The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Access to Patented Medicines in Developing Countries – Canada's Bill C-9

by

Faina Weitsman

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Abstract

TRIPS strengthened international patent protection, particularly in relation to pharmaceutical patents. A compulsory license mechanism is one of the exceptions from patent protection available under TRIPS. This mechanism applies mainly to domestic market supply. Underdeveloped countries with insufficient pharmaceutical manufacturing capacities are unable to use this exception to import medicines in public health emergencies. To resolve this problem, the WTO General Council's decision allows the export of generic versions of patented drugs under certain conditions. Canada's Bill C-9 was the first statute to implement the decision.

Bill C-9 bears both humanitarian and TRIPS-like provisions. The role of the Government is unjustifiably limited to participation in administrative and legislative processes, while the main operators in the scheme are the generic manufacturer and partly, the patent holder. This thesis proposes several different models to transform the Bill into a workable system for the export of drugs to underdeveloped countries afflicted with pandemics.

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Dedication

In loving memory of my father, Mr. David Irlakhman (1949 – 2000), whose unreserved love, support and kindness had always been there for me and would forever stay in my heart.

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Introduction

The Trade-Related Aspects of Intellectual Property (TRIPS) Agreement[1] is widely recognized as having established new patterns of Intellectual Property (IP) protection, especially regarding patent protection.[2]

Setting new, much stronger, standards of IP protection (especially in comparison to the previous level set by the WIPO Conventions),[3] TRIPS sharpened and intensified the strain between IP rights, particularly patents on pharmaceuticals, and public health issues. This controversy resulted in the Doha Declaration on TRIPS and Public Health (Doha Declaration),[4] adopted primarily as a response to developing countries' demands to respond to the public health crisis and to make compulsory license mechanism under TRIPS workable, so that the mechanism would allow the countries lacking sufficient pharmaceutical manufacturing capacities to import generic versions of patented drugs.[5]

Together with strengthening the international level of IP protection, TRIPS has also provided a few mechanisms of exception from patent protection in order to alleviate transfer to the new IP regime for developing countries.

One of these exceptions, a mechanism of compulsory license, outlined in Article 31 of TRIPS, is generally used for allowing manufacturing of generic versions of patented drugs to developing countries without a patent owner's authorization. Article

[1] See WTO legal texts, online: WTO <http://www.wto.org/english/docs_e/legal_e/legal_e.htm>.
[2] Leslie Gladstone Restaino & Katrine A. Levin, "Accord May Provide Means to Stop Copycat Drugs: Under TRIPS Agreement, WTO Has More Power to Pressure Countries Not in Compliance" (May 14, 2001) 23:38 Nat'l. L. J. C6., Col.1 at 2-3.
[3] Monique L. Cordray, "GATT v. WIPO" (1994) 76 J. Pat & Trademarks Off. Soc'y 121 at 124-125.
[4] WTO, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2 (2001), online: WTO <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>.
[5] The Doha Ministerial Declaration adopted on 14 November 2001 was to clarify implementation issues regarding the World Trade Organization's (WTO) agreements signed at the end of the Uruguay Round of Trade Negotiations in 1994. "The Doha Declaration explained", online: WTO <http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm>.

31(f) of TRIPS restricted the granting of compulsory license predominantly for domestic market supply. Therefore, poor countries with no sufficient manufacturing capacities would not be able to use this flexibility under TRIPS.

This problem was recognized in Par. 6 of the Doha Declaration. In August 2003, following the ministers' instructions, the WTO General Council adopted a decision that implemented Par. 6 of the Doha Declaration.[6] The decision waived members' obligations under Article 31(f) of TRIPS and allowed export of generic versions of patented drugs to developing countries with insufficient manufacturing capacities under certain conditions.

Canada was the first country to implement this decision in its national law. In May 2005, Bill C-9 (An Act to Amend Patent Act and Food and Drugs Act) was enacted.[7]

Chapter One of this thesis will provide an overview of the Intellectual Property regime that existed prior to TRIPS. This chapter will also analyze the reasons for TRIPS' creation. It will be argued that TRIPS was primarily an attempt of the US to fight trade in counterfeit goods and to provide a satisfying level of IP protection for US right owners (especially US-based multinational pharmaceutical companies) abroad. However, the Agreement did not aid in solving many other problems of the global pharmaceutical market.

Chapter Two will focus on the various deficiencies of the US pharmaceutical market, which also reflect the deficiencies of the global pharmaceutical market, because

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[6] WTO, General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540 and Corr.1 (1 September 2003), online: WTO <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>.

[7] Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act (Jean Chrétien Pledge to Africa)*, 3rd Sess., 37 th Parl., 2004, online: Library of the Parliament <http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_4/C-9_cover-e.html>.

most multinational research-based pharmaceutical companies are US-based. Additionally, the failures of a current drug development model will be analyzed.

Chapter Three of this thesis will review the process of TRIPS' emergence and the key features of the Agreement, stressing fundamental differences between developed and developing nations as to the scope and availability of IP protection that should have been included in TRIPS. Also, this chapter will analyze the patent section of the Agreement and the mechanisms of exception from patent protection available under TRIPS. Additionally, the problems of implementation of TRIPS will be discussed, while focusing on access to affordable medicines in developing and least-developed countries in a post-TRIPS period.

Chapter Four will provide an overview of the Doha Declaration and the WTO General Council's decision of 30 August 2003, and the attempts to balance patents rights with access to affordable pharmaceuticals in times of public health crisis.

Chapters Five and Six of the thesis will analyze Canada's Bill C-9, that was intended to implement the WTO General Council's decision in domestic laws, *i.e.,* to create a mechanism of export of generic versions of patented drugs under a compulsory license. These chapters will focus on the legislative history of the Bill and its gradual evolution from legislation intended strictly to implement the WTO decision into legislation that came close to becoming a part of Canada's global effort to aid underdeveloped countries in their fight against infectious diseases. In other words: a foreign aid program. The Bill's provisions will be analyzed, as well as the perspectives of different stakeholders, including the standpoint of the Canadian Government, various

non-governmental organizations and generic and research-based pharmaceutical manufacturers.

Finally, Chapter Seven will review similar legislation from other countries implementing the WTO General Council's decision and compare them to Canada's Bill C-9. Additionally, this chapter will outline the similarities of generic pharmaceutical market's operation and the IP regimes of Canada and Israel and analyze the possibility of legislating the same amendment into Israel's *Patent Act*.

It will be concluded that Canada's Bill C-9, in its present form, is more than a mere implementation of the WTO General Council's decision, but it has not yet acquired the whole range of humanitarian features of a foreign aid program. The Bill relies heavily on the private parties, especially on generic manufacturers, with no valid sponsorship from the Government. Also, it will be argued that although the Bill bears many humanitarian features, it operates in a semi-commercial way.

Several models will be proposed as to the operation of the system of export of generic drugs to underdeveloped countries afflicted with pandemics. One of them suggests that the Bill should acquire a completely humanitarian nature and become a full-scale foreign aid program. In this case, the Government will have to increase its involvement in the proposed mechanism of export and start making fiscal commitments and reimbursing a generic manufacturer and a patent holder accordingly.

Another possible solution is that the Government will buy the needed medicines from the patent holder (a completely humanitarian act) or from the generic manufacturer (an act that involves a compulsory license mechanism). Moreover, to turn the Bill into a foreign aid program will require adding a few other aspects that were not sufficiently

addressed in the current version of the Amendment. For example, legislation will have to relate not only to increasing generic competition in the pharmaceutical field and by that lowering the prices of pharmaceuticals, but also to find solutions to other valid reasons for inaccessibility and unaffordability of essential medicines in poor countries.

Another possible option is to consider the Bill as a mere implementation of the WTO General Council's decision, and therefore, to insert the mechanism proposed in the legislation into the TRIPS boundaries, *i.e.*, to narrow the mechanism to the flexibilities of TRIPS only. This solution includes a removal of all the extra-humanitarian features from the Bill and turns it into the TRIPS-driven mechanism similar to the one adopted by other countries to date. In that case, the Bill would follow TRIPS requirements more closely and focus on keeping the delicate balance between Canada's obligations under TRIPS and the requirements of the Doha Declaration and the WTO General Council's decision to relate to public health problems in underdeveloped countries.

Chapter One: TRIPS' Historical Background

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) is one of the agreements of the Final Act of the Uruguay Round of Trade Negotiations on General Agreement on Tariffs and Trade (GATT) that launched in Punto del Este in 1986. The Uruguay Round concluded on 15 April 1994 in Marrakesh, Morocco, where an agreement establishing the World Trade Organization (WTO) was signed.[8]

Even prior to the Uruguay Round, the United States (US) sought to ensure a stronger international level of intellectual property rights (IP or IPR) protection.[9] The growing dissatisfaction of the US with a low level of IPR protection regulated by the World Intellectual Property Organization (WIPO) treaties and the inability of the WIPO to enforce a desirable level of IPR protection brought the US to shift its efforts to establish a high level of international IPR standards.[10] These developments led to the US proposal on a detailed draft of TRIPS.[11] The proposal covered all aspects of intellectual property rights along with their acquisition and enforcement rules.[12]

TRIPS is the first agreement that interwove intellectual property rules into the multilateral trading system. Also, an attempt was made to narrow the gaps between the

[8] "Marrakesh Agreement Establishing the World Trade Organization", online: WTO <http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm>.
[9] Dylan A. MacLeod, "U.S. Trade Pressure and the Developing Intellectual Property Law of Thailand, Malaysia and Indonesia" (1992) 26 U.B.C.L.Rev. 343 at 343-344.
[10] *Supra* note 3. Another detailed draft of TRIPS was tabled by the European Community and it was similar to the one submitted by the US, a fact that indicated that the consultations between the two might have taken place prior to tabling the drafts. Based on Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, (London: Sweet & Maxwell, 2003) at 10 [Gervais].
[11] *Ibid.*
[12] Gervais, *supra* note 10.

IPR laws of different countries and to establish a minimum level of IP protection that each WTO member-country was obliged to provide.[13]

a. From GATT to WTO - Intellectual Property Rights Protection Prior to TRIPS

Prior to TRIPS there was no specific agreement on IP rights in the framework of a multilateral trading system.[14] However, some articles from the old GATT (1947) had defined measures, which could be undertaken under specific conditions to secure compliance with certain laws and regulations regarding IP rights.[15] Specifically, Article XX (d) of the old GATT dealt with the protection of patents, trademarks, copyrights and "deceptive practices"[16] (including trade in counterfeit goods, which was initially the main reason for encompassing intellectual property rights protection in the Uruguay Round of Negotiations). According to Art. XX (d), contracting parties were allowed to "secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including … the protection of patents, trademarks and copyrights, and the prevention of deceptive practices…".[17] However, the contracting parties could not change their patent law so that it would be inconsistent with the GATT provisions, which were designated to promote free trade.[18]

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[13] WTO, *Intellectual Property: Protection And Enforcement*, online: WTO <http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm>.
[14] WTO, *Frequently Asked Questions About TRIPS in WTO*, online: WTO <http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm>.
[15] GATT, *The General Agreement on Tariffs and Trade* (1947), online: GATT <http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf>.
[16] Gervais, *supra* note 10 at 6.
[17] *Supra* note 15, Art. XX (d).
[18] Gervais, *supra* note 10 at 6-7.

Attempts to create common rules to prevent trade in counterfeit goods have been made ever since the Tokyo Round of GATT negotiations (1973-1979).[19] A failure of such attempts justified the continuing efforts of the industrialized contracting parties of GATT to find a way to stop trade in counterfeit goods. As a result of these efforts, in November 1984, the Group of Experts on Trade in Counterfeit Goods was created.[20] The Group prepared a report stating that there was a growing problem of trade in counterfeit goods and that the existing provisions of international law[21] were insufficient to solve this problem. However, the report also stated that although it is necessary to prevent trade in counterfeit goods, "any measures taken … should not become an obstacle to trade in genuine goods".[22] Therefore, no agreement had been reached upon the question of GATT being an appropriate forum for these issues.[23]

The Level of IPR Protection Under WIPO

At the time, WIPO administered four main units that were to promote intellectual property protection: the Paris Convention for the Protection of Industrial Property (the Paris Convention), the Berne Convention for the Protection of Literary and Artistic Works (the Berne Convention), the Madrid Agreement Concerning the International Registration of Marks, and the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (the Rome Convention). These

[19] *Ibid*., at 7-8.
[20] GATT, *Trade in Counterfeit Goods: Fortieth session of the Contracting Parties on 30 November 1984*, GATT Doc. L5758 (20 December 1984), online: GATT <http://gatt.stanford.edu/bin/object.pdf?91120212>.
[21] Specifically, the Paris Convention for the Protection of Industrial Property.
[22] The Group was created in November 1984 and was assisted by an expert from WIPO. The report of the Group was tabled on 9 October 1985. *Supra* note 20 at 11-12 and see also Gervais, s*upra* note 10 at 8-9.
[23] WTO, *Meeting of the Negotiating Group* (held on 25 March, 1987), WTO. Doc MTN.GNG/NG11/1 (10 April 1987) at 2, online: WTO <http://docsonline.wto.org>. Also, s*upra* note 20 at para. 11.

Conventions concentrated mostly on national treatment, although the Berne Convention set up some minimum standards on the international level and the Rome Convention required international protection for certain kinds of IP rights as well.[24] Similarly to the Paris Convention, the Berne Convention provided a national treatment clause.[25] In other words, countries that provided no intellectual property protection for their own citizens, were not required to provide it for international entities either.[26]

One of the main reasons for the failure of the WIPO Conventions to provide a higher level of IPR protection was that many developing, and even some developed, countries did not agree to set up strong intellectual property standards and preferred instead to provide only limited protection in their national laws.[27]

While developed countries led by the US tried to enhance the international level of IP protection, developing countries sought to weaken the IP standards existing under WIPO.[28] One of the possible reasons for this was presented in an empirical research study co-sponsored partly by the United Nations Development Program.[29] The research showed that countries with a low level of technological capacity preferred weak IP rights

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[24] *Supra* note 3 at 124.
[25] The national treatment clause requires that a country provide for foreigners the same, and in any case, no less favorable, level of IP protection, that it provides for its own citizens. *Ibid.,* at 124.
[26] *Ibid.* However, the Berne Convention's version of the national treatment clause required the protection to be unconditional and independent of the existence of such protection in the country of origin. See "Summary of the Berne Convention for the Protection of Literary and Artistic Works (1886)", online: WIPO <http://www.wipo.int/treaties/en/ip/berne/summary_berne.html#fl>.
[27] This could be said in regard to patent protection for pharmaceuticals. Under the WIPO-administered IP regime, Member-countries were not obliged to provide patent protection for pharmaceuticals if they defined pharmaceuticals as a process. See R. Dhanjee & L. Boison de Chazournes, "Trade Related Aspects of Intellectual Property Rights (TRIPS): Objectives, Approaches and Basic Principles of the GATT and of Intellectual Property Conventions" (1990) 24:5 J. World Trade 5.
[28] *Supra* note 3 at 123-124.
[29] The research was conducted by Kamal Malhotra (Senior Advisor on Inclusive Globalization in the United Nations Development Program's Bureau for Development Policy) and an international team of experts. See "Making Global Trade Work for People" (2003) at 206-207, online: United Nations Development Programme <http://www.undp.org/dpa/publications/globaltrade.pdf>.

protection until they could reach a level of technology development where they could truly benefit from the IP protection.[30]

Due to developing countries' opposition, WIPO's abilities to strengthen IPR protection through multilateral agreements were limited. However, the major problem was inability to enforce IP protection, even at a weak level, and ineffective dispute settlement procedures.[31]

According to the Paris and Berne Conventions, disputes between countries had to be settled at the International Court of Justice (ICJ). But the Paris Convention itself, in Article 28(2), stated that the country was entitled to choose whether it was to be bound by the ICJ jurisdiction or not. Article 33(2) of the Berne Convention had the same clause. Moreover, dispute settlement procedures under ICJ were long and complex. Even if obtained, the judgment of the ICJ was not likely to be enforced. The enforcement of such judgment should have come only as a result of the voluntary cooperation of an affected member or by referral to the Security Council under United Nation's Charter.[32]

Furthermore, it has been stated that the problems generated by the WIPO-regulated IP regime appeared to be "a result of deficiencies in the protection accorded to intellectual property, both because of inadequacies in the scope and availability of intellectual property rights under many national laws and because of lack of effective procedures and remedies for the enforcement of such rights where they existed."[33] The

[30] This is for the following reasons: least-developed countries earned 0.05 percent of worldwide royalties and licensing fees, while developed, high-income countries (listed in the Organization for Economic Cooperation and Development up to 1998) had 86 percent of total patent applications filed and 85 percent of scientific and technical journal publications (according to the UNDP and World Bank reports of 2001). *Ibid.*

[31] *Supra* note 3 at 131.

[32] *Charter of the United Nations*, c. 14, art. 94, online: UN <http://www.un.org/aboutun/charter/>. See also *ibid*., at 131-132.

[33] *Supra* note 23.

problems of inadequate intellectual property protection often involved numerous countries in each case: the country of the owner of IP right, the country (or countries) that infringed that right, the country (or countries) in which unauthorized copies were being sold.[34] These problems caused trade distortions, such as the export of unauthorized copies of legitimate goods; a reduction of incentives for inventors to engage in research and development (R&D) to create innovative products and to invest in trade; the purposeful use of IP protection to discourage imports and encourage the local market.

However, not all of the ministers participating in the negotiating group on TRIPS were of the opinion that the WTO was the right forum for setting standards of IP protection or for strengthening the level of the IP enforcement procedures. There were proposals to narrow the debates to issues related to trade in goods only.[35] These participants suggested that the negotiating group was to deal only with the effects of the measures taken to protect IPRs on trade in goods. According to this position, the negotiating group was to ensure that these actions would not interfere with trade.[36]

b. Why did the United States Insist on Raising the Intellectual Property Protection Issues in the Uruguay Round?

The U.S. neither had much influence in the existing WIPO-regulated treaties nor was it satisfied with a few provisions of the GATT agreement indistinctly related to intellectual property protection. As stated in the US General Accounting Office report:

[34] *Ibid.*
[35] *Ibid.,* at para. 14.
[36] *Ibid.,* at para. 15.

> "Information from U.S. industry indicates that the impact of foreign piracy on the United States is significant. In the short term, such piracy (1) limits the ability of firms and individuals to obtain returns on their investments of time and resources in developing patented innovations, trademarked products, and copyrighted works, (2) deprives legitimate businesses of sales, profits, and the ability to provide employment, and (3) can threaten public health and safety. In the long term, piracy undermines the patent and copyright systems as mechanisms for encouraging innovation and creativity and the trademark system as an indicator to consumers of quality products and services."[37]

The US was not making any significant progress in its attempts to reduce the extent of foreign piracy (specifically, unauthorized use of US-owned patents) nor did it succeed in convincing foreign governments to enforce more significant protection of IPR.[38] The data presented in the GAO report shows clearly why the US has been so eager to bring all intellectual property aspects on the table of the Uruguay Round's negotiations. The combined loss of 82 firms that suffered from the infringements in this field reached 50 million dollars in lost sales only in 1982.[39] According to the International Intellectual Property Alliance's (IIPA) estimation, in 1985, piracy of copyrighted works in ten selected countries caused the US industry a loss of over one billion dollars annually. The Pharmaceutical Research and Manufacturer's Association of America (PhARMA) reported the same statistics in the same year. According to one of its member-company's statements, the company lost about 27 million dollars in potential sales on one patented product that was sold in unlicensed copies in five developing

[37] U.S. General Accounting Office, *Report to Selected Congressional Subcommittees: International Trade: Strengthening Worldwide Protection of Intellectual Property Rights*, GAO/NSIAD-87-65 (1987), online: GAO <http://archive.gao.gov/d2t4/132699.pdf>.
[38] *Ibid.*
[39] That is according to the report of the International Trade Commission in regard to the counterfeiting of trademarks. *Ibid.*

countries.[40] All in all, the International Trade Commission projected that the US industry could have lost about 43-61 billion because of infringements of IP rights abroad only in 1986.[41]

The US Attempts to Reach a Multilateral Agreement on IPR and an Internal Policy

In the Tokyo Round of GATT negotiations in 1979, the US tried to include an agreement to prevent counterfeiting.[42] In fact, the proposal had significant support (particularly from Europe). However, the opposition of developing countries was strong and the US proposal had been submitted late. As a result, the US initiative failed in that round of trade negotiations.[43]

Within the US, during the period of 1970-1980, the problem of continuous trade in counterfeit goods led the private sector's lobbying groups[44] to increase their pressure to demand greater action in the field of IP protection.[45] In 1988, long before the Uruguay Round was concluded and the final draft of TRIPS was tabled, President Reagan had signed the *Omnibus Trade and Competitiveness Act*.[46] In its §1301, the Act amended s. 301 of the *Trade Act* of 1974[47] and §1303 of the Act amended s. 182 of the *Trade Act* of 1974, an amendment known as *"Special 301"*.[48] According to these sections, United States Trade Representative's (USTR) Office had been authorized to identify so-called

[40] All the data was taken from the GAO report. *Ibid.*, at 15.
[41] Richard A. Morford, "Intellectual Property Protection: A United States Priority" (1989) 19:2 Ga. J. Int'l & Comp. L. 336 at 336-337.
[42] Gervais, s*upra* note 10 at 7-8.
[43] *Supra* note 41 at 337.
[44] Representing powerful American-based multinational corporations and companies whose products required IP protection. See Susan Sell, "Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property" (2001 - 2002) 14 Fla. J. Int'l L. 193 at 195-196.
[45] *Ibid.* Also see s*upra* note 41 at 337.
[46] *Omnibus Trade and Competitiveness Act of 1988*, 100 P.L. 418 (H.R. 4848), ss. 1301-1303.
[47] *Trade and Tariff Act of 1974 [Trade Act]*, 19 U.S.C §2411.
[48] *Ibid.*, §2242.

"priority countries", *i.e.,* countries that provide an unsatisfying level of IP protection in the US view.[49]

These countries were to become targets for retaliation if they "have the most onerous or egregious acts, policies or practices that: (i) deny adequate and effective intellectual property rights, or (ii) deny fair and equitable market access to United States persons that rely upon intellectual property protection."[50]

Additionally, USTR created the "Priority Watch List" naming countries (US trading partners) that had failed to provide adequate IP protection, enforcement or market access for American persons or entities that should have enjoyed IP protection in the same circumstances.[51] Thus, in making a decision to pursue various trade sanctions according to the annual *"Special 301"* report, the USTR was also required to take into account the prior record of the country (according to the Watch List), as well as the history of the US efforts to strengthen the said country's IP policy and the country's response to those efforts.[52]

Additionally, in 1983, the Intellectual Property Committee (IPC)[53] was founded.[54] IPC was a coalition of twelve powerful US-based corporations from various IP-related

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[49] *Ibid.*, § 2242 (a) states: "By no later than the date that is 30 days after the date on which the annual report is submitted to Congressional committees under section 2241(b) of this title, the United States Trade Representative… shall identify: those foreign countries that: (A) deny adequate and effective protection of intellectual property rights, or (B) deny fair and equitable market access to United States persons that rely upon intellectual property protection, and (2) those foreign countries identified under paragraph (1) that are determined by the Trade Representative to be priority foreign countries."

[50] *Ibid.*, § 2242(b)(1). See also *supra* note 44 at 197. See also Judith H. Bello & Alan H. Holmer, "Update: Special 301" (1990-1991) 14 Fordham Int'l L. J. 874 at 874-875.

[51] "Background on 'Special 301'", online: USTR <http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_Special_301/asset_upload_file223_7646.pdf>.

[52] *Supra* note 44 at 197.

[53] IPC delegations visited Europe and Japan in order to explain the advantages of a trade-based approach to the IP issues. See Carol J. Bizli, "Towards an Intellectual Property Agreement in the GATT: View from the Private Sector", (1989) 19:2 Ga. J. Int'l & Comp. L. 343 at 344.

industries. Each corporation was extremely interested in reaching a high level of IP protection, so the IPC was committed to creating an international agreement on IP. The IPC sought to ensure that the IP aspects would be included in the Uruguay Round of Trade Negotiations.[55] The *Omnibus Act of 1988* was, to a large extent, a result of the IPC efforts to bring Congress to turn an improved IP protection into a priority issue in the US trade policy.[56] Simultaneously, the IPC worked closely with the European Community and Japanese business groups to reach a consensus on the form and content of the multilateral IP agreement that should emerge from the GATT negotiations.[57]

Another important development in a bilateral level was the extension of the Generalized System of Preferences for developing countries under *Trade and Tariff Act of 1984*. [58] Under the new provisions, the President could name a country, whose IP laws succeeded in providing effective IP protection to foreign nationals, a "beneficiary developing country".[59] As a result, such a country could enjoy various benefits in tariffs and trade transactions with the US.[60]

Thus, it can be concluded that the private sectors in the US saw in the GATT negotiations a good opportunity to bring about the evolution of IP protection from being some abstract subject matter, which had not even been properly enforced, to being a

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[54] Edmund J. Pratt (Speech presented to the US Council for International Business Conference on Intellectual Property, March 1995), [unpublished].
[55] *Supra* note 53 at 343-344.
[56] *Ibid*., at 344.
[57] *Ibid*. See also "Trips – Chronology of Key Events", online: Patentmatics <http://www.patentmatics.org/pub2003/pub9b.htm>.
[58] *Trade and Tariff Act 1984*, Pub.L. 98-573, 98 Stat. 2948 (1984), H.R. 3398.
[59] *Ibid.*
[60] Susan K. Sell, "Intellectual Property as a Trade Issue: From the Paris Convention to GATT" (1989) 13:4 Legal Studies Forum 407 at 418.

trade-related topic connected with GATT's wide-scale agenda.[61] Moreover, the major achievement would have been to connect GATT's enforcement and dispute resolution mechanisms, obliging more than one hundred member states of the newly created WTO, to the IP issues.[62] It has been argued that many developing countries agreed to sign TRIPS hoping that this would satisfy the US (particularly, US-based multinational corporations) plans for reaching a high level of international IP protection.[63] However, it was only the beginning of the future globalization of the IP regime.[64]

Conclusions:

In the US view, inadequate IPR protection and trade in counterfeit goods were the major difficulties to overcome. Therefore, the natural way to solve these problems seemed to be to provide an adequate level of IPR protection on the international scale.

In regard to the pharmaceutical field, though, aside from trade in counterfeit goods (specifically, the unauthorized use of patented medicines and the lack of patent protection in some countries), there were numerous other factors that were responsible for the global pharmaceutical market's failures.

[61] The TRIPS negotiating group was one of the 14 negotiating groups on various topics that were established under the Group of Negotiation on Goods, which reported to the highest body: the Trade Negotiations Committee that supervised all of the negotiations. Gervais, s*upra* note 10 at 12.
[62] *Ibid.*
[63] Peter Drahos, "Expanding Intellectual Property's Empire: the Role of FTAs" (November 2003), online: bilaterals.org <http://www.bilaterals.org/IMG/doc/Expanding_IP_Empire_-_Role_of_FTAs.doc>.
[64] *Ibid.*

Chapter Two: Pharmaceutical Market Problems in the US

a. Pharmaceutical Patents and the Process of Drug Development.

A patent creates a contract between society and a patent owner. As an integral part of these relationships, an inventor (a patent owner) reveals his innovative, useful and non-obvious invention to society and, in exchange, the government grants him an official temporary monopoly on the innovative product or process.[65] A patent serves as an incentive for innovation: by granting an inventor exclusivity in the manufacture, use and sale of the invention, society rewards him for any investment put into this invention.[66]

However, there are certain angles to a pharmaceutical patent that require special consideration when analyzing the structure of the pharmaceutical market.

There are four kinds of pharmaceutical patents: 1) a patent protecting a drug substance;[67] 2) a patent that protects the method of use of the drug, *i.e.,* treatment of a specific medical condition, for instance, heart failure; 3) a patent that protects a formulation (a physical form of the drug and/or a method of use); and 4) a patent protecting manufacturing methods of producing the drug.[68]

Bringing an innovative drug into the market is a long and costly process.[69] First, it is necessary to understand the nature of the disease or condition and the possible means

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[65] *US Patent Act*, 35 U.S.C. §§ 100-103. See also Nuno Pires de Carvalho, "The Primary Function of Patents" (2001) U. Ill. J.L. Tech. & Pol'y 25 at 36-37.

[66] Bryan Schwartz & Marhi Kim, "Economic Prizes: Filling the Gaps in Pharmaceutical Innovation", 5 Asper Rev. Int'l Bus. & Trade L. at 30.

[67] Such a patent covers the chemical composition of active ingredients, such as a new chemical entity (NCE). See Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It,* (NY: Random House, 2004) at 175-176.

[68] *Ibid.*

[69] A study conducted by Tufts Center for the Study of Drug Development showed that in the US, 8.5 years were needed to move new medicines that were eventually approved by the US Food and Drug

of treatment. The potential treatments need to be described in a detailed way, on a molecular level.[70] This is the first, longest and most uncertain part of the R&D process, which is called "basic research".[71] The next step is to discover or synthesize a molecule that will be responsible for a cure or amelioration of the condition. This stage of the development part of the R&D process contains two sub-stages: pre-clinical trials and clinical ones. The purpose of a pre-clinical trial is to find potential drug candidates, *i.e.,* molecules that are capable of targeting disease-causing factors discovered in basic research and to test them on animals or human cells in test tubes.[72] Very few of the drug candidates will successfully pass the pre-clinical stage and evolve to the clinical trial, *i.e.,* testing on humans.[73]

If the safety and efficacy of a drug is proven, an application to the governmental authority for final approval of the drug may be submitted.[74] After the drug is approved, there is an additional phase of research (phase IV), which is needed to keep track of the new drug after it is being used widely.[75] This phase serves for testing the new drug for new uses, as well as for testing the effectiveness of the drug for other diseases.[76]

Administration through a clinical trials' phase and an approval phase from 2002-2004. See Tufts Center for the Study of Drug Development, News Release, "New Drugs are Taking Longer to Bring to Market in the U.S." (11 January 2005), online: Tufts Center for the Study of Drug Development <http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=58>.

[70] Angell, *supra* note 67 at 22.

[71] *Ibid.*

[72] All based on Angell, *ibid.*

[73] *Ibid*., at 23.

[74] In Canada, the governmental agency is the Therapeutic Products Directorate of Health Canada; in the US, it is the Food and Drug Administration (FDA), and in Australia, the Therapeutic Goods Administration. See "Drug Development Process – Drug Review and Approval", online: Patient Pathways – Canada's Research-Based Pharmaceutical Companies <http://www.canadapharma.org/Patient_Pathways/Drug_Process/drugappr_e.html>.

[75] *Supra* note 67.

[76] "Drug Development Process – Drug Discovery and Development", online: Patient Pathways – Canada's Research-Based Pharmaceutical Companies <http://www.canadapharma.org/Patient_Pathways/Drug_Process/drugdisc_e.html>.

b. Inefficiencies of Pharmaceutical Industry in the US

Statistics show that about 85% of medicines are consumed by developed nations, who are also responsible for about 99% of pharmaceutical inventions.[77] A significant part of this pie belongs to US-based pharmaceutical companies.[78] US-based multinational pharmaceutical corporations were among the main initiators of change in the global IP regime, which eventually led to the creation of TRIPS.[79] There is evidence that multinational corporations are also the main beneficiaries of TRIPS and that the agreement intensifies the existing public health crisis by increasing prices on pharmaceuticals and further limiting access to essential medicines.[80] Moreover, there is evidence supporting a claim that the profit-driven pharmaceutical industry is focused on producing medicines consumed by the wealthy minority of the world's population.[81] As a result, a lack of investment in R&D to develop new effective medicines for infectious diseases afflicting mostly poor countries causes a shortage in much needed life-saving drugs.[82] Therefore, a discussion regarding the inefficiencies of the US pharmaceutical market is needed in order to understand the problems of access to medicines in poor countries.

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[77] Adam Lewinberg, "Access to Medicines Guide: Guide for Policy Makers and Researchers: Understanding the Challenge: Making Essential Medicines Available to the World's Poor", online: Center for Innovation Law and Policy <http://www.innovationlaw.org/English/Access-to-Medicines-Guide.html>.
[78] Of the top ten pharmaceutical companies ranked by total product revenue, five are US-owned (Pfizer is No. 1 with $46,133 million), two companies are based in the UK, two in Switzerland and one in France. (Based on 2004 pharma revenue). See "2005 Top Companies", online: Contract Pharma <http://www.contractpharma.com/top_comp.php#pharma>.
[79] See Chapter I(b).
[80] *Supra* note 29.
[81] People's Health Movement *et al.*, *Global Health Watch* 2005-2006, (London: Zed Books Ltd., 2005) at 100-101, online: Global Health Watch <http://www.ghwatch.org/2005report/ghw.pdf>. See also *supra* note 66.
[82] *Ibid.*

Research-based pharmaceutical companies argue that it takes 10-12 years to develop an innovative drug.[83] Moreover, less than 10% of drug candidates entering the clinical trial stage evolve to the market, and approximately 30-50% of drugs past Phase III of the clinical trials do not acquire regulatory approval due to insufficient evidence of safety and efficacy.[84] Also, pharmaceutical companies argue that bringing a new drug into the market costs approximately $800 million.[85] These costs are the major barrier to the development of innovative, high-risk drugs or therapies for uncommon diseases or diseases that predominantly afflict poor nations. Product development in areas crucial to public health goals, such as antibiotics for infectious diseases such as HIV/AIDS or tuberculosis, has slowed down significantly during the past decade.[86]

Problems in the Drug Development Process

One of the major problems in the drug development process is the failure of the "classical drug development model". In order to maximize the profits from an investment in R&D, drug companies seek to discover a "blockbuster drug" that targets a large group of patients that could afford the drug.[87] Such a policy requires a great number of costly clinical trials, which may eventually prove the drug to be ineffective or unsafe. This

[83] *Supra* note 76.
[84] In January 2005, the US Food and Drug Administration and the Association of American Medical Colleges organized a workshop for research experts from the industry, academia and the National Institute of Health. The main goal of the workshop was to point out failures in the drug development process and to find a better way of collaboration among scientists from the academia, industry, and governmental agencies. See "Drug Development Science: Obstacles and Opportunities for Collaboration Among Academia, Industry and Government", *Report of an Invitational Conference Organized by the Association of American Medical Colleges* (2005), Washington DC, online: AAMC <https://services.aamc.org/Publications/showfile.cfm?file=version43.pdf&prd_id=135&prv_id=157&pdf_id=43> at 2 & 9 [Drug Development Science]. Also see *supra* note 67 at 23.
[85] *Drug Development Science, ibid.,* at 30.
[86] U.S., Food and Drug Administration, "Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products" (March 2004), online: FDA <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html#intro> at 3-5.
[87] *Drug Development Science, supra* note 84 at 28.

could happen even in the final phase of the clinical trial, when millions of dollars were already invested in the R&D. Such uncertainty increases the risk that an investment may turn out to be unprofitable.[88]

To avoid these risks and fulfill the major aim of a corporation, *i.e.,* to maximize profits to the satisfaction of shareholders, drug companies prefer to focus on less risky projects - so-called "me-too" drugs.[89] "Me-too" drugs are, in fact, innovations that only differ insignificantly from drugs already existing in the market.[90] Investing in R&D of "me-too" drugs means: 1) minimal expenditures on clinical trials;[91] 2) minimal risks that the new drug would not be approved by the drug approval agency;[92] 3) maximized profits that can be multiplied by heavy marketing efforts intended to convince physicians to prescribe to their patients a newer, more expensive drug, even if it has the same therapeutic ability as its predecessor.[93]

While the policy of focusing on developing "me-too" drugs seems to be totally acceptable for research-based drug companies, it forfeits the urgent public need for the development of innovative, progressive, and useful drugs, which will be able to respond to the growing need for life-saving medicines for such critical diseases as HIV/AIDS, tuberculosis, malaria, etc.[94]

The US drug approval authority, the Food and Drug Administration (FDA), is responsible "for ensuring that safe and effective medical innovations are available to

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[88] *Ibid.*
[89] Angell, *supra* note 67 at c.4-5. Also see *supra* note 66 at 30-31.
[90] Angell, *ibid*.
[91] All of the significant clinical trials have already been performed on the original drug.
[92] The original innovative drug has already been approved once.
[93] All based on Angell, *supra* note 67 at c.5. See also *supra* note 66 at 31-32.
[94] *Supra* note 66 at 30.

patients".[95] All New Drug Applications (NDAs) are divided into two categories according to innovativeness of a drug's active ingredient.[96] If the FDA has never approved the active ingredient of a new drug, the drug will be classified as a "New Molecular Entity" (NME).[97] Another category consists of new medicines whose active compounds have already been approved by the FDA, but they contain some changes in dosage or administration. These drugs are classified as "Incrementally Modified Drugs" (IMDs).[98] Additional classification is according to the clinical improvement of the NDA. If a new medicine (even if it has been classified as an IMD) provides a "significant clinical improvement" over drugs already on the market, it deserves to be reviewed in priority review order. If an NDA provides little or no clinical improvement, it will be reviewed in standard review order.[99]

To be reviewed in priority review order, the new medicine should possess one of the following factors: 1) evidence of increased effectiveness in treatment, prevention or diagnosis of the disease; 2) the elimination or substantial reduction of a treatment-limiting drug reaction; 3) a documented enhancement of patient compliance; 4) evidence of safety and effectiveness of a new subpopulation.[100] Unfortunately, innovation in an NDA is not one of the factors to grant a new drug priority review status. Therefore, a drug that is not truly innovative, *i.e.,* not an NME, but has an active ingredient that is already on the market will nonetheless be reviewed as a priority.

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[95] *Supra* note 86.
[96] "Changing Patterns of Pharmaceutical Innovation", *National Institute for Health Care Management (NIHCM) Research Report* (May 2002), online: NIHCM <http://www.nihcm.org/innovations.pdf> at 2.
[97] *Ibid.*
[98] *Ibid.*
[99] "Review management: Manual of Policies and Procedures", MAPP 6020.3, online: Center for Drug Evaluation and Research (CDER) <http://www.fda.gov/cder/mapp.htm#review> at 6020.3 at 1-2.
[100] *Ibid.*

Given the fact that innovativeness is not a significant factor for the FDA review process, it is not surprising that the majority of new drug applications approved by the FDA are IMDs, while the number of truly innovative products has decreased since 1996.[101] According to the *National Institute for Health Care Management (NIHCM) Report*, during the period of 1989-2000, there were 1035 NDAs approved by the FDA. Only 35% of them were NMEs (products with a new active ingredient). Over 54% were IMDs. The absolute majority (85%) of IMDs were viewed in standard review order and 58% of NMEs were reviewed by the FDA in standard review order. All in all, only 24% of the new drugs were rated as a priority, providing clinical improvement over currently marketed drugs, and only 15% of NDAs over a period of 12 years were rated as priority NMEs (the most innovative type of a new drug).[102] The situation hasn't changed much since 2000. Only 36 drugs out of 119 approved in 2004 were truly innovative, which is only about 30%. Twenty-nine of 119 medicines were reviewed in priority review and the other 90 were subject to standard review.[103]

Arguments of a Research-Based Pharmaceutical Industry

In an attempt to explain such a discouraging state of the US pharmaceutical market, research-based pharmaceutical companies blame the following factors:

[101] After a steady rise from 1993-1996. *Supra* note 84 at 1-2.
[102] All based on NIHCM report 2002. *Supra* note 96 at 7-9.
[103] U.S. Food and Drug Administration, "CDER 2004 Report to the Nation: Improving Public Health Through Human Drugs" (2005), online: FDA <http://www.fda.gov/cder/reports/rtn/2004/rtn2004.PDF> at 13.

