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A ONE-TIME-ONLY COMBINATION: EMERGENCY MEDICINE EXPORTS UNDER CANADA'S ACCESS TO MEDICINES REGIME

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ABSTRACT

In 2008, a Canadian generic pharmaceutical firm, Apotex Inc. (Apotex), shipped 7 million doses of antiretroviral drugs to Rwanda for the treatment of HIV/AIDS. While this event may be seen as a positive outcome of international patent changes that facilitate the fulfillment of health as a human right, the fact that there has been only one shipment of medication in response to these changes highlights the difficulties with both the Canadian legislation and with the international decisions that it implements. The shipment was authorized under Canada's Access to Medicines Regime (CAMR), which implements the World Trade Organization (WTO) General Council Decision (the Decision), made in 2003, to permit someone other than the patent holder to manufacture a lower-cost version of a patented drug or medical device for export to developing countries that do not have the capacity to manufacture such products. The Decision requires that the developing country announce its intention to use this mechanism, to specify the expected quantity of drugs to be supplied, and to issue a compulsory license for the drugs. The requirement of notification in particular may render developing countries vulnerable to pressure from pharmaceutical firms. Neither the mechanism created by the Decision nor Canadian legislation implementing it have facilitated the export of generic medicines to developing countries. To date, the Canadian shipment is the only one to have occurred using the WTO mechanism.

INTRODUCTION

In September 2008, the first shipment of generic AIDS drugs produced under Canada's Access to Medicines Regime (CAMR) left Canada for Rwanda.[1] While the shipment itself was a welcome development, the fact that there has been only one shipment of medication under the Regime to date highlights the difficulties with both the Canadian legislation and the international decisions that it implements. The Canadian legislation to permit the export of generic AIDS medications to developing countries followed years of negotiation at the international level to clarify conditions in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the issuance of compulsory licenses. Groups such as the Treatment Action Campaign (TAC), Médecins Sans Frontières (MSF), and Oxfam fought to have access to life-saving medication recognized as a human right that trumps intellectual property rights.[2] As a result of pressure from organizations arguing for treatment access, WTO member countries issued a Declaration on TRIPS and Public Health, known as the Doha Declaration, which recognized the severity of the domestic public health crises faced by developing countries and agreed that TRIPS neither did nor should prevent countries from taking steps to protect their populations' health.[3] While TRIPS permits countries to override pharmaceutical patents under certain circumstances, the Doha Declaration was the first official document to recognize the difficult position of countries that lack manufacturing capacity, and therefore need to import medications. No solution to this difficulty was proposed until

August 30, 2003, when the WTO General Council issued a decision on the implementation of Paragraph 6 of the Declaration (the Decision), permitting the export of generics to these countries under specific circumstances. CAMR brought the Decision under the umbrella of Canadian law, making it possible for Canadian generic companies to work with qualifying developing countries that lack manufacturing capacity to obtain a compulsory license to import otherwise patented and inaccessible medications.

Canada was not the only country that passed legislation to implement the WTO Decision. The European Union, the Netherlands, Switzerland, Norway, India, China, and South Korea have also established access-to-medicines regimes.[4] However, by the end of 2008, the only shipment of drugs under any of these legislative regimes was the one from Canada to Rwanda in September 2008.

The problem is not simply that countries need a license for export; during the same period, fewer than 12 countries had issued compulsory licenses for patented medication to be distributed in their own country.[5] The explanation for this failure to meet global public health emergencies with essential medications, despite the Decision, stems from the reluctance of both exporting and importing countries to exercise the public health flexibilities available under the TRIPS Agreement. Although there may be a number of legislative and procedural factors contributing to the unwillingness of countries to manufacture or import generic drugs under a compulsory license, this paper will argue that developing countries' fear of backlash from patent holders and trade partners continues to be the most significant bottleneck inhibiting production to date.

WHY IS GENERIC DRUG ACCESS IMPORTANT?

