[177] *Supra* note 1, s. 21.14(f).
[178] CAMR consultation paper, *supra* note 10, Annex B.
[179] See Annex A below.
[180] See "PM launches Initiative to Save a Million Lives", Office of the Prime Minister (26 November 2007), online: <http://www.pm.gc.ca/eng/media.asp?id=1911>.