1) first of all, the costs and length of the process of bringing new drug to the market;[104] 2) second, brand-name industry claims that uncertainty and risks in this field present a major problem for investors.[105] Only three out of ten prescription drugs produce revenues that can recoup the R&D investments;[106] 3) with no strong patent protection, there will be no life-saving medicines discovered because there will be no incentives to invest in R&D.[107]

Another argument of research-based manufacturers is that growing competition with generic companies does not allow the brand-name company that developed a new drug enough time to make profits in order to recoup the investments. Especially when one of every five dollars of revenue is reinvested in new research funding.[108]

That said, research-based pharmaceutical companies also argue that there is a steady stream of new medicines replacing expensive surgeries, providing new, better treatment for such diseases as HIV/AIDS, cancer, heart disease, Alzheimer's, etc.[109] However, given the fact that the decision as to which drug to develop is reached by taking into account the conditions of the market in which the drug will be distributed, it is safe to say that research-based manufacturers prefer to focus on developing therapies for diseases afflicting larger populations in more developed countries, where the profits will

[104] Such as the huge investments in R&D and a 12-15 year period required on average to discover and develop a new medicine. See Pharmaceutical Research and Manufacturers of America (PhRMA), "Why Do Prescription Drugs Cost So Much?", online: PhRMA <http://www.phrma.org/>.
[105] Of 5000 medicines tested, only about five will get to the clinical trial level and only one of them will be approved by the agency, which means that this one drug that is eventually brought into market will be responsible for producing revenue to cover for the investments in R&D of the other, less successful drugs that were not approved or didn't even reach the clinical trial level. See "What Goes Into the Costs of Prescription Drugs?", (24 August 2005) at 2, online: PhRMA <http://www.phrma.org/files/Cost_of_Prescription_Drugs.pdf>. Also see *ibid.,* at 2.
[106] *Ibid.* See also The Pfizer Journal, Global Edition, "Intellectual Property Protection for Pharmaceuticals: Emerging Issues in a Global Economy, (2000), online: The Pfizer Journal <http://www.thepfizerjournal.com/pdfs/TPJ13.pdf> at 7.
[107] The Pfizer Journal, *ibid.,* at 4-5.
[108] *Supra* note 105 at 3.
[109] *Supra* note 105 at 7.

be higher.[110] Also, it has been stated that strong patent protection itself is not enough to incentivize investments in R&D of diseases afflicting developing countries due to the lack of a significant market.[111]

Arguments of Civil Society Groups

On the other hand, Non-Governmental Organizations (NGOs)[112] and other public heath activists argue that the techniques used by research-based companies in an attempt to grow profits notwithstanding the urgent societal needs for cheaper drugs for infectious diseases, are definitely unacceptable. Among these techniques is biased research in favor of the drug's sponsor, which produces non-objective research results. Such non-objective research is possible due to the dominating control of research-based companies over the results of the clinical research of their products.[113] Additionally, research-based companies' profit-driven techniques include aggressive marketing methods and various legal tricks to stretch the patent monopoly as soon as the patent approaches its expiration date.[114] As a result, generic manufacturers are banned from entering the market, which prevents competition that could possibly lower drug prices.[115]

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[110] *Drug Development Science, supra* note 84 at 28.
[111] According to the report of the World Health Organization (WHO) Commission on Macroeconomics and Health. See "Integrating Intellectual Property Rights and Development Policy", *Report of the Commission on Intellectual Property*, (September 2002), online: Commission on Intellectual Property Rights <http://www.iprcommission.org/graphic/documents/final_report.htm> at c.2.
[112] Such as UNAIDS, Doctors Without Borders (MSF), Oxfam International, etc.
[113] Angell, *supra* note 67 at 239-244.
[114] *Ibid*., at 178-182.
[115] The anticompetitive practices of some companies, both research-based and generic, were mentioned in the Federal Trade Commission (FTC) testimony before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health. In this Committee, the results of the FTC's study on "Generic Entry Prior to Patent Expiration" were presented. It was stated that: "Although many drug manufacturers - including both brand-name companies and generics - have acted in good faith, others have attempted to 'game' the system, securing greater profits for themselves without providing corresponding benefits to consumers." Federal Trade Commission, "FTC Testifies on Competition in the US

One of the main claims of public health activists is that estimates of the costs of R&D presented by the pharmaceutical industry are much higher than they are in reality.[116] Additionally, they point out that the pharmaceutical industry, by focusing on "expensive lifestyle medicines such as *'Viagra'*, which claim to address the needs of the affluent minority of the world's population", deepens the existing mismatch between expenditures on pharmaceuticals and health needs in rich and poor countries.[117]

As a result of these shortcomings, the prices on pharmaceuticals are excessively high.[118] The high prices further limit access to pharmaceuticals in the US.[119] Given the fact that most of the new medicines are different variations of already approved drugs[120] and pharmaceutical companies are focused on finding the least risky ways of increasing their profits, the lack of incentives for investments in R&D of commercially unattractive diseases, such as TB and malaria, afflicting populations of developing countries, and therefore promising no significant revenues, is not surprising.

Pharmaceutical Industry (9 October 2002), online: Federal Trade Commission <http://www.ftc.gov/opa/2002/10/genericstestimony.htm>.

[116] James Love, **"**Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines", (September 2003), online: Consumer Project on Technology <http://www.cptech.org/ip/health/rnd/evidenceregardingrnd.pdf> at 5-6.

[117] According to the Global Health Watch report, 42% of the world population's expenditures on medicines is spent on 5% of world's population (in North-America), while 13% only is spent on the populations of Africa, Asia and the Middle East, while this region accounts for 72% of the world population. See *supra* note 81 at 101-102.

[118] According to the research report of the NIHCM foundation (May 2002), total spending on prescription drugs in the US, for example, increased in the period of 1995-2000 from about 64.7 billion to 132 billion dollars US. See *supra* note 96 at 10.

[119] *Supra* note 77 at 2.

[120] 67% of the increased spending on new drugs is attributable to standard-rated drugs. See *supra* note 96 at 10.

Conclusions:

The failures of the drug development model certainly affect the situation in the developing world, as well as the fact that as much as 99% of new medicines are invented in developed countries.[121] Although there is a great need for drugs in developing countries, there is no infrastructure for the creation and even delivery of the much-needed pharmaceuticals.[122]

Drugs that are necessary in developing countries are not the ones that could bring adequate revenues to pharmaceutical companies, and therefore, the companies are not interested in investing in R&D to create innovative drugs for diseases afflicting mostly developing countries.[123]

It is clear then that the pharmaceutical industry functions largely for the benefit of developed nations[124] and does not respond to the needs of people in the developing world.

[121] *Supra* note 77.
[122] *Ibid.*
[123] *Supra* note 66 at 36-37.
[124] *Supra* note 77.

Chapter Three: Trade-Related Aspects of Intellectual Property Agreement (TRIPS) – Strengthening Intellectual Property Protection Worldwide

a. *Emergence of TRIPS and the Fundamental Differences Between "North" and "South" Regarding the Scope of International Intellectual Property Protection*

Being one of the most enthusiastic adherents to the vision of including as many aspects of IP protection as possible in the Uruguay Round of Trade Negotiations, the US (along with Japan) submitted a wide-scale proposal to the Preparatory Committee on 11 April 1986. The Preparatory Committee was to prepare recommendations for the general program of negotiations to be adopted as a basis for discussions at the Ministerial Conference.[125]

While to the US the inclusion of IP issues was the foremost condition for the involvement in the negotiations, numerous participating countries (mostly, developing ones) were absolutely opposed to the idea of turning IP protection aspects into a trade issue.[126] The group of developing countries, named "the group of ten", submitted a draft communication to the Preparatory Committee, in which the countries argued against the inclusion of the IP issues in the GATT negotiations.[127] The developing countries claimed that the State's sovereignty included a right to decide what level of IP protection the State

[125] Gervais, *supra* note 10 at 10.
[126] Azza El Shinnawy, "A Reading Into the TRIPS Track Road", 10:3 *Newsletter of the Economic Research Forum, for the Arab Countries, Iran and Turkey* (Autumn 2003), online: Economic Research Forum <http://www.erf.org.eg/nletter/Newsletter_Vol10_Autumn03/P16-17.pdf>.
[127] Chakravarthi Raghavan, "New Efforts of Consensus Over Ministerial Meeting?" (26 August 1986), online: South-North Development Monitor <http://www.sunsonline.org/trade/process/during/86/08280086.htm>.

is willing to provide within its own territory.[128] Economic profitability of stronger IP protection for the developing nations was questioned as well. Finally, it has been argued that GATT is not the right forum for IP issues.[129]

The fundamental differences between the US, Japan and the EU,[130] on the one hand, and "the group of ten"[131] on the other hand, were not settled during the Preparatory Committee's meetings.[132] In the end, the text of Colombia and Switzerland was adopted as a basis for a future Ministerial Declaration conferring a mandate of the Uruguay Round Negotiations.[133]

This proposal extended the scope of the GATT negotiations to include trade-related aspects of intellectual property rights, including trade in counterfeit goods. However, this was conditional: only if measures undertaken in order to enforce IPR "do not themselves become a barrier to legitimate trade".[134] The fact that no basic consensus was reached regarding the scope of the issues that should be included in the mandate of the future Ministerial Conference had not affected the Preparatory Committee's report. TRIPS was included nonetheless.

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[128] Frank Emmert, "Intellectual Property in the Uruguay Round – Negotiating Strategies of the Western Industrialized Countries", (1989-1990) 11 Mich. J. Int'l L. 1317 at 1353-1354.
[129] *Ibid.,* at 1358-1359.
[130] The group of developed countries expanded later to the "group of forty", including industrialized, as well as twenty developing countries, chaired by Colombia and Switzerland. See T. N. Srinivasan, *Developing Countries and the Multilateral Trading System – from GATT to the Uruguay Round and the Future*, (Delhi: Oxford University Press, 1998) at 30-31 [Srinivasan].
[131] Led by Brazil and India.
[132] Srinivasan, *supra* note 130.
[133] Gervais, *supra* note 10 at 10-11.
[134] GATT, *Ministerial Declaration on the Uruguay Round*, MIN.DEC of 20 September 1986, online: GATT <http://gatt.stanford.edu/bin/object.pdf?91240152>. See also Gervais, *supra* note 10 at 10-11.

Was GATT the Right Forum to Raise IP Issues?

The question of GATT being the right forum for strengthening global IP protection was raised repeatedly during the GATT negotiations. This issue was raised again in the very beginning of the discussions of the Negotiation Group on Trade-Related Aspects of IP rights, including Trade in Counterfeit Goods (NG).[135] However, the NG was entitled to consider "the whole range of intellectual property protection rights", as opposed to specific aspects only.[136]

Several participants were of the opinion that the mandate given to the Negotiating Group by the Ministerial Declaration of Punta Del Este did not allow the extension of the discussions beyond the issues of trade in goods. Therefore, the NG had no authorization to deal with such issues as setting a higher level of IP protection or strengthening the enforcement procedures.[137] The advocates of the narrow approach claimed that the only aspects of IP protection that the NG was authorized to discuss, were the consequences of the IPR protection on trade in goods where they posed barriers to legitimate trade.[138] Some participants argued that connecting GATT's mandate to the relevant provisions of World Intellectual Property Organization (WIPO) treaties would be totally inappropriate. Moreover, it could lead to the wide-scale code approach to GATT, which was not a desired result in their view.[139]

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[135] During the meeting, numerous countries stated that the Negotiating Group (NG) should seek a proper balance between adequate IP protection and its effective enforcement on the one hand, and the risk that such protection would pose a barrier to international trade on the other hand. See WTO, *Meeting of the Negotiating Group* (held on 23 September 1987), WTO Doc. MTN.GNG/NG11/3 (8 October 1987), online: WTO <http://docsonline.wto.org> at 1.
[136] *Supra* note 23 at 2.
[137] *Ibid.*
[138] *Ibid.*
[139] *Ibid.* Being the only multinational agreement that set up international trade rules, GATT not only served as a code of rules but also allowed parties to negotiate on adding and improving such rules in order to reduce barriers to international trade. GATT also provided a broad exposure of various trade-related

Knowing the final results, *i.e.*, a broad scope of IP protection constituted in TRIPS, it could be argued that from the beginning, developing countries had no real choice but to succumb to the pressure of developed countries.[140] Therefore, the question whether the GATT forum was indeed the right forum to strengthen international IP standards is doomed to stay unresolved. The answer to this question will depend on the State's position in the international trade arena. Connecting the IP issues, which, under the WIPO Conventions, were akin to some abstract, intangible rights to trade, and turning them into a trade-related topic definitely serves the economic interests of developed countries (hosting most of the IPR owners). Even more so, given GATT's broad agenda, as well as its relatively effective enforcement and dispute resolution mechanisms, and the fact that its provisions oblige more than one hundred member states of the newly created WTO.[141]

This, however, was not the situation for developing countries. At least, not in the short-run. The WIPO Conventions had no intention of establishing some multilateral trade rules, but instead sought to lessen possible conflicts between the members as a result of different national IP regimes.[142] Such a policy allowed the countries as much freedom as possible (considering their weak enforcement system) to implement the IP laws as they saw fit, as long as these laws were based on national treatment and non-discrimination clauses.[143]

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aspects, therefore offering a possibility for package deals, i.e. making concessions in more developed areas of trade. See Emmert, *supra* note 128 at 1344-1345.

[140] *Supra* note 27 at 6.

[141] *Ibid.*

[142] *Ibid.*

[143] *Ibid.*

b. TRIPS Final Draft – Who Appeared to Win and What Was the Prize?

One of the arguments in favor of inclusion of the IP issues in the GATT agenda, even from the developing countries' point of view, was that the GATT negotiations' wide-scale agenda[144] provided numerous opportunities to retaliate and receive compensation for different concessions and renunciations made during the negotiations.[145] Potentially, bargains among developing and developed countries could have been made in various fields, where developing countries were able to compete, for example, in textiles and agriculture.[146]

In the end, Arthur Dunkel, then GATT Director-General, presented a final draft of TRIPS on December 1991.[147] It has been suggested that this text, which was by and large similar to the eventually adopted TRIPS, was much less a result of consensus on the disputed issues, but more of an attempt by the Director-General and the Secretariat to meet a deadline and to prevent a failure of the Uruguay Round, because of unresolved IP issues.[148] It seems, based on the previous analysis, that in the end, the TRIPS Agreement was designed and shaped by the group of developed countries led by the US. After all, their proposal, for the most part, was the basis for the final draft of TRIPS. The question is whether developing countries concluded a "worthy deal" by consenting to TRIPS.

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[144] With 14 negotiating groups in various fields of trade. Gervais, *supra* note 10 at 12.
[145] Robert E. Hudec, "GATT and the Developing Countries" (1992) Colum. Bus. L. Rev. 67 at 75.
[146] *Ibid.*
[147] Gervais, *supra* note 10 at 24.
[148] Sergio Escudero, "International Protection of Geographical Indications and Developing Countries", online: South Centre <http://www.southcentre.org/publications/geoindication/toc.htm#TopOfPage>; see also William O. Hennessy, ""Holy Spirits" – Part II", *IPFrontline.com* (22 February 2005), online: IPFrontline.com <http://www.ipfrontline.com/depts/article.asp?id=2160>; and also Chakravarthi Raghavan, "TRIPS – Dunkel's New Text Seen As More Partial to US" (7 April 1989), online: South-North Development Monitor <http://www.sunsonline.org/trade/areas/intellec/04070189.htm>.

What kind of balance had been achieved during such complicated and problematic negotiations?

The Deal of Developing Nations

In the 1990s, as a result of the debt-crisis created by constant borrowing, stagnated economies, the failure of inward-oriented economies, and the success of neighboring countries achieved by opening their markets to trade, some of the developing countries realized that this was a good time to abolish trade barriers and to adopt a market-oriented economic policy.[149] The way the final act of the Uruguay Round was constructed (as one package of obligations) and the way the final draft of TRIPS was presented (as a "take-it-or-leave-it" offer)[150] suggest at the very least that the bargain for developing countries shifted. For their concessions in the IP area,[151] they received a "one size for all" package, which they had a "choice" to adopt or to leave GATT.[152] All this package gave them was access to the developed countries' markets.[153]

All in all, it could be concluded that neither developed nor developing countries would have signed TRIPS as it appears in its final version, had it been the only agreement in the Uruguay Round.[154]

Succinctly, the fundamental differences regarding the issue of the scope and availability of IP protection were not settled. The question whether GATT was indeed the

[149] Srinivasan, *supra* note 130 at 35-36. See also *supra* note 145 at 74.
[150] Hennessy, *supra* note 148.
[151] Such as accepting the fact that the IP issues were negotiated and that the broad scope of IP protection was incorporated into the agreement.
[152] *Supra* note 145 at 76.
[153] Laurence R. Helfer, "Regime Shifting: the TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking" (2004) 29:1 Yale J. Int'l L. 1 at 3.
[154] Sergio Escudero *et al., supra* note 148.

right forum to raise international IP standards remained unresolved.[155] The balance between the interests of developed nations and developing ones was shifted in TRIPS to the side of developed nations. Despite strong opposition from the developing world, TRIPS does provide the broadest possible scope of IPR protection.

c. TRIPS Under a Magnifying Glass: New Aspects of Patent Protection

Despite the described complications and weird circumstances surrounding its creation, the TRIPS Agreement is considered to be the most comprehensive multilateral agreement on intellectual property.[156] Substantively, TRIPS determines seven main areas of the IPR: copyright and related rights, trademarks, geographical indications, industrial designs, patents and layout-designs (topographies) of integrated circuits and protection of undisclosed information (trade secrets).

This analysis will be concentrated mainly on patent protection in general and on pharmaceutical patents' protection specifically. However, the scope of the obligations and basic principles of TRIPS will be discussed briefly as well, because of its importance to a general understanding of the new principles conferred by TRIPS.

TRIPS is based on four main WIPO Conventions: the Paris Convention, the Berne Convention, the Rome Convention, and the Treaty on International Property in Respect of Integrated Circuits. Moreover, member-states are required to comply with specific obligations under the Paris Convention determining the scope and substantive provisions

[155] This question was actually answered by action: TRIPS became a part of the WTO Agreement and the international level of IP protection was raised in the Uruguay Round. However, the differences between developed and developing nations were definitely not settled.
[156] WTO, *Overview: the TRIPS Agreement*, online: WTO <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm>.

of patent protection.[157] Contrary to the Paris Convention, which had not established minimum standards of patent protection,[158] TRIPS determined that members are obliged to adopt the standards required by the Agreement. However, they may apply more extensive protection in their national laws.[159] In this way, TRIPS engages all WTO member-countries, even those who were not parties to the Paris Convention, into the basic IP framework.[160]

Additionally, in Art. 3.1, TRIPS preserves a national treatment clause, which also exists in the Paris and Berne Conventions. According to the national treatment clause in TRIPS, which is related to persons (owners of IP rights), member-states are required to not discriminate against the nationals of other member-states and to grant them no less favorable IP protection than their own nationals.[161]

Another important "innovation" introduced in Article 4 of TRIPS is a most-favored-nation (MFN) clause. According to the MFN clause, nationals of every member-state shall be granted the same level of IP protection. The MFN clause was not included in the WIPO Conventions, because presumably the national treatment clause was enough to ensure that member-states would not grant other nationals less favorable treatment than that granted to their own nationals.[162] The MFN clause in TRIPS attempts to create

[157] *Trade-Related Aspects of Intellectual Property Agreement*, 15 April 1994, online: WTO <http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm> Art. 1-2 [TRIPS], and *Paris Convention for the Protection of Industrial Property*, 20 March 1883, online: WIPO <http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P71_4054> Art. 1-12, 19 [Paris Convention].
[158] Paris Convention, *ibid*., at part 1.2 at 19.
[159] TRIPS, art. 1.1. See also Pedro Roffe *et al*., "Resource Book on TRIPS and Development: an Authoritative and Practical Guide to the TRIPS Agreement", *INCTAD-ICTSD Capacity – Building Project on IPRs*, online: IPRsonline.org <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm> at 24 [Roffe et al.].
[160] Gervais, *supra* note 10 at 94-95.
[161] Roffe *et al.*, *supra* note 159 at part 1.4 at 62.
[162] *Ibid.,* at part 1.4 at 63.

consistency with existing regional agreements.[163] This was achieved by exempting advantages, privileges or immunities that had been in existence according to international agreements, provisions of the Berne Convention, the Rome Convention, and others.[164]

Patent Section of TRIPS

The patent section of TRIPS[165] is considered to be a great success for the US. It defines the availability and scope of the international level of patent protection in the broadest manner possible, instead of referring that task to the national laws of members, as it was under the Paris Convention.[166] Article 27.1 of TRIPS determines that patents shall be available for products and processes with no discrimination as to the field of technology, place of invention and the place of production (whether the product is imported or produced locally).[167] This article has a special impact on the pharmaceutical industry. While in the "pre-TRIPS" era numerous countries (mostly developing and least-developed ones) did not provide patent protection for pharmaceuticals, this would no longer be possible with the full implementation of TRIPS.[168] [169]

According to Art. 27.1 of TRIPS, the inventions are to be new, involve an inventive step, and be non-obvious. Articles 27.2 and 27.3 of TRIPS determine exceptions from patentability when commercial exploitation of an invention (but not the invention itself) may endanger *ordre public* or morality and where the exception is

[163] *Ibid.*, at part 1.4 at 63-64.
[164] TRIPS, *supra* note 157 at Art. 4. See also *ibid.*
[165] TRIPS, *supra* note 157 at s. 5 at art. 27–34.
[166] Gervais, *supra* note 10 at 220.
[167] Roffe *et al*., *supra* note 159 at part 2.17 at 356.
[168] Transitional periods allow least-developed countries, for example, to implement TRIPS only in 2016. See TRIPS, *supra* note 157, Art. 66, 65(4). Also see WTO, News Release, "Council Approves LDC Decision with Additional Waiver", (28 June 2002), online: WTO <http://www.wto.org/english/news_e/pres02_e/pr301_e.htm#texts_decisions>.
[169] *Supra* note 2 at 2-3. See also Roffe *et al*., *supra* note 159 at part 2.17 at 356.

needed to protect human, animal or plant life, health or environment.[170] While Art. 27.2 apparently relates to inventions in general, Art. 27.3 determines special groups of inventions that might be excluded from the patent protection.[171]

In its Art. 28, TRIPS provides a definition of the exclusive rights that patents confer.[172] Another important "innovation" introduced in Article 33 of TRIPS is a minimum term of patent protection: twenty years from a filing date.[173]

Given all the new features introduced in TRIPS, the agreement did indeed create a relatively clear and definitely more effective mechanism, at least regarding patent protection, which constitutes the Agreement as the "most important multilateral instrument in the field".[174]

d. Problems with the Implementation of TRIPS - Access to Existing Drugs and the Public Health Controversy

Given the controversial negotiations of TRIPS and the broad scope of IP protection the Agreement provides, it was not expected to operate smoothly.[175] However, one area of TRIPS has caused especially deep and painstaking discrepancies. This,

[170] Gervais, *supra* note 10 at 222.
[171] Again, countries are free to determine whether they want to exclude these inventions or not. See Gervais, *ibid.*
[172] The exclusive rights being: the right to prevent a third party from making, using, offering for sale, selling, and importing the patented product or process. See TRIPS, *supra* note 157 at art. 28.
[173] The developed countries, especially the US, were interested in prolonging the patent protection period for the products requiring governmental approval (for example, the relatively long period that is needed to approve drugs for marketing, is counted into the patent term, although the exclusive rights cannot be exercised during this period without official governmental approval). However, the developed countries' position was not adopted in this case. See Roffe *et al*., *supra* note 159 at part 2.22 at 424.
[174] Gervais, *supra* note 10 at 220.
[175] Joseph Straus, "Bargaining Around the TRIPS Agreement: the Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions – a Comment on the Paper Presented by Professors David Lange, Duke University, and J.H. Reichman, Vanderblit University" (1998-1999) 9 Duke J. Comp. & Int'l L 91 at 95.

despite the fact that it was one of the very issues that initiated the revision of the US IP policy, which led to TRIPS' creation. This area is patented pharmaceuticals.

Patents are one of the most significant factors responsible for the rising costs of medicines, particularly when compared to the costs of generic drugs[176] manufactured under competition.[177] In some cases, for example, in cases of life-saving drugs for pandemics such as AIDS, tuberculosis or malaria, patent protection can limit access to drugs by making them unaffordable. This is primarily a consequence of monopoly pricing. Competition could possibly engender affordability.[178]

By strengthening the international level of patent protection, TRIPS has inevitably had a significant impact on access to life-saving pharmaceuticals in developing countries.[179] Especially on poor countries that have no pharmaceutical manufacturing capacities and are afflicted with pandemics. Also, on countries that were until now dependent on the importation of life-saving drugs in low prices from countries that provided no patent protection for pharmaceuticals.[180] In other words, TRIPS intensified the problem of access to essential medicines in affordable prices in the developing world.

[176] Which are "identical, or bio-equivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." US Food and Drug Administration, Center for Drug Evaluation and Research, "Organizational Components: What Are Generic Drugs?" online: CDER <http://www.fda.gov/cder/ogd/#Introduction>.
[177] *Supra* note 77.
[178] All based on "Access to Medicines: Understanding Patents on Pharmaceuticals", online: Center for Innovation and Policy <http://www.innovationlaw.org/English/Access-to-Medecines.html>.
[179] *Supra* note 77.
[180] *Ibid.*

Global Public Health Problems

Approximately three million people died from HIV/AIDS in 2001; 2.3 million of these deaths occurred in Sub-Saharan Africa.[181] Nearly 1.7 million people worldwide died from tuberculosis in the same year, and there should have been as many as 10.2 million new cases in 2005.[182]

It is common knowledge that most of these deaths are preventable, that the life-saving drugs do exist, and that the problem is inaccessibility of these drugs primarily for patients in poor countries afflicted with the diseases. In the Uruguay Round, developing countries were concerned that raising international IP standards, particularly, strengthening patent protection for pharmaceuticals, would decrease access to much needed medicines.[183]

Developed countries, for their part, argued time and again that only effective patent protection would create the incentives necessary for costly investments in R&D needed to create innovative effective drugs.[184] However, the findings of the study conducted on the connection between pharmaceutical innovations and the burden of diseases in developed and developing countries showed that pharmaceutical companies have no viable incentives (or, at best, very weak incentives) to develop drugs for infectious diseases afflicting developing countries, because of a lack of potential profits

[181] *Supra* note 111 at 1.
[182] *Ibid.*
[183] *Ibid.,* at 29.
[184] Henry Grabowski, "Patents and New Product Development in the Pharmaceutical and Biotechnology Industries" (July 2002), online: Duke University <http://www.econ.duke.edu/Papers/Other/Grabowski/Patents.pdf> at 4. See also C. Correa, "TRIPS and R&D Incentives in the Pharmaceutical Sector" (November 2001) *Commission on Macroeconomics and Health*, Working Paper Series, Paper No. WG2: 11 at 5-6, online: WHO <http://www3.who.int/whosis/cmh/cmh_papers/e/pdf/wg2_paper11.pdf>.

and remuneration for such investments.[185] Potential clients in developing countries simply cannot afford to pay for these products.

Partly as compensation for the concessions made by developing countries in the Uruguay Round negotiations, partly in response to developing countries' (especially South Africa's) efforts to find ways to alleviate access to HIV/AIDS drugs,[186] TRIPS addresses the problem of inaccessibility of essential drugs by offering a few mechanisms of exception from patent protection.

e. Exceptions from Patentability and Patent Protection Under TRIPS and Problems with the Implementation of Article 31.

General Exception from Patent Protection[187]

Another type of exception provided in Art. 30-31 of TRIPS is the exception from patent protection. Article 30 allows member-countries to provide limited exceptions to exclusive rights conferred by patent. There are two key conditions: 1) it should not unreasonably conflict with a normal exploitation of the patent; 2) the exception should not unreasonably prejudice legitimate interests of the patent owner, considering interests of third parties. Unlike Article 31 that provides specific conditions for the use of a

[185]Frank R. Lichtenberg, "Pharmaceutical Innovation and the Burden of Disease in Developing and Developed Countries" (2004), *Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)* Study Summaries, online: CIPIH <http://www.who.int/intellectualproperty/studies/StudySummaries.pdf>.

[186] *Supra* note 44 at 209.

[187] In addition to the general exception from patent protection, TRIPS provides also several exceptions from patentability. For example, Article 27(2) of TRIPS allows countries to exclude from patentability inventions whose commercial exploitation could harm *ordre public* or morality. Additionally, members may, pending implementation in the national law, refuse to grant a patent in order to protect human, animal or plant life or health, or to avoid serious prejudice to the environment. See Roffe *et al.*, *supra* note 159 at 2.19 at 375. These exceptions cover the way inventions are applied, and not the products and processes themselves. See Roffe *et al.*, *supra* note 159 at part 2.20 at 384.

patented invention without the right holder's authorization,[188] Article 30 provides a general exception rule.[189]

Given the restrictions of Article 31[190], Article 30 could theoretically be granted a broad interpretation. This article could be interpreted as generally authorizing the issuance of a license to manufacture drugs for export to another country where the same drug is patented and that issued a compulsory license for the import of this drug under Article 31. In fact, there were several attempts to use such a broad interpretation of Article 30 as an alternative mechanism for the grant of a compulsory license to export generic versions of patented drugs.[191]

The scope of Article 30 was interpreted narrowly in the WTO's panel decision in EU – Canada case.[192] In this case, the EU challenged some sections of the *Canadian Patent Act*[193] that permitted the manufacture and stockpile of patented drugs without the consent of a patent holder six months prior to expiration of a twenty-year patent term.[194] It has been ruled that Article 30's general exception provision did not overweigh the patent owner's exclusive rights which allow him to prevent all kinds of competition that

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[188] Otherwise called "compulsory license mechanism".
[189] Article 31 determines conditions for "other use" of an invention unauthorized by a patent holder, while the footnote of the article defines "other use" as "other than that allowed under Article 30". Gervais, *supra* note 10 at 241-242.
[190] Article 31(f) limits the use of a patented invention under a compulsory license "predominantly for the supply of the domestic market" of the country issuing the license. Therefore, while the importation of a patented invention produced under compulsory license is permitted under Art. 28, as it is certainly considered a "use" of patent, TRIPS prohibits the export of such an invention. Gervais, *supra* note 10 at 242.
[191] Thomas A. Haag, "TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?" (2002), 84 J. Pat. & Trademark Off. Soc'y 945 at 952-953.
[192] WTO, *Canada – Patent Protection of Pharmaceutical Products: Complaint by European Communities and their member States*, WTO Doc. WT/DS114R (17 March 2000), online: WTO <http://docsonline.wto.org> [Canada case]. See also *Ibid*., at 965-966.
[193] *Patent Act*, R.S.C. 1985, c. P-4.
[194] Canada case, *supra* note 192 at 7.

could significantly endanger his economic remunerations from the exploitation of his patented invention.[195]

General Principles of TRIPS as a Policy Statement

A possible way to interpret TRIPS so that it would allow the export of generic versions of patented drugs under compulsory license is to apply a general interpretation of the principles and objectives of TRIPS embodied in Articles 7 and 8. Article 7 determines that IP rights should contribute to the promotion of technological innovation and to the technology transfer "to the mutual advantage of producers and users" and "in a manner conducive to social and economic welfare, and to a balance of rights and obligations".[196] Additionally, Article 8 enables, but does not oblige, members implementing TRIPS to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development",[197] if such measures are consistent with TRIPS.[198] It has been suggested that in some cases involving the supply of life-saving drugs to people in need, the public interest prevails on the interest in preserving a monopoly to reward and incentivize inventors. Therefore, this could be the way to reach the balance mentioned in Art. 7.[199]

[195] Gervais, *supra* note 10 at 243.
[196] TRIPS, *supra* note 157, art. 7.
[197] TRIPS, *supra* note 157, art. 8.
[198] It has been argued that these two provisions reflected the strain between developing and developed countries during the GATT negotiations. Developing countries argued time and again that TRIPS reflects only interests of developed nations in regard to raising standards of IP protection, while the interests of developing countries in promoting technology transfer and development were ignored. See Roffe *et al.*, s*upra* note 159 at part 1.20 at 119.
[199] Gervais, *supra* note 10 at 119.

The same public interest could suffer if, as a result of the exclusion from patent protection, the patent as a form of incentive for investments in R&D would be rendered ineffective. Less new technologies would become a part of public domain; therefore the promotion of innovations and a transfer of technologies could be delayed.[200]

In Par. 19 of the General Doha Declaration, Articles 7-8 of TRIPS had been granted a special status: the TRIPS Council was to be guided in its Work Program by the objectives and principles determined in these articles. Moreover, it had been pointed out that the development dimension should be taken into consideration.[201] Therefore, it has been argued that Articles 7-8 could be used as a basis for interpretation of different TRIPS provisions, such as Art. 30-31.[202]

Although these two articles have been granted the status of general guidelines of interpretation for TRIPS, it should be stated that any interpretation conferred by these articles should be confined within the TRIPS boundaries. In other words, the effect of these articles is limited. Article 7 states: "the protection and enforcement of intellectual property rights should contribute … ". One possible interpretation is that such a protection will not guarantee the desired results, *i.e.*, the promotion of technological innovation and technology transfer, but will only lead toward these results.[203] Furthermore, Art. 8 requires that the measures undertaken for the protection of public health and nutrition, the promotion of the public interest, and the prevention of the abuse of IP rights by right holders should be consistent with the Agreement. This means that

[200] *Ibid.,* at 119-120.
[201] WTO, *Ministerial Declaration on 14 November 2001*, WTO Doc. WT/MIN(01)/DEC/1, 4th Sess., online: WTO <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm#trips>. See also Gervais, *ibid.,* at 120.
[202] Gervais, *ibid.*
[203] Roffe *et al.*, s*upra* note 159 at part 1.20 at 126.

Art. 8 restrains the discretion of the member-countries to adopt the measures they consider necessary for the protection of public health in that these measures will not violate the TRIPS provisions.[204]

The limitations of Articles 7-8 in relation to the interpretation of Art. 30 of TRIPS were also acknowledged in the WTO panel's decision in the EU-Canada case. It has been stated that Articles 7-8 should not serve as a basis for the "renegotiation of the basic balance of the Agreement".[205]

Compulsory License Provision - Article 31

While all types of exceptions described above were used in different circumstances to justify the export of generic versions of patented drugs to developing countries in need, the most effective, and at the same time, controversial provision in this regard seems to be Article 31 of TRIPS.

Article 31 provides a specifically designed mechanism that has been applied particularly to the import of patented pharmaceuticals and which is named a "compulsory license" mechanism.[206] This mechanism allows a government or a governmental agency to grant a license to exploit a patented invention without patent holder's authorization.[207] It has been argued that the compulsory license mechanism is often used to limit monopoly powers of right owners when these powers are exercised against the public interest.[208] Going back to Article 8 allowing members to adopt measures necessary to

[204] Roffe *et al.*, s*upra* note 159 at part 1.20 at 126-127.
[205] *Ibid.*, at part 1.20 at 128-129. See also Canada case, *supra* note 192.
[206] Rosalyn S. Park, "The International Drug Industry: What Future Holds for South Africa's HIV/AIDS Patients" (2002) 11 Minn. J. Global Trade 125 at 131-132.
[207] Adi Gillat, "Compulsory Licensing to Regulated Licensing: Effects on Conflict Between Innovation and Access in the Pharmaceutical Industry" (2003) 58 Food Drug L. J. 711 at 712.
[208] Roffe *et al.*, *supra* note 159 at part 2.25 at 461.

protect public health and promote public interests in vitally important sectors, some argue that this article provides a general umbrella for using a compulsory license mechanism for the protection of public health.[209] Therefore, Article 31 also may be used to allow the manufacturing of generic versions of patented drugs in a public health crisis.

Similarly to Article 30's general definition, Article 31(a) establishes no specific grounds for issuing a compulsory license, leaving it to the members to decide in which circumstances the license will be granted.[210] However, it would be safe to state that this single similarity ends a list of resemblances between the two articles.

The distinctions between the provisions are obvious. Although Article 30 tends to broaden the scope of permissible exceptions by adding that "legitimate interests of third parties" should be considered, it is clear from Article 31 that the grant of a compulsory license should be restricted to the conditions defined in this article.[211] This distinction between the two Articles is designed to specify rules for granting a compulsory license under Article 31 (e.g. for a specific patent, to a specific company). This is instead of incorporating this mechanism in a more general frame such as legislation or an amendment, which could evolve from Art. 30.[212]

A paradoxically restrictive approach of Article 31 to licensing conditions, given the fact that the article is intended to provide flexibilities, can be seen in almost each and every sub-section of the article. I will examine only certain restrictions related to the topic. This article reflects a desperate attempt to balance the need for flexibilities in TRIPS to allow developing and least-developed countries to adjust to the new, stronger

[209] *Supra* note 206 at 132.
[210] Roffe *et al.*, *supra* note 159 at 462.
[211] According to Art. 31's footnote, "other use" refers to use other than that allowed under Article 30.
[212] Roffe *et al.*, *supra* note 159 at part 2.25 at 462.

standards of IP protection with the desire of developed nations to prevent infringements of patents.

Article 31(b) obliges a future licensee to attempt to obtain a voluntary license from the patent holder on reasonable commercial terms and conditions. Generic drug manufacturers and developing countries argued that this obligation could be an obstacle in acquiring a compulsory license.[213] A compulsory license, therefore, can be granted only when a future user failed to obtain such an authorization from the right's owner "within a reasonable period of time".[214]

Full of ambiguities,[215] this provision can possibly neutralize the essence of the exception. A patent holder having exclusive rights to sell, distribute and use his invention, while bargaining conditions of a license, would probably ensure the highest possible compensation.[216] This compensation would still constitute a "reasonable commercial term",[217] given the fact that huge investments were made by the patent owner to obtain a patent, which a licensee is asking to exploit.