In 2007, there were approximately 33 million people around the globe living with HIV — a number equivalent to the population of Canada. Approximately 2.5 million were children, over 300,000 of whom died in that year.[6] In 2008, AIDS became for the first time the deadliest disease in China.[7] UNAIDS reports that "[e]very day, over 6800 persons become infected with HIV and over 5700 persons die from AIDS, mostly because of inadequate access to HIV prevention and treatment services."[8] Sub-Saharan Africa has the highest rates of infection and AIDS-related deaths. Stephen Lewis, the former United Nations Secretary-General's Special Envoy on HIV/AIDS in Africa, has written that "[i]t is impossible to write about the Millennium Development Goals without writing about HIV/AIDS, and that's not simply because defeating the pandemic is one of those goals. It's because every goal, at least in Africa, is put in jeopardy by AIDS."[9]

In North America and Europe, antiretroviral drugs (ARVs) developed in the 1990s have turned HIV/AIDS from a death sentence into a manageable illness. A combination therapy that delays the onset of AIDS became available in developed countries in 1996, and the death rate from HIV/AIDS in these countries dropped by 84% within four years.[10] At the time of their release, combination ARV therapies produced in developed countries under patent by brand-name pharmaceutical firms cost between US$10,000 and US$15,000 annually.[11] At this price, developing countries were unable to supply their populations with the medications.

ARV production by generic firms has had an important impact on reducing prices for these goods in developing countries. Since 2000, the price of first-generation ARV treatment has decreased by 99%.[12] An initial drop in prices occurred when the Indian company Cipla offered to produce generic versions of the drugs for approximately US$350 per person in 2001.[13] According to Heinz Klug, it is "only when three or more generic companies [are] competing to supply a particular drug that the cost falls to anywhere between 70% and 90% below the original price."[14] India, with a number of generic pharmaceutical suppliers, has since become the largest supplier of generic drugs to the developing world; Brazil, Thailand, and South Africa also produce generic drugs in significant quantities.[15]

While developing countries, advocacy groups, and academic analysts have emphasized the importance of drug access, some analysts, as well as the brand-name pharmaceutical industry, have argued that the real barrier to treatment in developing countries is not caused by patents, but by the absence of health care providers and infrastructure.[16] In the Canadian debate, industry representatives have argued that Canada should be addressing the lack of infrastructure rather than facilitating the export of generic drugs.[17] However, drug access and improved health infrastructure are not mutually exclusive strategies. Brazil produced ARVs under compulsory licenses

domestically and then integrated drug distribution with health care programming.[18] Health providers believe that ARV treatment may make it more likely that people will volunteer for HIV testing and will practice safer behavior. Treatment also reduces an individual's viral load, thereby making disease transmission less likely.[19] Klug notes that "[w]hile patents are not the sole reason why developing countries have failed to adequately respond to the [HIV] pandemic, it is only access to ARVs that will enable countries to respond to the crisis in an effective way."[20] Access to ARV treatment, therefore, while not sufficient in itself, is necessary to help reduce disease transmission, encourage testing, and save the lives of those already infected with HIV.

The pricing issues that first arose in the 1990s are now being repeated as second-line ARVs come onto the market. Individuals who have been treated with the ARV drugs that were developed in the 1990s are now beginning to develop resistance, which means that these individuals require newer, and often more expensive, forms of drug therapy.[21] The experience with first-line medications, as outlined above, suggests that if second-line medications are to be made available to the many AIDS patients in developing countries, access to cheaper generic versions will be extremely important.

TRIPS, THE DOHA DECLARATION, AND THE WTO GENERAL COUNCIL DECISION

The TRIPS Agreement was negotiated during the Uruguay Round of trade talks, which culminated in the creation of the WTO in 1995. The Uruguay Round, and the agreements that led to the WTO's creation, were groundbreaking in two major respects. First, the agreements were presented as a package — countries did not have the option to select the agreements with which they would comply but had to accept or reject the entire set of treaties. Second, a number of the Uruguay Round Agreements covered issues — such as trade in services, investment measures, and intellectual property — that had been excluded from earlier negotiations. The pharmaceutical industry was one of the key stakeholders lobbying the United States Trade Representative (the USTR) to have intellectual property rights included in the Uruguay Round agenda.[22]

The TRIPS Agreement requires that all WTO members introduce domestic legislation to protect and enforce intellectual property rights through the provision of patent protection.[23]

Patent protection is a monopoly right granted by a member state to an innovator in exchange for making the invention — and knowledge about how to reproduce it — publicly available.[24] Article 27 of TRIPS states, with some specific exceptions, that patentable subject matter shall include any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.[25] Such dissemination of information is a public good in that it contributes to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of innovators and users.[26] As with any public good, once knowledge is established, it becomes both non-excludable and non-rival and is thus subject to the problem of free ridership. Therefore, by adopting the TRIPS Agreement domestically, WTO members have agreed to award monopoly privileges to innovators in order to promote technological innovation as a public good. Article 14 of the TRIPS Agreement extends patent protection for intellectual property to 20 years from the date of filing an application.

The tradeoff with awarding monopoly privileges to innovators to encourage further innovation is that these anti-competitive practices create opportunities for innovators to earn what is known as "economic rent," the difference between what a factor of production is paid and the amount of payment required to keep it in its current use.[27] Patent holders can also distort the value of a good on the market by raising the price and reducing the output.[28] The TRIPS Agreement does, however, include certain exceptions to the rights awarded to patent holders. Article 6 affirms the principle of exhaustion, also known as parallel importing, of an intellectual property right once a product has been sold. Under this provision, once a patent holder has consented to the initial sale of its product, it cannot prevent or challenge the subsequent resale of the product to a third party on different sale terms (such as a lower price). Article 8(1) gives member states flexibility in formulating or amending their domestic laws to adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socioeconomic and technological development.[29] Article 40 allows member states the right to enforce their domestic

laws when there are concerns that the licensing practices for intellectual property rights are having adverse or anti-competitive effects. Article 30 states the WTO Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[30]

However, it is not Article 30 but Article 31 that has become the focus of the compulsory license debate. Article 31 articulates circumstances under which the use of patents may occur without the authorization of the rights holder. Under these circumstances, a compulsory license is issued by a government to allow someone else to produce the patented product or process. To issue a compulsory license, a member state must show that 1) it has given authorization based on consideration of the individual merits of the application; 2) the proposed user has made efforts to obtain authorization from the rights holder on reasonable commercial terms and has been unsuccessful within a reasonable period of time; 3) limitations are put on the scope and duration of the patented item's use; 4) use shall be non-exclusive; 5) use shall be non-assignable; 6) use shall be authorized predominantly for the supply of the domestic market of the respective member state; 7) use is terminated when the circumstances that led to the compulsory license's issuance cease to exist or are unlikely to occur; 8) adequate remuneration shall be paid to the patent holder; and 9) the authorization is subject to judicial review. If the compulsory license is being issued in response to a national emergency, in response to other circumstances of extreme urgency, or in cases of public non-commercial use, then the requirement to obtain authorization from the rights holder is waived. Such was the case in the Canadian example discussed below, where a compulsory license was issued in response to a public health emergency. Further, if a compulsory license is issued to remedy anti-competitive practices, then the two requirements — to obtain authorization from the rights holder and that the use be predominantly for domestic supply — are also waived.[31]

While the TRIPS Agreement applies to all fields of technology, it has received the most attention with regard to public health and debates over the net benefits of allowing strong patent protection for pharmaceutical innovators at the cost of facilitating access to essential medicines.[32] In the pharmaceutical industry, the cost of drug innovation is very high, while the cost of imitation is relatively low, meaning that once a drug is developed, it can be generically reproduced at a fraction of the cost. WHO argues that

> [i]ntellectual property rights have an important role to play in stimulating innovation in health-care products in countries where financial and technological capacities exist, and in relation to products for which profitable markets exist. In developing countries, the fact that a patent can be obtained may contribute nothing or little to innovation if the market is too small or scientific and technological capability inadequate.[33]

Prior to the Uruguay Round, there were 40 countries that did not provide patent protection for pharmaceuticals. These countries have since incorporated the TRIPS Agreement into their domestic laws. Further, while Articles 65 and 66 permitted developing and least-developed countries additional time to comply with TRIPS, by 2005 all developing countries were brought into the regime. Least-developed countries, which had their compliance times extended under the Doha Declaration, will be incorporated in 2016 with regard to pharmaceutical patents.[34]

Although the TRIPS Agreement includes some flexibilities that can be used to allow member states to issue compulsory licenses in situations of national emergency, in other circumstances of extreme urgency, or in cases of public non-commercial use, in practice these flexibilities have rarely been used. Both prior to and since the Doha Declaration (discussed below), patent holders have taken action against governments seeking to use TRIPS-compliant flexibilities. In 1998, the South African Pharmaceutical Manufacturers' Association and a number of primarily multinational drug firms sued the South African government on the grounds that a 1997 Act violated both TRIPS and the South African Constitution.[35]

The South African case raised the ire of social movements domestically and globally. The prospect that South Africa, with one of the highest rates of HIV/

AIDS infection in the world, could be forced to drop legislation facilitating access to essential medicines had the effect of mobilizing developing country governments. This mobilization led to the creation of the Global Treatment Access Group (GTAG), a network of NGOs that included the Treatment Action Campaign South Africa, Act Up US, MSF, and Oxfam.[36]