Importantly, Article 31(b) offers a waiver of this requirement in cases of national emergency or other circumstances of extreme urgency or in cases of public non-

[213] This was an approach of civil society organizations, such as Medecins Sans Frontieres, the Canadian HIV/AIDS Legal Network, *etc.*, during the debates on Canada's Bill C-9 that implemented TRIPS' compulsory license mechanism in *Canada's Patent Act*, including Article 31(b) provision. See Canadian HIV/AIDS Legal Network, "Global Access to Medicines: Will Canada Meet the Challenge?" *Submission to the Standing Committee on Industry, Science and Technology Regarding Bill C-9, An Act to Amend the Patent Act and the Food and Drug Act* (26 February 2004), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/SCIST%20Submission_Feb2604.PDF>.
[214] TRIPS, *supra* note 157, Art. 31(b).
[215] Such as "reasonable commercial terms", "reasonable period of time", *etc.* Roffe et al., *supra* note 159 at part 2.25 at 469.
[216] Theodore C. Bailey, "Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs" (2001) J.L. Tech. & Pol'y 193 at 202.
[217] TRIPS, *supra* note 157, Art. 31(b).

commercial use.[218] It seems that Art. 31(b) explicitly authorizes the grant of compulsory license in case of public health crisis, and furthermore, leaves it up to each country to decide what constitutes this condition, because the article does not provide any definition of the term.[219]

Article 31(h) requires that adequate remuneration be paid to the right holder. However, the requirement is relatively flexible because it does not define a formula for calculation of remuneration to be paid, but allows considering "the circumstances of each case".[220] Although Article 31(h) requires "taking into account the economic value of the authorization" it does not oblige an issuing authority to establish a rate of compensation for this value.[221]

The main problem for developing countries wishing to grant a compulsory license to import generic versions of patented drugs results from Art. 31(f).[222] Article 31(f) authorizes the use of a compulsory license predominantly for the supply of the domestic market of the authorizing member.[223] The language of Art. 31(f) theoretically seems to allow the use of a compulsory license for export in some cases, because the provision states that the use should be "predominantly", and not exclusively, for the domestic market's supply. However, this provision was interpreted as prohibiting the export under a compulsory license if such export constitutes the main use of the compulsory license.[224] In other words, the export under a compulsory license is allowed as a marginal

[218] In each case, the right holder shall be notified, but prior negotiation is not required. Gervais, *supra* note 10 at 250-251.
[219] *Ibid.,* at 251.
[220] Roffe *et al.*, *supra* note 159 at part 2.25 at 475.
[221] *Ibid.*
[222] This article was one of the primary causes for the adoption of a separate Doha Declaration on TRIPS and Public Health. See *supra* note 4.
[223] The only case where Members are not obliged to abide by Article 31(f) is where a compulsory license is granted as a remedy to anti-competitive practice. See TRIPS, *supra* note 157, Art. 31(k).
[224] Gervais, *supra* note 10 at 252.

component in the production intended for the domestic market. The language of the provision suggests that a government may not authorize the export of products under a compulsory license unless the license provides that more than fifty percent of the product will be produced for the domestic market.[225] Therefore, it has been agreed that Art. 31(f) will have a major impact on countries unable to produce medicines locally and wanting to import generic versions of patented drugs to cope with public health crises. Such countries will have difficulties finding an exporting country that will be able to supply them with drugs produced under a compulsory license.[226]

This provision, therefore, renders some developing countries with insufficient manufacturing capacities in the pharmaceutical field incapable of using the proposed mechanism without infringing TRIPS. Paragraph 6 of the Doha Declaration on TRIPS and Public Health instructed the TRIPS Council to find an expeditious solution to this problem *(hereinafter: "Par. 6 problem")*.

As stated earlier, in the pre-TRIPS period, countries were not obliged to provide patent protection for pharmaceuticals. They could export generic drugs at lower prices as long as the drugs were not patented in the importing country or, in case the product was patented there, a compulsory license was issued.[227] After TRIPS is implemented, this option will no longer be possible.[228] Therefore, countries that possess pharmaceutical

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[225] Roffe *et al.*, *supra* note 159 at 474.
[226] WTO, "Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions", online: WTO <http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#parallelimports>.
[227] Carlos Correa, "Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", University of Buenos Aires, Essential Drugs and Medicines Policy, WHO/EDM/PAR/2004.4 (April 2004), online: WHO <http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf> at 1.
[228] Considering the transitional periods, TRIPS will not be implemented in least-developed countries, for example, till 2016. Developing countries were given a five-year extension in the implementation of TRIPS. Developing countries that did not provide patent protection in some areas of technology beforehand were

manufacturing capacity and that can produce generic drugs locally will not be able to export the drugs because of the Article 31(f) restriction. On the other hand, countries lacking manufacturing capacities that could grant a compulsory license to import a needed generic drug would not be able to find an exporting country.[229]

Conclusions:

By strengthening the international level of IP protection, TRIPS intensified the existing problem of access to essential medicines at affordable prices in developing countries. The Agreement defines the broadest scope of patent protection.

Patent protection is considered to be one of the primary causes of high prices of pharmaceuticals and therefore, it hinders access to patented life-saving medicines in poor countries whose populations are mostly afflicted with pandemics and cannot afford the drugs. On the other hand, patent protection is one of the most important incentives for investments in R& D to create innovative and effective medicines.

TRIPS provides a few mechanisms of exception from patent protection along with two policy-making articles[230] that can possibly be construed as policy guidelines allowing to relate to public health problems and to interpret TRIPS accordingly.

Article 31(f) prevents developing countries with no sufficient manufacturing capacity from using a compulsory license clause by requiring that the use be predominantly for domestic market supply.

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allowed to delay the implementation of the TRIPS' patent section for ten years after signing the agreement. See TRIPS, *supra* note 157, Art. 66, 65(4), and also *supra* note 168.

[229] *Supra* note 227 at 1-2.

[230] TRIPS, *supra* note 157, art. 7-8.

Chapter Four: Doha Ministerial Declaration and the WTO General Council's Decision of 30 August 2003

The implementation of the WTO Agreements was the key issue at the Doha Ministerial Conference.[231] Problems from the TRIPS flexibilities, especially the anticipated inability to use a compulsory license clause under Article 31, brought some developing countries[232] to request that TRIPS requirements be clarified at the Doha Ministerial Conference. Additionally, Par. 17 of the Doha General Declaration stated that it is important to implement and interpret TRIPS "in a manner supportive of public health, by promoting both access to existing medicines" and R&D of new medicines.[233]

Badly affected by the HIV/AIDS pandemic,[234] South Africa was one of the main initiators of consultations on the authoritative interpretation of TRIPS in order to find a solution to the public health controversy.[235] This led to adoption of the separate Declaration on TRIPS and Public Health (Doha Declaration).[236] In its Par. 5, the Doha Declaration provided members with reasonably detailed instructions as to how to interpret the flexibilities provided in TRIPS.[237]

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[231] *Supra* note 5.
[232] Specifically, the African Group, which consisted of all the African Members of the WTO. See *supra* note 226.
[233] Doha Ministerial Declaration, *supra* note 201.
[234] 19.94% of the 21 million adults in South Africa suffer from the disease. *Supra* note 216 at 195-196.
[235] Kenneth C. Shadlen, "Patents and Pills, Power and Procedure: The North-South Politics of Public Health in the WTO" (2004) 39:3 Studies in Comparative International Development 76 at 78.
[236] *Supra* note 4.
[237] For example, according to the Declaration, each Member is entitled to determine the suitable grounds for granting compulsory licenses (Par. 5(b)); each Member can state what constitutes a case of national emergency, while pandemics (AIDS, tuberculosis, and malaria) are automatically proclaimed "national emergency or other circumstances of extreme urgency" (Par. 5(c)). Developed countries were made responsible for promoting and encouraging technology transfer to least-developed countries and the decision to grant the latter an additional extension period for complying with the patent section of TRIPS until 1 January 2016 was reaffirmed (Par. 7). *Ibid.*

In Paragraph 1, the Doha Declaration recognized the gravity of the public health problems afflicting many developing and least-developed countries. AIDS, tuberculosis, and malaria were named as particular examples of public health problems and were automatically considered as "national emergency or other circumstances of extreme urgency".[238] Also, in Par. 3, the Doha Declaration recognized how important IP protection was for the development of new drugs. The Declaration also emphasized that TRIPS should not prevent the members from acting to protect public health and particularly promote access to medicines for all.[239]

a. Paragraph 6 of the Doha Declaration on TRIPS and Public Health

One of the unresolved questions left to the TRIPS Council was how to make the mechanism of compulsory license feasible for developing countries with no sufficient manufacturing capacities in the pharmaceutical field? ("Paragraph 6 Problem")

The Doha Declaration stated clearly that Article 31(f) of TRIPS prevents some developing countries from using compulsory licensing to alleviate public health crisis.[240] Paragraph 6 gave a mandate to find the solution to the inability of some countries to use TRIPS flexibilities. It has been argued that Paragraph 6 was meant only to level countries with insufficient manufacturing capacity that cannot use a compulsory license mechanism

[238] *Ibid.*, at Paragraphs 1, 5(c). See also R. Elliott, "TRIPS from Doha to Cancun… to Ottawa: Global Developments in Access to Treatment and Canada's Bill C-56" (2003) 8:3 Canadian HIV/AIDS Policy & Law Review 1 at 2.
[239] *Supra* note 4 at Par. 4. Also see *supra* note 226.
[240] *Supra* note 191 at 951-952.

with countries that can use it.[241] The argument is that all Paragraph 6 really does is diminish the results of the disadvantage that the developing countries with insufficient manufacturing capacities in pharmaceutical field have experienced because of Art. 31.[242]

Of course, for developing countries, the Doha Declaration and its interpretation of TRIPS constituted a great and promising success. There appeared to be a chance to shift the TRIPS unbalanced (from the developing countries' point of view) mechanisms to their side and to permit the export of patented drugs at lower prices in times of public health emergencies.[243]

b. WTO General Council's Decision of 30August 2003

Following the instructions of the Doha Declaration, TRIPS Council commenced its work in regard to finding a solution to the Paragraph 6 Problem prior to the end of 2002.[244] During the TRIPS Council's meetings, representatives of numerous developing and least-developed countries,[245] as well as representatives of some developed countries[246] and a representative of the WHO, had the opportunity to present their positions.[247]

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[241] Amir Attaran, "Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and Non-justiciability Solution" (2003) 17 Emory Int'l L. Rev. 743 at 745.
[242] *Ibid.*
[243] *Supra* note 191 at 952.
[244] *Ibid.*
[245] Such as Kenya, Zimbabwe, India, Brazil, Sri Lanka, Pakistan, Malaysia, Indonesia, China, Argentina, Peru, and others.
[246] Such as the US, the EU, Japan, Canada, Switzerland, and Norway.
[247] The proposals were from the following countries or groups of countries: the African group (the proposal of Kenya on behalf of the African group), the EU, the United Arab Emirates, the Group of Developing Countries, and the US. See WTO, General Council, *Minutes of Meeting* (held on 5-7 March 2002), WTO Doc. IP/C/M/35, online: WTO <http://docsonline.wto.org>.

By mid-June 2002, the Secretariat of TRIPS Council received five Communications on the Paragraph 6 Problem.[248]

The US Proposal

The US proposal suggested the narrowest possible interpretation of TRIPS provisions, *i.e.,* to limit a solution of the Paragraph 6 Problem only to pharmaceuticals needed to treat pandemics referred to in the Doha Declaration: AIDS, tuberculosis, and malaria. Additionally, the US insisted on informing the patent holder if a country applied for the use of a patented product under compulsory license. Such disclosure would allow the patent holder to offer the product at lower prices. The US asked to provide strict safeguard mechanisms to ensure that compulsory licensing would not be used for re-selling and re-distributing exported products.[249]

There were four suggestions as to the possible legal solution for making a compulsory license mechanism under TRIPS workable: 1) either by broad interpretation of Art. 30 that would authorize the export of patented products under compulsory license, or 2) an amendment of Article 31 in order to authorize such use of the mechanism, or 3) waiver of Article 31(f) requirements, or 4) by a dispute settlement moratorium to determine non-compliance with Article 31(f).[250] Out of these solutions, the US proposed either a moratorium for dispute settlement or a waiver of obligations under Article 31(f).[251]

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[248] WTO, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation*, (11 July 2002), WTO Doc. IP/C/W/363 online: WTO <http://docsonline.wto.org>.
[249] All based on WTO, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Communication from the United States* (14 March 2002), WTO Doc. IP/C/W/340 online: WTO <http://docsonline.wto.org>. Also see *Proposals on Paragraph 6 of the Doha Declaration, ibid.*
[250] *Supra* note 191 at 953-954.
[251] *Supra* note 248 at 17.

The Proposals of the African Group and the Group of Developing Countries

The proposals of the African Group and the Group of Developing Countries[252] suggested the broadest possible interpretation of TRIPS as a solution to the Paragraph 6 Problem. Developing countries claimed that pharmaceuticals exported under a compulsory license mechanism should not be limited to the drugs for treatment of the specific conditions mentioned in the Doha Declaration. Instead, they should also include related technical equipment and processes.[253] The importing countries' list should not be limited either. Every country that needs to address a public health crisis shall be able to use the mechanism.[254] The African Group and the Group of Developing Countries also proposed that safeguards against abuses of patent protection will not be burdensome, costly, and complicated, and will not limit the flexibilities of TRIPS.[255]

As to the legal solutions for the Paragraph 6 Problem, the proposal of the African Group was different from the proposal of the Group of Developing Countries. The African Group proposed either to revise all provisions of Article 31 or to remove or neutralize the Article 31(f) provision, and to apply the remaining provisions of Article 31 as they were.[256] The Group of Developing Countries proposed to interpret Art. 30 in a way that would authorize the export of generic versions of patented products under a compulsory license.[257]

[252] Brazil on behalf of the delegations of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand, and Venezuela.
[253] *Supra* note 248 at 4.
[254] *Ibid*., at 5.
[255] *Ibid*., at 9.
[256] *Ibid*., at 13.
[257] *Ibid*.

The EU Proposal

The EU proposal was a mediating one between the proposal of the US and those of the African and the Developing Countries' groups. At the beginning of its Communication, the EU stated:

> "… Even when manufactured under a compulsory license, medicines may still be unaffordable for certain segments of the population in poor countries. After all, production of medicines, even by a manufacturer other than the patent holder, always has a cost, and manufacturers have to make a reasonable return on investment if they are to stay in business. Second, any solution that emerges from the discussions in the TRIPS Council will never be a panacea for the problem of access to medicines. It is widely agreed that improving such access requires a mix of complementary measures in different areas. These measures include: public financing of drugs purchases; strengthened health care systems, including the infrastructure for distributing drugs and monitoring their usage; improved information and education; and increased research and development."[258]

The EU suggested that the scope of patented products available for issuing compulsory licenses would not be limited solely to the drugs referred to in the Doha Declaration. Instead, the requirement should be that these pharmaceutical products (including those produced through patented processes) be connected to the public health crises afflicting numerous developing and least-developed countries.[259]

Contrary to the US position, the EU was willing to admit that in some cases the product for which a compulsory license was needed could be not patented in the country that requested a license and still be subject to a compulsory license.[260] Also, the EU held a more flexible opinion as to the safeguards. While recognizing the necessity of such

[258] WTO, *Concept paper relating to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* WTO Doc. IP/C/W/339 (4 March 2002) at 1-2, online: WTO <http://docsonline.wto.org>.
[259] *Supra* note 248 at 4.
[260] *Ibid.*, at 6.

safeguards, the EU added that their complexity should be reasonable.[261] As to the legal solution, the EU proposed to eliminate Article 31(f) and to simply apply the remaining provisions of Article 31.[262]

The Adopted Solution

Unfortunately, the decision adopted by the TRIPS Council was far from balanced. Of the four solutions,[263] the TRIPS Council adopted an interim waiver of obligations under Article 31(f), pending an amendment of TRIPS within the first half of 2004.[264]

The decision does attempt to fully incorporate the position of the developing countries. According to the decision, the definition of pharmaceutical products eligible for export under a compulsory license is rather broad.[265] This definition unifies the proposals of the EU as well as the African Group and the Group of Developing Countries (both of them will be referred to as "developing countries").[266] The definition of eligible importing country was also based mainly on the developing countries' proposal.[267] Eligible importing countries are: 1) any least-developed country (automatically); 2) any

[261] However, the EU proposal did not determine what exactly constitutes the term "reasonable". *Ibid.,* at 9.
[262] *Ibid.,* at 13.
[263] Suggested solutions included: a broad interpretation of Article 30 authorizing the export of patented products under a compulsory license; an amendment of Article 31 to allow such export; the waiver of Article 31(f) requirements and dispute settlement moratorium to determine non-compliance with Article 31(f). See *Supra* note 191 at 953-954.
[264] *Supra* note 6. See also WTO, "Decision removes final patent obstacle to cheap drug imports", Press Release, Press/350/Rev.1 (30 August 2003), online: WTO <http://www.wto.org/english/news_e/pres03_e/pr350_e.htm>.
[265] The eligible pharmaceutical products will include not only patented pharmaceuticals themselves, but also products produced through a patented process. *Supra* note 248 at 4.
[266] *Ibid.*, at 4.
[267] *Supra* note 6 at par. 1(b). Also see *ibid.*, at 5.

other country that notified the TRIPS Council.[268] An eligible exporting country can be any state, which produces the needed drug.[269]

The adopted solution - the waiver of members' obligations under Article 31(f) - was proposed by the developing countries. However, the number of safeguards that were meant to lessen the probability of any abuses and trade diversions makes it hard to believe that a country facing a public health crisis would be able to comply with all the requirements of the mechanism outlined in the decision.[270]

The reasons for such an abundant supply of safeguards are understandable. It is necessary to establish procedures that would prevent, to some extent, abuses of the system and diversions of medicines produced under a compulsory license.[271] It is also necessary to ensure that the medicines would not be re-sold in the country of origin.[272]

However, the TRIPS Council's mission was to find a feasible solution for the Paragraph 6 Problem. Even though the views of the developing countries were incorporated in the WTO decision of August 30, it still seems too unfeasible for a developing country facing a public health emergency situation to use.

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[268] A number of countries (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the US) declared that they would not use the system under any circumstances. Some countries stated that they would use the system only in cases of national emergency or other circumstances of extreme urgency. These countries are: Hong Kong (China), Israel, Korea, Kuwait, Macao (China), Mexico, Qatar, Singapore, Chinese Taipei, Turkey, the United Arab Emirates. See *Supra* note 6 at Par. 1(b). See also WTO, "The General Council Chairperson's Statement", WTO News Release (30 August 2003), online: WTO <http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm>.

[269] The definition of the eligible exporting country was adopted against the advice of the US as well. The US advised to exclude any developed country and to determine that only developing countries with manufacturing capacities could export drugs under this system. This is in order to create incentives for the developed country to participate in a future technology transfer. *Supra* note 6 at par. 1(c). Also see *supra* note 248 at 8.

[270] The safeguards that are mentioned in Paragraphs 2 and 4 of the WTO General Council's decision are: specification of the expected quantities; evidence required of every non-least-developed importing country to establish a lack or insufficiency of manufacturing capacities, with no detailed instructions as to the kind of evidence that would satisfy this requirement; various notifications, etc.

[271] *Communication from the United States, supra* note 249 at 1-2.

[272] *Ibid.*

Nevertheless, then WTO Director-General, Supachai Panitchpakdi, declared that the decision was "a historic agreement for the WTO …".[273] The General Council Chairperson stated that the decision should be used in good faith for the solution of public health problems, rather than for commercial use, and that it is essential to ensure the medicines get into right hands.[274] Moreover, the WTO presents the safeguards not only as measures to prevent diversions, but also as means of disclosure that are necessary to keep all the members informed.[275] According to this interpretation, phrases such as "reasonable measures within their means" and "proportionate to their administrative capacities"[276] are meant to prevent the mechanism from becoming burdensome and unfeasible.[277]

The decision of the TRIPS Council attempts to continue the "tone" of shifting the balance to the side of developing countries that was set in the Doha Declaration. As opposed to what happened in TRIPS, in which the developed countries determined most substantive definitions and provisions, in the decision, substantial definitions were based mostly on the proposals of the African Group and the Group of Developing Countries. Even the final solution (waiver of Art. 31(f) and allowing the export of generic versions of patented drugs) had been proposed by the developing countries (and the EU). However, the procedural provisions inserted by the developed countries created a major obstacle. The obstacle being that in determining how a compulsory license will work in times of public health crisis, the numerous rules and procedures deemed to protect the

[273] *WTO Press Release*, *supra* note 264.
[274] *Ibid.*
[275] *Supra* note 226.
[276] Relating to measures required to be taken to ensure that the products produced under a compulsory license will be used for health purposes in the importing country.
[277] *Supra* note 226.

products exported under a compulsory license from trade diversions and abuses are most likely to prevent developing countries from using the mechanism altogether.

Canada was the first country to implement the WTO General Council's decision and incorporate the scheme of export of generic drugs under compulsory license in its national laws.

Conclusions:

The Doha Declaration on TRIPS and Public Health stressed the importance of public health problems and pointed out that TRIPS should be interpreted accordingly.

HIV/AIDS, tuberculosis and malaria were automatically considered to be the national emergency situation.

The WTO General Council's decision of 30 August 2003 adopted a waiver of Article 31(f) of TRIPS. The decision was loaded with numerous safeguards that were meant to prevent trade-diversions and other possible abuses of the mechanism of export of generic medicines under a compulsory license.

The adopted solution was neither prompt nor feasible for underdeveloped countries.

Chapter Five: Canada's Bill C-9 – Legislative History

On 12 February 2004, Bill C-9 - *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*[278] (hereinafter: Bill C-9) was introduced in the House of Commons in the third session of the 37th Parliament.[279] The Bill was intended to implement the WTO General Council's decision of 30 August 2003, by establishing an effectively operating system that would eliminate the barriers to export of generic versions of patented drugs at affordable prices to developing and least-developed countries in need.[280]

Bill C-9's predecessor, Bill C-56,[281] had not had an opportunity to progress further than the second reading and died on the Order Paper because the Parliament was prorogued on 12 November 2003.[282]

Since Bill C-9 was reintroduced in the new Parliament's session in substantially the same form as Bill C-56, the Bill was reinstated at the same legislative stage as was reached by Bill C-56 before Parliament prorogued.[283]

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[278] Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act*, S.C. 2004, c. 23.
[279] Lalita Acharya & Kristen Douglas, "Bill C-9: An Act to Amend the Patent Act and the Food and Drugs Act: Legislative History of Bill C-9", online: Legislative Summaries <http://www.parl.gc.ca/common/Bills_ls.asp?Parl=37&Ses=3&ls=C9>.
[280] Industry Canada, "Coming into Force of the Jean Chrétien Pledge to Africa", News Releases (13 May 2005), online: Industry Canada <http://www.ic.gc.ca/cmb/welcomeic.nsf/261ce500dfcd7259852564820068dc6d/85256a5d006b972085257000006c78bf!OpenDocument>.
[281] Which received its first reading on 6 November 2003 and the second reading on 7 November 2003.
[282] "Status of the Bill: Bill C-56", online: Parliament of Canada <http://www.parl.gc.ca/LEGISINFO/index.asp?Lang=E&Chamber=N&StartList=A&EndList=Z&Session=11&Type=0&Scope=I&query=3791&List=stat>. To say that the sponsors of Bill C-56 tried to promote it very fast is an understatement at the very least. The fact that the second reading of the Bill took place on the last day of debates of the House of Commons *(2d session of the 37d Parliament)*, while the Bill's first reading took place on the previous day, speaks for itself. In fact, the issue of such a late introduction of the Bill and its hurried promotion was raised in the second reading. See Canada, Legislative Assembly, *Edited Hansard*, 153 (7 November 2003) at 1230 (James Rajotte), online: Parliament of Canada <http://www.parl.gc.ca/37/2/parlbus/chambus/house/debates/153_2003-11-07/han153_1230-E.htm>.

a. Bill C-56 – Background: the First Step Toward the Future Legislation

Introducing the legislative changes that were supposed to result from Bill C-56, Allan Rock, Canada's Minister of Industry, said: "Our goal is to address a pressing humanitarian problem, and we have worked with the two pharmaceutical associations and with non-governmental organizations that provide on-the-ground public health assistance to develop legislation that will be part of the solution. At the same time we recognize the need to respect intellectual property rights, which are critical to the development of new products and therapies in Canada…"[284] On 25 September 2003, Mr. Rock, along with the Minister of International Trade, Pierre Pettigrew, announced that they were working on proposing changes to *Canadian Patent Law* that would allow the export of generic medicines still under patent protection to developing countries unable to manufacture the drugs locally in times of public health emergencies and pandemics.[285]

In fact this initiative was a response to a plea advanced by Mr. Stephen Lewis, UN envoy for AIDS in Africa.[286] In that speech Mr. Lewis emphasized that Canada has

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[283] The First and the Second readings of Bill C-9 were processed on the same date and the Bill was immediately referred to the Standing Committee on Industry, Science and Technology (INST Committee). See Parliament of Canada, "Bill C-9: Reintroduced from the previous session", online: Parliament of Canada <http://www.parl.gc.ca/LEGISINFO/index.asp?Lang=E&Chamber=N&StartList=A&EndList=Z&Session=12&Type=0&Scope=I&query=4094&List=aka>.

[284] Industry Canada, "Government of Canada Introduces Legislative Changes to Enable Export of Much-needed, Low-cost Pharmaceutical Products to Developing Countries", News Release (6 November 2003), online: Industry Canada <http://www.ic.gc.ca/cmb/welcomeic.nsf/ffc979db07de58e6852564e400603639/85256a5d006b972085256dd6005017e3!OpenDocument>.

[285] "Canada to Change Drug Patent Law" (2003), 7 Bridges, online: The International Center for Trade and Substantial Development (ICTSD) <http://www.ictsd.org/monthly/bridges/BRIDGES7-7.pdf> at 21.

[286] At the HIV/AIDS Legal Network Conference in Montreal on 12 September 2003, and later at the 13th International Conference on AIDS and Sexually Transmitted Infections in Africa, in Nairobi, Kenya on 25 September 2003. See "Drug access: UN Envoy for AIDS in Africa Calls on Group of Seven Nations to Allow Generic Antiretroviral Drug Exports" (26 September 2003), *Kaiser Daily HIV/AIDS Report*, online: kaisernetwork.org <http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=20052&dr_cat=1>.

to lead the implementation of a compulsory licensing policy for exportation of generic drugs because of "Canada's large generic drugs industry and Prime Minister's Jean Chrétien's decision to make HIV/AIDS a foreign policy priority."[287]

At the G8 Summit, in June 2002, Prime Minister Jean Chrétien stressed future development of Africa, as well as issues of poverty, AIDS, and the social and economic challenges of Africa, were all part of the moral obligations and economic interests of the nations of the world.[288]

At that meeting,[289] the G8 agreed on the New Partnership for Africa's Development plan (NEPAD).[290] NEPAD obliged African nations to carry out social, political, and economic reforms in return for aid and trade opportunities provided by developed nations.[291]

Even before the G8 summit of 2002, Canada contributed significantly in promoting this initiative. In December 2001, the Canadian Government was the first to establish $500 million Fund for Africa that was allocated to fight HIV/AIDS, to promote economic growth, *etc.*[292] Based on such an approach, it is not surprising that Mr. Lewis called on the Canadian Government to head the initiative of amending its *Patent Act* to allow a compulsory license for the export of generic drugs for countries in need.

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[287] *Ibid.*
[288] "The Road to Kananaskis: Africa at the Heart of the G8 Summit" (2002), 15 Canada World View, online: Foreign Affairs Canada <http://www.dfait-maeci.gc.ca/canada-magazine/issue15/15t5-en.asp>.
[289] Several African leaders were present at the G-8 Summit in Kananaskis, Alberta.
[290] This plan was an improved version of New African Initiative (NAI) presented by a delegation of African leaders in the G8 Summit in Genoa (Italy) in 2001. *Supra* note 288. Also see "G8 agrees Africa action plan", *BBC News* (27 June 2002), online: BBC News <http://newswww.bbc.net.uk/1/hi/business/2069632.stm>.
[291] *BBC News*, *ibid.*
[292] "Canada Fund for Africa: The Fund: New Vision, New Partnership", online: Canadian International Development Agency <http://www.acdi-cida.gc.ca/canadafundforafrica>.

Moreover, the initiative received support from different sectors and officials within the country and at the international level.[293] The decision of the Canadian Government to promote this legislation was expected to be positive both for people and for economies, in that " … the decision will expand overall availability of antiretrovirals in poor countries and it will encourage competition …".[294] As mentioned, this initiative was introduced to Parliament as Bill C-56.

Overview of the Provisions of Bill C-56

Bill C-56 proposed to amend the *Patent Act*[295] by adding sections 21.01 – 21.17, following Section 21 of *Patent Act*, under the title "Use of Patents for International Humanitarian Purposes to Address Public Health Problems". The declared purpose of the amendment was "to facilitate access to pharmaceutical products to address public health problems" in developing and least-developed countries, especially diseases such as

[293] The UNICEF executive director, Carol Bellamy, praised the Canadian initiative to enact legislation that would allow generic companies to export cheaper versions of patented medicines to developing countries afflicted with pandemics. See UNICEF, Press Release, "UNICEF Hails Canada's Move to Expand Access to AIDS Drugs" (29 September 2003), online: UNICEF <http://www.unicef.org/media/media_14812.html>. The Canadian AIDS Society (CAS) and the Canadian Treatment Action Council (CTAC) saluted the Canadian Government for this initiative taken on such a short notice from the WTO Decision of 30 August 2003. So did the Canadian HIV/AIDS Legal Network. See Paul Lapierre, "National AIDS Organizations Salute Government of Canada – Federal Government to Amend the Patent Act", Media Release, (26 September 2003), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/e-press-CAS-CTAC-sept2603.htm>. Also Ralf Jürgens, "The Fight Against HIV/AIDS Must Continue", Press Release (29 November 2003), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Media/press-releases/e-press-nov2903.htm>. Canadian Generic Pharmaceutical Association (CGPA) issued a statement of support for the future piece of legislation and agreed to participate in the consultations on the issue. See Jeff Connell, "CGPA Statement Regarding the Government of Canada Initiative to Allow the Export of Canadian-made Generic Medicines to Developing Countries in Health Crises", News Release (1 October 2003), online: CGPA <http://cdma-acfpp.org/en/news/oct_01_03.shtml>.

[294] *UNICEF Press Release, ibid.*

[295] *Supra* note 193.

AIDS, tuberculosis, and malaria.[296] Bill C-56 was to waive certain obligations under TRIPS.[297] The WTO General Council's decision allowed the export of generic versions of patented drugs to some developing countries under certain conditions,[298] which will be discussed further.

Almost immediately with the beginning of the drafting of Bill C-56, waves of diverse criticism began to arrive. With the recognition of the fact that Canada was the first industrialized nation proposing to implement the WTO General Council's decision[299] came warnings that the proposed Bill was seriously flawed.[300] The Bill was praised for not containing a restricted list of specific diseases to be addressed by a compulsory license, as well as for not restricting the list of countries eligible to import generic versions of patented drugs solely to countries facing health emergencies.[301]

The Bill was also criticized for creating so-called "TRIPS-plus" provisions allowing patent owners to block generic producers from obtaining compulsory licenses.[302] For example, the "right of first refusal", stated in ss. 21.04(6)&(7), required notifying the patentee when an authorization to manufacture his patented product was requested. The patentee had to be granted a right to decide (within 30 days) whether he was interested in supplying the targeted drugs under the same conditions that were

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[296] Canada Bill C-56, *An Act to amend the Patent Act and the Food and Drugs Act*, 2nd Sess., 37th Parl., 2002-2003, ss. 21.01 (First Reading), online: Parliament of Canada <http://www.parl.gc.ca/37/2/parlbus/chambus/house/bills/government/C-56/C-56_1/90247bE.html>.
[297] Such as the requirement of Article 31(f) of TRIPS that a compulsory license should be predominantly for domestic market supply.
[298] *Supra* note 284.
[299] And therefore to allow generic companies to export patented drugs to developing countries lacking sufficient manufacturing capacities.
[300] Richard Elliott, "Flirting with Flawed Patent Law Amendment Canada May Undermine Welcome 'Access to Medicines' Initiative", Comment (November 2003), 8 Bridges, online: ICTSD <http://www.ictsd.org/monthly/bridges/BRIDGES7-8.pdf> at 21-22.
[301] *Ibid.*, at 21.
[302] *Ibid.*

negotiated earlier by a licensee requesting an authorization.[303] The patentee could also grant the generic company (the licensee) a right to produce the patented drug for export on the payment of royalties in an amount of 2% of the value of the pharmaceutical product.[304]

The flaws that appeared in Bill C-56 were the same flaws that reappeared in the first reading version of Bill C-9, which was introduced by the Government in the House of Commons in February 2004. Given the fact that Bill C-56 died on Order Paper, its consequences are particularly limited and could serve only as a background to understanding Bill C-9.

b. "Adopted Child" of the Next Government

Why did Canada's Government decide to continue the legislative process of the amendment to the *Patent Act*? In the Speech from the Throne it was stated:

> "There is a moral imperative to do all we can to make medical treatment accessible to the untold millions suffering from deadly infectious diseases, notably HIV/AIDS, particularly in the poorest countries of Africa. The Government of Canada will therefore proceed with legislation to enable the provision of generic drugs to developing countries …".[305]

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[303] Bill C-56, *Supra* note 296, s. 21.04(6)(a).
[304] *Ibid.*, ss. 21.04(6)(b) & 21.08(a).
[305] Canada, *Speech from the Throne to Open the Third Session Thirty-Seventh Parliament of Canada*, online: Parliament of Canada <http://www.parl.gc.ca/information/about/process/info/throne/index.asp?lang=E&parl=37&sess=3> (Delivered by The Right Honourable Adrienne Clarkson, Governor General and Commander-in-Chief of the Canadian Forces).

In light of such a commitment, Bill C-9 was reintroduced in the House of Commons and was immediately referred to the Standing Committee on Industry, Science and Technology.

Like Bill C-56, Bill C-9 was meant to implement the waiver of the requirement that the export of generic versions of patented inventions under a compulsory license be "predominantly for the supply of the domestic market."[306]

There was no unified formula for the implementation of the WTO General Council's decision. It was up to each country to decide to what extent to implement the decision and which specific legislative amendments to endorse in their domestic laws. Thus, Bill C-9 received profound and substantial examination at the meetings of the Standing Committee on Industry, Science and Technology (INST Committee) between 24 February 2004 and 22 April 2004.[307] Therefore, the study of the Bill was expected to be compelling and to have encompassed a diversity of aspects and challenges of issuing a compulsory license for the export of generic drugs to developing and least-developed countries in need.

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[306] As stated earlier, the waiver of this requirement should have enabled WTO Member-countries to authorize a production of generic versions of patented pharmaceuticals exclusively for the export to developing and least-developed Members with insufficient manufacturing capacities in pharmaceutical field, provided that the Members would implement the WTO General Council's decision in their national laws. See Use of Patented Products for International Humanitarian Purposes Regulations: Regulatory Impact Analysis Statement, C. Gaz., (2 October 2004) 138: 40, online: Government of Canada <http://canadagazette.gc.ca/partI/2004/20041002/html/regle9-e.html>.

[307] Speakers from diverse sectors, including Ministers of Industry and Health, authoritative representatives of the Departments of International Trade and Industry, the Canadian International Development Agency, representatives of Canada's Research-Based Pharmaceutical Companies, as well as a representative of the Canadian Generic Pharmaceutical Association, had been heard. Canada, House of Commons, *Study: Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act*, Meetings of the Standing Committee on Industry, Science and Technology (INST), 37th Parliament, 3d Session (February 24, 2004 – April 22, 2004), online: Parliament of Canada <http://www.parl.gc.ca/committee/CommitteeList.aspx?SelectedElementId=e22_.2&Lang=&ParlSession=373&StudyActivityId=810500>.

The Ministers of Industry and Health[308] presented the reasons for the reinstallation of the legislation proposed by the previous Government. One of the significant arguments in favor of such a decision was that Canada would take initiative and be the first country to implement the WTO General Council's decision.[309] However, being the first country to do so presented inevitable challenges as well. The Government had no other jurisdictions to learn from, no precedent to rely upon, and, on the other hand, had to pass legislation that would not be considered a "dead weight," being unfeasible and impractical.[310] Therefore, the proposed Bill attempted to find a balance between encouraging the supply of essential medicines to countries in need in a timely manner, preserving the IP rights of Canadian patent holders, and, along the way, not forfeiting compliance with obligations under TRIPS as they were interpreted in the Doha Round and the WTO General Council's decision.[311] The WTO General Council's decision itself provided one of the major challenges to the stakeholders. The vague language of the decision left much room for interpretation as to the scope and nature of drugs that were to be covered by the law.[312]

[308] Hon. Lucienne Robillard and Hon. Pierre Pettigrew (respectively).
[309] Canada, House of Commons, Standing Committee on Industry, Science and Technology (INST), 37th Parliament, 3d Session (24 February 2004), Hon. Pierre Pettigrew, online: Parliament of Canada <http://www.parl.gc.ca/infocomdoc/37/3/inst/meetings/evidence/instev02-e.htm#Int-821029> [INST Debates (24 February 2004)].
[310] This was the official reason for making the Bill subject to a review three years after its enactment. See Hon. Lucienne Robillard, *ibid*.
[311] *INST Debates* (24 February 2004), *supra* note 309.
[312] Hon. Lucienne Robillard, *ibid.*

Bill C-9 – From the First Reading Version to the "Grand Finale"

One of the most criticized provisions of the Bill's first version was the so-called "right of first refusal".[313] If the product intended for production under a compulsory license was patented, a generic manufacturer should have sought the authorization of the patentee to use the patented invention. Alternatively, the patentee could have notified the Commissioner of Patents that he would supply the drugs on terms no less favorable than those negotiated by the generic company with the country requesting the products. In other words, the generic company could have successfully negotiated the terms and conditions of the supply of a pharmaceutical, and after spending time and resources for reaching the optimal contract, the patentee would have replaced him in the contract. Eventually, it would be the patentee who would enjoy the profits. Therefore, this scheme could disincentivize generic manufacturers from participating in the system and render the mechanism unworkable.[314]

The civil society organizations, as well as the Canadian Generic Pharmaceutical Association (CGPA), have heavily criticized this provision. It has been argued that this provision could permit brand-name companies to block the issuance of compulsory

[313] Canada Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act*, 2nd Sess., 37th Parl., 2002-2003, Ss. 21.04(6) & (7) (First Reading), online: Parliament of Canada <http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_1/C-9_cover-e.html>.

[314] These concerns were expressed at the first meeting of the INST. See Andy Savoy and Brian Masse, *supra* note 309. The Canadian Generic Pharmaceutical Association argued that the right of first refusal would allow brand-name companies to take over the contracts negotiated by generic manufacturers and would give research-based companies the legislative preference by limiting competition and an ability of generic companies to participate in the scheme. See Jim Keon, "Canada first to pass legislation on delivering generic medicines to developing countries", online: WHO <http://www.who.int/intellectualproperty/events/CGPApaper.pdf>. Eventually, the provision was removed from the final version of the Bill. See Canadian HIV/AIDS Legal Network, "Canada's Patent Act Amendment: Allowing Compulsory Licensing for the Export of Generic Pharmaceutical Products" (20 April 2004), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/submissions0304/Bill%20C-9_Update_20%20April%202004.pdf>.

licenses altogether.[315] The "right of first refusal" also seemed to be incompatible with the humanitarian character of the proposed amendment.[316]

One of the possible reasons for the inclusion of this provision was that initially there were several different approaches to view the Bill. As follows from the opening speeches of the Ministers of Industry and Health, it can be concluded that the Bill has been viewed as an autonomous piece of legislation expressing an attempt of Canada to fulfill its obligations under TRIPS and the WTO General Council's decision. Therefore, the Bill had to be compatible with the provisions of Art. 31 of TRIPS that were not waived in the WTO August 30 decision.[317] As it was stated by the Minister of Industry, Lucienne Robillard, in her opening speech:

> "Ultimately, the government was confronted with the need to ensure that these amendments maintain the integrity of Canada's intellectual property regime for pharmaceuticals, while at the same time facilitating the flow of low-cost medicines to countries in need."