In response to US criticism on this issue, President Bill Clinton signed the Executive Order on Access to HIV/AIDS Pharmaceutical and Medical Technologies, directing the US government to refrain from seeking the revocation of any law or policy imposed by a beneficiary sub-Saharan government to promote access to essential medicines.[37] In 2001, the TRIPS Council examined the TRIPS Agreement's impact on access to medicines and proposed the Doha Declaration to clarify the public health flexibilities included in TRIPS. The pressure on member states to recognize developing countries' rights to override patents in the interest of public health increased following the anthrax attacks in the US in 2001, when the federal government threatened to issue a compulsory license on the anthrax drug ciprofloxacin without consulting the patent holder (Bayer); it later withdrew this threat.[38] The US action in the face of a relatively minor threat undermined its moral authority to demand concessions from developing countries faced with the HIV/AIDS pandemic and other severe health problems.[39]

The Doha Declaration was an acknowledgement of states' rights to protect public health and provide access to medicines.[40] Paragraph 5(b) of the Declaration recognizes the right of member states to grant compulsory licenses under carefully defined conditions and to determine the grounds upon which such licenses will be granted. Paragraph 5(c) notes that member states have the right to determine what constitutes a national emergency or other circumstances of extreme urgency; it also states that it is understood that public health crises may fall under these categories. However, because Section 31(f) of TRIPS states that such compulsory licenses are to be issued "predominantly for the supply of the domestic market," this left open the question of how countries with little or no manufacturing capacity were to legally satisfy the requirements under Article 31 of the TRIPS Agreement in the face of a public health emergency. The parties were unable to resolve this issue and referred the question back to the TRIPS General Council.[41]

The Decision rendered on August 30, 2003 sets out the conditions under which Article 31(f) (supply predominantly to the domestic market) and 31(h) (payment of adequate remuneration to the rights holder) may be waived. The exporting member state must itself issue a compulsory license in order to supply drugs predominantly to another market. A waiver is granted to the exporting member state when the importing member has notified the TRIPS Council of the name and expected quantities of the drug that it requires, the destinations of the supply, the duration of the license, and that the product is labeled or marked in such as way as to distinguish it from pharmaceuticals not produced under this system. The exporting member state must also ensure that the compulsory license is being issued due to a lack of sufficient manufacturing capacity in the importing member country and that the compulsory license is issued in accordance with Article 31. Finally, it is the responsibility of the exporting member state to provide adequate remuneration to the patent holder by building a reasonable royalty rate into the value of the license.[42]

Although the Doha Declaration was intended to clarify the legal rights of countries to issue compulsory licenses in the case of public health emergencies, action by pharmaceutical firms and the USTR continues today. When Thailand issued a compulsory license for an HIV/AIDS drug made by Abbott Laboratories, the company protested by refusing to launch several newer drugs in Thailand.[43] The US placed Thailand on its Priority Watch List for issuing compulsory licenses for several medicines, including two HIV/AIDS drugs in 2007 and again in 2008 after Thailand issued compulsory licenses for three anti-cancer drugs. Inclusion on the Priority Watch list has the effect of stifling bilateral trade discussions between the US and the listed country, and sends a worrisome signal to developing countries, which might fear a backlash in trade relations. Thailand's inclusion on this list in 2009 was not related to violation of pharmaceutical patents; instead the US commended the country for respecting intellectual property rights, stating that "the United States is also encouraged by Thailand's expressed intentions to decrease the uncertainty created by the previous Government's policies concerning the issuance of

compulsory licenses and patented pharmaceutical products."[44] It is worth noting that, prior to the breakdown in negotiations with Thailand in 2006, the US had been actively lobbying to introduce more stringent intellectual property rights into their bilateral Free Trade Agreement (FTA). Similar negotiations have taken place between the US and other developing countries over bilateral FTAs, leading to the adoption of what advocacy groups have referred to as "TRIPS-plus" provisions.[45]

CANADA

Since 1987, Canada's intellectual property regime has become increasingly harmonized with the international and regional regimes codified in TRIPS and the North American Free Trade Agreement (NAFTA). Canada transformed its patent regime in three stages, with Bill C–22 in 1987, Bill C–91 in 1991, and a review of the latter piece of legislation in 1997. Bill C–91 in particular was a response to the NAFTA negotiations that were taking place at that time. Klug argues that the Pharmaceutical Manufacturers of America (PMA) wanted NAFTA to provide the kind of intellectual property protection that the 1989 Free Trade Agreement, between Canada and the US, had failed to provide. Quoting a representative from the PMA, Klug suggests that Canada's intellectual property regime was important to the drug manufacturers, not in its own right, but because it set an example for developing countries of a first-world nation that did not respect patent law.[46] Bill C–91 eliminated compulsory licensing and extended patent protection for twenty years.[47] Although the legislation did mandate a price-control mechanism in the form of the Patented Medicines Price Review Board, which may demand that patent holders lower their prices in Canada, the end of compulsory licensing meant a significant shift in the regime "in which the priorities of pharmaceutical patent regulation moved from encouraging equitable access to health care…to incorporating Canada into a global, 'innovative,' community of health provision."[48] Rather than having a distinctive national regime, Canada became a participant in the global regulatory structure.