Therefore, the Government opted for the mechanism that was initially proposed in the Bill for several reasons. First of all, one of the main purposes of the Bill was to allow quick delivery of medicines to countries in need. Thus, the Bill provided an opportunity

[315] *Ibid.* See also *supra* note 213.
[316] The humanitarian purpose was to provide low-cost medicines to countries in need.
[317] Only two provisions of Article 31 were waived in the WTO General Council's decision: 1) Article 31(f) requiring that a supply be "predominantly for the domestic market"; 2) Art. 31(h) was changed so it determined the percentage of royalties. However, there were other provisions of TRIPS that remained valid, such as Article 31(b) requiring that prior to the grant of a compulsory license an applicant must attempt to obtain a voluntary license from the patentee on "reasonable commercial terms".

to involve the patentee, "the most immediate source," in the process instead of waiting two to five years for a generic producer to develop a generic version.[318]

Additionally, for the sake of "procedural fairness" and in order to maintain the proper level of IPR protection, the Government considered it necessary to notify the patentee. Moreover, as the first country to implement the WTO decision, the government wanted to encourage the international community to follow Canada in this initiative. Therefore, by involving brand-name manufacturers in this scheme, the government hoped to send "a positive signal to the international community that humanitarian initiatives in this area can be effective and yet have due regard for the property rights of patentees".[319]

The second approach, advocated mostly by the civil society organizations, was to view the proposed amendment as part of a more general picture, *i.e.,* a part of Canada's effort to help developing and least-developed countries to fight infectious diseases such as AIDS, tuberculosis, and malaria.[320] According to this approach, the major effort was to build the necessary infrastructure so that developing and least-developed countries would be able to deal with health care issues, to receive delivered medicines, and to be able to use the drugs properly.[321] As the Minister of Health stated, the Bill will go together with Canada's other initiatives that are currently in the works, such as the WHO's "three by

[318] Hon. Lucienne Robillard, s*upra* note 309.
[319] *Ibid.*
[320] As David Maloney, Vice-President of the Policy Branch of the CIDA, stated in the INST meeting on 24 February 2004: "CIDA has put a very direct and significant focus on building the capacity of countries in the area, especially in the care and treatment of HIV/AIDS. To give you some numbers, between 2000 and 2005, for example, CIDA has committed to doubling our spending in the area of health and nutrition, in the order of around $150 million to $300 million. In the area of HIV/AIDS, we have the commitment to quadruple the amount, from roughly $20 million to $80 million a year… Across five years the global fund to fight HIV/AIDS, tuberculosis, and malaria--CIDA has a commitment of $540 million…" See David Maloney, *supra* note 309.
[321] *Supra* note 309.

five" campaign.[322] Whereas a representative of the Canadian International Development Agency (CIDA) claimed that Canada was one of the founding donors of the WHO initiative.[323] The Bill was seen as one of the mechanisms to help Canada to call other developed countries to act in the same framework.

These two different approaches[324] could possibly explain why the mechanism outlined in the proposed Bill was so controversial. If the Bill was only an attempt to implement the WTO August 30 decision, then the Government was obliged to adhere to the principles of TRIPS and could only waive the requirements waived in the decision itself. Therefore, the Bill's nature would not be entirely humanitarian, because the Bill would inevitably contain "TRIPS- like" provisions. The Government would not be able to forego its obligations under TRIPS, such as strengthening IP rights and raising the global level of IP protection.

If the Bill was part of Canada's general effort to contribute to the global fight against infectious diseases in the developing world, then the Bill could acquire a mostly humanitarian character so that it would fit into the general framework of TRIPS exceptions,[325] which were intended to protect, among others, public health issues.

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[322] The "three by five" initiative was launched by the UNAIDS and the WHO in 2003. The initiative was designated to provide three million people living with HIV/AIDS in low- and middle-income countries with essential anti-retroviral medicines towards the end of 2005. The initiative focused on simplifying tools to deliver medicines; ensuring effective, reliable supply of the medicines and diagnostics; training health workers, developing health systems, and building health care infrastructure. See WHO, "The 3 by 5 Initiative: Treat Three Million People Living with HIV/AIDS by 2005", online: WHO <http://www.who.int/3by5/about/en/>.

[323] David Maloney, *supra* note 309.

[324] The narrow one: seeing the Bill as an implementation of the WTO General Council's decision only; and the broad one: viewing the Bill as a part of Canada's general effort to supply affordable drugs to underdeveloped countries in need.

[325] Such as Art. 7-8 of TRIPS that determined that the protection and enforcement of IP should be "in a manner conductive to social and economic welfare…" (Art. 7) and that the Members may adopt "measures necessary to protect public health… and to promote public interest in sectors of vital importance to their socio-economic and technological development…" (Art. 8) See TRIPS, *supra* note 157 at art. 7-8.

The "Right of First Refusal": Further Developments

Prior to the INST Committee's first report, the testimonies of numerous stakeholders were heard.[326] Even after the stakeholders completed their presentations, the government could not finalize its amendments.[327] It has been argued that the "right of first refusal" was the most divisive issue and caused major disagreements among the stakeholders.[328]

As mentioned earlier, for the government, this provision was intended to ensure there was a balance between the positions of the different stakeholders and to allow the brand-name pharmaceutical industry to participate in the system. One of the advantages was that such involvement would expedite the drug supply. After all, a patentee already had the drug developed and ready for sales, while a generic manufacturer would need approximately a two to three-year period to create a generic equivalent of the patented drug and acquire all the necessary authorizations.[329]

The research-based pharmaceutical industry's position was that the "right of first refusal" would provide much-needed transparency and disclosure in the process of acquiring a license.[330] However, the industry was not interested in discouraging "any

[326] Representatives of the research-based industry as well as Generic Pharmaceutical Association, numerous NGOs, such as Medecins Sans Frontieres (MSF), Oxfam, Canadian HIV/AIDS Legal Network, and also representatives of the United Church and World Vision Canada and the academia.
[327] Canada, House of Commons, *Main Estimates 2004-2005*, Meeting of the Standing Committee on Industry, Science and Technology (INST), 37th Parliament, 3d Session (April 1, 2004), Hon. L. Robillard, online: Parliament of Canada <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=77180>. At this meeting, the government was called to explain the reasons for postponing the discussions of the amendments and the delay in presenting government's amendments for the Bill.
[328] *Ibid.*
[329] Marie-Josee Thivierge, *supra* note 309.
[330] Canada, House of Commons, Standing Committee on Industry, Science and Technology (INST), 37th Parliament, 3d Session (26 February 2004), Terry McCool, online: Parliament of Canada <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=73324>[INST Debates (26 February 2004)].

stakeholders from participating with us in this endeavour."[331] Therefore, research-based companies (hereinafter: Rx&D) proposed an alternative solution that, in their view, provided both a generic and a research-based manufacturer with an equal opportunity to participate in the system.[332]

The "equal opportunity" provision, as proposed by the Rx&D, required that a generic manufacturer, once contacted by an importing country, notify the Commissioner of Patents and the patentee. Once notified, the patentee would have an opportunity, during a 30-day period, to negotiate a contract with an importing country together with the generic producer. If the patentee's attempts did not lead to an agreement with the importing country on the one hand, and he did not agree to grant a voluntary authorization to a generic company on the other hand, the latter could apply to the Commissioner for a compulsory license.[333]

Although generic manufacturers saw in the "right of first refusal" one of the biggest flaws of the Bill, they were not opposed to the alternative "equal opportunity" solution proposed by the Rx&D.[334] Moreover, Canada's Generic Pharmaceutical Association (hereinafter: Generic Association) proposed notifying a patentee at an early stage regarding a generic producer's intention to enter a contract with an importing country.[335] The Generic Association was not opposed to the possibility that the brand-

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[331] *Ibid.*
[332] Canada's Research-Based Pharmaceutical Companies (Rx&D), "Providing Affordable Medicines to Patients in the Developing World", *Submission to the House of Commons Standing Committee on Industry, Science and Technology Regarding Bill C-9* (February 2004), online: Canada's Research-Based Pharmaceutical Companies <http://www.canadapharma.org/Meds/Submission_to_Industry_Committee_E.pdf> at 16-17 [Rx&D Submission].
[333] *Ibid.*, at 17.
[334] Jim Keon, President of Canadian Generic Pharmaceutical Association, *supra* note 330.
[335] *Ibid.* See also "Bill C-9 an Act to Amend the Patent Act and the Food and Drugs Act – Comments from Canada's Generic Pharmaceutical Industry", *Brief to the INST Standing Committee* (February 2004),

name company would make a bid to negotiate a contract for itself.[336] However, the timeframe for seeking a voluntary license from a patentee was limited in the Generic Association's proposal to a short period of only seven days.[337]

This proposal might be considered surprising, especially coming from the generic producers. That is given the fact that the proposal allowed a brand-name company to negotiate a contract and possibly deprive a generic producer from supplying drugs according to the contract that could potentially be negotiated by the generic producer. The logic behind such a proposal could be explained by a desire of the generic manufacturers to comply with Art. 31(b) of TRIPS.[338] The only problem is that TRIPS, in Art. 31(b), provided a possibility to waive the requirement of early notification of a patentee in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. However, in the Bill C-9 discussions, neither of the proposals (neither that of the Rx&D nor that of the Generic Association) had ever mentioned such a waiver.

It has been argued that contrary to their initial intent, patent holders and generic producers could never work together on providing access to medicines, because of their "fierce antagonism".[339] Moreover, it was said that inviting a patent holder, a dominant actor in the field, to interfere with the negotiations of the generic company and to make

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online: Canadian Generic Pharmaceutical Association (CGPA) <http://www.cdma-acfpp.org/en/news/feb_26_04.shtml> at 3-4 [CGPA Submission to the INST].

[336] *CGPA Submission to the INST, ibid.,* at 4.

[337] *Ibid.*

[338] Article 31(b) required seeking a voluntary license from the right holder prior to applying for a compulsory license.

[339] "The decision at the WTO was in no way predicated on friendly relations between patent holders and generic producers; just the opposite. It is based on the assumption that strong, new legal rules were needed to allow the generic producers to make and sell medicines...". See Canada, House of Commons, Standing Committee on Industry, Science and Technology (INST), 37th Parliament, 3d Session (10 March 2004), Frederick Abbott, online: Parliament of Canada <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=75333> [INST Debates (10 March 2004)].

his own offer in an attempt to win the contract with an importing country, would be "unrealistic, unworkable and also highly anti-competitive".[340] That is given the fact that the purpose of the Bill was to increase generic competition in order to lower prices on essential drugs.[341]

The critical flaw of the alternative, "equal opportunity" solution was that it ignored the fact that in cases of public health emergencies,[342] there was no requirement for obtaining a patent holder's permit prior to applying for a compulsory license.[343]

The most aggressive resistance to the "right of first refusal" came from the side of the NGOs. Their position was that this provision could potentially stop competition and disincentivize generic producers, turning the Bill into an unworkable and unnecessary piece of legislation.[344] Therefore, according to NGOs, this provision should not have been included in the Bill in any form.[345]

Eventually, the government proposed an amendment that replaced the "right of first refusal" with an obligation to seek a voluntary license from a patentee prior to applying for a compulsory license.[346] Under the new provision, the applicant is only

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[340] Frederick Abbott, *ibid.*
[341] *Ibid.*
[342] AIDS, tuberculosis, and malaria were to be automatically considered as public health emergencies. See *supra* note 4 at para. 1.
[343] Frederick Abbott, *supra* note 339.
[344] Rachel Kiddell-Monroe, *supra* note 330.
[345] The same unequivocal position on potential harmfulness of the "right of first refusal" was expressed by Richard Elliott, Director, Policy and Legal Research, Canadian HIV/AIDS Legal Network, at the INST meeting on 26 February 2004; Mrs. Chantal Blouin, Researcher, Trade and Development, North-South Institute, at the INST meeting on 9 March 2004; Gauri Sreenivasan, Policy Coordinator, Canadian Council for International Cooperation, at the INST meeting on 9 march 2004; Rev. John Dillon, Coordinator, Global Economic Justice Program, KAIROS, United Church of Canada, at the INST meeting on 9 March 2004; Dr. Frederick Abbott, Edward Ball Eminent Scholar, Professor of International Law, Florida State University College of Law (As Individual), at the INST meeting on 10 March 2004, and more.
[346] Canada, House of Commons, Standing Committee on Industry, Science and Technology (INST), 37th Parliament, 3d Session (20 April 2004), Hon. Joe Fontana, online: Parliament of Canada <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=79062> [INST Debates (20 April 2004)].

required to confirm that he sought a voluntary license (as opposed to the requirement to notify a patentee about the ongoing negotiations).[347] It could be argued that by attempting to receive a voluntary license from a patentee, a licensee is notifying him of his intent to use a patented invention.[348] However, the license can be sought after a generic manufacturer has already concluded a contract with an importing country, and so it turns out to be a *post facto* notification.[349]

Measures Against Trade Diversions - Administrative Procedures

Aside from the problematic "right of first refusal" provision, stakeholders stressed another major difficulty: how to ensure that the drugs produced under a compulsory license reach the right hands, *i.e.*, the patients? In other words, what measures should be undertaken to prevent trade diversions and to ensure that the drugs reach their final destination? Furthermore, how to ensure that the drugs will be administered properly, especially when the country of destination has neither a social nor a pharmaceutical infrastructure?

One of the measures against trade diversions included in the *Amendment of the Food and Drugs Act* was the requirement for generic manufacturers to distinctively mark and label pharmaceuticals produced under a compulsory license.[350] As Minister of Health, Hon. Pierre Pettigrew, stated:

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[347] *Ibid.*
[348] Douglas Clark (Acting Senior Project Leader, Patent Policy, Department of Industry), *ibid.*
[349] Douglas Clark, *ibid.*
[350] Hon. Pierre Pettigrew, *supra* note 309. The proposed amendment required not only to label certain group of products, but also to label individual capsules and tablets. Moreover, there was a requirement for an inspection of the shipment prior to drugs' exportation in order to ensure that the drugs produced under a compulsory license were properly labeled. Bill C-9, in c. 3, s. 37(2), required examining drugs and devices for the export as though they were intended for the consumption in Canada. While prior to the Bill's

> "In the requirements relating to the prevention of diversion, we have found it appropriate to go beyond mere labelling and require the marking of individual capsules and tablets. We recognize that divergence could take a number of forms and that black marketing could involve the removal of labels. In addition, we are proposing that the government be provided the ability to inspect shipments before they are exported under compulsory licences to ensure that the marking and labelling requirements are met."[351]

On the one hand, the proposed measures were to ensure that medicines produced under a compulsory license would not be re-sold, re-exported or otherwise diverted from reaching the patients in the importing country. On the other hand, the distinctive marking and labeling were intended to provide conditions for inspection of the drugs that were to be shipped in order to ensure their safety, efficacy, and quality.[352]

The most immediate critique was that the costs of the production of pharmaceuticals would escalate, because each pill would have to be separately labeled. Therefore, the goal of producing cheaper pharmaceuticals would be forfeited.[353] In response to this concern, it has been argued that since labeling is something that is done on a regular basis in the business, and all capsules and tablets are typically marked anyway, these measures will not be so burdensome.[354] This statement, however, proved to be premature.

It seems that there was a consensus among MPs regarding the marking and labeling of the medicines produced for export under a compulsory license. The issue prompted no profound discussion at the INST meetings. However, the Canadian Generic Pharmaceutical Association (CGPA) did object to the inclusion of the regulations that

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enactment, products for export were excluded from the application of the *Food and Drugs Act* and therefore, were not required to meet Canadian standards of safety, quality and efficacy. See *supra* note 279.

[351] Hon. Pierre Pettigrew, *supra* note 309.

[352] David Lee, *supra* note 309.

[353] CGPA Submission to the INST, *supra* note 335.

[354] David Lee, *supra* note 309.

required undertaking more burdensome measures than the requirements of the WTO General Council's decision.[355] According to Par. 2(b)(ii) of the WTO decision, products intended for exportation under a compulsory license "shall be clearly identified … through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price … ".[356] The requirements adopted into the Canadian legislation definitely overlooked the last condition of this provision, *i.e.*, the feasibility and lack of a significant impact on price.

Canada's Bill, in s. 21.04(3)(b)(ii), requires not only distinguishing generic pharmaceuticals produced under a compulsory license from the brand-name ones, but also acquiring notification from the Minister of Health that such products comply with the special regulations under the *Food and Drugs Act.* One of the requirements of the regulations under the *Food and Drugs Act* is that pharmaceuticals exported under a compulsory license be distinctly different from any other version of the similar product sold in Canada.[357] Another requirement is to submit to the Ministry of Health a statement

[355] CGPA Submission to the INST, *supra* note 335 at 7.
[356] *Supra* note 6 at para. 2(b)(ii).
[357] Regulations Amending the Food and Drug Regulations (1402 – Drugs for Developing Countries), C. Gaz. (2 October 2004) 138:40, online: Government of Canada <http://canadagazette.gc.ca/partI/2004/20041002/html/regle7-e.html > [Amendment to the Food and Drug Regulations]. There are different requirements to be met, e.g., "for solid dosage forms, such as tablets and capsules, the letters "XCL" must be marked on the dosage form and the colour must be significantly different than the version sold in Canada. For non-solid forms, such as suspensions and powders for reconstitution, the letters 'XCL' must appear on the immediate container. For all labels, 'XCL' must be permanently displayed, followed by the Health Canada issued export tracking number (unique for each authorization). In addition, all labels must display the phrase 'FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA' …" See C.07.008 of the Amendment to the Food and Drug Regulations.

of intent to apply for authorization from the Commissioner of Patents.[358] Additionally, a "Distinguishing Features" package must be submitted to Health Canada, and more.[359]

The CGPA argued that the measures intended to distinguish pharmaceuticals produced under a compulsory license should be in accordance with Par. 2(b)(ii) of the WTO General Council's decision. Instead, the measures that were included in Canada's legislation added unnecessary "regulatory scrutiny".[360] According to this argument, such overburdened procedures will dissuade generic producers from participating in the system, because it will increase the length of time needed to bring a product into the market and to comply with all the requirements, which will also divert time and money from future projects.[361]

Obviously, the concerns of trade diversions, such as re-sale and re-exportation of medicines produced under a compulsory license should not be ignored.[362] Provided that low-income markets will not be able to establish a regulatory system to prevent trade diversion, this burden should be on the exporting country.[363] However, creating over-burdened, excessively complicated, and completely inflexible administrative procedures, even if they are intended to ensure the safety and efficacy of the products and to prevent trade diversions, may render the system inefficient and unfeasible, especially for the generic producers that bear most of the burden in the scheme.

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[358] *Ibid.*, at C.07.003 (a).
[359] *Ibid.*, at C.07.003 (c). This "Distinguishing Features" package should include all the distinguished marking, colouring and labels related to the drug, if the drug is already on the market.
[360] CGPA Submission to the INST, *supra* note 335 at 7.
[361] *Ibid.*
[362] Geoff Blackie, "Breathing Life Into the August 30th Agreement", online: University of Toronto Faculty of Law <http://www.law.utoronto.ca/accesstodrugs/documents/TRIPS%20geoffblackie%20trips.doc> at 16.
[363] *Ibid.*

The List of Eligible Medicines – Schedule 1

Another significant issue raised in the Committee hearings was a limited list of medicines (Schedule 1) to be covered by the proposed Bill.[364] The Canadian HIV/AIDS Legal Network[365] argued that Schedule 1 was to be removed.[366] In their view, sovereign developing countries had the right to decide what kind of pharmaceuticals they needed in order to cope with the public health crisis. By including Schedule 1 in the Bill, Canada adopted a "TRIPS-plus" measure that would defeat the purpose of the legislation. Moreover, in the Non-Governmental Organizations' (NGOs) opinion, by limiting the list of eligible pharmaceuticals, Canada would pose as a "gatekeeper for developing countries' access to medicines". By deciding which drugs would fit better for treatment of a certain disease in an importing country, Canada would infringe the sovereignty of this country. [367]

Moreover, the NGOs argued that the requirement to limit the list of eligible drugs appeared in neither TRIPS nor the WTO General Council's decision. The argument was that if the WTO August 30 decision referred to a "pharmaceutical product" in general terms, there was no reason for Canada's Federal Cabinet to add "TRIPS-plus" provisions by making a decision regarding the kinds of medicines needed for developing

[364] The Bill contains a list of initial groupings of drugs patented in Canada, which is based on the WHO's model list of essential medicines. The WHO's model list serves as a guide for the most efficacious, safe and cost-effective medicines for priority conditions in basic health care systems. See WHO, *Explanatory Notes: Essential Medicines: WHO Model List* (March 2005), 14th ed., online: WHO <http://whqlibdoc.who.int/hq/2005/a87017_eng.pdf>. To provide some flexibility, in the Bill C-9, the Governor in Council is authorized to approve additional pharmaceuticals to be added to Schedule 1 without any Parliamentarian decisions.

[365] The Canadian HIV/AIDS Legal Network is a Toronto-based national charitable organization working in the area of policy and legal issues related to HIV/AIDS. See "About the Network", online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/about.htm>.

[366] Canadian HIV/AIDS Legal Network, *Submission to the INST Standing Committee, supra* note 213 at 18.

[367] INST Debates (26 February 2004), Rachel Kiddell-Monroe, *supra* note 330. Also see Canadian HIV/AIDS Legal Network, *Submission to the INST Standing Committee, ibid.*

countries.[368] The NGOs claimed that during the consultations of the WTO General Council prior to the August 30 decision, a number of countries, such as the U.S., proposed to limit the list of medicines that would be eligible for production under a compulsory license. However, the WTO General Council rejected this proposal.[369]

The government explained the necessity of inclusion of such a schedule into the Bill[370] based on the need to reach a compromise between the stakeholders that wanted a narrow definition of the scope of drugs and those who did not want a limited list of drugs at all.[371] According to this approach, the optimal solution was to create a list of drugs patented in Canada and included in the WHO Model List of Essential Medicines.[372] One of the major reasons for using the WHO Model List was that it contained the most efficacious, safe, and cost-effective drugs for priority conditions in basic health care systems.[373] The NGOs, on the other hand, argued that many medicines that are used as a primary treatment for AIDS are not included in the list.[374] Their main claim was that some of the most essential drugs, such as fixed-dose combinations of antiretrovirals (ARVs) recommended by the WHO treatment guidelines, but whose prices exceeded the

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[368] *Ibid.,* at 18-19.
[369] In the WTO General Council's decision, "pharmaceutical products" were defined as "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems." See *supra* note 6 at para. 1(a). While Par. 1 of the Doha Declaration provides general definition of "health problems", stressing HIV/AIDS, tuberculosis, and malaria. See *Supra* note 4. Also see Canadian HIV/AIDS Legal Network *et al.*, Press Release, "Latest Amendments to Canada Patent Act a Good Start, but Still Need Work" (20 April 2004), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Media/press-releases/e-press_apr2004.PDF>. Also see *ibid.*, at 19.
[370] And therefore the limitation of the scope of eligible drugs.
[371] Hon. Lucienne Robillard, *supra* note 309.
[372] As was said, the WHO Model List was chosen to be guidelines in establishing Schedule 1 because it provided most efficacious, safe, and cost-effective medicines for priority conditions in a basic health care system. See Hon. Lucienne Robillard, *supra* note 309. Also see *WHO Model List, supra* note 364.
[373] Hon. Lucienne Robillard, *supra* note 309.
[374] Rachel Kiddell-Monroe, *supra* note 330.

"cost-effective" parameter of the WHO Model List criteria, were excluded from the Schedule.[375]

The government's response to this argument was to suggest providing a provision that allowed the Governor in Council to amend Schedule 1 following the recommendations of an expert advisory committee, with no need for Parliamentary hearings.[376]

The NGOs claimed that the WHO Model List did not encompass all needed medicines, but only determined the medicines necessary for priority health care needs. Moreover, the Canadian AIDS Legal Network argued that it was inappropriate to integrate the WHO Model List into Canada's *Patent Law* restricting in this way the kinds of pharmaceuticals that could be produced under a compulsory license.[377] The WHO Model List of Essential Medicines was neither intended to be a part of legislation nor did it comprehensively address all health needs.[378]

The CGPA joined the NGOs in this argument and proposed to remove Schedule 1 "in the spirit of the Doha Declaration."[379] The CGPA added that limiting eligible drugs would limit generic producers' abilities to promptly adapt to the rapidly changing conditions in developing countries.[380] In other words, generic manufacturers feared they

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[375] For example, "Navirapine", which is the essential medicine for prevention of vertical transmission of AIDS, *i.e.*, from mother to child. This medicine, although patented in Canada, was not on the list of eligible drugs. The NGOs stressed that if there were drugs that were already missing from Schedule 1, that was to show that there would always be flaws in the list, which was one of the reasons to remove the Schedule altogether. See INST Debates (26 February 2004), Rachel Kiddell-Monroe, *supra* note 330. See also Canadian HIV/AIDS Legal Network, *Submission to the INST Standing Committee, supra* note 213 at 19.
[376] Hon. Lucienne Robillard, *supra* note 309.
[377] That is especially if one of the criteria considered by the WHO regarding the inclusion of essential medicines on the list is their cost-effectiveness, *i.e.*, more expensive but effective medicines may be excluded from the list just because of their cost. Canadian HIV/AIDS Legal Network, *Submission to the INST Standing Committee, supra* note 213 at 19-20.
[378] *Ibid.*, at 20.
[379] CGPA Submission to the INST, *supra* note 335 at 5.
[380] *Ibid.*

would not be able to produce certain drugs needed in an importing country just because the requested medicine was not on the list.

The brand-name industry suggested that there was no need to focus on the drugs eligible to be exported under a compulsory license, because to make the drugs available is a necessary, but not a sufficient measure.[381] According to this argument, reasonably operating health care systems[382] are necessary features for successfully delivering aid to developing countries. Therefore, the main challenge before the INST Committee was to find sufficient funding and to "make the best possible use of the available resources that are allocated with those funds."[383]

It has been argued, mostly by the NGOs, that although the absence of a local infrastructure and of a way to ensure the efficient delivery of drugs to their "final destination" – a patient – do pose serious problems, there should be no trade-off between solving these problems and solving the problem of access to essential medicines.[384]

Eventually, the INST Committee recommended including Schedule 1. However, the Committee also advised the inclusion of the possibility to amend the list by adding any patented drug based on the recommendation of the Ministers of Industry and Health. Additionally, s. 21.18 was amended so that within three years from the day the Bill came into force, the Ministers would establish an advisory committee to amend the Schedule.[385] Some essential medicines that were initially missing from the Schedule were added during the INST Committee meetings.[386]

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[381] Jean-Francois Leprince, *supra* note 330.
[382] That included an appropriate health care infrastructure, trained medical personnel, an ability to monitor patients and drug administration, *etc*.
[383] Jean-Francois Leprince, *supra* note 330.
[384] Rachel Kiddell-Monroe, *ibid.*
[385] Canada, House of Commons, The First Report of the Standing Committee on Industry, Science and Technology, 37th Parliament, 3rd Session, online: Parliament of Canada

Why Leave the Schedule?

Regarding the more general question of why the Schedule that posed so many problems from the very beginning should have been left in the Bill, the Committee presented several reasons. The members wanted to ensure the issues of safety and efficacy of the exported drugs, including the precise dosage, were satisfied.[387] Drugs that were recently approved in Canada without post-market experience were not recommended for inclusion in the list.[388]

At one stage, it was suggested to remove Schedule 1 and to adopt instead the definition of pharmaceutical products that appeared in the WTO General Council's decision.[389] However, the language of the decision, as broad as it seemed to be, was considered more restrictive than that of the Schedule, and therefore, the proposal was withdrawn.[390]

<http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?COM=8794&Lang=1&SourceId=77159> (as adopted by the Committee on 22 April 2004) [The First Report of the INST Committee]. See also Canada, House of Commons, Standing Committee on Industry, Science and Technology (INST), 37th Parliament, 3d Session (22 April 2004), Brian Masse, online: Parliament of Canada <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=79224> [INST Debates (22 April 2004)].

[386] The drugs added in the INST Committee's report are: "abacavir (ABC)", "amprenavir", "delavirdine", "didanosine", "lamivudine", "nevirapine (NVP)", "zalcitabine". Two of the new medicines are fixed dose combinations: "abacavir" + "lamivudine" + "zidovudine" and "lamivudine" + "zidovudine". See *The First Report of the INST Committee*, *ibid.* The reason that these drugs were not on the list initially was that the Schedule had been initiated by Industry Canada. Industry Canada took all the drugs that were on the WHO Model List and simply included those patented in Canada. See *INST Debates (22 April 2004)*, David Lee, Director, Office of Patented Medicines and Liaison, Department of Health, *supra* note 385.

[387] *INST Debates (22 April 2004)*, Dr. Robert Peterson, Department of Health, *supra* note 385.

[388] This was the case with the drug "tenofovir". The drug was meant for treatment of AIDS, but not as a first-line therapy. It was difficult to combine it with certain drugs because of a rapid resistance of HIV virus to such combinations. The drug should have been administered in a specific way with the food because of a high rate of kidney toxicity. There was a need of further experience with this drug before it could have been put on the list. See *ibid.*

[389] Brian Masse, *supra* note 346.

[390] As it was stated by Douglas Clark at the INST meeting on 20 April 2004: "As it stands with patented products, the definition [adopted in the WTO decision] does not place any limitations whatsoever on the meaning of the term. [In the definition proposed in the Bill] It would derive its meaning and interpretation from the context of the Bill and would therefore reflect the purpose of the Bill to get drugs to developing and least developed countries for humanitarian purposes. So our view would be that this [the definition adopted in the WTO decision] is more restrictive …". See *supra* note 346.

Eventually, the members reached the decision that such a schedule was needed.[391] The list of eligible drugs was intended to indicate which drugs were patented in Canada and approved by Health Canada. Therefore, the Schedule aided in identifying which patents could be waived by issuing a compulsory license.[392] Also, the list was meant to prevent any confusion as to which drugs were on the Canadian market and made a mechanism of export feasible and practical.[393] Moreover, the government was confident that the proposed mechanism of adding drugs to the Schedule[394] would allow the simple and uncomplicated addition of any necessary drug to the Schedule in a prompt and efficient manner, making it eligible for export.

Even though the list of eligible pharmaceuticals was eventually included in the Bill's final version, the prognosis of the NGOs that a decision on adding drugs or removing them from the list would be more political than medical appears to be correct.[395]

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[391] Hon. Joe Fontana & Marlene Jennings, *supra* note 346.

[392] As it was stated by Dr. Robert Peterson at the INST meeting on 20 April 2004: " … Schedule 1 constitutes a guidance to industry that allows them to understand which products Health Canada has knowledge and experience on in order to allow them to negotiate a contract and submit an abbreviated new drug submission. The Minister of Health must advise the Commissioner of Patents on whether the product meets Canadian regulatory requirements. We can only do so in a facilitated process, using an abbreviated new drug submission, if those products have been regulated in Canada as a brand or in another format. So the list itself is essential in order for companies to bring that type of facilitated application to us." *Ibid.*

[393] Hon. Joe Fontana, *ibid.*

[394] The mechanism was that the Governor in Council could add any drug to the Schedule, based on an advice of two Ministers, who based their advice on the findings of advisory committee. See *The First Report of the INST Committee, supra* note 385 at ss. 21.03 (1)(a) & 21.18.

[395] For example, Bayer Inc. pressured to remove its drug for pneumonia therapy, "moxifloxacin", from Schedule 1. The company argued that this would prevent using the drug inappropriately for conditions the drug is not approved for. "Moxifloxacin" has not yet been approved as a drug for tuberculosis, although clinical trials for the approval were in progress. See Glen McGregor, "Drug Bill Lets 'Big Pharma' Call the Shots Government Yields to Pressure from Bayer to Keep New Drug Off List of HIV/AIDS Program", *The Ottawa Citizen* (4 May 2004).

The Lists of Eligible Countries - Schedules 2-4

The Bill proposed three more schedules. Schedule 2 determined that all least-developed countries (WTO members or not) are eligible to use the system. Schedule 3 determined the same for developing countries that are members of the WTO.[396] Twenty-three WTO members declared that they would not use the system in any case.[397]

In the first hearing of the INST, stakeholders raised the issue of the exclusion of developing countries non-WTO members from the schedules.[398] The government argued that since the proposed amendments were an implementation of the WTO August 30 decision, it should have applied to the WTO members only.[399] However, as a gesture of assistance to underdeveloped countries, Canada allowed all least-developed countries that were not members of the WTO to automatically be covered by the Bill.[400]

It has been argued that Schedules 2-4 were based on the WTO August 30 decision and the WTO General Council's Chairman's statement, so that about eighteen countries that were neither members of the WTO nor in the process of acceding the WTO, would be excluded from the Bill.[401] For the countries that were not covered by the system, the government proposed other initiatives.[402]

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[396] And that did not reserve the use of the mechanism as importers only for cases of national emergency or other cases of extreme urgency. Schedule 4 defined developing countries, Members of the WTO, which have declared the above. See *supra* note 268.
[397] The countries that self-identified as non-users: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. *Supra* note 268.
[398] Andy Savoy, *supra* note 309.
[399] Suzanne Vinet (Director General, Trade Policy, Services, Investment and Intellectual Property Bureau, Department of International Trade) and Marie-Josée Thivierge (Director General, Marketplace Framework Policy Branch, Department of Industry), *supra* note 309.
[400] Vinet, *ibid*.
[401] Paragraph 1(b) of the WTO General Council's decision determined that any least-developed country and those of developing countries that are Members of the WTO and had notified the TRIPS Council regarding their intention to use the system, are considered eligible importing countries. General Council Chairperson's statement determined that the system was to be used "in good faith to protect public health

The decision to exclude some countries from using the system of export of cheaper drugs under a compulsory license was subject to the heavy criticism of the NGOs, particularly the Canadian HIV/AIDS Legal Network.[403] The NGOs argued that the fact that the WTO General Council's decision did not extend to non-WTO members should not preclude Canada from exporting generic drugs to these countries.[404] Additionally, it has been stated that there were numerous countries in the process of accession to the WTO, who had already expressed their wish to become WTO members, and even under the government's arguments, there was no reason to exclude them from using the system.[405]

The Rx&D stressed its support for the inclusion of least-developed countries that are non-WTO members from a humanitarian prospective, but added that this extension would give even more reasons for a patentee to participate in the system, because of a lack of safeguards and remedies for IPR infringement in these countries' national laws.[406]

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and… not be an instrument to pursue industrial or commercial policy objectives…". See *The General Council Chairperson's Statement*, *supra* note 268.

[402] As mentioned, these Schedules excluded about eighteen developing countries, non-WTO Members, such as Algeria, Lebanon, Bosnia, Vietnam, Iraq, and East Timor, from being eligible to unconditionally use the Bill for the import of generic drugs. See Mark Fried, Oxfam Canada, s*upra* note 330. Also see Dave Toycen, World Vision Canada, *supra* note 339. The proposal was that instead of including these countries in the legislation that had been designed to implement a decision of the organization they were not related to, these countries would be part of certain humanitarian initiatives of the CIDA. See Vinet, *supra* note 309.

[403] The critics argued that countries such as Vietnam, East Timor, Lebanon, Uzbekistan that are afflicted with diseases, and experiencing public health problems and poverty, although not Members of the WTO should not be denied the opportunity to use the compulsory license system. This claim was based on the Canada's international human rights obligations. The NGO representatives called the government to extend this legislation beyond the limits of the WTO rules and to include developing countries non-Members of the WTO as well. See Canadian HIV/AIDS Legal Network, *Submission to the INST Standing Committee, supra* note 213 at 22.

[404] Richard Elliott, Canadian HIV/AIDS Legal Network*, supra* note 330.

[405] Frederick Abbott, *supra* note 339. However, the government's position was that Canada has already extended the WTO General Council's decision, which applied only on the WTO Members, by allowing all least-developed countries to use the mechanism. Suzanne Vinet, Department of International Trade, *supra* note 309.

[406] *Supra* note 332 at 20.

A proposal to remove Schedules 2-3 did not come up during the debates in the House of Commons. The government was of the opinion that providing a relatively quick procedure for amending the schedules would be enough to fulfill the purpose of the Bill.[407] Eventually, the Committee recommended amending Schedules 2 and 3, so that on the recommendation of the Ministers of Foreign Affairs, International Trade and International Cooperation, a country that had not been included in the Schedule previously, would be added.[408] Another recommendation was to add several requirements for the inclusion of a non-WTO member least-developed country in Schedule 2.[409]

Schedule 4 included countries that declared that they would use the mechanism of compulsory licensing only in public health emergencies and other circumstances of extreme urgency. While Schedule 2 contained the names of all least-developed countries and Schedule 3 excluded developing countries that were non-WTO members, Schedule 4 provided an option for developing countries that were non-WTO members to participate in the system. Again, on the recommendation of the three ministers,[410] a non-WTO member-country interested in using the mechanism had to fulfill several conditions:

1. The country has to be named by the Organization for Economic Cooperation and Development (OECD) as eligible for official development assistance, and;
2. The country has to notify the Governor in Council in writing, through diplomatic channels, about its intent to use the system, and;

[407] Joe Fontana, *supra* note 346.
[408] *The First Report of the INST Committee, supra* note 385 at s. 21.03(1)(b)-(c).
[409] The requirements being: 1) The country is to state that imported pharmaceutical products will be used only for a non-commercial purpose, and 2) the country will adopt anti-diversion measures in accordance with TRIPS. See *ibid.,* s. 21.03(1)(c). See also Joe Fontana, *supra* note 346.
[410] Ministers of Foreign Affairs, International Trade and International Cooperation.

3. The country has to state that it is facing a national emergency or other circumstances of extreme urgency, and;
4. The country has to specify the name of a pharmaceutical product as well as the quantity of this product needed in order to cope with the emergency, and;
5. The country is to state that it has insufficient pharmaceutical capacity to produce the requested product, and;
6. To state that the country agrees to comply with the TRIPS obligations regarding taking measures against trade diversions, and to use the exported product only for non-commercial purposes.

Schedule 4 expressed the view of several members of the INST Committee that the responsibility to effectively use the mechanism of the export of generic drugs under a compulsory license lay not only with Canada, but with the countries that wanted to be included in the system as well.[411]

Why Leave Schedules 2-4?

The INST Committee's recommendations were adopted word-for-word into the final version of the Bill. However, the question of whether Schedules 2-4 had to be included in the Bill in the first place was left unresolved. Although a procedure for amending the schedules provided in the Bill did not involve parliamentarian debates or hearings in various committees, the reasons for including such schedules are still doubtful.

[411] Joe Fontana, *supra* note 346.

If the Bill is indeed a humanitarian act, as was stated in its purpose, then the NGOs' approach should be accepted. According to this approach, not only was Canada not precluded from extending the Bill to the non-WTO member countries, but it was obliged to do so. Moreover, according to the NGOs' position, Canada, as a signatory of numerous Human Rights' Conventions, should have recognized the right to health as one of the basic human rights.[412] Canada's foreign policy should have targeted the promotion of human rights.[413] Hence, to alleviate access to medicines in the developing world in order to promote the right to health should have been considered Canada's commitment to the global development.[414] It has been argued that according to the report of one Canadian polling company, 93% of Canadians are of the opinion that rich countries have a moral responsibility to facilitate access to drugs in poor countries.[415] Therefore, was the Bill to fit into this frame, Schedules 2-3 should definitely have been removed.