Just as NGO campaigns pushed the TRIPS Council and WTO to clarify and implement flexibilities in the TRIPS agreement, domestic and international NGOs pushed the Canadian government to introduce legislation to implement the WTO Council Decision. The advocacy groups succeeded in having an initial bill, Bill C–56, proposed in the House of Commons; they also succeeded in having this version of the bill withdrawn when they concluded that its flaws negated any positive impacts it may have had.[49] After a number of revisions and modifications, the bill was reintroduced as Bill C–9 (An Act to amend the Patent Act and the Food and Drugs Act, also referred to as the Jean Chrétien Pledge to Africa) and was passed in May 2004.[50]

The language and scope of Bill C–9, as well as the subsequent legislative regime it introduced, reflect the Canadian government's desire to strike a balance between competing industry and humanitarian interests. Despite the good intentions of Canadian policy makers to create a functional piece of legislation, under pressure from a variety of international and domestic stakeholders, the legislation became watered down and convoluted. In many ways, Bill C–9 became another opportunity to debate the balance already struck between intellectual property rights and public health that had played out at the international level when drafting TRIPS, the Declaration, and the Decision. By again opening up these discussions with the domestic C–9 legislation, more concessions were made in favor of intellectual property rights. In the end, Canada chose to make concessions rather than implement a strong regime that could make a practical difference in removing barriers to access.

The Canadian legislation specifies additional requirements that are not written into the WTO General Council Decision. The WTO Decision applies only to member countries; it does not include a designated list of drugs, a limitation on the length of the contract, or a clear procedure for determining reasonable remuneration. Further, it requires notification of the issuance of a compulsory license but does not require any type of approval once notification has been made, and it does not place any limits on the types of entities that can engage in contracts, which leaves open an opportunity for NGOs to negotiate contracts.

In contrast, the CAMR provisions include the following: a requirement to seek a voluntary license from the patent holder (although TRIPS allows this requirement to be waived under certain circumstances); a two-year limit on the duration of the compulsory license; a schedule listing the medications that are eligible for a compulsory license; a requirement to meet

all health and safety regulatory requirements applicable to products sold in Canada; and specification of the conditions under which patent holders may take legal action against the generic producer. There has been a mixed response to these Canadian additions.

The one additional provision of the legislation that has been well received by NGOs is that which outlines a means to calculate royalty payments to the patent holder. This provision has been lauded by international actors and domestic NGOs as a fair and reasonable mechanism for calculating royalty payments.[51] The Canadian formula links the royalty rate paid on a contract to the importing country's ranking on the United Nations Development Programme's Human Development Index; the lower the importing country ranks on the index, the lower its royalty rate.[52] The Canadian formula also sets a precedent for the definition of commerciality: if the average price of the generic product is equal to or above 25% of the patent holder's average price in the Canadian market, the patent holder may apply to the Federal Court for a review of the authorization on the grounds that the contract is commercial in nature. Other than the royalty formula, the provisions of the Canadian regime have not been as well received, with the exception of the brand-name companies that have candidly praised the Canadian government for this industry-friendly legislation.[53]

The current Canadian law requires the generic firm to apply for a voluntary license from the patent holder before requesting a compulsory license. If the patent holder does not grant the license within 30 days of this application, the Commissioner of Patents "shall" grant a compulsory license. This provision is similar to that in 31(b) of the TRIPS agreement, which specifies that a compulsory license may only be extended if the generic producer has first attempted to obtain a license from the patent holder. However, the TRIPS Agreement provides an exception, that is, that this requirement may be waived in the case of a national emergency, in other circumstances of extreme urgency, for governmental use (public, non-commercial), and to remedy anti-competitive practices. Given that the Canadian legislation is intended to support the public health objectives of TRIPS and the WTO General Council, the inclusion of a voluntary licensing requirement that delays the process without providing a similar emergency exception seems paradoxical. Furthermore, the generic producer Apotex Inc. (Apotex) has argued that the Canadian voluntary licensing process is fraught with delays and obstacles, and that it legitimizes actions by brand-name companies to subvert production for export.[54]

The voluntary licensing requirement means that the applicant must provide to the brand-name manufacturer information about the quantity of medication and the country to which it will be exported. Apotex, the only company that has attempted to engage this process, has argued that this requirement presents an obstacle to the export of drugs, both because the country with whom it was dealing did not wish to be identified, and because there was more than one patent holder. The president of Apotex noted that "[w]e are prepared to provide these life-saving products at our cost, but cannot tie up our resources to fight a battle in order to get the license."[55]

The Canadian legislation also requires more specificity from the generic producer with regard to the quantities exported. Whereas the WTO Decision asks for the "expected" quantity to be divulged, the Canadian law requires that the "maximum" quantity be stated. While the Canadian law is more stringent in this regard, both requirements have presented obstacles to generic manufacturers. One generic producer, Gilead Sciences, argued that any quantity requirement present in legislation is likely to disrupt the supply of essential medicines. In its work with developing countries and NGOs, Gilead Sciences has had difficulty determining what future needs will be, making it difficult — if not impossible — to meet the basic criteria for issuance of a compulsory license.[56]

Therefore, in order to get a compulsory license under CAMR, the generic producer must have already entered into an agreement with a developing country, attempted to get a voluntary license, and determined the maximum quantity of drugs required under the compulsory license. This creates a Catch-22, since the developing country cannot enter such an agreement without first opening the contract for tender and ultimately selecting the best applicant according to a set of criteria. In the end, the Canadian manufacturer may not even be successful in the tendering process, illustrating that in general, CAMR is not compatible with the average developing country tendering process. To resolve this quandary, international human rights lawyers have recommended that generic manufacturers be able to apply for a license that does not

specify the quantity of drugs or to whom the drugs will be exported.[57]

Time is an additional element in the restrictions. CAMR places a two-year limit on contracts between developing countries and generic companies. This limit may be extended for a further two years only if the manufacturer was not able to ship all of the quantity specified in the first two years. Additional quantities cannot be shipped by renewing the license.

The Canadian law incorporates a list of medicines (identified in the legislation as Schedule 1) that generic manufacturers may export. The government has argued that this list minimizes the discretion of the Commissioner of Patents and restricts the circumstances under which patent holders will challenge the license.[58] NGOs and generic firms, however, have argued that the list is another factor that inhibits the regime from functioning. In order for a drug to be added to Schedule 1, the Federal Cabinet must make additions through an Order-in-Council, and politicians may thus be subject to pressure from patent-holding companies through this process. New Democratic Party (NDP) MP Brian Masse stated that Bayer contacted him to get certain drugs off the Schedule 1 list.[59] International human rights lawyer Sarah Perkins has stated that "[t]he list contains virtually none of the medicines that [developing countries] are most interested in and are most desperate to provide their populations."[60]

The Canadian law specifies several circumstances under which litigation may take place. Only Canada has codified the patent holder's right to challenge a license on the grounds that it is intended to serve commercial rather than public health objectives. However, this provision highlights a larger conflict underlying the TRIPS legislation and the Doha Declaration, which assume that public health objectives can be distinguished from commercial ones. As long as medications are produced by for-profit firms, whether generic or brand-name, it will be difficult to demarcate commercial from public health objectives. CAMR also permits the patent holder to argue in court for a termination of a compulsory license.[61]

Under CAMR, medications produced by a generic firm must be approved by Canada's federal health department, Health Canada, prior to export. NGOs have argued that this is an unnecessary requirement that is not imposed on other drugs; however, Canadian generic firms have supported this element of the legislation, adamant that they must uphold their reputations for providing quality products.

The Canadian government's concern for accountability, and brand-name companies' concerns with diversion of shipments to higher-priced markets for a profit, led to the inclusion of additional contracting requirements for NGOs and international organizations, such as WHO. Under CAMR, NGOs and international organizations may solicit orders from Canadian generic companies only after obtaining permission from the government of the importing developing country.