On the other hand, if the Bill was merely an implementation of the WTO General Council's decision, then why would it include least-developed countries that were non-WTO members? The government's argument in regard to extending the Bill for humanitarian reasons in accordance with its humanitarian purpose contradicts the exclusion of developing countries that are non-WTO members. Moreover, the Bill poses numerous conditions for the developing non-WTO member-countries to be able to use

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[412] Canada, House of Commons, Standing Committee on Industry, Science and Technology (INST), 37th Parliament, 3d Session (9 March 2004), Chantal Blouin, North-South Institute, online: Parliament of Canada <http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=73883> [INST Debates (9 March 2004)].

[413] *Ibid.*

[414] *Ibid.*

[415] See Dave Toycen, *supra* note 339. Toycen referred to the "Global Issues Monitor" report (2004) of the company named "Globescan". One of the findings of the poll that was conducted worldwide was that there was a "world wide consensus" (84%) that "rich countries have a moral responsibility to help poor countries develop … ". See Globescan, Media Release, "World Public Opinion Says World Not Going in Right Direction" (4 June 2004), online: Globescan <http://www.globescan.com/news_archives/GlobeScan_pr_06-04-04.pdf>.

the system. These conditions require the non-WTO member-countries to comply, for example, with anti-diversion obligations under the Agreement, to which they are not parties.

The inclusion of Schedules 2-4 seems to be even harder to understand considering the fact that pandemics have no borders. As it has been stated in the INST hearings, a health problem in any developing country can quickly pass to Canada or any other country.[416] The experience Canada had with Severe Acute Respiratory Syndrome (SARS) proved it once again.[417] As Mr. Terry Duguid, President and CEO of the Winnipeg-based International Center for Infectious Diseases (ICID), [418] said:

> "… We learned a lot from SARS. We learned how to not do things … We learned that our public health systems were weak. China learned a lot about transparency, that you could not hide these things … [people] in China, who jammed the internet and were telling everyone around the world that the government was deceiving people. Then the government corrected itself… and said: 'we have a problem, we need the world to tell us how to help ourselves.' Essentially, what happened with SARS was called 'a giant wake-up call' … ".

This shows, once again, that it would be unwise to distinguish developing countries that are WTO members from developing countries that are non-WTO members in regard to public health problems and access to drugs to prevent them. Precluding non-WTO member-countries from using a system that could, if feasible, facilitate access to

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[416] Mark Fried, Oxfam Canada, *supra* note 330.
[417] *Ibid.* During only four months since the first case of SARS emerged in Chinese province of Guangdong in November 2002, the disease had spread to 27 countries, causing death of 774 people and more than 8000 cases. See WHO, Disease Outbreak News, "Laboratory Confirmation of a SARS Case in Southern China – Update 2" (5 January 2004), online: WHO <http://www.who.int/csr/don/2004_01_05/en/>.
[418] The interview was conducted by the author on 12 April 2006, at the Center for Commercialization of Biological Research, ICID headquarters, in Winnipeg, Manitoba. Mr. Duguid spoke as an individual; the views expressed in this interview do not necessarily reflect the views and policies of the ICID.

drugs to prevent the spread of a pandemic, could not only be unwise, but also truly harmful. As Mr. Duguid stated:

> "By protecting others, we are protecting ourselves, we are protecting the global economy … [In regard to Avian Flu] We all know that the pandemic… it is not coming from Canada, it is coming from Guangdong province in China. So, we should be working with the Chinese on agricultural policy, on … vaccinating birds, on doing everything we can as a global community. Together. So that we prevent it from coming to our shores. We help them – we help ourselves. Small outbreak in China becomes [a worldwide pandemic] … I think there needs to be much more focus on prevention, because that is the ultimate solution."

NGOs' Procurement

Another concern was the fact that governments or governmental agents were the only applicants eligible for the grant of a compulsory license. In particular, NGOs were excluded from the scheme in that they were not allowed to contact a generic manufacturer directly, *i.e.,* to request the grant of a compulsory license.[419]

The Canadian HIV/AIDS Legal Network called for the government to acknowledge the reality, stating that UN agencies and NGOs played a fundamental role in the distribution of health care services in developing countries. Therefore, the NGOs should have been allowed to directly contact generic manufacturers for ordering cheaper drugs.[420] The failure to permit NGOs to deal directly with generic manufacturers so that they would be able to distribute the medicines in the field was presented as one of the key shortcomings of the proposed legislation (then Bill C-56).[421] However, CIDA's

[419] Réal Ménard, *supra* note 309.
[420] Canadian HIV/AIDS Legal Network, *Submission to the INST Standing Committee, supra* note 213 at 22-23.
[421] Letter from the CEOs of 14 Canadian Civil Society Organizations to Prime Minister Paul Martin (13 January 2004), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/Letter_Gov_%20BillC-56_13Jan.PDF>.

representative stressed the fact that it would be better to use a compulsory license mechanism only when the partner was the government. The involvement of the government from the beginning of the process was definitely a positive factor that could add certainty to the system. [422]

In response to these concerns, the Canadian government did indeed introduce an amendment allowing any person or entity to contact a generic producer in order to enter a contract for the supply of drugs.[423] The word "agent" used in the first version of the Bill was replaced by the words "person or entity".[424] It seemed that the amendment allowed NGOs to buy drugs without receiving a permit from the government of an importing country.[425] However, there were other provisions in the Bill that ensured that the license could not be granted unless the government of an importing country took some necessary measures.[426] Therefore, even if the NGOs could approach a generic manufacturer directly, still the process of supply under a compulsory license would not occur without the government's involvement.[427]

The CGPA argued that Canada's government initially introduced an amendment allowing NGOs to buy drugs with no need to contact the government of an importing country, and afterwards, under pressure from the brand-name industry, changed the

[422] David Maloney, *supra* note 309.
[423] Marlene Jennings, *supra* note 346. See also Jim Keon, *supra* note 314 at 3.
[424] Éric Dagenais, Department of Industry, *supra* note 346.
[425] Paul Crête, *ibid.*
[426] For example, there is a requirement in s. 21.04(3)(i) of the Bill that a licensee shall provide the Commissioner of Patents with a certified copy of the notice in writing that the government of an importing WTO Member-country has provided the TRIPS Council with. Another example of government's involvement can be found in s. 21.04(3)(i)(B). According to this section, a licensee shall provide the Commissioner with a certified copy of the notice in writing provided to the TRIPS Council by the government of an importing WTO Member-country and showing that the importing country is in compliance with Article 31 of TRIPS and the WTO General Council's decision. If the importing country is a non-WTO Member, the notices in writing regarding the same matters are to be sent, instead of the TRIPS Council, to the government of Canada through diplomatic channels. See *supra* note 278, ss. 21.04(3)(ii) & 21.04(3)(ii)(B). See also Éric Dagenais, *ibid.*
[427] Éric Dagenais, *ibid.*

amendment so that the NGOs had to receive permission from the government.[428] However, this argument is not accurate, first of all, because such an amendment never existed. The proposed addition of the words "permitted by the government of the importing country" to the phrase "person or entity" was just a clarification of the situation that was already in existence beforehand.[429]

Eventually, the requirement that only a person or entity that received a governmental permit could be the one to apply for a compulsory license was included in the Bill. It has been argued that this was done for the purpose of clarity in the process.[430] Moreover, it was stated that because this was an implementation of the WTO agreement, the mechanism had to operate on the governmental level.[431]

It seems that the amendment allowing NGOs to directly contact a generic company (with permission from the government of an importing country), which was adopted into the Bill word-for-word, did not solve the problem. It has been argued that the purpose of the Bill was to provide essential medicines to patients in poor countries in a prompt and efficient manner. Therefore, preventing NGOs from directly contacting generic manufacturers, without the government's involvement, would defeat this purpose.[432] Being dependent on the decision of the government of an importing country, NGOs would not be able to fulfill their mission of distributing drugs and improving health care systems, because they would not be able to ensure that health care issues are on the political agenda of the government of the importing country. This is especially so

[428] Jim Keon, *supra* note 314 at 3.
[429] Paul Crête, *supra* note 346.
[430] *INST Debates (22 April 2004)*, Marlene Jennings, *supra* note 385.
[431] *INST Debates (22 April 2004)*, Joe Fontana, *ibid.*
[432] Mark Field, Oxfam & Michelle Munro, CARE Canada, *supra* note 330.

when it is a poor country. Countries struggling to cope with an economic crisis have to respond to even more immediate concerns.[433]

It seems, however, that the opposite concern has outweighed these arguments. The need to ensure that issuance of a compulsory license would not be easily achieved by every small NGO, and therefore, to ensure that such activity would be coordinated with the government of an importing country.[434]

Amendments to the *Food and Drugs Act*

Although the Bill seems to be more related to Industry Canada, Health Canada claimed its part in this initiative as well. It has been argued that Health Canada plays the key role in ensuring that standards of safety, efficacy, and quality of Canadian pharmaceuticals exported under a compulsory license do not fall from the domestic standards.[435] To this end, the amendments to the *Food and Drugs Act* were proposed.

The *Food and Drugs Act* set up a new procedure for assessment of the safety, efficacy, and quality of drugs produced for export under a compulsory license mechanism.[436] Prior to the amendment, products for export covered by the *Food and Drugs Act* were not required to meet the above standards, unlike products that were meant for the Canadian market. This amendment was intended to protect countries that

[433] Rachel Kiddell-Monroe, *ibid.*
[434] Paul Crête & Don Kilby, *ibid.*
[435] Additionally, Health Canada was to undertake measures against diversions by ensuring proper labeling and marking. See Hon. Pierre Pettigrew, *supra* note 309.
[436] Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act*, S.C. 2004, R.S., c. F-27, cl. 3, s. 37(2), online: Parliament of Canada <http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_1/90247b-1E.html#3>.

were unable to assess the drugs in an extensive manner because of a lack of the necessary pharmaceutical infrastructure.[437]

Royalty Rates

Another disputable subject that stirred lengthy discussions was the issue of royalty rates that a licensee had to pay to a patentee as remuneration for using the patented invention while the patent was still valid. As was stated earlier, the first version of the Bill, in s. 21.08, proposed a fixed royalty rate of 2%. Research-based companies argued that a fixed rate is inconsistent with TRIPS.[438] The brand-name industry suggested that the issue of royalties should be resolved by the Commissioner of Patents if there was a disagreement between the generic company's and the patentee's proposals.[439] According to this approach, the calculation of royalties would be based on the value of the agreement for the importing country.[440] Although in many developing and least-developed countries the royalty rates were supposed to be close to zero, it would be compensated by the rates in high-income developing countries, where the value of the contract would be higher.[441]

Similarly to the proposal of the brand-name industry, the Intellectual Property Institute of Canada's representative suggested granting discretion to the Commissioner of Patents to make a final decision as to the rate of royalties.[442] To support this argument, it

[437] Pierre Pettigrew, *supra* note 309.
[438] Article 31(h) of TRIPS determines that a patentee is to be paid an "adequate remuneration in the circumstances of each case … ", while economic value of the license to an importing country should be brought into consideration. See also Hon. Robillard, *supra* note 309.
[439] *Supra* note 332 at 18.
[440] Terry McCool, *supra* note 330.
[441] *Ibid.*
[442] Patrick Smith, Intellectual Property Institute of Canada, *supra* note 412.

was stated that when Canada had had a compulsory license clause in its *Patent Act*,[443] the Commissioner had discretion to decide on the issue of royalties based on the proposals of a licensee and a patentee. The rate usually had been determined as 4% for the domestic market.[444]

Although generic manufacturers agreed on the need for paying royalties, they saw no reason for leaving the rate of royalties to the sole consideration of the Commissioner of Patents without a formula for their calculation that would include a cap. The CGPA suggested that the 2% proposed in the Bill's first version could serve as a cap for a flexible rates' formula that would be determined in the final version of the Bill.[445]

Another proposal was to determine a rate that would vary from 4% down to zero, depending on the circumstances of the specific license.[446] The "4% rate" was the royalty rate in Canada's *Patent Act* that applied to a compulsory license mechanism for pharmaceuticals, with which Canada had had extensive experience.[447]

Eventually, the government proposed an amendment to the fixed rate that appeared in the Bill's first version. The proposal was to calculate a formula according to the importing country's ranking in the United Nations Human Development Index (UNHDI). According to this formula,[448] countries with the least economic abilities would

[443] Which has been from 1923-1993, until the compulsory license mechanism was removed from the *Patent Act*. See Patrick Smith, *supra* note 412.
[444] *Ibid.*
[445] Jim Keon, *supra* note 330.
[446] Frederick Abbot, *supra* note 339.
[447] Richard Elliott, *supra* note 330.
[448] The formula was adopted later into the Regulations. Royalties were calculated by multiplying a monetary value of the supply agreement by an amount determined based on the country's standing on the UNHDI. The formula is: 1 plus the number of countries currently on the UNHDI (177 to date) minus the importing country's rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. See Use of Patented Products for International Humanitarian Purposes Regulations, C. Gaz. (10 May 2005) 139:11 at para. 8, online: Government of Canada <http://canadagazette.gc.ca/partII/2005/20050601/html/sor143-e.html> [Regulations]. The Regulatory Impact Analysis Statement brought an example of the calculation of royalties in case of Nigeria. Nigeria is

pay royalties close to zero (or a licensee would pay close to zero according to the ranking of the importing country) and the ceiling would be about 4%, practically.[449]

But the INST Committee did not set a cap of 4%. It has been argued that a cap on royalties would bring brand-name companies to charge as close to the cap as possible.[450] The Committee did provide brand-name companies with an opportunity to appeal to the Federal Court should a patentee be not satisfied with the rate.[451] An appeal would not stop a transaction, *i.e.,* the shipment of pharmaceuticals to an importing country, because the only issue challenged in this case would be the royalties and not the license itself.[452]

By providing an opportunity for a patentee to appeal the royalty rates, the government assumed that it fulfilled its obligations under TRIPS, according to which the rate of remuneration must be subject "to some form of independent legal oversight or judicial oversight".[453] After all, according to ss. 21.08(7)(a)-(b) of the Bill, to issue an order, the Federal Court is to take into account: 1) the humanitarian and non-commercial reasons for the issuance of a license, and 2) the economic value of the use of the invention to the importing country.[454]

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ranked 151 of the 177 countries on the UNHDI. The royalty rates payable in case of export of pharmaceuticals to Nigeria would be: [(1+177-151)/177] × 0.04 = 0.0061. Therefore, a licensee (or a country, if the product is patented there) will pay 0.61% of the value of the agreement to the patentee. See *supra* note 306.

[449] On the example of Sierra Lione, which has the lowest ranking on the UNHDI as for today, the country would pay a rate of 0.02%. See *INST Debates (22 April 2004)*, Eric Dagenais & Joe Fontana, *supra* note 385.

[450] Joe Fontana, *ibid*.

[451] *The First Repost of the INST Committee*, *supra* note 385 at ss. 21.08(4)-(5). The Committee's recommendations were adopted word-for-word into the Bill.

[452] *INST Debates (22 April 2004)*, Douglas Clark, *supra* note 385.

[453] TRIPS, in Article 31(i), states: "the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member…" See also *ibid.*

[454] *The First Repost of the INST Committee, supra* note 385. See also *ibid.*

The formula for royalties' calculation was named the "made in-Canada" formula and was considered to be a very "unique model".[455] Indeed, the formula appeared to achieve seemingly unreachable goals: 1) to provide a way for each country to pay according to its economic abilities in case an exported product was patented in the importing country; 2) if an exported product was patented only in the country of origin, a licensee would pay according to the economic value of the product in the country of destination, *i.e.*, according to his profits, and 3) the formula provided the cap of 4% without actually embedding the cap into the legislation. In other words, the ceiling was determined by a rate payable by a country with the highest UNHDI ranking, but the formula did not set a determined rate, which a patentee might attempt to reach notwithstanding the economic abilities of the importing country.

The only dubious aspect of this formula is the fact that it can be appealed. Although the possibility to bring the issue of royalties to the judicial review is positive for a research-based manufacturer, to a generic producer it brings uncertainty, as well as a possibility of lengthy and costly litigations.

Limited License Period

Another issue was a limitation period for a compulsory license.[456] Section 21.09 of the Bill in its First Reading version allowed the authorized use of a patented invention for a period of two years only (if not otherwise prescribed). An option for renewal was

[455] *INST Debates (22 April 2004)*, Joe Fontana & Eric Dagenais, *supra* note 385.
[456] The issue of a limitation of compulsory license term to two-year period was named one of the key shortcomings of the Bill C-56 in the letter of the NGOs to Prime Minister Paul Martin. See *supra* note 421.

given if not all quantities of the product authorized for export were exported prior to the authorization's expiration.[457]

The concern was that even if a generic company negotiated a contract for the supply of medicines and a patentee did not take over the contract, it would all become negotiable again in a two-year period. It has been argued that this provision may discourage generic manufacturers from engaging in the system.[458] The reason for such a limitation, as the government explained, was that, again, since the legislation was intended to implement the WTO General Council's decision, the Bill should comply with TRIPS. Article 31(c) of TRIPS determines that the duration of a compulsory license will be limited in compliance to the purpose of the grant. The government considered the two-year period to be reasonable, taking into account standard contracts of drug supply. Moreover, safety issues, such as drugs' limited shelf life, obliged the government to limit the period of licenses.[459]

The Rx&D argued that the period of license limited to two years was a reasonable limitation.[460] Moreover, the Rx&D suggested that in case of any uncertainty raised by the provision, a patentee should be granted an opportunity to bring his claims before the Commissioner of Patents.[461]

On the other hand, the CGPA did not see any reason to limit the period of a license.[462] It seems that such an approach allows viewing a compulsory license, which

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[457] *Supra* note 313 at s. 21.12.
[458] Réal Ménard, *supra* note 309.
[459] Marie-Josée Thivierge, *supra* note 309.
[460] *Supra* note 332 at 21. This argument contradicted TRIPS, which in Article 31(c), required the duration of a license to be limited to the particular purpose of the license in each case.
[461] *Ibid.*, at 21.
[462] It has been stated that after spending three to five years and millions of dollars to develop a drug, the generic manufacturer "should be able to sell it for as long as the company can attract buyers with low prices." See Jim Keon, *supra* note 314 at 3.

should be considered an exception to the normal state of affairs, as a legitimate means to make a profit on behalf of a generic producer.

However, in a two-year period, the circumstances under which the license was issued, as well as drug prices may completely change.[463] Moreover, new and more effective drugs could appear on the market during this period, so that prices fixed for more than two years could render the mechanism inefficient.[464] However, it has also been argued that limiting the period of a license to two years and, therefore, requiring from a generic producer to reapply in two years and to go through the entire procedure once again, would create an additional unnecessary restriction on the generic manufacturer.[465]

That said, although a limitation of the license period could serve as a disincentive for the generic manufacturer,[466] at the same time, it could be seen as a positive factor. In two years time, the patent status may change as well. In other words, the patent could expire, which would provide a generic manufacturer with a possibility to export an already developed product with no restraints or limitations.[467]

Eventually, the Bill, in s. 21.09, incorporated the provision limiting a license for two years. However, there is an option for one renewal for another two-year period, if the quantities of the drug produced under a compulsory license were not exported in whole before the licence's expiry.[468]

[463] *INST Debates (22 April 2004)*, Joe Fontana, *supra* note 385.
[464] *Ibid.*
[465] Brian Masse, *ibid.*
[466] Réal Ménard, *supra* note 309.
[467] *INST Debates (22 April 2004)*, Brian Masse, *supra* note 385.
[468] *Supra* note 278 at s. 21.12(1).

Termination of a License by the Federal Court's Order – Issues of Legal Certainty

It seems that one of generic producers' most important quests was a quest for legal certainty, so as not to be subjected to lengthy and costly legal procedures initiated by the research-based industry.[469] The CGPA argued that the legislation ought to be a "straightforward and faithful implementation of the WTO decision."[470]

The WTO General Council's decision does mention in Par. 4 that the importing member-country should take reasonable measures to prevent commercial exploitation of the contract, such as re-exportation of the products. However, at no point does the decision put an onus on a developed country to provide a judicial review either to assess the rates of royalty or to determine whether the contract is of a commercial nature.

That said, the INST Committee recommended the inclusion of two clauses in the legislation: a royalty clause and a good faith clause.[471] Section 21.17 of the Bill provides a so-called "good faith" clause.[472] The procedure under this clause allows a patentee to apply to the Federal Court if the average price of exported products is 25% or higher than the average price of the product's innovative equivalent.[473] The agreement then would be considered to be of a commercial nature.[474] According to s. 21.17(3)(a) of the Bill, if the

[469] Jim Keon, *supra* note 330.
[470] Jim Keon, *supra* note 314 at 2.
[471] *The First Repost of the INST Committee, supra* note 385 at ss. 21.08(4-5) & 21.17. The recommendation was adopted word-for-word into the Bill.
[472] According to s. 21.16(1), 15 days after the agreement of supply entered into force and the license was granted, the licensee must provide the Commissioner of Patents and the patentee with a copy of the supply agreement and a declaration of total monetary value of the agreement and the quantities of the products that were to be exported. Following compliance with this provision, the licensee could export the products and the patentee could assess the average price of the exported products. See *supra* note 278 at s. 21.16(2). See also *INST Debates (22 April 2004)*, Douglas Clark, *supra* note 385.
[473] *Supra* note 278 at s. 21.17(1). See also *INST Debates (22 April 2004)*, Douglas Clark, *ibid.*
[474] As it was explained in the INST hearing on 22 April 2004: "In determining whether the patentee's arguments have merit and the agreement is commercial in nature, the court will look to the ordinary levels of profitability in Canada of commercial transactions relating to pharmaceuticals. They'll also look to the need for the license holder to gain a reasonable return sufficient to sustain continued participation in a humanitarian endeavor. The third thing they look at, is the United Nations trends for the prices of

Federal Court decided that the contract was indeed commercial, the Court could order termination of the license. Another option was that a licensee would compensate a patentee for the commercial use of the patent if the license was not terminated.[475]

Although a generic manufacturer still had an absolute defence in this process,[476] the CGPA argued that most probably a generic manufacturer would not want to spend time and money on this kind of litigation over this kind of contract. Moreover, it has been argued that the generic manufacturer would likely prefer to withdraw once litigation had been initiated.[477] The CGPA claimed that generic producers endure lengthy and costly litigations as it is, under Canada's *Patent Act*, in regard to the supply of generic drugs in the domestic market, and they would not endure such litigation for the export of low-cost drugs.[478] Moreover, it was mentioned that there was a possibility that the brand-name industry would use this provision to disincentivize generic manufacturers and cause them not to pursue this kind of contract.[479]

It seems that by providing the "good faith" clause, as well as the option for a judicial review of royalty rates, the INST Committee wanted, partly, to satisfy the Rx&D quest for giving discretion to the Commissioner of Patents so that a patentee would be

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pharmaceutical products sold in a humanitarian context…" *INST Debates (22 April 2004)*, Douglas Clark, *ibid.* See also *the First Repost of the INST Committee, supra* note 385 at s. 21.17(2).

[475] *The First Repost of the INST Committee, ibid.*, at s. 21.17(3)(b). Also see *INST Debates (22 April 2004)*, Douglas Clark, *ibid.* However, despite the ongoing litigation, the license is deemed valid and the contract will be in force until the Federal Court gives the order.

[476] The absolute defense is: if a licensee proves that the average price of the exported products does not exceed an amount needed to manufacture this product plus 15% of that value, the Court may not terminate the license. See *supra* note 278 at s. 21.17(5). As it was explained, this clause covered the situations, in which the drug was too expensive to produce, while the percentage rate was taken from the European Access to Medicines Program that protected from re-importation of the products exported to the developing countries at lower prices. See *INST Debates (22 April 2004)*, Douglas Clark, *ibid.*

[477] Jim Keon, *supra* note 314 at 2.

[478] *Ibid.*

[479] *Ibid.,* at 3. The same concerns were expressed by the Canadian HIV/AIDS Legal Network. See Richard Elliott, "Update: Canadian Patent Act Amendments and Generic Pharmaceutical Exports" (7 June 2004), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/BillC-9_Update7June04.pdf> at 4.

heard in a fair process.[480] The proposals to grant discretion to the Commissioner to decide on the final conditions of the license were raised a number of times during the INST hearings.[481] Moreover, during Canada's long-term domestic experience with the compulsory licensing of pharmaceuticals, the Commissioner of Patents could refuse to grant a license if there was a valid reason.[482] However, it has been argued that by giving discretion to the Commissioner to decide on the issuance of licenses or on royalties, the system would be more burdened and loaded with unnecessary details.[483] Another concern was that such discretion would significantly increase litigation.[484]

In the end, the Commissioner of Patents was not given discretion to decide whether to grant a license upon fulfilment of all the requirements by the future licensee. However, instead of appearing before the Commissioner, a patentee may bring issues of the licence's commercial nature, as well as a claim to increase the rates of royalties before the Federal Court. In the Committee hearings, the concerns were expressed in regard to the volume of litigation and the legal uncertainty that would be brought into the mechanism, if the Commissioner was granted discretion. However, these concerns did not affect the decision to include the possibility of appeal to the Federal Court.

It is clear that the patentee has to have a say in the issues related to the possible use of his invention. However, it seems that the provision obliging a licensee to seek a voluntary license meets such a requirement. Should a patentee become interested in being involved into the process of determining royalty rates, the license period, or any other

[480] *Supra* note 332 at 19-20.
[481] Patrick Smith, *supra* note 412. See also *INST Debates (22 April 2004)*, Marlene Jennings, *supra* note 385.
[482] *INST Debates (22 April 2004)*, Douglas Clark, *ibid.*
[483] Joe Fontana, Douglas Clark, Brian Masse, *ibid.*
[484] *Ibid.*

detail of the contract between a generic producer and an importing country, he may agree to grant a voluntary license. In this way, the patentee would have a degree of control in the fate of his invention. However, the patentee's refusal to grant a voluntary license could be considered a waiver of the right to control or to be involved in the process of supply of a specific generic drug to an importing country.

The possibility of bringing the issues of royalties or the nature of the contract before the Federal Court and, therefore, of pulling a licensee into lengthy and costly litigation, places an unnecessary burden on generic manufacturers. Moreover, it can possibly dissuade them from using the system altogether.[485]

c. Main Features of the New Mechanism – Brief Overview of the Bill's Final Version

The new mechanism of export of generic drugs under a compulsory licensing system is complex and, at times, unclear. While the WTO General Council's decision is related only to the WTO member-countries, Canada's Bill C-9, in ss. 21.03(1)(d)(ii) and 21.03(1)(b)(ii), opens doors for least-developed countries that are not WTO members to use the system.[486]

Aside from Schedule 1, which determines a list of medicines that could be subject to a compulsory license, there are Schedules 2-4 that constitute the lists of eligible importing countries.[487] Although, the government claimed that the proposed amendments

[485] Jim Keon, *supra* note 314 at 3.
[486] By authorizing the Governor in Council to amend the list of least-developed countries eligible to apply (Schedule 2) and to add any country recognized as a least-developed by the UN, and also to add any developing country that is not Member of the WTO, if the country is eligible for a development aid according to the OECD's definition.
[487] Schedule 2 determines least-developed countries eligible to import drugs under a compulsory license (s. 21.03(1)(b)); Schedule 3 contains a list of the developing WTO Member-countries that did not declare that

were an implementation of the WTO August 30 decision and as such should apply to the WTO members only, as a gesture of assistance to underdeveloped countries, Canada added all least-developed countries to be covered by the Bill.[488]

There are no restrictions on the exporting countries, though. In s. 21.04(1), the Bill states that any person can be authorized by the Commissioner "to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it for export to a country… ". However, an applicant, if not related to the government, must request the permission of the governmental authority in the country where the invention is patented (s. 21.04(2)(f)). This provision prevents NGOs, such as Medecins Sans Frontieres (MSF), Oxfam, and others, from directly contacting the generic manufacturer in order to import needed drugs, unless the local governmental agency permitted it.[489]

The requirement of s. 21.04(3)(c) to seek a voluntary license from a patentee 30 days prior to filing an application comes in lieu of the "right of first refusal". The application can be filed only upon presenting a statement that an attempt to receive a voluntary license was not successful.[490] The Canadian Generic Pharmaceutical Association claimed that the brand-name company owning a patent does not need a

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they would use the mechanism as importers only in cases of national emergency or other cases of extreme urgency. (s. 21/03(1)(c)); Schedule 4 defines developing countries Members of the WTO, which declared that they would use the mechanism as importers only in cases of national emergency or other cases of extreme urgency.

[488] Suzanne Vinet, *supra* note 309.

[489] Richard Elliott, "Steps Forward, Backward and Sideways: Canada's Bill on Exporting Generic Pharmaceuticals" (2004), 9:3 HIV/AIDS Policy & Law Review 15 at 18, online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Maincontent/otherdocs/Newsletter/vol9no32004/forward-generic.pdf>.

[490] Despite an enthusiastic opposition of the NGOs, research-based pharmaceutical industry was able to include this provision in the final version of the Bill. Brand-name industry's representatives argued that the attempt of generic producers to receive a voluntary license is of the utmost importance, because it ensures the participation of both the patentee and the generic manufacturer in the system. Thus, it could provide an equal opportunity to supply. See Terry McCool, Eli Lilly Canada Inc., *supra* note 330.

compulsory license system to make, sell, or donate drugs. However, generic producers were not opposed so much to the idea of early-stage negotiations with a patentee, as long as they had legal certainty that the contract would be carried out to the stage of actual development and export of the patented products.[491]

Another provision that confirmed the Bill's humanitarian nature was a royalty rate payable to a patentee (s. 21.08). In determining the rate of royalties that a generic producer must pay, the Bill refers to regulations.[492] The regulatory formula for calculation of royalties takes into account the humanitarian and non-commercial basis for a grant of compulsory license.[493]

A licensee is to pay royalties within 45 days of the export notice, which should be provided at least 15 days before the export occurs.[494] It has been stated that the fact that the royalties' rates are related to the United Nations Human Development ranking of the importing country is definitely a "positive feature of Canada's law".[495] Given the fact that in the first version of the Bill, the royalties were set at the steady rate of 2 percent of the value of pharmaceutical products exported under compulsory license,[496] this statement seems to be correct.

As was said earlier, the period of a compulsory license was limited to two years from the day a license is granted (s. 21.09).[497] To justify this provision, the government

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[491] Jim Keon, *ibid.*
[492] *Regulations, supra* note 448 at para. 8.
[493] According to this formula, the lowest royalty rate possible is 0.02 percent of the value of the supply agreement, while the highest rate would stand on 3.5 percent. In any case, the rate ceiling will be 4 percent. See *supra* note 306.
[494] *Ibid.*
[495] *Supra* note 489 at 19.
[496] *Supra* note 313 at ss. 21.04(6)-(7).
[497] There is an option for one renewal for additional two-year period if the quantities of medicines authorized for export were not exported in whole during the period of the first two years See *supra* note 278, ss. 21.12(1)–(4).

argued that the Bill must comply with Article 31(c) of TRIPS, which determines the limited duration of a compulsory license. The government considered the two-year period reasonable, taking into account standard contracts on drug supply and given the fact that the safety issues as well as drugs' limited shelf-life necessitate a limit on the period of licenses.[498]

Trying to create a mechanism that would comply with Canada's obligations under TRIPS and, at the same time, express humanitarian purposes, was not an easy task. The Bill's sections range from largely humanitarian, such as the rate of royalties or exclusion of the "right of first refusal" provision, to strictly TRIPS-like, such as limited lists of eligible medicines and eligible importing countries. This is to attest to the extreme difficulty to decide which purposes the legislation should pursue. Whether it will be closer to an additional feature of Canada's general humanitarian effort on the global scene or a mere implementation of the WTO General Council's decision, shifting more to the spirit of TRIPS.

Conclusions:

Initially Bill C-9 was aimed to implement a waiver of Article 31(f) of TRIPS adopted in the WTO General Council's decision. However, the Bill also had sought a feasible balance between: 1) encouraging the prompt supply of life-saving medicines to the countries in need; 2) preserving the IPR of Canadian patent owners; 3) complying with the rest of TRIPS obligations, and 4) sending the right message to other industrialized nations that were to create the same kind of legislations.

[498] Marie-Josée Thivierge, *supra* note 309.

There were two different approaches to the Bill. 1) The Government's initial approach – the Bill is an autonomous piece of legislation implementing the WTO General Council's decision. Therefore, the Bill should comply with TRIPS and bear the TRIPS-spirit. 2) Civil Society Groups' approach – the Bill is a part of Canada's global effort to aid underdeveloped countries by, for example, helping them to build health care infrastructure.

Eventually, a detailed, at times overloaded with administrative procedures, mechanism of export of generic drugs under a compulsory license was created. The nature of the Bill remained unclear. The Amendment bore both humanitarian features of yet another foreign aid program and explicit characteristics of a commercially structured mechanism.

Chapter Six: Canada's Perspective on Bill C-9

a. The Bill and the Balance of Interests

Creating minimum international standards of IP protection and incorporating a stronger level of IP protection in national laws of the WTO member-countries were the major goals of the TRIPS Agreement. While setting relatively clear, and most importantly, enforceable rules of IP protection,[499] TRIPS connected IP issues with effective WTO enforcement and dispute settlement mechanisms. Despite the fact that TRIPS is often being criticized for ineffectiveness and for allowing developing and least-developed countries a free ride on the economic and technological advantages provided by industrialized members,[500] its mechanisms are also named a "cornerstone of today's globalized research, development, production, and trade".[501]

The Doha Declaration, on the other hand, emphasized the humanitarian aspects that were, for the most part, neglected in TRIPS.[502] The attempts to balance the patent rights of drug manufacturers with the public interest in access to affordable drugs are

[499] Gervais, *supra* note 10 at 287. See also J.H. Reichman and David Lange, "Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions" (1998-1999), 9 Duke J. Comp. & Int'l L. 11 at 17.
[500] Reichman & Lange, *ibid.,* at 19-20.
[501] Joseph Straus, "Bargaining around the TRIPS Agreement: the case for ongoing public-private initiatives to facilitate worldwide intellectual property transactions", Editorial Comment, (1998-1999) 9 Duke J. Comp. & Int'l L. 91 at 95.
[502] In the Doha Declaration, the WTO Members agreed that TRIPS should not prevent members from taking measures to protect public health and that TRIPS should be interpreted and implemented in a manner supportive of promoting access to medicines for all. Moreover, the Doha Declaration explicitly justified using the flexibilities of TRIPS to that end. See *supra* note 4 at para. 4. Also see Richard Elliott, *supra* note 238 at 2-3. Also see Jean Bizet, "The TRIPS Agreement and Public Health", (Report Presented at the Cancun Session of the Parliamentary Conference on the WTO, September 2003), online: Inter-Parliamentary Union <http://www.ipu.org/splz-e/cancun/5b.pdf> at 2.

evident in the Declaration.[503] The vague language of the Doha Declaration was preserved as a response to the demands of developing countries to retain the spirit of humanitarian aid and shift an accent to public health issues.[504]

Does Canada's Bill C-9 accommodate the correct balance?[505] Obviously, the title of the amendment to the *Patent Act: "Use of Patents for International Humanitarian Purposes to Address Public Health Problems"*, as well as its purpose[506] are supposed to attest to the humanitarian nature of the Bill. However, do the contents of the amendment agree with its title?

As was said, one of the most criticized provisions of the Bill (in its initial version) was the so-called "right of first refusal" provision.[507] This provision was not included in the final version of the Bill and the only requirement that was left was that the generic manufacturer would attempt to seek a voluntary license from the patentee "on reasonable terms and conditions".[508] The fact that the "right of first refusal" was removed from the Bill's final version attests to the humanitarian nature of the amendment.

Another obvious feature of the Bill's humanitarian nature is that the Bill waives one of the fundamental requirements included in Par. 1(b) of the WTO General Council's decision. The requirement being that the members would use the system only in cases of "a national emergency or other circumstances of extreme urgency… ". Although the purpose of the Bill is to alleviate access to medicines to address public health problems, it

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[503] *Supra* note 489 at 2-3.
[504] For example, the broad definition of the diseases that could be subject for a compulsory license: "AIDS, tuberculosis, malaria, and other epidemics" used in the Doha Declaration or a definition of "public health crisis". See *supra* note 4 at para. 1 (a)) & 4 (respectively). Also see Jean Bizet, *supra* note 502 at 3.
[505] The Royal Assent version of the Bill will be analyzed (14th May 2004). See *supra* note 278.
[506] The declared purpose of the amendment is to facilitate "access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those relating from HIV/AIDS, tuberculosis, malaria and other epidemics." See *supra* note 278 at s. 21.01.
[507] *Supra* note 313 at ss. 21.04(6)-(7). (See discussion in Chapter V). Also see Jim Keon, *supra* note 314.
[508] *Supra* note 278 at ss. 21.04 (3)(c)(i-ii).

does not limit the use of the Bill for the cases of public health emergencies. The requirement of "a national emergency or other circumstances of extreme urgency" is only invoked when an importing country is not a WTO member and is not listed in the list of eligible importing countries (s. 21.03(1)(d)(ii)(A)). The concept of allowing non-WTO member countries to use the system proves the system to be of a humanitarian character, especially given the fact that the WTO General Council's decision itself applies only to the WTO member countries. Moreover, a waiver of a requirement that the importing country should face a national emergency in order to use the mechanism is obviously a humanitarian gesture.

On the other hand, the Bill obviously bears characteristics of the TRIPS-plus agenda as well. For example, Schedule 1, which has a limited list of medicines covered by the Bill. Civil Society Organizations called to remove this provision from the Bill's final version because of its inconsistency with the Doha Declaration that had not in any way restricted the definition of eligible pharmaceutical products.[509]

Regarding the nature of the Bill, *i.e.,* whether it is a humanitarian or TRIPS-like legislation, we can once again use a theory of two possible approaches. (See discussion in Chapter V(b)). According to the "TRIPS-like" approach, the Bill is to be seen as an autonomous piece of legislation expressing Canada's attempt to fulfill its obligations under TRIPS and the WTO General Council's decision. The humanitarian approach suggests viewing the proposed amendment more as part of a general picture, *i.e.,* part of Canada's effort to help developing and least-developed countries fight infectious diseases. (See discussion in Chapter V(b).)

[509] *Supra* note 213 at 18-19.

b. Possible Implications for Developing Countries and the Canadian Generic Pharmaceutical Industry

Although the WTO General Council's decision is considered to be the one that changed the IP regime in the field of export of generic medicines[510] and despite the fact that the decision was reached almost three years ago, no country seems to be in a rush to use the mechanism set in the decision. The same can be said about Canada's Bill C-9. Although the legislation was enacted in May 2005 and Canada is one of the biggest generic producers in the world, no developing country has yet requested a grant of a compulsory license.[511]

This fact seems to be even more surprising given the magnitude of the problem of access to drugs in developing countries afflicted with pandemics. Moreover, the dilemma of access to life-saving drugs and patent protection strengthened by TRIPS was at the center of global debate ever since the dispute about the *South African Medicines and Related Substances Control Amendment Act of 1997*.[512] This act authorized a grant of compulsory licenses for supply of cheaper generic drugs in order to protect public health "notwithstanding anything to the contrary contained in the Patent Act".[513] The Act was

[510] *The General Council Chairperson's Statement*, *supra* note 268.
[511] Geoff Blackie, *supra* note 362 at 1.
[512] *Medicines and Related Substances Control Amendment Act*, No. 90 of 1997, online: Department of Health <http://www.doh.gov.za/docs/legislation/acts/1997/act90.pdf>.
[513] *Supra* note 216 at 200-201. See also Kara M. Bombach, "Can South Africa Fight AIDS ? Reconciling the South African Medicines and Related Substances Control Amendment Act with the TRIPS Agreement", 19 B. U. Int'l L. J. 273.

challenged by the US for violation of TRIPS.[514] At approximately the same time, the US – Brazil process at the WTO had been initiated.[515]

A compulsory license seems to be one of the effective means to lower prices of essential drugs. If so, why are developing countries in no hurry to use the system that allows a grant of such means? To answer this question, it is necessary to analyze it from two different angles: the importing countries' point of view; and that of potential exporters, *i.e.,* generic manufacturers.