The Bill C–9 legislation specified that it should be reviewed two years after coming into force (Bill C–9, 21.2 [1]). In response to criticism of the legislation at the 2006 World AIDS Conference, Health Minister Tony Clement stated that the review process would be accelerated, and a government consultation document, requesting responses, was released in late 2006. While both Industry Canada (Canada's federal department on the market, economy, industry, and sustainable communities) and the House of Commons Committee on Industry, Science and Technology conducted reviews of the legislation, the House of Commons Committee held further hearings. Two of the major advocacy groups involved, the Canadian HIV/AIDS Legal Network and the North–South Institute, organized an international expert consultation on the law in order to bring in developing country perspectives. They suggested the following: the WHO drug prequalification program should be substitutable for the Health Canada regulatory approval process (where the generic firm and developing country agree); the voluntary licensing procedure should be waived; and the requirement that NGOs seek authorization from the target country to import drugs should be eliminated. They were also concerned that the one-product, one-country, time-limited procedure restricted the possibilities for improving drug access.[62] The Global Treatment Access Group recommended that a generic manufacturer should be able to obtain an open-ended license for the export of a particular drug and that the two-year time limit should be removed. Through engagement with the Canadian process, NGOs, including MSF and the HIV/AIDS Legal Network, have argued that the August 30 WTO General Council Decision

is itself flawed. Coupled with their experience of trying to put the Decision into action, these NGOs have begun advocating for a Canadian law based not on the Decision but, rather, on the less cumbersome language of Article 30 of TRIPS, which states that

> [m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[63]

In the view of these NGOs, a new law based on this simpler wording would provide Canada with greater flexibility and is a legal option because "the August 2003 Decision was explicitly adopted as being without prejudice to the other flexibilities under TRIPS."[64]

The review process provided an opportunity to assess the parallels and distinctions in the various stakeholders' positions. While NGOs and generic firms were largely in agreement about necessary changes to the law, their views did diverge with regard to the importance of the Health Canada regulatory process. The brand-name pharmaceutical firms did not wish to see any changes in the legislation. One government official expressed the views of brand-name pharmaceutical companies as follows: "Canada is just shaking off the stigma of not being friendly to pharmaceutical innovation. . . . [P]lease don't screw it up by creating instability and going back to amend [the law] for no reason."[65]

Ultimately, the review process was a disappointment for the generic firms and NGOs. Despite the comprehensive review, the government did not make any changes to the legislation.

APOTEX

In September 2008, Apotex shipped 7 million doses of Apo-TriAvir to Rwanda under the Canadian regime. The Canadian legislation was a necessary, but not sufficient, condition to enable Apotex to produce medicines for export to Rwanda. This shipment occurred because the following conditions were present: Rwanda's willingness to use the WTO mechanism, Apotex's commitment to produce medicine for export, the assistance of the Clinton Foundation and MSF in bringing the parties together, and the assistance of the Canadian bureaucracy in negotiating the regulatory process.

After the Canadian legislation passed in June 2004, MSF, the Canadian Generic Producers Association (CGPA), and Health Canada met to discuss how Canadian firms might begin to supply drugs to developing countries.[66] In December, Canada's largest generic pharmaceutical manufacturer, Apotex, agreed to produce a three-in-one, fixed-dose combination antiretroviral, Apo-TriAvir, containing zidovudine/lamivudine/nevirapine (AZT/3TC/NVP). The drug was not on the Schedule 1 list of medicines appended to Bill C–9; therefore, the Federal Cabinet had to approve the addition of this drug to the list, following recommendations from the Ministers of Industry and of Health Canada. This occurred in September 2005.[67] The product then went through the Canadian regulatory process and was approved in July 2006. A year later, in July 2007, Rwanda notified the WTO of its intent to import, and Canada informed the WTO of its compulsory license in October 2007. A tender process was held in which Apotex won the successful bid and was then able to export the drugs in 2008.

Apotex's commitment to producing ARVs for developing countries dates back to the 1990s, when its President, Jack Kay, had discussions with the federal government and several sub-Saharan African countries regarding the possibilities for medicine shipments. At that time, however, there were no mechanisms to facilitate export. After Bill C–9 was passed, Apotex discussed with Industry Canada, Health Canada, and the Canadian Intellectual Property Office (CIPO) how to proceed under the legislation. Apotex was willing to sell the product at the cost of the ingredients — waiving the manufacturing costs — and sourced the raw materials at a price that allowed them to compete with Indian firms.[68]

The federal government bureaucracy also assisted Apotex with the process; an Apotex spokesperson stated that cooperation from the bureaucracy "has been stellar." Health Canada, CIPO, Industry Canada, and other groups met with Apotex to work through the process. Health Canada established a consultation process with Apotex and the medical community

regarding product development, and the drug was approved in six months.[69]

The greatest difficulty that Apotex encountered was finding a developing country willing to request the WTO to use the August 30 mechanism. As an Apotex spokesperson put it, "the biggest flaw is that we are asking the developing world to navigate the First World's legal nightmare." MSF had been conducting talks with a number of developing countries to encourage them to make use of the mechanism, but all efforts had been unsuccessful until Apotex was put in touch with the Clinton Foundation, which led Apotex to Rwanda.[70]