The example of Guatemala illustrates the importing developing countries' perspective.[516] It has been argued that Guatemala, which is apparently in need of life-saving medicines, would not be able to use the mechanism proposed in the Bill.[517] Here are several reasons for this inability to use the system: 1) the drug needed for AIDS treatment (a fixed-dose combination of ARVs) was not included in Schedule 1, and therefore is not eligible for the export under a compulsory license; 2) the MSF is an NGO and therefore, would not be able to directly procure medicines, because it neither has any relation to the government of Guatemala nor is it a governmental agency; 3) in a country in which the AIDS issue is not on the government's political agenda, the chances of receiving the government's permission to import generic drugs, as the Bill requires, are very slim.

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[514] Bailey & Bombach, *ibid.*
[515] The US challenged Brazilian compulsory license mechanism through the WTO dispute resolution system. See *supra* note 362 at 3.
[516]This example was brought by Rachel Kiddell-Monroe (Coordinator (Canada) Access to Essential Medicines Campaign, Doctors Without Borders and Dr. Virginia Gularte (MSF Guatemala, Doctors Without Borders). Only $38 per person per year can be spent in Guatemala on health care, while the costs of a year of treatment for HIV/AIDS and other associated infections are far beyond this limit. See *supra* note 330.
[517] Although the example of Guatemala was related to the first draft of the Bill, the changes in its last version are related only to the elimination of the "right of first refusal" provision.

It is obvious that one of the main obstacles for people in poor countries to reach essential drugs are the high prices of medicines.[518] Only in the last few years the prices began to fall, mostly due to generic companies' competition.[519] To be able to participate in the system proposed in the Bill, generic manufacturers must have a prospective reward.[520] As the Director of the Asia & Pacific International Group of one of the largest generic companies[521] (*hereinafter: an Interviewed Person*) stated: " … If there is no patent issue, any pharmaceutical company will market the products just if there [is] a profitable gross margin… ".

Ideally, the effective legislation would provide a flexible, efficient, and certain process allowing the export of medicines under a compulsory license, so that a generic producer would be commercially motivated to apply for a compulsory license.[522] Given the answers of the Interviewed Person, the important factors that could serve as incentives for a generic manufacturer to enter a contract under a compulsory license, except for potential profits, are: "a reimbursement system and easy and cheap registration process … ".[523] Although Apotex announced its desire to produce the generic equivalent of Retrovir-AZT (Apo-Zidovidine) the day after Bill C-56 (Bill C-9's predecessor) was

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[518] *Supra* note 362 at 2-3.
[519] Indian generic manufacturer, "Cipla", started offering to the NGOs a package of ARVs for 350$ a year, and by 2004, after two more Indian companies and a South African one entered competition, the price dropped to about 140$ a year. See *ibid.,* at 2.
[520] *Ibid*., at 12.
[521] The author corresponded with the Interviewed Person through electronic mail. The name of this person is not to be disclosed according to his/her wish. The answers of the Interviewed Person were received on 2 April 2006.
[522] For example, despite a lack of incentives to produce generic drugs for small markets, some generic companies could be incentivized by huge volumes of pharmaceuticals needed in poor importing country. Therefore, the generic producers could find it rewarding to export the drugs even if the prices in the country of destination are extremely low. See *supra* note 362 at 19-20. Also see Keith Maskus, "On TRIPS, Drug Patents and Access to Medicines – Balancing Incentives for R&D with Public Health Concerns" (September 2003), online: Development Gateway <http://old.developmentgateway.org/download/206719/Maskus_on_>.
[523] From the correspondence with the Interviewed Person: "There are some countries that ask for clinical trials as part of the registration process, which cost money and reduce profitability… ".

introduced,[524] it seemed to be more of a humanitarian gesture than a desire to use the new mechanism.

All in all, the Bill seems to be loaded with administrative obstacles and it seems too inflexible toward an applicant[525] to provide a commercially worthy deal for a generic manufacturer to motivate him to even enter a contract with an importing country.

Another critical issue is that for a humanitarian and non-commercial act, the Bill is too heavily relying on private parties, *i.e.,* a generic manufacturer and a patentee. The governments of exporting and importing countries are not so much involved in the proposed system. Aside from complying with all the administrative provisions the Bill requires in order to grant a license, the governments are relieved from any other form of participation in the system.

However, if the government of a developed country could even partly reimburse a generic manufacturer for a supply of drugs to the developing world, it could allow people in poor countries access to cheaper drugs, while the generic manufacturer would enjoy even partial profitability.[526] According to the Interviewed Person: "… If a pharmaceutical company receives an obligation from a government to receive some incentives, such as tax, free infrastructure to build a manufacturing site, the pharmaceutical company may provide some products free of charge, but will have higher profitability in the future.

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[524] The Apotex Group, Press Release, "Canadian-Owned Generic Company Prepared To Provide HIV/AIDS Drug to Developing Nations" (7 November 2003), online: The Apotex Group <http://www.apotex.com/PressReleases/20031107-01.asp?flash=Yes>. See also *supra* note 362 at 20.

[525] One of the major factors for the legal uncertainties of the Bill is its s. 21.14, which allows termination of a license by the order of Canada's Federal Court following patentee's application. That is, provided that the patentee established the inaccuracy of the information provided by the licensee or that the obligations of the licensee were not met or that the product was re-exported from the importing country. See *supra* note 279. See also *supra* note 362 at 22.

[526] Based on the answers of the Interviewed Person.

Other option is to provide several products with very low profitability and some others with high gross margin."

Therefore, ideally, humanitarian legislation would oblige an exporting government to sponsor a generic manufacturer should his contract with an importing country become too risky. From the correspondence with the Interviewed Person:

> (Q) "According to your knowledge of Asia's market, what would be the lowest possible price that would allow local population in a poorest country in Asia to buy an exported drug … and would still be profitable for a generic producer?"
>
> (A) "I cannot provide figures, but if the government were involved, the price for the patients might be reasonable, even for poor people."

Instead of involving the government, the Bill solves the problem of a risky contract in a completely different way, again shifting the accent on the private parties. The Bill, in ss. 21.14(a)-(i), allows a patentee to apply for the Federal Court's order to terminate the license following the occurrence of one of nine different circumstances. The difficulty in such a solution is that although it grants a patentee a certain level of control over the fate of his invention, it also increases the uncertainty of the system for a licensee, *i.e*., a generic manufacturer.

Both a generic manufacturer and a research-based company enter the system with the same purpose, although pursued in different ways. Unfortunately, this purpose can in no way be named "non-commercial". A generic manufacturer intends to make profits from supplying drugs to a country in need, even if supplying medicines at extremely low prices. On the other hand, a patentee would want to protect his patented invention from

being used in a commercial way, when he does not receive adequate remuneration for such use.

Considering this fact, the system that does not rely so much on governmental involvement, but instead depends mostly on the generic producer and the patentee, could not possibly be called "humanitarian and non-commercial".

c. Perspective on the New Amendment from the Research-Based Pharmaceutical Industry's Point of View

Brand-name pharmaceutical companies argue that they are actively participating in the global effort to fight diseases and improve public health in developing countries.[527] However, their main argument is that such an effort is only one part of the solution for alleviating access to health care. According to this approach, governments and international aid communities should make a combined effort to achieve the purpose of making essential drugs accessible to the poor.[528] As part of this agenda, Rx&D declared their support of the Bill C-9, but stressed that the system should be strictly humanitarian and non-commercial.[529] Rx&D suggested that the Bill could be considered successful only if it combined means to ensure that: 1) patients are properly diagnosed; 2) have

[527] Such combined initiatives are: the Academic Alliance for AIDS Care and Prevention in Africa, funded by Pfizer (one of the largest research-based pharmaceutical companies in the world); the Accelerating Access Initiative, which is country-led, cooperative initiative of the UNAIDS, WHO, UNICEF, the World Bank, and six research-based pharmaceutical companies (Merck, Boehringer Ingelheim, Bristol-Myers Squibb, Roche, GlaxoSmith-Kline and Abbott), and more. These initiatives aim to build infrastructure, train medical personnel, and also improve access to pharmaceuticals by providing drugs at more affordable prices. See "Building Healthier Societies Through Partnership", *International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Report* (August 2003), online: IFPMA <http://www.ifpma.org/site_docs/Health/Health_Initiatives_Brochure_0912.pdf> at 5-6.
[528] *Ibid*. at 3. See also *Rx&D Submission to the INST Committee, supra* note 332 at 12-15.
[529] *Rx&D Submission to the INST Committee, ibid*., at 3-5.

access to adequate medical facilities; 3) medicines are correctly administered; and 4) patients' compliance with doctors' instructions is monitored.[530]

A research-based company (a patentee) is mentioned several times in the mechanism proposed in the Bill. A patentee is to accept or decline a request of a licensee for a voluntary license. Additionally, if a compulsory license is issued, the patentee is to receive suitable remuneration.[531] There are several provisions that were meant to preserve interests of the right owner.[532]

It has been argued that there would be no impact on incentives to invest in the R&D of new medicines for infectious diseases afflicting mostly developing nations. Research-based companies have no viable incentives, or have the weakest incentives at the most, to develop drugs for such diseases, because of a lack of potential reward for such an investment.[533]

As for the remuneration formula,[534] although the formula provides certainty for a generic manufacturer by that it is relatively clear and simple,[535] for a research-based company, the formula presents a problem. Being related to the UN Human Development Index and providing a *de facto* ceiling of 4% and the lowest compensation's rate of 0.02%, the formula could be considered by the Rx&D as inadequate remuneration, as

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[530] *Rx&D Submission to the INST Committee, ibid*., at 11.
[531] *Supra* note 522.
[532] For example, importing countries must prevent trade diversions and re-selling of the drugs produced under a compulsory license, while other countries must prevent an entry of such drugs to their territories. *Ibid.*
[533] *Ibid.* See also *supra* note 185. The study was conducted in regard to relationship between pharmaceutical innovations and the burden of diseases in developed and developing countries.
[534] As prescribed by the regulations. See *Regulations, supra* note 448 at s. 8.
[535] *Supra* note 362 at 15.

opposed to the WTO General Council decision's requirement.[536] The Rx&D argued that even a fixed rate of 2%, proposed in the initial version of the Bill, was inadequate and non-compliant with TRIPS.[537] However, as mentioned earlier, according to ss. 21.08 (4)-(7) of the Bill, a patentee can request the Federal Court's order to increase royalty payments, if the royalties are "not an adequate remuneration for the use of invention".[538] This provision reduces a level of certainty for a generic manufacturer,[539] but it does add to the level of certainty of a research-based company, knowing that if remuneration is inadequate, the patentee has the means to intervene in the process.

It seems that although research-based pharmaceutical companies played a significant role in designing the legislation, it eventually would bear no major impact on them. It has been argued that the Rx&D were disappointed that the research-based industry was practically left behind and its expertise was not recognized in the Amendment.[540] Suggesting an "equal opportunity to supply the country in need",[541] the research-based industry expressed its desire to fully participate in the system. However, as the President of the Canadian Generic Pharmaceutical Association stated, should brand-name companies so desire, they can sell medicines at any price, or even donate

[536] According to Par. 3 of the WTO General Council's decision, adequate remuneration was to be paid on a case-by-case basis "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member". See *supra* note 6 at para. 3.
[537] *Supra* note 332 at 20.
[538] All that, while taking into account humanitarian and non-commercial grounds for issuing a license and economic value of the use of an invention to the importing country.
[539] By that it increases chances for long and costly litigation.
[540] Letter from Jean-Michel Halfon to Mathew Fraser, Editor-in-Chief of The National Post (26 April 2004), online: Canada's Research-Based Pharmaceutical Companies <http://canadapharma.org/Media_Centre/News_Releases/2004/NP-Apr26-04.pdf>.
[541] So that both a patentee and a generic manufacturer could attempt to negotiate a contract with an importing country during 30 day-period following a request of the importing country for the supply of drugs. See *supra* note 332 at 17.

them, at any time with no need for a compulsory license system, because they are the right holders.[542]

d. The Role of the Government or Who Will Pay for the Consequences?

In May 2004, the Federal Government of Canada (the Government) announced that with the passage of Bill C-9, Canada moved a step closer to the implementation of its initiative to provide affordable medicines to developing and least-developed countries.[543] Earlier, in April 2004, while presenting proposed amendments before the INST Committee, the Government stressed that by passing this legislation, "Canada is showing partners worldwide how international trade policy can help significantly improve the lives of people in developing countries … ".[544] A year later, after the Bill was enacted, it was stated that Bill C-9 came together with other humanitarian efforts of the Government in aiding developing and least-developed countries in their fight against pandemics.[545]

Bill C-9 was not Canada's first initiative in assisting the developing world in its fight against infectious diseases.[546] However, the Bill is different from any other attempts

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[542] Jim Keon, *supra* note 330.
[543] Hon. Pierre Pettigrew, Minister of Health, said addressing the issue of the Bill's enactment: "The Government of Canada has shown tremendous leadership in this move to help people in developing and least-developed countries fight HIV/AIDS, malaria, tuberculosis, and other public health problems by facilitating their access to safe, effective and much-needed medicines … " See Industry Canada, News Release, "The Jean Chrétien Pledge to Africa Act Approved by Parliament" (13 May 2004), online: Industry Canada <http://www.ic.gc.ca/cmb/welcomeic.nsf/cdd9dc973c4bf6bc852564ca006418a0/85256a5d006b972085256e93007efa18!OpenDocument>.
[544] Industry Canada, News Release, "Government of Canada Moving Forward with the Legislation to Improve Access to Medicines in Developing Countries" (20 April 2004), online: Industry Canada <http://www.ic.gc.ca/cmb/welcomeic.nsf/558d636590992942852564880052155b/85256a5d006b972085256e7c004d3207!OpenDocument&Highlight=2,peterson>.
[545] *Supra* note 280.
[546] Since 1994, Canada donated $22 million to programs against malaria; supplied about $1.6 million annually to the Special Program for Research and Training in Tropical Diseases. Additionally, about $100

to aid the developing world because it provides a mechanism that is not based entirely on governmental involvement. While other humanitarian initiatives led by the Government did not involve private parties for the most part,[547] the Bill seems to be almost entirely based on the research-based and generic pharmaceutical companies' efforts. According to the Bill, the Government's role in the export of generic drugs under a compulsory license is limited to only a few aspects.[548] All these aspects are more procedural than substantive. In fact, the Government seemed to consider that its task was but to create the mechanism that would permit generic companies to facilitate the flow of low-cost drugs to underdeveloped countries. This could be achieved by allowing generic pharmaceutical companies to enter a competition in order to lower prices of essential drugs in poor countries' markets.[549] Another important task was to ensure the safety, efficacy, and quality of exported drugs,[550] while at the same time maintaining the integrity of Canadian patent right holders.[551]

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million were donated to the Global Fund to Fight AIDS, TB, and malaria. The Canadian International Development Agency (CIDA) committed about $100 million in African-led efforts for care, treatment and prevention of AIDS. See *supra* note 544.

[547] The private parties had their own ongoing initiatives intended to aid the developing world, such as Canada's Research-based Pharmaceutical Companies' combined initiatives. See Canadian Research-Based Pharmaceutical Companies, "Our International Commitment: Alleviating Diseases and Illness in Developing Countries", online: Rx&D <http://www.canadapharma.org/International_Commitment_Tsunamis_05_EN.pdf>. Generic manufacturers have their own aid programs, such as donations of the Apotex Inc. in Tsunami relief in 2005. See The Apotex Group, News Release, "Canadian Pharma Company Sets Bar For Company Donating For Tsunami Relief Efforts" (5 January 2005), online: The Apotex Group <http://www.apotex.com/PressReleases/20050105-01.asp?flash=Yes>.

[548] Such as amending Schedules 1-4, based on the recommendations of the appointed Ministers (s. 21.03); granting an authorization, subject to fulfillment of all the requirements by the applicant, while the Commissioner of Patents has no discretion (s. 21.04); making regulations as to the rate of remuneration paid to a patentee by a licensee (s. 21.08(2)); renewing an authorization (again, with no discretion on behalf of the Governor in Council) (s. 21.12(1)), and establishing advisory committee to amend Schedule 1 three years after the Bill's enactment (s. 21.18).

[549] Ministers Lucienne Robillard and Pierre Pettigrew, *supra* note 309.

[550] Hence, an amendment of s. 37(2) of the *Food and Drugs Act* stating that the drugs produced for the export under this mechanism would be viewed as though they were produced for the consumption within Canada and be subject to the strict inspection as such. See *supra* note 436.

[551] Ministers Lucienne Robillard and Pierre Pettigrew, *supra* note 309.

The efficiency of such a solution was challenged by the study conducted by the Fraser Institute. It has been argued that the Government has actually gone too far and granted generic companies unfair industrial advantages at the expense of brand-name companies.[552] According to this study, while brand-name companies most certainly will not benefit from the compulsory license regime, generic manufacturers receive a competitive advantage in that they can enter another market that they would not be able to compete in without the compulsory license mechanism.[553]

Moreover, it has been found that the rationale for the Bill, as expressed by the Government, was unfeasible in itself. Patent protection, in the authors' opinion, does not pose a barrier to access to affordable drugs in developing countries. The poverty, though, is the barrier that makes selling drugs in these countries unprofitable.[554] Following this argument, the mere fact that the Government created the mechanism of export under a compulsory license would not significantly aid poor countries, but it is more likely to interfere with the pharmaceutical market by granting an opportunity to the generic producer to market new products at the expense of an opportunity for a brand-name company to supply its products in this market.[555] [556]

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[552] Brett J. Skinner, "Generic Drugopoly: Why Non-patented Prescription Drugs Cost More in Canada than in the United Stated and Europe?" (August 2004) 82 Public Policy Sources, online: The Fraser Institute <http://www.fraserinstitute.ca/admin/books/files/GenericDrugopoly.pdf> at 21-22.

[553] *Ibid.,* at 25.

[554] It has been stated: "In markets where the average annual spending on drugs is US$2 per person and where national health budgets average about US$8 per year in per capita spending, it is unlikely that generic companies will have any economic incentive to distribute drugs in these countries, even at lower prices ... This could explain the lack of generic commercial distribution to these markets, the reluctance to seek patents, and the charitable activities of many companies in place of normal marketing… ". *Ibid.,* at 21-22.

[555] *Ibid.*, at 22.

[556] Although it has to be said that such an opportunity is only theoretical, because research-based companies have no incentives to distribute their products in poor markets due to the lack of adequate reward, given the rates of investment in developing the new product. See *supra* note 185.

That said, it seems that although generic competition could significantly lower the prices of essential medicines,[557] it would not ensure that the prices would reflect the purchasing power of people in poor countries. Moreover, nothing in the mechanism of export established in the Bill provides effective measures to ensure that the exported drugs would reach the actual patients instead of being lost in various corrupt structures in the country of destination.

Obviously, to make a feasible mechanism, the Government had to be more involved in the practical implementation of the system. As Mr. Terry Duguid stated:

> "Solutions these days are in multi-party … multi-sectoral approaches. The Government cannot do it alone. They need non-profit partners on the ground, in the countries; the private sector that has management expertise, they often have the drugs they created through their ingenuity. So solutions are coming from partnership …".[558]

It could be argued that providing a mechanism for encouraging the export of generic drugs to countries, in which Canadian pharmaceutical manufacturers, otherwise, would not claim any market share, is sufficient for the Government's involvement. The following data can substantiate the claim that the volume of Canadian export of pharmaceuticals to poor countries is extremely low as it is. Export of pharmaceutical products from Canada to the most countries in Africa between the years 2001 – 2005 was less than 0.1% of the total export of pharmaceutical products. The situation with Asia was

[557] After Indian generic manufacturers, such as "Cipla", "Hetero" and "Ranbaxy" started marketing their triple-combo therapy medicines against AIDS, the prices dropped from 900-1500 per patient per year (the price of the patented triple-combo with significant discount) to 295-350 per patient per year (the price of the generic drug). See Brook K. Baker, "Producing HIV/AIDS Medicines for Export/Import Under TRIPS, Articles 31(f), (k), and 30" (6 November 2001), online: Trans Atlantic Consumer Dialog (TACD) <http://www.tacd.org/db_files/files/files-239-filetag.doc> at 6-7.
[558] *Supra* note 418.

almost the same. Japan, which is neither developing nor poor, was the only country that the volume of export of medications from Canada exceeded 1% in the last five years. The volume of export of pharmaceutical products to all other countries in Asia, except Burma (Mayanmar), in 2002, has not risen higher than 0.5% of total Canadian exports. (See Fig. 1 and Fig. 2.)

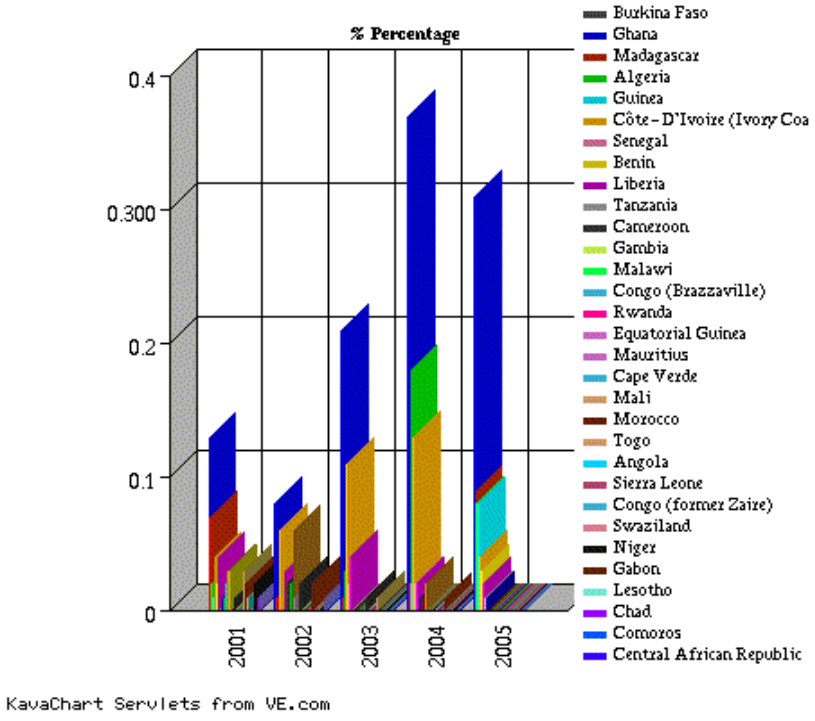

Fig. 1 – Canadian exports of pharmaceutical products to Africa (excl. Middle East) in the latest five years. Source: Industry Canada, "Trade Data Online: Trade by Product (HS) – HS Codes", online: strategis.gc.ca <http://strategis.ic.gc.ca/sc_mrkti/tdst/tdo/tdo.php#tag>.

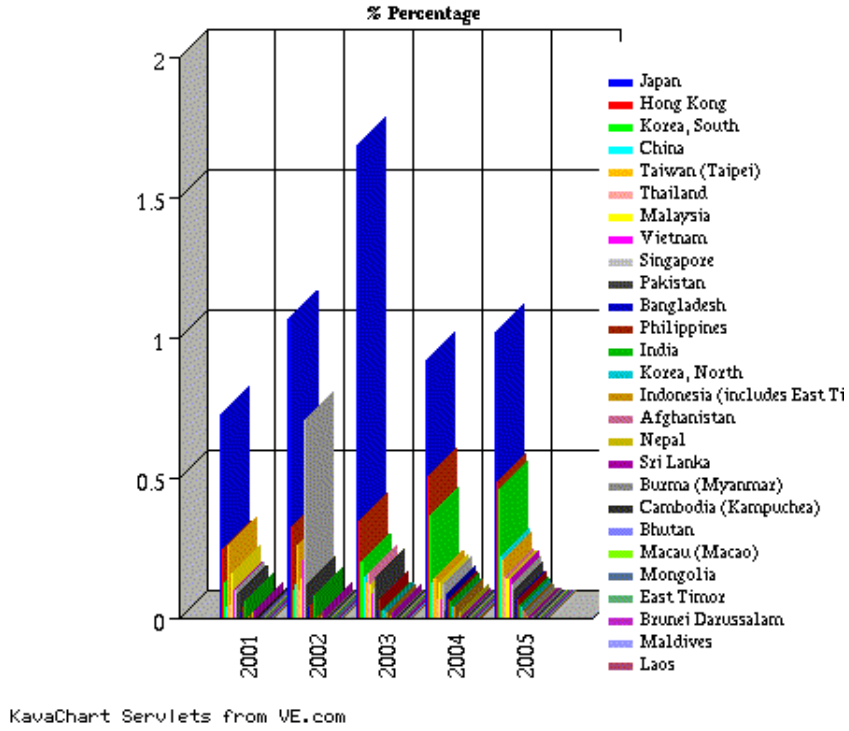

Fig. 2 - Canadian exports of pharmaceutical products to Asia (excl. Middle East) in the latest five years. Source: Industry Canada, "Trade Data Online: Trade by Product (HS) – HS Codes", online: strategis.gc.ca <http://strategis.ic.gc.ca/sc_mrkti/tdst/tdo/tdo.php#tag>.

To substantiate this claim from the opposite side of the chain, *i.e.,* generic companies, the example of Teva Pharmaceutical Industries Ltd., can be examined. Israeli-owned Teva[559] reported that its sales from January – June 2005 to countries other than Europe and North America comprised of only 11.5% of total sales during that period. That is compared to 58.9% of sales to North America and 29.6% to Europe.[560]

Setting up a mechanism that could possibly change the situation and encourage the export of essential pharmaceuticals to countries which otherwise would not be attractive markets, without ensuring that the mechanism would actually work, is hardly a

[559] "Teva" now owns Canada's second largest generic company, "Novopharm". See *supra* note 552 at 22.
[560] Teva Pharmaceutical Industries Ltd., "Teva Reports the Results for the Second Quarterly of 2005", Summary of the Data Analysis (1 August 2005), online: Teva Pharmaceutical Industries Ltd. <http://www.tevapharm.com/hebrew/pdf/Q2-05-PR-H-Combined-final-010805.pdf> at 8 (Hebrew) [translated by author].

winning policy. The question is: how could the Government be more involved in the practical implementation of the mechanism proposed in the Bill? Should the Government actually take over the mechanism and turn it into yet another governmental aid program? Or should it just increase its own involvement in the system that would then be based on the collaboration of the Government, generic and research-based industry as well as NGOs?

Canada's Foreign Aid Programs

Through Canada International Development Agency (CIDA), Canada established the $500 million Canada Fund for Africa.[561] One of the Fund's initiatives was the research and development of an HIV/AIDS vaccine. The Canada Fund for Africa donated $5 million to the African AIDS Vaccine Program, which is set to identify sites and infrastructure for vaccine trials, as well as build laboratories for African scientists to perform the needed research, train professional personnel, *etc*.[562] As was stated by the Hon. Aileen Carroll, Minister of International Cooperation:

> "It works with African institutions, governments, and the voluntary sector to deal with some of the most critical issues of our time: HIV/AIDS, peace and security, and governance. The Canada Fund also helps spur economic growth, bridge the digital divide and support local efforts to increase food production and manage critical natural resources …".[563]

[561] The fund was established as a response to the New Partnership for African Development (NEPAD) that was announced at the G-8 Summit in Kananaskis, Alberta. Canadian International Development Agency, "Canada Fund for Africa: the Fund: New Vision, New Partnership", online: Canadian International Development Agency <http://www.acdi-cida.gc.ca/canadafundforafrica>.
[562] Canadian International Development Agency, "Investing in the Future: Health Challenges in Africa: The Best Hope: HIV/AIDS Vaccine Research and Development", online: Canadian International Development Agency <http://www.acdi-cida.gc.ca/CIDAWEB/acdicida.nsf/En/REN-218125228-PL7#1>.
[563] Canadian International Development Agency, the Hon. Aileen Carroll, "Building New Business with Africa: What Works!" (Speech at the Conference on Forging a Partnership on Africa — Public and Private

In November 2002, the Minister for International Cooperation announced that Canada would provide another $19 million through CIDA to support different initiatives, such as slowing the spread of AIDS in Cambodia, Thailand, Vietnam, and the Lao People's Democratic Republic; clinics and outreach programs in southern Vietnam; combating AIDS in Nigeria, *etc*.[564]

Additionally, the Canadian and South African governments run a government-to-government program named "Official Development Assistance" (ODA). The program is intended to directly support South African growth and development and is also channeled through CIDA.[565] The program amounts to as much as $700 million annually and Canada plans to provide $6 billion through this program for five years, beginning in 2002.[566]

Another initiative was to establish the Canada Investment Fund for Africa to encourage private sector investments in Africa's development.[567] The Government donated $100 million in order to make the private sector to contribute the same amount. This was to ensure implementation of the New Partnership for African Development (NEPAD) principles, such as good governance, transparency, *etc*.[568]

Although factors such as good governance, building capacity and engaging civil society groups were named "factors of central importance to the effective use of aid

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Sector Initiatives for Africa, 6 April 2004), online: Canadian International Development Agency <http://www.acdi-cida.gc.ca/CIDAWEB/acdicida.nsf/En/JER-324144537-R77>.

[564] CIDA, News Release, "Canada Fights HIV/AIDS in Developing Countries" (28 November 2002), online: Canadian International Development Agency <http://www.acdi-cida.gc.ca/CIDAWEB/acdicida.nsf/En/JER-330162057-T2S>.

[565] Government of Canada, "Canada-South Africa Official Development Assistance", online: Government of Canada <http://www.dfait-maeci.gc.ca/southafrica/cida-en.asp>.

[566] Government of Canada, "Canada Implements the G-8 Africa Action Plan: Delivering on Commitments, One Year Later" (May 2003), online: Government of Canada <http://www.g8.gc.ca/att-en.asp>.

[567] *Ibid.*

[568] *Ibid.*

investments"[569] and were to be incorporated into considerations while setting up a suitable policy, Canada's foreign aid programs still bore stern criticism. It has been argued that not only Canada's foreign aid policy does little to enhance the economic growth of developing countries, but it also tends to harm the economies of poor countries or at the very least, it remains ineffective.[570] The biggest flow of aid goes to the world's poorest nations, which happen to be the most poorly governed ones.[571] As a significant part of the poor country's resources, such aid protects the same governmental policies that are responsible for the failed economy of the country.[572]

This critique seems to be more accurate in relation to the project-based approach to foreign aid policies.[573] It has been stated that the program-based approach could be much more beneficial.[574] The new, program-related approach of CIDA should have included measures to encourage economic growth and sustainable development in accordance with the United Nations Millennium Development Goals.[575] For example,

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[569] CIDA, "Canada Making a Difference in the World: A Policy Statement on Strengthening Aid Effectiveness" (September 2002), online: Canadian International Development Agency <http://www.acdi-cida.gc.ca/INET/IMAGES.NSF/vLUImages/pdf/$file/SAE-ENG.pdf> at 5.

[570] According to this study, aid that flows directly to the government of the recipient country can distort the local decision-making process; the amounts of aid can be bigger than the country's governmental expenditure; the aid's evaluation can be concentrated on narrow project-specific measures, and so on. Moreover, the aid dollar could be turned to the wrong objectives, according to the priorities of the recipient country's government that are not always similar to the intentions of a donor-government. See Dexter Samida, "A Hand Out Instead of a Hand Up: Where Foreign Aid Fails", 30 Public Policy Sources, online: The Fraser Institute <http://www.fraserinstitute.ca/admin/books/files/For-aid(v8).pdf> at 7.

[571] *Ibid.,* at 10.

[572] *Ibid.*

[573] While the project-based approach has been considered the most natural means to provide development aid for a long period, its flaws, such as, for example, it being focused on the specific mission, made the government turn to the program-based approach. The program-based approach is focused on encouraging local development programs. See *supra* note 569 at 5-6.

[574] *Ibid.,* at 6.

[575] The United Nations Millennium Declaration (Resolution 55/2) was adopted in September 2000. One of the millennium goals stated in the Declaration was encouraging development and elimination of poverty, based on good governance within each country as well as on the international level. See *United Nations Millennium Declaration*, GA Res. 55/2, UN GAOR, 55th Sess., UN Doc. A/RES/55/2 (18 September 2000), online: United Nations <http://www.un.org/millennium/declaration/ares552e.pdf> at s. III, para. 11-14. Generally, the goals are to eradicate extreme poverty and hunger; to achieve universal primary education;

CIDA decided to replace the policy of tied aid[576] with the new programming approach. According to this approach, the aid programs are to be based on coordination between the donor and the local governments, emphasize building capacity and encourage sustainable development in developing countries.[577]

Is Bill C-9 Yet Another Foreign Aid Program?

Given the structure of the mechanism of export of generic drugs to underdeveloped countries proposed in the Bill, it absolutely cannot fit into the frame of project-based foreign aid policy. The Bill is a long-term program built into Canada's patent system and it includes various mechanisms of collaboration (even if mostly theoretical for now) between different players in the pharmaceutical industry. Therefore, the Bill could probably fit into the frame of the newly developed program-based foreign aid policy.

As was said earlier, the purpose of the Bill, stated in s. 21.01, is to facilitate "access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries …". Therefore, the amendment could theoretically be a part of the long-term "commitment of the Government of Canada towards strengthening the effectiveness of its development assistance program …".[578] The Government admitted the need for a multifaceted solution. It has been stated that

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to promote gender equality and empower women; to reduce child mortality; to improve maternal health; *to combat HIV/AIDS, malaria and other diseases*; to ensure environmental sustainability, *to develop a global partnership for development*. See "UN Millennium Development Goals", online: United Nations <http://www.un.org/millenniumgoals/>.

[576] The practice of "tied aid" means that aid funds will be used for purchases in donor countries. This practice was criticized for being incompatible with "the promotion of effective development partnerships, local ownership, and capacity building strategies". See *supra* note 569 at 19-20.

[577] *Ibid.*, at 22.

[578] *Ibid.*, at 32.

allowing access to drugs at lower prices would not be enough to effectively aid developing countries in strengthening, or building anew, their health care systems.[579] This position is to attest to the fact that whatever intentions the Government had when the Bill was submitted,[580] after it left the INST Committee, the Bill was presented as a "part of Canada's contribution to the global effort to combat disease in developing countries".[581]

Indeed, there is an example of productive collaboration between the private and public sectors that succeeded in bringing relief to the developing countries' fight against infectious diseases: the Bill and Melinda Gates Foundation.[582] Bill C-9, on the other hand, although seems to involve all of the essential players in the pharmaceutical field, still is not that efficient. The problem is that the way the parties are expected to carry out the collaboration according to the Bill is far from effective. Because of the initial intent of

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[579] During the debates of the House of Commons at the Third Reading, the Hon. Aileen Carroll, Minister for International Cooperation, stated: " … we recognize that access to less expensive generic versions of medications alone is not enough. Without well-trained health care workers and the adequate infrastructure, developing countries will be unable to reverse the spread of these diseases. That is why in addition to moving forward on Bill C-9, Canada continues to help developing nations build their capacity in their health care systems. By moving on these two fronts at once, increasing access to drugs and strengthening health care systems, Canada is working very hard to enable poor countries to scale up the treatments …". See Canada, Legislative Assembly, *Edited Hansard*, 44 (29 April 2004) at 1245 (the Hon. Aileen Carroll), online: Parliament of Canada <http://www.parl.gc.ca/37/3/parlbus/chambus/house/debates/044_2004-04-29/han044_1245-E.htm>.

[580] The Government initially presented the Bill as a strict implementation of the WTO General Council's decision, rather than a part of Canada's general attempt to aid developing countries. (See discussion on that issue in chapter V.)

[581] Aileen Carroll, s*upra* note 579.

[582] "Bill & Melinda Gates Foundation: About Us", online: Bill & Melinda Gates Foundation <http://www.gatesfoundation.org/default.htm>. Mr. Terry Duguid mentioned in the interview that there is a consortium between the International Center for Infectious Diseases, Sanofi Pasteur Inc., the Gates Foundation, the Government of Canada, the University of Manitoba, the University of Montreal and National Microbiology Laboratories. This R&D collaboration is meant to bring for creation of a new HIV/AIDS vaccine and is sponsored by the Gates Foundation. The Gates Foundation offered to pay 50% of the costs of R&D in that project. See *supra* note 418 (from the interview with Mr. Duguid). Additionally, the Gates Foundation plans to commit $1.5 billion for the Global Alliance for Vaccines and Immunization (GAVI), which is the alliance between the private and public sectors bringing together governments of developing and developed countries, pharmaceutical manufacturers, NGOs, UNICEF, the WHO, the Gates Foundation and the World Bank. See "What is GAVI?", online: GAVI Alliance <http://www.vaccinealliance.org/General_Information/About_alliance/index.php>. Also see "Foundation Fact Sheet", online: Bill & Melinda Gates Foundation <http://www.gatesfoundation.org/MediaCenter/FactSheet/>.

the Government to present the Bill only as an implementation of the WTO General Council's decision, the Bill was too restrained in the boundaries of TRIPS to bear the nature of a humanitarian aid program. The role of the Government itself, or almost the lack of it, in the proposed mechanism indicated that the purpose was to build a semi-commercial system to allow generic competition in the poor countries' markets that would rely almost entirely on the private sectors.

If the Government was to set up another long-term foreign aid program, it should have assigned for itself a much more active role in the system. For example, the Government could have bought the patented drugs needed in a certain developing country from the patent owners, with considerable discounts due to the quantity of purchased drugs. Afterwards, the Government could have distributed the drugs through the government channels of the developing country, while the latter would subsidize the drugs so that the patients would be able to buy them for a low or even no cost.

The major problem of this system would be to ensure that the drugs reach the right people, *i.e.,* the patients that need them, instead of being re-exported or otherwise diverted. Another problem would be to ensure that the drugs were distributed in such a way that they would not end up on the shelves past their expiration date because of bureaucratic obstacles or corrupt government-officials. The bureaucracy apparatus in the country of destination and numerous administrative procedures that have to be undertaken before the foreign aid services get to the people in need are harshly criticized and blamed for the failure of foreign aid programs.[583]

[583] William Easterly, "The Cartel of Good Intentions: Bureaucracy Versus Markets in Foreign Aid", Working Paper 4 (2002), online: Center for Global Development <http://www.cgdev.org/content/publications/detail/2786/>.

Even if the Government were to present the Bill as yet another foreign aid mechanism, would it be able to supersede the effectiveness of competition that generic companies could have brought into the poor countries' markets?[584] Although before answering this question, it is necessary to decide to what extent the scheme proposed in the Bill is to relate to the WTO General Council's decision and TRIPS? Possible answers to these questions may be found in the experience of other governments with similar legislating mechanisms.

Conclusions:

Although the Bill was intended to be humanitarian legislation, its mechanism relies too heavily on private parties, especially on generic manufacturers. Moreover, the Bill puts too light a responsibility on the Government.

To motivate a licensee, *i.e.*, a generic producer, to participate in the system, the mechanism is to provide a flexible, efficient, and certain process. In cases in which the contract of export becomes excessively risky for a licensee, the government of the exporting country would have to sponsor or reimburse the generic manufacturer, should the legislation be based on humanitarian principles. Unfortunately, the Bill does not provide for such an option.

[584] For example, Indian generic company Cipla offered its "Duovir", the generic version of GlaxoSmithKline's (GSK) "Combivir", for sale in Ghana for 1.74$ per patient per day. This caused GSK to drop its price from 16$ to just 2$ a day. Cipla offered to provide drugs for the big governmental aid programs for 600$ a year per patient, which is, according to Cipla's President, a break point for the company. Cipla sells the same set of drugs in India for 1100$ a year. See Bradly J. Condon, *NAFTA, WTO and Global Business Strategy: How AIDS, Trade and Terrorism Affect our Economic Future* (London: Quorum Books, 2002) at 100-101 [Condon].

Both private parties (generic and research-based companies) participate in the mechanism of export proposed in the Bill for, even partly, commercial reasons. A generic producer expects to make profits from the contract of supply of generic medicines to a developing country, if not to gain profits, then to gain access to a market that would otherwise have been closed to the generic company as long as the patent was still valid. A patentee expects to protect his invention from being commercially exploited unless adequate remuneration is paid.

In such circumstances, a Bill that does not rely on governmental fiscal sponsorship cannot be named "non-commercial".

According to the Government's position, its task was to create a mechanism of export that would allow generic producers to enter competition that would lower the prices of essential medicines in a developing country's market, while ensuring the safety, efficacy, and quality of the exported drugs.

Lowering the prices in itself, although necessary, is definitely not a sufficient condition for alleviating access to essential medicines in underdeveloped countries. Lack of adequate health care infrastructure; lack of trained medical personnel; lack of a way to monitor proper drug administration by patients; lack of a mechanism to ensure that the drugs reach the right hands – all these factors interfere with the effective operation of the system created by Bill C-9.

The Bill certainly bears some characteristics of yet another foreign aid program. However, within the boundaries of TRIPS-like legislation, because of the Government's initial intention to present the Bill as an implementation of the WTO General Council's

decision only, the amendment in its present form cannot acquire a truly humanitarian nature.

Chapter Seven: International Implications of Canada's Amendment

To appraise the effectiveness and feasibility of Canada's Bill C-9, it would be useful to examine how the Bill is related to TRIPS and the WTO General Council's decision the Bill was intended to implement. It would be helpful to know which provisions of TRIPS were incorporated in the Bill and which provisions of Canada's legislation could be included in the WTO General Council's decision and incorporated into TRIPS thereafter.

Also, it is necessary to consider Canada's Bill in light of similar foreign legislation. Other countries' experience with implementing the WTO General Council's decision could clarify Canada's own perspective on the Bill's provisions. Furthermore, such a study could reveal the deficiencies of the Bill, as well as its advantages when compared to the provisions of foreign legislation, and also show what could have been changed in Canada's legislation to improve its efficiency.

a. Changing TRIPS Following Bill C-9 or Improving the Bill Based on TRIPS?

On 6 December 2005, the WTO members adopted a waiver of Article 31(f) and a change of Article 31(h) of TRIPS,[585] finally turning it into a permanent amendment to TRIPS (the Amendment).[586] The text of the Amendment is almost similar to that of the

[585] Which were proposed in the WTO General Council's decision of August 2003. See *supra* note 6.
[586] The waiver remains in force until 1 December 2007. To this date, the Amendment is open for acceptance by the members, while two thirds of the WTO member-countries have already ratified the Amendment. The Amendment added Art. 31 *bis* following Article 31 of TRIPS. See WTO Press Release, "Members OK Amendment to Make Health Flexibility Permanent" (6 December 2005), online: WTO <http://www.wto.org/english/news_e/pres05_e/pr426_e.htm>. See also WTO, General Council,

WTO Decision. The General Council Chair's statement attached to the Amendment stressed once again that the Amendment should be used in good faith "to protect public health and … not be an instrument to pursue industrial or commercial policy objectives."[587]

The question is: what changes could have been made in the Bill following the Amendment and what changes could have been inspired by the Bill to be included in the Amendment?

The Amendment is loaded with ambiguous definitions similar to the text of the WTO General Council's decision. For example, the requirement for an importing member to establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector, whereas there are no clear procedures as to the assessment of manufacturing capacities for any other country except least-developed ones.[588] The Bill drops this requirement, making the process easier and more certain for all eligible importing countries.[589]

Another provision that is better defined in the Bill is the formula for calculation of remuneration. The protocol of the Amendment, in Article 31*bis*(2), sets a requirement for "adequate remuneration … taking into account the economic value to the importing member of the use that has been authorized by the exporting member." The language of

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Amendment of the TRIPS Agreement, WTO Doc. WT/L/641 (8 December 2005), online: WTO <http://docsonline.wto.org/DDFDocuments/t/WT/L/641.doc> [Amendment of the TRIPS Agreement].

[587] WTO, "Chairman's Statement", online: WTO <http://www.wto.org/english/news_e/news05_e/trips_319_e.doc>.

[588] A least-developed country will be automatically considered as having no sufficient capacities in the pharmaceutical field. See *Amendment of the TRIPS Agreement, supra* note 586 at "Appendix to the Annex to the TRIPS Agreement" at 7.

[589] It could be argued that by dropping this requirement the Bill acquired a more humanitarian nature, because it no longer applied one of the important conditions of Par. 6 of the Doha Declaration: the requirement that the mechanism of compulsory license would be available only for the countries with no sufficient manufacturing capacities. See *supra* note 4 at para. 6.

this provision is too unclear to provide certainty to the exporting country as to the rate of remuneration that is to be paid to a patentee. Contrary to the Amendment, the Bill sets a precise formula for calculation based on the UN Human Development Index (UNHDI). Again, while the Amendment sticks to the TRIPS provision,[590] the Bill shifts to humanitarian aspects, providing a formula that takes into account an importing member's ranking in the UNHDI.[591]

However, in regard to the list of drugs eligible to be subject to a compulsory license, the Amendment included a more comprehensive range of pharmaceutical products.[592] This makes it more effective compared to the Bill, especially for those countries that are in need of drugs that are not included in Schedule 1 of the Bill.

Additionally, the Bill is burdened with administrative details that make the procedure of acquiring a compulsory license too inflexible.[593] However, the actual administrative procedures determined in the Amendment are too vague and unspecific to provide parties with the necessary level of certainty in regard to what procedures they are required to comply with in order to use the system.

Overall, it may be said that a well-balanced system can be achieved by combining the requirements included in the Amendment with the provisions of Canada's Bill C-9. However, it is hard to say how many of the humanitarian aspects would be left in such a combined system and how much of a TRIPS-like character such a hybrid could bear.

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[590] Article 31(h) of TRIPS used almost the same ambiguous definition of required remuneration.
[591] *Supra* note 278 at s. 21.08. See also Regulations, *supra* note 448 at s. 8.
[592] According to Art. 31*bis*(a) of the Amendment: "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems" can be subject to a compulsory license. The language is the same as the one used in Par. 1(a) of the WTO August 30 decision. See *supra* note 6 at para. 1(a).
[593] *Supra* note 362 at 12.

b. Other Countries' Versions of Legislation Implementing the WTO General Council's Decision

Until January 2005, developing countries with no pharmaceutical manufacturing capacities had no need to use the mechanism of compulsory license, because the transitional periods determined in Articles 65-66 of TRIPS allowed an extension in complying with the Agreement. Therefore, developing countries, such as India, one of the largest exporters of generic drugs that had not provided patent protection for pharmaceuticals prior to TRIPS, could continue to export generic versions of drugs not patented in their territories.[594] However, after TRIPS is fully implemented, the need for legislation such as Canada's Bill C-9 in potential exporting countries will be unequivocal.[595] Therefore, it would be useful to briefly overview similar foreign legislation acts.

Norway enacted its regulations amending the *Patent Regulations* (in accordance with the WTO General Council's decision) on 14 May 2004.[596] Contrary to the Canadian legislation, the Norwegian regulations do not impose a condition of declaring a health emergency for a non-WTO member country to be eligible to import.[597] However, the eligible state, other than the least-developed country, should establish insufficient

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[594] "Denmark and Italy: Trade–Related Intellectual Property Rights, Access to Medicines and Human Rights" (October 2004), online: 3D Trade Human Rights Equitable Economy <http://www.3dthree.org/pdf_3D/3DCESCRDenmarkItalyBriefOct04en.pdf> at 3.
[595] *Ibid.,* at 4.
[596] *Regulations Amending the Patent Regulations (In Accordance with the Decision of the WTO General Council of 30 August 2003, Paragraphs 1(b) and 2(a))*, online: Norwegian Ministry of Foreign Affairs <http://odin.dep.no/ud/english/topics/trade/p30003923/032121-990069/dok-bn.html> [Norwegian Regulations].
[597] *Ibid.* Also see *supra* note 362 at 10.

manufacturing capacity in accordance with the WTO General Council's decision.[598] As was stated earlier, the WTO decision does not determine any clear procedure to establish the insufficiency of manufacturing capacity.

The same is true about the remuneration formula. The Norwegian legislation does not provide any clear way of assessing the appropriate remuneration, but uses the vague language of the WTO General Council's decision instead.[599] Also, there is no clearly outlined procedure and timeframe for a licensee to follow, once he attempts to acquire a voluntary license.[600]

That said, it is clear that the Norwegian legislation follows the WTO General Council's decision more closely than does Canada's Bill C-9. Along with the disadvantages of vagueness, this brings certain advantages, though. For example, the regulations refer, in s. 108(2), to the WTO decision for determining eligible pharmaceutical products to be covered by the system. The WTO decision, contrary to the Canadian amendment, does not limit the list of eligible pharmaceuticals. Also, the Norwegian legislation does not limit the period of a license, but it only states in s. 107(3) that the product would be produced to cover the importing country's needs to solve the public health problem.

India has also informed the WTO that its law implementing the WTO decision is complete.[601] India's generic pharmaceutical industry is the largest supplier of cheap

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[598] *Norwegian Regulations*, *ibid.,* at s. 107(1).
[599] The Norwegian Regulations state that in order to determine a rate of remuneration "account shall be taken of the economic value to the importing State of the use of the invention…" See *Norwegian Regulations*, *ibid.,* at s. 108. See also *supra* note 362 at 10.
[600] The only requirement is that "the producer has tried to obtain a license by agreement…" See *Norwegian Regulations*, *ibid.,* at s. 108(1).
[601] The WTO Press Release, *supra* note 586.

medicines in the developing world.[602] Therefore, the impact of the Indian amendment on the global generic pharmaceutical market was expected to be quite serious. However, instead of setting clear rules for the granting of a compulsory license, Indian legislation gave only a general permit to export patented pharmaceutical products to countries with inadequate production capacities in order to cope with public health emergencies.[603]

The only mention of a compulsory license mechanism can be seen in the new provision, s. 92A, added to the *Indian Patent Act*. The amendment did provide, though, other measures facilitating exports, such as parallel import.[604] However, as to the granting of compulsory licenses, the Indian amendment did not establish any procedures.[605]

Again, in accordance with the WTO General Council's decision, there is neither a limit on pharmaceutical products eligible for licensing, nor a limited list of eligible importing countries.[606] The only requirement is that the eligible importing country should have insufficient manufacturing capacity in the pharmaceutical sector. However, the lack

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[602] The Indian generic industry could actually be considered the size of the Canadian one. See *supra* note 501 at 10. See also Frederick M. Abbott, "The Patents (Amendment) Bill 2003 and Future of India's Public Health" (Extracted and Reproduced from the Speech at IndiaChem 2004, International Conference on Chemicals, Petrochemicals, Pharmaceuticals and Technologies, Process Plant Machinery, Control and Automation Systems at Mumbai, November 2004), online: pharmabiz.com <http://www.pharmabiz.com/article/detnews.asp?articleid=24905&sectionid=50>.

[603] Earlier, in December 2004, Indian government issued the *Patent (Amendments) Ordinance 2004* that introduced, in s. 54, for the first time, a provision that allowed the granting of a compulsory license to export to countries with insufficient manufacturing capacity facing health emergency situations. The government's ordinance was slightly changed by the *Patent (Amendments) Bill 2005*. See Embassy of India in Washington D.C., Press Release, "The Patents (Amendment) Bill 2005 Passed by Indian Parliament"(4 March 2005), online: Embassy of India <http://www.indianembassy.org/press_release/2005/Mar/12.htm> [Indian Patent Bill]. Also see *supra* note 362 at 11. Also see Government of India, *The Patents (Amendment) Ordinance, 2004*, Ord. No 7 of 2004, online: Ministry of Law and Justice, Government of India <http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf> [Indian Patents Ordinance].

[604] *Indian Patent Bill, ibid.*, s. 107A(b). Parallel import means that products were sold by the patent owner to the importing country and afterwards, exported to another country without a patent holder's authorization. The principle of the parallel import is based on the rule of exhaustion of the IP rights (TRIPS, Art. 6), which means that after the first sale, the patent on the product "expires" and the patent holder loses his control over the product. See Condon, *supra* note 584 at 105.

[605] *Supra* note 362 at 11.

[606] *Indian Patents Ordinance*, *supra* note 603 at s. 54. See also *Indian Patent Bill*, *supra* note 603 at s. 92A(1).

of manufacturing capacity may relate only to the specific product needed for solving public health problems, and not a general inability to produce drugs locally.[607] The Controller is given discretion to determine the terms and conditions of the license.[608]

In July 2005, the EU Committee on International Trade published a final report on the proposal for regulations of the European Parliament and Council on the compulsory licensing of patented pharmaceutical products for export to countries with public health problems.[609] Contrary to the Canadian and Norwegian legislation, the EU's draft regulations only apply to the WTO member countries.[610] The proposal to limit eligible importing countries bore heavy criticism. It has been stated:

> "… It makes no sense from a public health perspective to limit the application of the system to WTO members. Whether a country is a WTO member or not, does not constitute a valid criterion for allowing or not exports of low priced drugs to address public health needs. Threats to public health do not recognize such arbitrary legal distinction. In addition, public health problems in a non-WTO member may have serious implications in WTO members …".[611]

Nor do the regulations include a waiver of the obligation to seek a voluntary license in cases of public non-commercial use.[612] Additionally, contrary to Canada's Bill,

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[607] *Indian Patents Ordinance, ibid.* See also *Indian Patent Bill, ibid.*
[608] *Indian Patents Ordinance, ibid.* See also *Indian Patent Bill, ibid.*
[609] EC, European Parliament, 2004-2009, *Report on the Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems* (July 2005), Sess. Document A6-0242/2005, online: European Parliament <http://www.europarl.eu.int/registre/seance_pleniere/textes_deposes/rapports/2005/0242/P6_A(2005)0242_EN.doc>.
[610] *Ibid.* at 34/82. See also Richard Elliott, "Generics for the Developing World: A Comparison of Three Approaches to Implementing the WTO Decision", online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/Maincontent/issues/cts/Scrip-article-RElliot-241104.pdf> at 2.
[611] *Supra* note 609 at 34/82.
[612] The draft regulations do propose a waiver of this obligation in cases of national emergency, though. *Ibid.*

the EU's draft neither specifies a timeframe for prior negotiations with the patent holder nor does it determine any additional grounds for waiving the obligation to seek a voluntary license, except in cases of public health emergency.[613]

Similarly to Canada's Bill C-9, the EU's draft regulations include a requirement for an application to have a permit "from an authorized representative" of the importing country.[614] Similarly to the Norwegian legislation, the EU's draft sticks to the vague language of the WTO General Council's decision in regard to adequate remuneration.[615] By that, the draft legislation decreases predictability and creates uncertainty for potential users.[616]

The Netherlands enacted the Policy Rules on Issuing Compulsory License in December 2004.[617] While similar to the legislation of the other countries in most aspects, the Dutch legislation differs in its definition of eligible importing countries. Similarly to Canada's Bill C-9, the Dutch Policy Rules determine that only least-developed countries and the WTO members would be able to use the system.[618] However, contrary to the Canadian amendment, the Dutch one requires a non-WTO member least-developed country to provide a declaration stating that the country has insufficient manufacturing capacity and that it will take appropriate measures to prevent diversions.[619]

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[613] *Ibid.*
[614] Which means that no NGO will be allowed to contact a generic producer directly. *Ibid.,* at 35/82.
[615] The draft legislation requires that the patentee is paid adequate remuneration "taking into account the economic value of the use that has been authorized under the license to the importing WTO member(s) concerned… ". *Ibid.,* at 36/82.
[616] *Ibid.*
[617] *Supra* note 362 at 11.
[618] The Netherlands, State Secretary for Economic Affairs, *Policy Rules on Issuing Compulsory Licenses Pursuant to WTO Decision WT/L/540 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Under Section 57, Subsection 1, of the Kingdom Act on Patents of 1995*, online: cptech.org <http://www.cptech.org/ip/health/cl/netherlands-export-rules.html> at articles 1(f) & 3.
[619] See *ibid.,* at art. 3 (a)-(b). The Canadian amendment only requires that from developing countries that are not WT O members. See *supra* note 278 at s. 21.03(1)(d)(ii)(A).

An interesting distinguishing feature of this legislation is that for the first time, NGOs are considered potential applicants, if acting for a state or for a group of states.[620]

Succinctly, foreign legislation implementing WTO General Council's decision seems to adhere to the language of the decision more closely than Canada's Bill C-9. Thus, the legislation of other countries bears the same features and the same criticism as the WTO decision, *e.g.*, vague language that decreases predictability and certainty for the future users of the system. Unclearly defined provisions regarding such significant issues as remuneration formula, conditions for a voluntary license, procedures to establish insufficient manufacturing capacities of some developing countries were included in the legislation of the other countries following the WTO General Council's decision.

Canada's Bill strayed farther away from the language of the WTO decision and incorporated clearer procedures and more accurate definitions. Although such procedures can be seen as over-burdened with administrative details, and therefore inflexible, Canada did attempt to establish a workable and carefully considered system that would allow its generic industry to implement it in practice.

Not all countries that could serve as potential exporters of generic medicines have implemented the WTO General Council's decision yet. Since the WTO decision has recently become a part of the TRIPS Agreement,[621] every WTO-member country bound by TRIPS would be required to incorporate the mechanism of a compulsory license, as part of TRIPS, in its domestic law. Even more so if a country has a well-developed generic pharmaceutical industry and has bio-industrial capacities to produce and export life-saving medicines to the underdeveloped countries in need. One of such potential

[620] *Dutch Policy Rules, ibid*., at art. 3(2). See also *supra* note 362 at 11.
[621] *Amendment of the TRIPS Agreement*, *supra* note 586.

exporting countries is Israel. Thus, it would be interesting to examine the possibility of including legislation similar to Canada's Bill C-9 in the Israeli legal system.

c. Does Canada's New Mechanism of Export of Generic Drugs Fit for Israel?

The choice of Israel as a subject of the following examination is not accidental. This country, in the last few decades, has become a leading competitor in advanced technology and innovation.[622] Today the field of life sciences represents 35 percent of Israeli research activity and "the country is recognized worldwide for its revolutionary academic research and scientific infrastructure".[623]

Israel's generic pharmaceutical industry is well-developed and this field of export is the most prosperous.[624] In 2001, Israelis spent about $675 million on drugs, which is approximately 13% of the national health expenditure.[625] The local production of drugs, mostly generic, amounted to $1.25 billion.[626] Twenty-four generic pharmaceutical manufacturers were registered in Israel in 1999, whereas five major companies manufacture more than 80% of local pharmaceutical products.[627] Israel's biotechnology

[622] In 1995-1996 the Israeli government allocated about US$46 million to R&D in life sciences and since then the industry turned into one of the world's centers for innovation. See Ketaki Sood, "Israel's Flourishing Biotech Industry" (10 May 2004), online: Larta Institute <http://www.larta.org/lavox/articlelinks/2004/040510_usisrael.asp>.
[623] *Ibid.*
[624] In the last 10 years, the pharmaceutical export ("pharmaceutical" including medicines, chemical pharmaceutical ingredients, veterinary medications, *etc*.) increased by about 800% (from $280 million in 1995 to $2.513 milliard in 2005). Only in 2005 alone, the export increased by 40%. See "Pharmaceutical Export Increased by 40% in 2005", online: Chamber of Commerce and Industry, Beer-Sheva and the South <http://www.negev-chamber.org.il/html/index.asp?top=2&subfolder=11&docid=1573> (Hebrew) [translated by author].
[625] Amihood Blay, "The Pharmaceutical Industry in Israel", *Report to the Business Briefing: Pharmatech 2002*, online: touchbriefings.com <http://www.touchbriefings.com/pdf/17/pt031_r_8_blay.pdf> at 2.
[626] Teva is holding a leadership in the generic market, with $2.2 billion of global sales. See *ibid.*
[627] The five leading generic producers are "Teva", "Agis", "Dexxon", "Taro" and "Rakkah". See *ibid.*

industry, although not as developed as the pharmaceutical one, amounted to about $375 million in 2000.[628]

Israel's evident biotech and pharmaceutical capacities, as well as its flourishing generic pharmaceutical industry attest to the strong possibility that this country can serve as a potential exporter of generic medicines to developing and least-developed countries in need. However, firstly, Israel will have to incorporate the new Amendment to the TRIPS Agreement and craft legislation similar to Canada's Bill C-9. To understand which scheme of exporting generic drugs under a compulsory license fits better into the Israeli legal system, it would be useful to briefly overview a general economic background of this country, as well as its IP regime.

As it was stated in the WTO 3rd Trade Policy Review of Israel:

> "… As a small country with limited natural resources, Israel is highly dependent on foreign trade as an engine for growth and the further development of an innovative, competitive and outward-looking economy…".[629]

With a total export of goods of $33 813 million and a GDP of $117 548 million in 2004, Israel is in first place for total expenditures on R&D as a percentage of GDP.[630] As an open, developed economy, Israel meets the criteria to become a member of the

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[628] *Ibid.*, at 3.
[629] WTO, *Trade Policy Review: Report by the Secretariat: Israel* (24 March 2006), WTO Doc. WT/TPR/S/157/Rev.1 at part 3 (Trade Policy Review Body), online: WTO <http://docsonline.wto.org>.
[630] *Ibid*., at part 2. See also The State of Israel, "The Israeli Economy at a Glance" (August 2005), online: Ministry of Industry, Trade and Labor <http://www.moit.gov.il/NR/rdonlyres/AAD43696-3185-40B7-881A-BAB1B3C64F2E/0/2005_ISRAELECENOMY.pdf> at 9 (data refers to 2004) [The Israeli Economy at a Glance]. See also The State of Israel, "Investment Climate in Israel" (June 2005), online: Ministry of Industry, Trade and Labor <http://www.moit.gov.il/NR/rdonlyres/AD6C2761-8A7D-460E-8666-956B183E47B5/0/IsraelInvestmentClimateRedesigned.ppt> [Investment climate in Israel].

OECD.[631] Israel has also been a member of GATT since 1962, and in 1995, Israel signed the WTO Agreements.[632] In regard to its TRIPS obligations, Israel declared itself a developing country. Therefore, a transition period to implement the Agreement in the national laws ended on 1 January 2000.[633] While stating that Israel is fully committed to TRIPS, the Minister of Regional Cooperation, Mr. Roni Milo, added that Israel "recognizes the flexibilities built-in to the Agreement for every member to deal with public health issues."[634]

According to the IMD World Report of 2004, Israel is in fourth place according to the criteria of how the legal environment affects R&D, *i.e.*, that it does not restrain business development.[635] However, it seems that the last amendment of 1998 to the *Patent Act (1967)* tends to ruin this achievement. It has been argued that the amendment was enacted under the pressure of "Teva Pharmaceutical Industries Ltd." (Teva).[636] The amendment allowed early manufacturing and stockpiling of generic versions of patented drugs while the patent was still valid, so that a generic producer would be able to market the product immediately after the patent expired.[637]

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[631] In 2002, Israel adhered to the OECD Declaration on International Investment and Multinational Enterprises and the OECD Guidelines for Multinational Enterprises. See *Investment climate in Israel*, *ibid.* See also *The Israeli Economy at a Glance*, *ibid.*, at 9 & 40.
[632] *The Israeli Economy at a Glance*, *ibid.*, at 40.
[633] *Supra* note 629 at part 4.
[634] Roni Milo, "Statement at the Closing of Doha Round" (Speeches of Israeli Representatives at the Doha Round, 19 November 2001), online: Ministry of Industry, Trade and Labor <http://www.moit.gov.il/NR/exeres/7AC7208A-0D0A-44F4-BE14-9D43B4F5B2A7.htm> (Hebrew) [translated by author].
[635] *Investment Climate in Israel*, *supra* note 630.
[636] It has even been named "the Teva Law". See Michal Bartov, "Have you both murdered and inherited?" (24 July 2005), The Israel BAR Publications, online: The Israel BAR <http://www.israelbar.org.il/article_inner.asp?pgId=25275&catId=287> (Hebrew) [translated by author].
[637] *Ibid.*

Because of its IP policy, Israel was put on the US Trade Representative's (USTR) Special 301 Priority Watch List in 2001, and was upgraded to the Watch List in 2003.[638]

Legal Environment for the Israeli Pharmaceutical Market

Patent protection is one of the most important factors for the pharmaceutical market's operation. It provides incentives for investment in R&D and therefore, for creating innovative drugs.[639] The *Israeli Patent Act (1967)*, in Article 3, which was amended in 2000 in accordance with Israel's obligations under TRIPS, provides patent protection for products as well as processes in every field of technology, if they are new, useful, and involve an innovative step.[640] Methods of medical treatment of the human body, as well as new varieties of plants and animals,[641] are excluded from patentability.[642]

According to Art. 52 of the *Patent Act*, patent protection is granted for a period of 20 a years from the day of filing (again, in accordance with TRIPS). In 2005, the *Patent Act* was amended so that a patent for medicine may be extended for up to five years more.[643]

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[638] One of the reasons for being included in the USTR priority watch list was that *Israeli Pharmacy Act* allowed generic pharmaceutical manufacturers to rely upon confidential test data submitted by the brand-name company in order to receive a governmental approval for marketing. The US argued that such a policy is inconsistent with Art. 39(3) of TRIPS. The situation has changed in 2005, when the Knesset (Israeli Parliament) passed an amendment to the *Pharmacist Ordinance (Protection of Confidential Data)*. See Office of the United States Trade Representative, "Special 301 Watch List" (2003), online: USTR <http://www.ustr.gov/Document_Library/Reports_Publications/2003/2003_Special_301_Report/Special_301_Watch_List.html>. Also see Office of the United States Trade Representative, "2002 Special 301 Report Priority Watch List" (2002), online: USTR <http://www.ustr.gov/Document_Library/Reports_Publications/2002/2002_Special_301_Report/2002_Special_301_Report_Priority_Watch_List.html>. Also see *ibid.*

[639] Condon, *supra* note 584 at 97.

[640] *Supra* note 629 at part 4.

[641] Except microbiological organisms not derived from the nature.

[642] *Patent Act (1967)*, art. 7, online: Ministry of Justice <http://www.justice.gov.il/MOJHeb/RashamHaptentim/Ptentim/HokHapatentim.htm> (Hebrew) [translated by author]. See also *supra* note 629 at part 4.

[643] *Patent Act*, *ibid.*, at s. 1b at art. 64a-64q. Also see *supra* note 629 at part 4.

The prices of drugs are regulated by the Ministry of Health according to the *Ordinance on Regulation on Prices of Goods and Services (The Maximal Prices on Prescription Medications), 2001*.[644] Manufacturers that produce goods covered by the *Act of Regulation on Prices of Goods and Services* are obliged to announce a forthcoming increase in price. The manufacturer can increase the prices only after receiving permission from the Commissioner of Prices on Goods and Services. The Commissioner or Director-General of the Ministry of Industry and Trade or the Ministry of Finances should carefully examine the motion for an increase in prices.[645] Medicines and related pharmaceutical products are covered by this Act. Therefore, the prices on pharmaceuticals cannot just randomly and unreasonably increase according to the wish of pharmaceutical manufacturers.[646]

An additional mechanism regulating the operation of the pharmaceutical market is a compulsory license system. According to s. 7, part A of the *Patent Act*, patent protection may be limited or removed altogether for the protection of public interest. According to Art. 117(a) of the *Patent Act*, the Commissioner of Patents and Trademarks may issue a compulsory license in case a patentee abuses his exclusive rights. The license cannot be issued until three years after the date of issuance of a patent or four years from

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[644] *Supra* note 636 at 1.

[645] Ministry of Industry, Trade and Labor, "Regulation of Prices: General Background", online: Ministry of Industry, Trade and Labor <http://www.tamas.gov.il/NR/exeres/636B8142-B88B-4927-894A-48FD074FA8B0.htm> (Hebrew) [translated by author].

[646] One of the main purposes of the *Act of Regulation on Prices of Goods and Services* is to protect consumers from unreasonable and economically unjustified increase in prices of products manufactured or imported by the manufacturers with a monopolistic power or by cartels. If the revenues that a manufacturer gains are higher than the maximal revenues determined by the Ministry of Industry, Trade and Labor, or if the investments of the manufacturer decrease, the Ministry initiates decrease in prices on the certain goods. See Ministry of Industry, Trade and Labor, "Measures for Consumer's Protection: Regulation on Prices of Goods and Services", online: Ministry of Industry, Trade and Labor <http://www.tamas.gov.il/cmsTamat/InternalPage.aspx?NRORIGINALURL=%2fNR%2fexeres%2fAF83F977-3B01-4DC0-AC33-C3E975B3C8F8%2ehtm&FRAMELESS=false&NRNODEGUID=%7bAF83F977-3B01-4DC0-AC33-C3E975B3C8F8%7d&NRCACHEHINT=Guest#a14> (Hebrew) [translated by author].

the date of filing a patent application (Art. 117(b)). While deciding on the motion to issue a license, the Commissioner should take into account, among others, the following aspects: 1) to which extent the abuses caused by the patentee may be fixed by the licensee (Art. 122(1)); 2) whether a more extended volume of production/import of the patented product is needed for the sake of public interests (Art. 122(2)); 3) adequate remuneration taking into account the nature of the invention (Art. 122(3)); 4) the nature of the invention, the period of time passed from the issuance of a patent and what has been done by the patentee in order to exploit the invention in Israel (Art. 122(5)).

Additionally, Art. 31(f) of TRIPS reflects onto the Israeli legislation in that Article 123 of the *Patent Act* limits the issuance of a license predominantly for domestic market supply. The Commissioner of Patents and Trademarks is also authorized to annul a patent if convinced that the issuance of a compulsory license did not amend the abuses of the monopoly (Art. 129(a)). However, the annulment cannot take place until two years after the issuance of the license (Art. 129(b)).

The system of compulsory licensing adopted in the Israeli law as amended in 2000 is quite similar to the provisions of Article 31 of TRIPS.

In 1998, the *Patent Act* was amended[647] so that it excluded from the patent protection the experiments and trials conducted in order to obtain an approval for

[647] It has been argued that the amendment named "Teva Law" was brought into the *Patent Act* as a result of the pressure of the largest generic producer in Israel: Teva. Wellcome and Eli Lily, who owned the patents for "Prozac" and "Acyclovir" respectively, sued Teva for manufacturing generic versions of these two medicines, while the patents registered in Israel were still valid. Wellcome refused to distribute the drugs in Israel because of the Arab embargo that was in effect in that period. Thus, Teva invoked a compulsory license clause according to the *Patent Act*. Teva claimed that the generic versions of these drugs should be distributed in Israel for the sake of public interest. Eventually, Wellcome won based on the fact that Teva was approached by a non-existent foreign company's salesperson and agreed to sell its product outside of Israel as well. See A. Tally Eitan, "The Israeli 'Sting'" (October 2001), online: technolawgy.com <http://www.technolawgy.com/fs_lawyers1.asp?SearchWord=compulsory+license>.

marketing generic products after the expiration of the patent.[648] The purpose of the amendment was to enable generic manufacturers start marketing a generic version of a patented drug straight after the patent expired.[649] The legislation was intended to create an acceptable balance between numerous factors: 1) generic manufacturers' interests in performing all needed trials and experiments to receive the mandatory approval for marketing; 2) public interest in not prolonging *de facto* the period of rights exclusivity for brand-name manufacturers; and 3) bringing in competition between the generic and brand-name producers in order to lower the prices on pharmaceuticals.[650]

On the other hand, the interests of the brand-name pharmaceutical industry needed to be taken into account. One was a need to compensate research-based pharmaceutical companies for the period when they could not market a new product because it was waiting for governmental approval.[651] A generic manufacturer was not allowed to compete in the market while the patent was still valid nor to distribute the product in this period. Therefore, it has been argued that the amendment allowed a generic manufacturer to produce and stockpile generic drugs only to receive a governmental approval so that the product would be ready for marketing when the patent expires.[652]

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[648] *Patent Act*, *supra* note 642 at art. 54a (as amended in 1998).
[649] Commissioner of Patents and Trademarks, *Decision on the Application for Extension of the Period of Patent No. 78250, Janseen Pharmaceutica N.V.*, (Halachot) online: halachot.co.il <http://www.halachot.co.il/dwlfls/Patent%2078250.pdf> at 3 (Hebrew) [translated by author]. See also *supra* note 636.
[650] *Janseen Pharmaceutica N.V., ibid*., at 3-4.
[651] *Ibid*.
[652] The State of Israel, The Knesset (Israeli Parliament), "Patent Bill: Amendment No. 7 to the Patent Act", *Parliamentary Debates*, Plenary Sess. 305 (21 December 2005), online: The Knesset <http://www.knesset.gov.il/plenum/data/104263905.doc> at 132 (Speech of Michael Eitan) [translated by author].

To create the balance between the interests of generic and brand-name companies, the amendment of 1998, the "Teva Law", also contained an option to extend patent protection in certain conditions. It has been argued that the extension of a patent was possible under the amendment for the shortest period of time among the periods allowed in other designated reference countries,[653] which made the whole procedure highly impracticable.[654] However, another explanation could be suggested. One of the major aims of this amendment was to abolish the differences between provisions of the *Israeli Patent Act* and the Patent Acts of other designated reference countries where generic producers were allowed to stockpile their products in order to start distributing them right after the patent expired.[655] For this reason, while deciding on the extension period, the Commissioner of Patents and Trademarks should compare it to the extension period in the first country where such an extension expired in regard to the invention related to the patent in question.[656]

The amendment caused genuine confusion regarding applications for the extension of the patents submitted mostly by foreign brand-name companies holding patents in Israel. Only in 2004-2005, as a result of the demands of brand-name companies, an additional amendment was added. This last amendment attempted to clarify the unclear and confusing provisions of the previous one, but did not entirely succeed.[657]

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[653] "Designated Reference Countries" include: the United States, Canada, the European Union, Norway, Switzerland, Iceland, Japan, Australia, and New Zealand. See *Patent Act*, *supra* note 642 at annexes A-B.
[654] *Supra* note 636.
[655] The State of Israel, *Statute Memorandum of Patent Act: Amendment: Extension of the Original Patent's Period* (2004), online: Ministry of Justice <http://www.justice.gov.il/NR/rdonlyres/E02F8EFB-1157-4C34-AEB0-E2C1041EE3B7/0/patentim_zavei_haracha.pdf> (Hebrew) [translated by author].
[656] *Ibid.*
[657] *Ibid.*

As for today, the *Patent Act*, in Articles 64a-d, provides an opportunity to extend the period of the original patent. The amendment states that generally the extension will not be granted, but only following the occurrence of certain conditions (Art. 64d). The extension is to be given for the shortest period that would be calculated in comparison to the periods of extension given for the related patent in any other designated reference country. In any case the extension should not exceed a five-year period (Art. 64i-64j). It has been argued that the statute's strict conditions for issuance of the extension make it almost impossible to achieve.[658]

Another disputable issue that has been at the center of the conflict among all the players in the Israeli pharmaceutical market is the issue of data exclusivity. Additional legislation related to pharmaceutical manufacturing in Israel is the *Pharmacists Act*.[659] Before the last amendment in 2005, the *Pharmacists Act (1981)* allowed generic manufacturers to base their applications for marketing approval of a generic version of a patented drug on the confidential information held by the Ministry of Health. This confidential information is submitted earlier by the brand-name company, when the brand-name producer pursues governmental approval for the patented drug. It has been argued that this Act infringes Art. 39(3) of TRIPS that prohibits unfair commercial use of the confidential information submitted to the authorities.[660]

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[658] *Supra* note 636.

[659] The Pharmacists Department of the Ministry of Health is the regulation authority for the approval of any medicine, chemical entity, materials that related to medicines, *etc.*, for marketing and distribution. According to the *Pharmacists Act*, a company that applies for a governmental approval for the marketing of a medication has to submit additional information that would prove the safety and efficacy of the medication. The information submitted to the Ministry should include, aside from the chemical and pharmaceutical data, also data concerning experiments and clinical trials, as well as pre-clinical trials information. See Matty Barzam, "Satisfying the Villain" (19 June 2005), The Israel BAR Publications, online: The Israel BAR <http://www.israelbar.org.il/article_inner.asp?pgId=23673&catId=287> (Hebrew) [translated by author].

[660] *Supra* note 636.

The issue was examined by the Tel-Aviv District Court, which ruled that there was no unfair commercial use of the confidential information by the generic company. It was actually the Ministry of Health that used this information in order to grant approval for marketing, and not a generic company.[661] Moreover, it has been argued that while TRIPS prohibited public access to the confidential information submitted to the Ministry of Health by a patentee, the Agreement did not limit the ability of employees from the Pharmacists Department of the Ministry to examine this information in order to grant approval of the generic drug.[662]

The provision of the *Israeli Pharmacists Act* allowing reliance on confidential information was nevertheless a reason for the USTR to put Israel on the priority watch list. Also, the issue stirred numerous suits based on the *Act of Commercial Civil Wrongs (1999)*[663] and the ruling of the Supreme Court of Israel that allowed this kind of suit under the doctrine of עשיית עושר ולא במשפט (unlawful gain of wealth).[664] The brand-name pharmaceutical companies argued that while the legislation did not define confidential information, reliance on such information infringes the property rights of brand-name

[661] *Merck et al., v. Teva Pharmaceutical Industries et al.*, (2005) 2292/04 & 1080/05 **(Tel-Aviv Dist. Ct.)** (Hebrew) [translated by author]. Merck sued Teva for manufacturing and distributing a generic copy of the drug "Posalan 70 mg" that was patent-pending in Israel. Teva produced its generic version named "Alendronat Teva 70 mg", while Unifarm Ltd., another generic producer, manufactured another generic version of "Posalan 70 mg": "Maxibon 70". The patent application for "Posalan 70 mg" was actually an improvement of the medicine that was patented in Israel in 1998 and was different only in dosage and administration. Merck submitted a motion to prevent Teva and Unifarm from manufacturing generic drugs that were patent-pending based on the alleged violation of the *Unlawful Gain of Wealth Act.* The Merck's motion was denied. Also, The Supreme Court of Israel sitting as the High Court of Justice ruled the same earlier in Bristol–Myers v. Minister of Health case. See *Bristol–Myers v. Minister of Health*, 5379/00, 55(4) **Israel H.C.J. Decisions** 447 (This case was referred to in the *Merck v. Teva* case) (Hebrew) [translated by author].