In discussion with MSF, developing countries reported that they did not wish to self-identify because of pressure from pharmaceutical firms and the World Bank.[71] Unless a country self-identifies, generic firms are not able to obtain a voluntary or compulsory license, so the process stalls. For months, until Rwanda came forward, it appeared as if no drugs would ever be produced under CAMR. In fact, facilitation by the Clinton Foundation followed on that foundation's discussion with the Canadian HIV/AIDS Legal Network at the 2006 XVI International AIDS conference in Toronto regarding use of the legislation.[72] Uncertain about what a formal request from a developing country would involve, Apotex received assistance from Health Canada in drafting a template that could be used by Rwanda to make the request.[73]

Apotex found it difficult, however, to negotiate a voluntary license with the patent holders, which is essential under CAMR before a compulsory license can be granted. Although negotiations are capped at 30 days, Apotex stated that informal negotiations — before a country had even come forward — took approximately six months. At first glance, the process may appear straightforward, but as Apotex found, when the drug involves more than one patent, negotiations can become extremely complicated and time-consuming. In the case of Apo-TriAvir, the GlaxoSmithKline, the Wellcome Foundation, Shire Biochemical, and Boehringer Ingelheim Pharmaceuticals owned relevant patents; three of these firms were not prepared to issue a voluntary license without further conditions.[74] Apotex was unable to reach an acceptable settlement with the brand-name companies through the voluntary process; ultimately, a compulsory license was granted, and the brand-name companies did not oppose it. Even after the compulsory license was issued, however, Apotex approached the brand-name companies wishing to negotiate a voluntary license to supply countries in addition to Rwanda, but reported that "the brands were not willing to have that discussion."[75] Apotex found the process "absolutely excruciating and painful."[76]

The CGPA and the advocacy groups believe that the shipment to Rwanda will be the only time that CAMR is used unless this process is simplified and streamlined. The circumstances leading to the Rwanda exports were exceptional, particularly because Apotex is a privately held company and therefore does not have the responsibility to shareholders that could make the process even more complicated for other public firms, preventing them from investing the necessary resources irrespective of profits. Most other generic companies, listed publicly and thus accountable to their shareholders, would never be able to engage in a similar process when it holds no prospect of generating profits. A CGPA representative stated that "it is hard to imagine that any sane generic company would ever try to use this regime — especially after seeing what Apotex has gone through and spent."[77]

The problems that Apotex experienced while trying to engage in CAMR highlight fundamental flaws in the Canadian process. Such challenges can only be overcome if the process is further streamlined to cut out unnecessary costs and time delays that make it a money-losing venture for generic manufacturers. One solution that has taken shape in recent months is the introduction of patent pools, which are groups of patents held by different patent holders that are bundled together and made available to generic manufacturers upon payment of a royalty fee. Since patent pools have worked well in other industries such as digital telecommunications and aeronautics, MSF has argued, based on these successes, that patent pools may be a new means for promoting innovation and information sharing in the pharmaceutical industry in a manner that is less prone to adversarialism and litigation.[78] While such solutions may assist Apotex and other manufacturers to navigate the CAMR process domestically in Canada, such solutions will not work in isolation. The future success of CAMR hinges on the ability of Apotex and activists to build political support at the domestic and international levels to alleviate the pressure being exerted on countries that dare to issue compulsory licenses.

CONCLUSION

CAMR has facilitated the shipment of generic HIV/AIDS drugs from Canada to Rwanda, but this shipment occurred as a result of factors whose conjunction will not likely be repeated. These factors include the commitment of the generic manufacturer Apotex; the cooperation of MSF, the Clinton Foundation, and Canadian regulatory agencies; and perhaps most importantly, the willingness of Rwanda to use the WTO mechanism. The fact that there has been only one such contract to date highlights difficulties with the Canadian legislation and with the WTO mechanism itself. Although the Canadian legislation creates additional requirements for generic firms and developing countries to negotiate, the WTO mechanism itself fails to live up to the promise of the Doha Declaration, as it requires countries to identify themselves under the mechanism, thereby exposing them to pressure from brand-name pharmaceutical firms and their respective governments. The specification of the expected quantities of the drug, the issuing of a compulsory license, and the coordination with an exporting firm may all present challenges for developing countries. These challenges will become critical once again as second-line medications appear on the market and developing countries need lower-cost options for their citizens who have become resistant to first-line pharmaceuticals. These experiences suggest the need to revisit the Doha Declaration, the WTO General Council Decision, and even TRIPS itself.

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