[662] Barzam, *supra* note 659.

[663] The Act defined a distrustful use of commercial secret against the contract obligation as an act of civil wrong. See The State of Israel, *Act of Commercial Civil Wrongs (1999)*, online: patentim.com <http://www.patentim.com/forum_articles.asp?Fnumber=22&ArticleID=65> at part B at art. 5-10. Also see *ibid.*

[664] *A.Sh.I.R v. Forum of Accessories and Commodities*, 5768/94, 52(4) **Israel S.C.** 289 (The Supreme Court of Israel sat in this case as a Court of Appeals) (Hebrew) [translated by author].

companies, and therefore is an unlawful gain of wealth, as well as a commercial civil wrong.[665]

In 1 July 2005, the amendment to the *Pharmacists Act* came into force. According to the new Art. 47d, the Ministry of Health shall not rely on confidential information unless one of the following conditions occurs: 1) the rightful owner of the information on the original medicine agreed that an applicant would rely on the information; 2) five years after the original medication was registered and approved or five and a half years after the new chemical entity of the original medication was registered and approved in one of the designated reference countries; 3) an applicant submitted all the information regarding the safety and efficacy of the product for the satisfaction of the examiner; 4) use of the new medicine is needed for a public health emergency that was officially declared by the Minister or in case of pandemic that risks public health (as defined in the *Public Health Ordinance (1940)*).[666]

Even after Israel implemented TRIPS and amended the *Pharmacists Act* accordingly, there still were skeptics claiming that the situation essentially had not changed; at least not for research-based companies.[667] As it was stated by the Chairman of the Labor, Social Affairs and Health Committee (the initiator of the amendment of 2005), Mr. Shaul Yahalom:

> "The State of Israel produces generic drugs. Patented drugs are imported from the outside and registered in Israel only as a protection …".[668] And also: "… the amendment … will fortify the Israeli pharmaceutical industry. While the struggle

[665] *Supra* note 659.
[666] *Ibid.*
[667] *Supra* note 636.
[668] The State of Israel, The Knesset, "Patent Bill: An Amendment: Extension of the Original Patent Period, 2005", *Parliamentary Debates*, Plenary Sess. 250 (25 May 2005), online: The Knesset <http://www.knesset.gov.il/plenum/data/100307205.doc> at 38 (Hebrew) [translated by author].

> to the increase number of drugs covered by governmental funds is based on the budget problems, this amendment will allow to provide more drugs to more people."[669]

The impression is that generic manufacturers in Israel receive the same kind of industrial favoritism from the government as their colleagues in Canada.[670] The issue of expanding the "Sal Ha-trufot" (list of medications covered by governmental funds) by lowering the prices and increasing the number of generic drugs available on the market, has been at the center of public debates for decades.[671] Obviously, because generic medicines are 80% cheaper than the patented versions, they are believed to improve the chances of increasing the number of drugs on the list of medications covered by governmental funds. Therefore, generic medicines are believed to be the first step in saving patients suffering from cancer or asthma, for example, that otherwise would never be able to obtain the essential drugs.[672]

On the other hand, Israel desires to attract foreign investments and to be the country where it would be profitable to register an invention.[673] Thus, ever since signing TRIPS and, even more so, since implementing the agreement, Israel has attempted to fit

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[669] Shaul Yahalom, "The Legislation Passed the First Reading: An Amendment to the Patent Act that will Lower the Prices of Drugs in Israel" (25 May 2005), online: shaulyahalom.co.il <http://www.shaulyahalom.co.il/yahalom/article.asp?aid=408> (Hebrew) [translated by author].
[670] *Supra* note 552 at 23-25.
[671] Just in April 2006, the Medical Union petitioned the Supreme Court of Israel sitting as a High Court of Justice to order the government to add 310 million NIS to the 2006's budget allocated to funding the "Sal Ha-trufot". See "The Medical Union to the High Court of Justice: Order to Add 310 Million NIS to the 'Sal Ha-trufot'" (24 April 2006), online: YNET ("Yediot Ahronot": the latest news), <http://www.ynet.co.il/articles/0,7340,L-3243195,00.html> (Hebrew) [translated by author].
[672] "Let Us Live: People Whose Drugs did not Enter the List of Medications Funded by the Government" (10 April 2006), online: YNET <http://www.ynet.co.il/articles/0,7340,L-3238224,00.html> (Hebrew) [translated by author].
[673] Eitan, *supra* note 647.

its national laws into international standards that required to strengthen Israeli patent regime.

The tension between allowing generic competition on the one hand and preserving the strong patent regime on the other hand was also one of the contradictory issues discussed during the debates on Canada's Bill C-9. (See discussion in Chapter V.) All in all, there is a basic resemblance between the patent protection regimes and the relations between the government and generic producers between Canada and Israel. Therefore, the question is: would the compulsory license mechanism similar to Canada's Bill C-9 fit in the *Israeli Patent Act*? And if so, how would this mechanism integrate into the Israeli humanitarian aid system?

Israel and Humanitarian Aid

Israel has always effectively and quickly responded to requests for help from other countries. As it was stated:

> "Israel, by tragic circumstances, is possibly the world's leading expert in dealing with mass casualty situations. Israel has gained vast experience in responding to such situations resulting from war or terror, leading to the development of extremely effective procedures for rapid and effective response in case of emergency …".[674]

Being involved in numerous wars and being subject to countless terror attacks, Israel developed an extremely efficient "returning-back-to-the-normal-life" system. The governmental humanitarian aid is usually based on cooperation between the Israeli

[674] The State of Israel, Ministry of Foreign Affairs, "What We Do: Humanitarian Aid", online: MASHAV Center for International Cooperation <http://mashav.mfa.gov.il/mfm/web/main/Document.asp?SubjectID=43850&MissionID=16210&LanguageID=0&StatusID=3&DocumentID=-1>.

Defense Forces (IDF),[675] the Ministry of Defense and the Ministry of Foreign Affairs.[676] The aid is generally extended on a case-by-case basis, although there is a long-term foreign aid program running under the Department for International Cooperation in Israel's Ministry of Foreign Affairs, named "MASHAV".[677] Being responsible for Israel's official Humanitarian Assistance Program, MASHAV provided: medical equipment after the earthquake in Tbilisi, Georgia, in May 2002; funds to buy water purification devices and medical equipment following tropical storm in Micronesia in July 2002; medical equipment for the train crash relief in Tanzania, *etc*.[678]

Aside from the governmental humanitarian aid activities, there are numerous NGOs in Israel that are committed to providing humanitarian aid.[679] Generic

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[675] Special units of the IDF Home Front Command named "rescue divisions" are trained and qualified for different kinds of rescue activities, as well as for the operation of technological rescue equipment.

[676] As it was, for example, when Israel provided Sri Lanka with humanitarian and medical aid after the tsunami in 2004. Additionally to the shipment of medicines, water, food, and other essential appliances, Israel sent to the area of the disaster medical and rescue personnel. See The State of Israel, Ministry of Foreign Affairs, "Israeli Humanitarian and Medical Aid to Sri Lanka" (28 December 2004), online: Israel Ministry of Foreign Affairs <http://www.mfa.gov.il/MFA/Government/Communiques/2004/Israeli%20humanitarian%20and%20medical%20shipments%20leave%20for%20Sri%20Lanka>. In January 2006, Israel sent a rescue team to provide help rescuing people from under the building that collapsed in Nairobi, Kenya. The IDF rescue delegation was sent according to the decision of the Minister of Defense in coordination with the Ministry of Foreign Affairs. See The State of Israel, Ministry of Foreign Affairs, "Humanitarian Aid from Israel to Kenya" (24 January 2006), online: Israel Ministry of Foreign Affairs <http://www.mfa.gov.il/MFA/About+the+Ministry/MFA+Spokesman/2006/Humanitarian+aid+from+Israel+to+Kenya+24-Jan-2006.htm>. Numerous aid deliveries (one of them carrying about 15 tons of humanitarian aid and equipment, as well as IDF medical crews) were sent by the IDF to the areas destroyed by the Hurricane Katrina. See Joel Leyden, "Israel: IDF Sends Humanitarian Aid Delegation to New Orleans" *Israel News Agency* (7 September 2005), online: Israel News Agency <http://www.israelnewsagency.com/israelneworleanskatrinahumanitarianaid4890907.html>.

[677] One of the fields MASHAV's operation is the program for combating HIV/AIDS. MASHAV sponsors courses in Ethiopia to train medical personnel. The courses are organized by the Israeli Hospitals Consortium. MASHAV's projects concentrate on building capacity and training professionals. See The State of Israel, Ministry of Foreign Affairs, "What's New in MASHAV?", online: MASHAV Center for International Cooperation <http://mashav.mfa.gov.il/mfm/web/main/missionhome.asp?MissionID=16210&>.

[678] "Recent MASHAV Activities", *supra* note 674.

[679] For example, "Latet" (Hebrew for "to give") Humanitarian Organization was founded in 1996. One of its programs is dedicated to international humanitarian aid. This program specializes on helping people that were affected by natural disasters and civil wars. "Latet" provides the supply of food, water, medical and engineering assistance. See "Emergency Aid", online: Latet: Israeli Humanitarian Aid <http://www.latet.org.il/english/Emergency.asp>. "IsraAID" is an Israeli forum for international

pharmaceutical manufacturers are also actively involved in providing aid by donating drugs, first aid kits, *etc*.[680]

Because Israel is very active in the field of Foreign Humanitarian Aid on the governmental, industrial, and NGO level, it is important to examine the mechanism of providing generic versions of patented drugs to countries facing a public health crisis on a humanitarian basis. Moreover, since the WTO General Council's decision became a part of TRIPS, the chances that such a mechanism may become an integral part of *Israeli Patent Act* are increasing.

"Bill C-9" in Israeli Law?

If the Israeli government had put forward legislation such as Canada's Bill C-9, it could have created many challenges for all parties involved. The government would have had to take a very active role in bringing such a mechanism to life. Although generic manufacturers are the main players in the Israeli pharmaceutical market, the number of generic companies in Israel is relatively small, unlike Canada. Therefore, they would not be able to bear the whole burden of manufacturing and exporting drugs at unprofitable prices with no additional incentives from the government. It would therefore be up to the government to remunerate or create a system of incentives for generic manufacturers for

humanitarian aid that contains more than 35 Israeli and Jewish NGOs that provide a development and relief work in developing countries. See "What is IsraAID", online: IsraAID <http://www.israaid.org.il/background.asp>.

[680] For example, Teva Pharmaceuticals and Rafa Laboratories offered help to flood victims in Maharasha, India. Antibiotics and first aid equipment were sent to the area. The aid delivery was a combined activity of the Ministry of Foreign Affairs, the Ministry of Health, the Chief Medical Officer, "Latet" Organization, and these two generic pharmaceutical companies. See "Israeli Aid to Indian Flood Victims" (9 August 2005), online: IsraAID <http://www.israaid.org.il/story_page.asp?id=691>. Although not so welcomed by the Indonesian Government and despite the fact that Indonesia has for a long period treated Israel as an enemy, Israeli pharmaceutical companies sent about 75 tons of the equipment valued at $450 000, including 20 tons of medicines donated by Teva Pharmaceuticals. See Gary Fitleberg, "Tsunami, Tzedakah and Tikkun Olam – II" (2 March 2005), online: OpinionEditorials.com <http://www.opinioneditorials.com/guestcontributors/gfitleberg_20050302.html>.

their participation in the mechanism of the export of cheaper drugs to developing countries.

If the government granted tax reductions or free infrastructure to build an additional manufacturing site, it might be possible to enact such a mechanism. After all, a generic producer would have access to an additional market that he probably would not be able to enter otherwise while the patent is still valid.[681] In this case, though, the mechanism of export of generic versions of patented drugs to countries in need could hardly be named "humanitarian". It would, after all, be based on the expectations of higher profits in the future on the part of generic companies.[682] Moreover, it could hardly be categorized as a "donation", because one of the system's basic requirements is the requirement to remunerate a patent holder. Thus, the nature of the mechanism could possibly contradict the General Council Chairperson's statement.[683] Although it would still be a "public non-commercial use", as required in Par. 1(b) of the WTO General Council's decision, on the part of an importing country.

The Canadian Bill implemented the "public non-commercial use" requirement in an interesting way: for all the least-developed countries and for the WTO member developing countries, the Bill waived the requirement that the importing country limit the use of the system only to cases of national emergency or other circumstances of extreme urgency. The only requirement left in s. 21.03(1)(b) of the Bill was that non-WTO member developing countries would agree that the product imported under the Bill would be used for non-commercial purposes. Also, the requirement of the country facing a

[681] Based on the correspondence with the Interviewed Person. See *supra* note 521.
[682] *Ibid.*
[683] It has been stated: " … the system that will be established by the decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the decision, not be an instrument to pursue industrial or commercial policy objectives…" See *supra* note 268.

public health emergency was left only in regard to developing countries that were non-WTO members (s. 21.03(1)(d)(ii).

Contrary to Canada's legislation, it would be more suitable for Israeli reality if the Israeli amendment was more restricted, *i.e.*, if the mechanism was made applicable only to importing countries that faced a public health emergency. Although, this step would take the mechanism farther from being a humanitarian one, and therefore would require more involvement from the government in order to balance the system.

On the other hand, Israel itself invoked the status of a developing country in the WTO, although stating that the preferential rights granted to a developing country would be invoked only on certain occasions.[684] It has been stated:

> " …The geopolitical circumstances in our region necessitate that Israel reserves the rights to which developing countries are entitled. The burden of security expenses on the national budget, the vulnerability of our economy to political unrest in the region and its implications on our financial markets, industry, employment *etc.*, require us to maintain flexibilities afforded by developing country status … ".[685]

Moreover, Israel itself did not rule out the possibility of using the mechanism established in the WTO decision as an importer in "situations of national emergency or other circumstances of extreme urgency".[686] For the same reasons, *i.e.*, vulnerability of the economy and the political unrest in the region, it seems that the government cannot commit to constantly running a humanitarian aid program. Instead, the government could

[684] The State of Israel, *WTO Trade Policy Review: Israel's Statement* (3 February 2006), online: Ministry of Industry, Trade and Labor <http://www.moit.gov.il/NR/rdonlyres/165108D9-D86F-47F9-AED9-E27A9E016F09/0/secondstatement.doc> at 4-5.
[685] *Ibid.*
[686] Contrary to Canada, which declared that it would not use the system as an importer in any case. See *supra* note 6 at para. 1 (b) at the note 3. Also see *supra* note 268.

create a semi-commercial mechanism of export under a compulsory license that would also rely on private parties, and therefore, would not be entirely non-commercial. However, such a mechanism would allow the government to rely on market powers instead of relying only on the governmental budget allocated to humanitarian purposes.

Research-based pharmaceutical companies are positioned from the opposite side of the barricade. Canada's Bill C-9 allowed a patent holder to apply to the Federal Court to request the order in case there was a concern that the mechanism could be used in a commercial way. Possible Israeli version of such legislation, in which the balance would be shifted more to the side of the government, should have no similar provision. Research-based companies that register their patents in Israel are, for the most part, multinational corporations that import their products to Israel.[687] According to the claims of the brand-name industry, Israel provides a low level of IP protection. Prior to the recent amendment, the *Israeli Patent Act* was considered to be contradicting TRIPS and the US Patent Laws (see discussion earlier in this chapter). This is to suggest that if Israel were to include the provisions of a possible appeal similar to the ones included in Canada's Bill C-9, Israeli generic manufacturers would in no time find themselves involved in lengthy and costly litigation as to the "commerciality" of their contracts with importing countries. At the same time, the Israeli government could possibly find itself in the situation of the South-African government. The South African government passed an amendment to the *Patent Act* that allowed the issuance of compulsory licenses for the import of generic drugs to cope with the AIDS crisis that was challenged by the US for infringing TRIPS.[688]

[687] Eitan, *supra* note 647.
[688] *Supra* note 512. See also *supra* note 216 at 200-201.

Israeli generic companies could possibly have benefited from legislation similar to Canada's Bill C-9, if the Israeli version was less loaded with administration provisions that could render the mechanism inflexible.[689] Although, in the reality of an unstable economy dependent on an even more unstable security situation in the region, there is almost no chance that an Israeli mechanism of export could rely so heavily on the generic manufacturers as the Canadian Bill does. They simply would not take such risks. Along with the benefits coming from gaining access to new markets that would otherwise be closed for the generic companies until the patent expired, generic manufacturers would have had to receive government sponsorship in order to participate in such a system. Moreover, the mechanism would not be purely unprofitable, because the smaller the number of the competitors in the market, the higher the prices of the product. When a government of the importing country can contact only five generic companies (this is the number of major generic producers operating in the Israeli market), the lowest price that the country would be able to reach would higher than it could have been, were there ten generic companies operating in the pharmaceutical market.

Therefore, if a mechanism of export similar to Canada's Bill C-9 was legislated in Israel, it would have to be quite different from the Canadian legislation. Because of the differences in the economic and political situations of the two countries, a mechanism that relies so heavily on private parties would be unfit for the Israeli reality. Two other options are quite possible, though:

1) the mechanism would be well sponsored by the government, in that it would propose significant incentives for a generic manufacturer,

[689] Based on the correspondence with the Interviewed Person. See *supra* note 521.

such as tax reductions or even partial payment for manufacturing the products for export, or;

2) the mechanism of export would be, even if partly, commercial in nature (after all, it is difficult to name it a "humanitarian" one as it is).

In the case of a mechanism that is commercial in nature, the unique Canadian formula of remuneration would not fit either. Israeli generic manufacturers would have to remunerate a patentee much more substantially. Moreover, in that case, the procedures to apply for the termination of a license based on inadequate remuneration should be made available for a patentee. Otherwise, the *Israeli Patent Act* would once again contradict TRIPS and be said to be "providing an unsatisfying level of IP protection", while Israel would be reinstated on the US Priority Watch List, as it was in 2002.[690]

Conclusions:

Based on the analysis of the legislation of other countries, Canada's amendment seems to bear many characteristics of a foreign aid program, instead of being a mere implementation of the WTO General Council's decision. The Canadian legislation strayed farther away from the WTO decision. While attempting to establish a relatively clear and feasible mechanism, Canada's Bill C-9 dropped the vague language of the WTO decision and replaced it with relatively accurate definitions. Obviously, it could be argued that providing detailed, and often very burdened, procedures rendered the mechanism inflexible.

[690] *Supra* note 638.

The vague and unclear regulations would definitely add to the uncertainty and unpredictability of the process of the granting of compulsory licenses. Moreover, if Canada's government had wanted only to craft legislation implementing the WTO August 30 decision, it could have closely followed the language of the decision. Given the fact that the legislation of other countries is so similar to one another and, excluding a few aspects, similar to the WTO General Council's decision, Canada could have done the same: just follow up. Instead, Canada's government created a unique and detailed mechanism that differs from those of other countries in numerous aspects.

Given the fact that Canada is the only country from the countries that implemented the WTO decision, except India, that has a big generic pharmaceutical market,[691] the government was preoccupied to create a workable system, detailed and carefully considered, in order to allow the Canadian generic market to operate under the new regime. This argument can possibly explain why the Bill includes several TRIPS-like aspects that are totally uncharacteristic for a foreign aid program. [692]

Eventually, the real effect of Canada's Bill will be seen when it is actually used by developing countries in need of generic drugs.[693] As for today, there is one project under way that was initiated in order to apply the Bill to the export of generic drugs (mostly ARVs) to Ghana.[694] This initiative is mostly a humanitarian act. Besides supplying Canadian generic drugs to Ghana, it includes such measures as drafting patent

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[691] Blackie, *supra* note 362 at 10.
[692] Such as a limited list of eligible drugs, a limited list of eligible importing countries, a requirement that the NGOs are to receive permission from the government of the importing country, conditions for termination of a license, and so on.
[693] *Supra* note 362 at 22.
[694] During the visit of the "Access to Drugs Initiative" (ADI) delegation to Accra, Ghana, in November 2005, a memorandum of understanding was signed between the ADI and the Ghanaian Ministry of Health. See "Access to Drugs Initiative: History", online: University of Toronto Faculty of Law <http://www.law.utoronto.ca/accesstodrugs/History.htm>. Also see *ibid*., at 23.

legislation for Ghana that would: integrate TRIPS flexibilities; aid in the establishment of domestic manufacturing of ARVs; train Ghanaian medical professionals to ensure the sustainability of treatment sites and build additional medical facilities.[695] Whether Ghana is indeed going to become the first country to use the Canadian compulsory license mechanism is still unknown.

Regarding the possibility of including similar legislation in Israeli Law, such legislation would have to differ from Canada's Bill C-9 in that it should either be a mechanism well sponsored by the government or a mechanism that would be, even partially, commercial in nature.

[695] *Access to Drugs Initiative*, *ibid.*

Summary

Created, by and large, by developed countries and, at least in short-run, for developed countries, TRIPS was an explicit expression of the age-old tension between industrialized and developing nations. This tension was greatly emphasized in the clash between IP protection and public health issues.

Throughout the patent section of TRIPS we can observe various mechanisms that aim to strengthen patent protection. However, stronger patent protection of pharmaceuticals was not the sole problem of the global pharmaceutical market. As a result of shortcomings of the global pharmaceutical market in general, and the US pharmaceutical market in particular (the US is home to most multinational pharmaceutical corporations), the prices on pharmaceuticals became excessively high.[696] The high prices are believed to be the main reason, although not the only one, for limited access to pharmaceuticals.[697]

By strengthening the international level of patent protection, TRIPS intensified the problem of access to essential medicines in underdeveloped nations. The Agreement obliged all WTO member countries to provide patent protection for pharmaceuticals.

The Agreement also provides some flexibilities, such as mechanisms of exception from patentability in Article 27 (2)-(3) or a general exception from patent protection in Art. 30. However, even in these flexibilities an attempt to "alleviate" the consequences of granted exceptions on the general IP protection agenda can be observed. For example,

[696] *Supra* note 96 at 10.
[697] *Supra* note 77 at 2. Other valid reasons are: the lack of pharmaceutical infrastructure, the lack of trained medical personnel, the inability to monitor a proper administration of drugs by patients, *etc.*

one of the purposes of a compulsory license clause was to allow developing countries to import generic versions of essential drugs at affordable prices. Nevertheless, the mechanism turned out to be unworkable for underdeveloped countries with insufficient manufacturing capacities in the pharmaceutical field.

As a response to this problem, the Doha Declaration on TRIPS and Public Health was adopted. However, the Declaration left the problem of access to affordable medicines in developing countries lacking sufficient manufacturing capacities for the resolution of the TRIPS Council.

The Decision of the TRIPS Council has attempted to continue the tone of shifting the balance to the side of developing countries, the tone that was set up in the Doha Declaration. The final solution (waiver of Art. 31(f) and allowing the export of generic versions of patented drugs) was based mostly on the developing countries' proposals. However, the developed countries were the ones to determine the rules and procedures according to which the mechanism of compulsory license would operate. The difficulty was that in determining how a compulsory license would work in times of public health crisis, the numerous rules and procedures deemed to protect the production exported under a compulsory license from trade diversions and abuses, were most likely to prevent developing countries from using the mechanism altogether.

Canada's Bill C-9

Canada's Bill C-9 could certainly be considered an attempt to overcome the obstacles created by the ambiguity of the WTO decision. Driven by the desire to be a leading player in the world's arena of providing aid for developing countries in their fight

against infectious diseases, Canada's government attempted to create legislation that aside from serving a humanitarian purpose would also attempt to find a balance between numerous controversial interests.[698] As a result of this attempt, the Bill's provisions range from purely humanitarian in nature[699] to "TRIPS-plus" provisions that were not even mentioned in the WTO decision itself.[700]

The difficulty in deciding whether the legislation should bear the characteristics of a humanitarian act or an act merely implementing the WTO General Council's decision was one of the main difficulties in establishing the nature of the future Bill's provisions.

The True Nature of the Bill – Canada's Bill and Other Countries' Legislation

By comparing Canada's legislation to the other countries' attempts to implement the WTO General Council's decision we could possibly reveal the true character of the Bill. Contrary to Norway and India's legislation and the EU's draft of regulations, Canada's Bill C-9 strayed farther away from the language and contents of the WTO General Council's decision. The Bill establishes much clearer procedures than the ones outlined in the WTO decision. However, one of the side effects of such clarity is that the legislation is burdened with administrative details. It could be argued that the vaguer the provisions, the more flexible the legislation. On the other hand, the WTO decision lacks clear definitions of such important provisions as the grounds and timeframe for seeking a voluntary license, it lacks a formula for the calculation of remuneration payable to a

[698] These interests are: encouraging the supply of essential medicines to the countries in need in a timely manner; preserving the IP rights of the Canadian patent holders and preserving compliance with Canada's other obligations under TRIPS. Based on *INST Debates (24 February 2004)*, *supra* note 309.
[699] Such as the formula for the calculation of remuneration.
[700] Such as the limited list of pharmaceuticals eligible to be subject to a compulsory license.

patentee, *etc.* These deficiencies can render the mechanism unreliable and uncertain in view of its future users.

Had Canada's Government only wanted to craft legislation implementing the WTO August 30 decision, it could have closely followed the language of the decision. As did the legislation of other countries, which is so similar, excluding a few aspects, to the WTO General Council's decision. Instead, Canada's government created a unique and detailed mechanism that differed from those of other countries in numerous aspects. Moreover, Canada's Bill C-9 dropped the vague language of the Decision and replaced it with relatively accurate definitions.

Although the WTO General Council's decision is considered to be the one that changed the IP regime in the field of the export of generic medicines[701] and despite the fact that the decision was reached almost three years ago, no country seems to be in a rush to use the mechanism set in the decision. The same can be said about Canada's Bill C-9. The legislation was enacted in May 2005, but no developing country has yet requested the grant of a compulsory license.[702]

Would Canada's Bill Fit for Israel?

I found a basic resemblance between patent protection regimes of Canada and Israel, which after TRIPS' full implementation are supposed to be internationally unified. The resemblance was also found in the relations between the government and the generic producers in these two countries. Moreover both countries are actively participating in the field of humanitarian aid.

[701] *Supra* note 268.
[702] *Supra* note 362 at 1.

In both countries, generic manufacturers seem to enjoy favoritism expressed by the government. Therefore, my question was: would the system of a compulsory license issued to a generic company to produce drugs for export to poor countries, similar to Canada's Bill C-9, fit in Israel's *Patent Act*? And if so, how would this mechanism integrate into Israel's humanitarian aid system?

If the Israeli government had put forward legislation similar to Canada's Bill C-9, it could have created many challenges for all parties involved. The government would have had to take a very active role in the operation of such a mechanism. Israel's unstable economic and political reality would require the amendment to be more restricted than the Canadian Bill. In other words, if only importing countries that face public health emergency would be allowed to take part in the system. However, this step would take the mechanism farther away from being humanitarian, in that it would significantly limit the number of eligible countries. Furthermore, it could increase the risks undertaken by a generic producer, because a potential reward in a poor country coping with a public health emergency can be quite doubtful. Therefore, to cover these risks and to create incentives that would motivate a small number of generic companies operating in the Israeli pharmaceutical arena, the government would have to be more involved.

Hence, if an amendment such as Bill C-9 was to be legislated in Israel, it would have to be quite different from Canada's Bill. The differences in the economic and political situations between the two countries could render a mechanism, which relies so heavily on private parties, unfit for the Israeli reality.

In my opinion, two different directions are possible for the Israeli amendment. One is that the mechanism would be well sponsored by the government, in that it would

propose significant incentives to a generic manufacturer for participating in the system, such as, for example, tax reductions or even partial payment for manufacturing the products for export. This is if the amendment would be the first, permanently running Israeli foreign aid program. The second avenue that the potential legislation could take is if the mechanism of export could be, even partly, commercial in nature. In this case, Israeli generic manufacturers would have to remunerate a patentee much more substantially and the Canadian formula of remuneration would not fit due to its purely humanitarian nature. Such a mechanism would then rely mostly on the market powers. This version of the mechanism of export would fit better into the Israeli reality, given the fact that it would require no fiscal commitments from the government. And, as history showed, the Israeli government's commitments in the field of public health were not at their best.[703]

[703] See the example of the "Sal Ha-trufot" discussed in Chapter VII at 156-157. *Supra* note 671.

Conclusion

The major deficiency in Canada's Bill C-9 is its over-reliance on private parties, *i.e.*, licensees and patentees, and insufficient Government involvement. The Government's association with the system is limited to establishing a general frame for the mechanism and taking part in several administrative procedures. There are no fiscal commitments. The Government takes almost no part in stimulating the parties to participate in the system. The Government has no involvement in the drug distribution process. For humanitarian legislation, *i.e.*, a humanitarian act sponsored by the Government that was intended to aid the developing world in its battle against infectious diseases, the Government definitely overlooked its own part in the mechanism.

The Bill does bear more humanitarian features than the WTO decision. The question remains: will the Bill be yet another foreign aid program? Canada is one of the leading players in the field of humanitarian aid to the developing world. In most of the foreign aid programs, Canada's Government takes a very active part. Moreover, most of the programs are established and implemented entirely by the Government. Therefore, if the Government established another long-term foreign aid program, again, it should assign itself a much more active role in the system. However, in that particular aspect, the Bill followed the language of the WTO General Council's decision that prescribed no active role for the government of an exporting country.

This thesis proposes various models upon which the mechanism of the export of generic drugs to underdeveloped countries could be based, and that should be examined in light of the aims of the Doha Declaration.

Different Models to Solve the Problem of Inaccessibility of Essential Medicines and Canada's Bill C-9 Standing

One possible way to make drugs affordable to underdeveloped countries is to let the Government buy the patented drugs needed for the particular developing country from the patent owners and distribute it in that country. Such a purchase would probably be subject to considerable price discounts due to the quantity of purchased drugs. Of course, such a mechanism would require the involvement of the government of the developing country in regard to distribution of the drugs directly to the patients. The Government could distribute the drugs through the government channels of the developing country, while the latter could subsidize the drugs so that patients would be able to buy them at low or even no cost.

Following this model, which is completely humanitarian, Canada will definitely preserve the spirit of the Doha Declarations (both the General Doha Declaration and the Declaration on TRIPS Agreement and Public Health). As part of Canada's foreign aid program, this model would compose a feasible solution to the public health problems of underdeveloped countries in accordance with Par. 1 of the Doha Declaration. After all, despite all the criticism, Canada's foreign aid programs do operate quite successfully aiding to fight infectious diseases in underdeveloped countries (see discussion in Chapter VI (d)). Moreover, the proposed mechanism of drug purchase and distribution by the government of the exporting country through the government channels of the importing country would be an explicit humanitarian act. As such, it would extend beyond the TRIPS boundaries (as well as beyond the confining boundaries of the WTO General Council's decision). Thus, Canada's obligations under TRIPS would not pose an obstacle

in "taking measures to protect public health".[704] The fact that the Government will buy medicines directly from the patent owners can definitely make purchases quite expensive. However, no issues of patent protection and compulsory licensing will arise. For research-based manufacturers, it will reduce the risks of lengthy and costly litigation in an attempt to protect their IP rights.

This model, though, leaves out one important player from the pharmaceutical field completely. The proposed model would not involve generic producers. This deficiency has its own costs. Buying patented medicines from the research-based pharmaceutical manufacturer in the quantities needed for poor countries afflicted with pandemics would require the contribution of significant resources, even if some considerable discounts were made.

Another possible model of facilitating access to life-saving medicines in developing and least-developed countries is for the Government to buy the medicines, at significantly lower prices, from generic manufacturers. Of course, the lower the price of a particular drug, the greater the extent of the aid program that the Government might be able to launch, *i.e.*, more drugs can be bought, a larger variety of medications can be included, more projects can be carried out in additional underdeveloped countries.

This model does, however, inevitably contain the mechanism of a compulsory license, and therefore, all the issues of IPR protection discussed in Chapter III(c)-(e). The model that includes the participation of the generic producers and the issuance of a compulsory license to produce generic versions of patented drugs is closer to the current version of Bill C-9. Such a scheme would still preserve its humanitarian nature. After all, the Government would buy the medicines from generic companies and distribute it

[704] *Supra* note 4 at paras. 2 & 4.

through the government channels of the developing country. The risks for a generic manufacturer in such a scheme would be minimal. The involvement of the Government would increase the certainty of the contract for the generic manufacturer, particularly regarding reimbursement. There would be no risk that the developing country would not be able to fulfil its obligations according to the contract, because the developing country would not be a part of this scheme.

On the other hand, the developing country would definitely benefit if the purchase and distribution of drugs could be processed through government channels, while initiated by the government of the exporting country. The resources that the Government invested in the foreign aid program (and this scheme should be part of the foreign aid program) would allow the lowering of the prices of the medicines distributed in the country of destination. Moreover, if the drugs were subsidized by the government of the developing country, they could be delivered to patients at a lower or no cost. Therefore, if the government of a developed country could buy from, or even partly reimburse, a generic manufacturer for the supply of drugs to an underdeveloped country, it would allow people in poor countries access to cheaper drugs, while the generic manufacturer would be rewarded for his investments in R&D.

There is an additional scheme for improving access to essential medicines in developing countries: the one proposed in the WTO General Council's decision. It should be acknowledged that there are certain deficiencies in this model. Since it is loaded with numerous safeguards as a result of the developed nations' demands, the decision has, for the most part, proved to be unfeasible (see discussion in Chapter IV(b)). Thus, the

mechanism that closely follows the language of the decision would most probably prove to be unfeasible as well.

If examined in light of the declared aims of the Doha Declaration, *i.e.*, promotion of the members' rights to protect public health and to improve access to medicines for all (Par. 4), the WTO decision did not absorb the spirit of Doha. Although, the decision did technically implement the instructions given in Par. 6 of the Doha Declaration.

The current version of the Bill is a combination of the last two models. On the one hand, the Bill extends beyond the vague language of the WTO decision and proposes a clearer mechanism of the export of generic drugs to underdeveloped countries. This mechanism does involve generic manufacturers, and moreover, it is practically based on their participation.

On the other hand, the Bill does not envisage the practical application of the scheme it proposes to enact. For example, the Bill does not relate to aspects such as distributing drugs in a country of destination, decreasing the risks of generic producers, or encouraging generic manufacturers to enter the contracts. All these aspects would require the Government's involvement. However, instead of involving the Government, the Bill solves the problem of a risky contract by shifting the emphasis onto the private parties. Both the generic manufacturer and the research-based company enter the system with the same purpose, although they pursue it in different ways. Unfortunately, this purpose can in no way be named "non-commercial". While the generic manufacturer intends to make profits from supplying drugs to a country in need, even if supplying the medicines at extremely low prices, the patentee would want to protect his patented invention from being used in a commercial way when he receives inadequate

remuneration for such use. A system that does not rely on governmental support, but depends mostly on private parties, could not possibly be "humanitarian and non-commercial". Therefore, paradoxical as it is, a system that seems to bear a lot of humanitarian characteristics[705] turns out to be operating in a relatively commercial way.

Another imperative deficiency that could turn the Bill into an unworkable piece of legislation is its limited range of operation. The Bill suggests that, for the most part, generic competition can solve the problem of inaccessibility of essential medicines in underdeveloped countries. Although generic competition can indeed lower the prices on pharmaceuticals and, as was stated, excessively high prices are one of the main factors contributing to the inaccessibility of medicines, there are other factors. The Bill does not relate to the other significant obstacles, such as: the lack of adequate health care infrastructure; lack of trained medical personnel; lack of a way to monitor proper drug administration by patients; lack of a mechanism to ensure that the drugs reach the right hands, *etc*.

Whichever model the Bill implements, it will have to undergo significant changes in order to increase the Bill's efficiency and feasibility.

[705] Based on the analysis of the legislation of other countries, Canada's Amendment indeed seems to bear more characteristics of a foreign aid program than any other foreign legislation. See discussion in Chapter VII(a)-(b).

Suggestions Regarding Certain Provisions of Canada's Bill:

	If the Bill is a Part of Canada's Foreign Aid Effort	***If the Bill is Less Humanitarian, i.e., Closer to the WTO Decision***
List of Eligible Medicines	Should be removed.	Should be removed.
List of Eligible Importing Countries	Should be removed.	Only WTO member countries should be able to use the system. The exception of inclusion of least-developed non-WTO member countries would create problems, such as requiring a non-WTO member country to comply with measures against trade diversions established in the WTO Agreements to which the country is not a party.
NGO Procurement	Should be allowed. Given the fact that the NGOs are the ones that distribute drugs on the field and are actively involved in helping poor countries to strengthen their health care infrastructure. Requiring the NGOs to receive permission from the government of an importing country could delay or even ruin (due to corrupt governmental structures) the NGOs' efforts to supply drugs directly to patients.	The current mechanism, allowing NGOs to participate with permission from the governments of importing countries, is well suited for this version of the Bill.
Limited License Period	Should be removed. The drugs should be supplied on the basis of the importing country's needs.	The current solution, stating a two-year period of license with an option for one renewal, is well suited for this version of the Bill.

Royalty Rates	The current solution, establishing a unique formula based on the importing country's ranking in the UN Human Development Index, is well suited for this version of the Bill.	Patentee has to have a say in establishing royalty rates prior to issuing the license and not *post facto*. Remuneration should be determined, therefore, on a case-by-case basis, while "taking into account the economic value to the importing member of the use that has been authorized in the exporting member."[706]
Government's Involvement	The Government should take an active part in carrying out the mechanism. For example, the Government could buy drugs from research-based or generic companies and distribute them in the poor country through local government channels. The government of the receiving country could subsidize the drugs bought from Canada to the point where the specific drug would be affordable for the patients. This way, excluding cases of corruption of governmental agents, Canada's Government would also ensure that the drugs arrive to the right hands, *i.e.*, to the people in need. However, one of the critiques of such a system is that even giving drugs away in countries lacking health care infrastructure would not contribute to better access to medicines.[707]	The Government can rely more on private parties, *i.e.*, a licensee and a patentee, and on the market powers. However, the Government would need to ensure that no trade diversions occur after the drugs leave the exporting country. The measures established in the current version of the Bill (particularly in the *Amendment to Food and Drugs Act*) seem to be sufficient. Although these provisions oblige importing countries to undertake certain actions to comply with.

[706] *Supra* note 6 at para. 3.
[707] *Supra* note 552 at 22.

Should an Importing Country Declare a Public Health Emergency in Order to Use the Mechanism?	No, such a requirement would contradict the humanitarian nature of the mechanism. It should not make any difference what is the extent of a public health problem afflicting a poor country. Moreover, the importing country is the one to assess its need for certain drugs for certain diseases. As was proven more than once, even a small health problem in one country may quickly become a global pandemic nowadays.	Yes, it would fit the requirements of the WTO General Council's decision.[708]

All in all, it is true that the actual test for any legislation is the reality test.[709] As for today, there is only one ongoing attempt to use the Amendment to provide generic ARVs to Ghana.[710] Hopefully, the Amendment will not wind up being a dead weight on Canada's attempts to facilitate access to essential drugs at affordable prices in underdeveloped countries afflicted with pandemics.

[708] *Supra* note 6 at para. 1(b).
[709] *Supra* note 362 at 22.
[710] *Access to Drugs Initiative, supra* note 694.

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