

ELIMINATING BARRIERS TO THE EXPORT OF GENERIC VERSIONS OF PATENTED DRUGS TO DEVELOPING COUNTRIES — FROM DOHA TO BILL C-9

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INTRODUCTION**

THE DOHA MINISTERIAL DECLARATION, adopted on 14 November 2001 in Doha (Qatar) at the Fourth Ministerial Conference, was created to clarify implementation issues regarding World Trade Organization (WTO) agreements signed in 1994, at the end of the Uruguay Round of Trade Negotiations.¹ One of the subjects on the agenda was the implementation and interpretation of the *Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement* signed as a part of the Final Act of the new *WTO Agreement*.² While strengthening international intellectual property (IP) protection and establishing new patterns of patent protection, *TRIPS* has also provided a few mechanisms of exception to patent protection in order to help developing countries to adjust to the new IP regime.

One of the exceptions outlined in Article 31 of *TRIPS* is the compulsory license, which is meant to allow generic versions of patented drugs to be manufactured without a patent owner's authorization. Article 31(f) of *TRIPS* restricts granting compulsory licenses "predominantly" for domestic market supply.³ Therefore, poor countries with insufficient manufacturing capacities are unable to benefit from this exception.

In Paragraph 6 of the Doha Declaration on *TRIPS* and Public Health (Doha Declaration) adopted in November 2001, ministers recognized the problematic consequences of such a restriction.⁴ In August 2003,

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** A more extended background to this paper can be found in my other article, "TRIPS, Access to Medicines and the 'North-South' Conflict after Doha — the End or the Beginning?" (2006) 6 *Asper Rev. Inter. Bus. & Trade L.* 67.

¹ "The Doha Declaration explained," online: WTO <http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm>.

² "WTO legal texts," online: WTO <http://www.wto.org/english/docs_e/legal_e/legal_e.htm>; *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> [*TRIPS*].

³ *TRIPS*, *ibid.*, art. 31(f).

⁴ WTO, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2 (2001) at para. 6, online: WTO

following the ministers' instructions, the WTO General Council adopted a decision on the implementation of Paragraph 6 of the Doha Declaration (WTO General Council's decision).⁵ The decision waived members' obligations under Article 31(f) of *TRIPS* and allowed generic versions of patented drugs to be exported, under certain conditions, to developing countries that had insufficient manufacturing capacities. Canada was the first country to implement this decision. In May 2005, Bill C-9 — *An Act to amend the Patent Act and the Food and Drugs Act* — came into force.⁶

Part I of this paper briefly analyzes the developments that led to the WTO General Council's decision and stresses the role of the flexibilities of the *TRIPS Agreement* in providing developing countries with an opportunity to integrate and accommodate the new IP regime. Part II examines whether Canada's Bill C-9 succeeded in creating an effective and balanced model for compulsory licenses for exporting generic drugs to developing and least-developed countries. Part III provides a substantive analysis of the Bill's provisions, concentrating on the feasibility of the proposed mechanism, possible risks for a generic manufacturer and the role of research-based and generic companies, *i.e.*, patent holders and licensees, in the system. Finally, Part IV analyzes other countries' experiences in implementing the WTO General Council's decision, and what Canada could learn from this experience in order to make Canada's amendment more efficient.

The paper concludes by arguing that Canada's Bill C-9, when compared to other countries' legislations, creates a more detailed and reliable mechanism to export generic versions of patented drugs to developing countries; nonetheless, the mechanism is too problematic to be used as it is. However, the actual test for the Bill's feasibility will be the number of times countries in need will use the mechanism and that remains to be seen.

<http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>.

⁵ *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: Decision of the General Council of 30 August 2003*, 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>.

⁶ Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act*, 3rd Sess., 37th Parl., 2004, online: Library of the Parliament <<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=toc-1>>.

I. HISTORICAL OVERVIEW OF DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH AND WTO GENERAL COUNCIL'S DECISION

ON 14 NOVEMBER 2001, AT THE FOURTH MINISTERIAL CONFERENCE that took place in Doha, Qatar, the Doha Ministerial Declaration was adopted.⁷ One of the major aims of the Doha Ministerial Declaration was to clarify the problems with implementing the World Trade Organization agreements, which were signed at the Uruguay Round of Trade Negotiations in 1994.⁸ The Doha Ministerial Declaration stressed the need to promote economic development, alleviate poverty, and put developing countries' needs "at the heart of the Work Programme" outlined in the Declaration.⁹ Moreover, the members reaffirmed their commitment to help least-developed countries integrate into the multilateral trading system shaped in the Uruguay Round, made previously in the Doha Ministerial Conference.¹⁰

One of the subjects listed on the agenda was the implementation and interpretation of the *TRIPS Agreement* enacted on 1 January 1995 as a part of the *Final Act* of the new *WTO Agreement*.¹¹ Pursuant to the general spirit of the Doha Ministerial Conference, *i.e.*, the members' support for, and emphasis on, developing and least-developed countries, the separate Declaration on the TRIPS Agreement and Public Health was adopted (Doha Declaration).¹² The Doha Declaration was intended to solve the controversial problem of access to affordable life-saving medicines.¹³ The problem of access to medicines becomes even more

⁷ WTO, *Ministerial Declaration*, WTO Doc. WT/MIN(01)/DEC/1 (20 November 2001), (adopted on 14 November 2001), online: WTO <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm#trips>.

⁸ The Doha Ministerial Declaration focused on several specific issues, such as agriculture, services, relations between trade and investments, interaction between trade and competition policy, and dispute settlement understanding, *etc.* Moreover, the separate decision on "Implementation-related issues and concerns" was adopted, and although the majority of issues were left for further negotiations, for about 12 problematic fields the optimal settlement was found. "The Doha Declaration explained," online: WTO <http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm>.

⁹ *Supra* note 7 at paras. 1-2.

¹⁰ *Ibid.* at para. 3.

¹¹ *Supra* note 2.

¹² *Supra* note 4.

¹³ *Supra* note 1. See also "TRIPS Update: a regular briefing on the WTO TRIPS Agreement and related international intellectual property issues" (February

divisive when the need to provide incentives for investments in the costly Research and Development (R&D) of new medicines is taken into consideration. Moreover, one of the ways to provide such incentives is to strengthen patent protection. Such a controversy resulted from the rather “inflexible” flexibilities of *TRIPS*, *i.e.*, exceptions from patent protection provided by the Agreement.

a. Existing Exceptions from Patent Protection under TRIPS

The history of *TRIPS* suggests that the agreement was designed mostly by developed nations (led by the U.S.)¹⁴ and was fuelled by their desire to reduce trade in counterfeit goods that grew more and more extensive in the pre-*TRIPS* period.¹⁵ The patent section of *TRIPS* is regarded as a major achievement of the U.S. because it defines the broadest possible scope of patent protection.¹⁶

Setting new, much clearer and stronger standards of patent protection, the *TRIPS Agreement* intensified the already existing strain between patents on medicines and public health issues and deepened

2001), online: Australian Government Department of Foreign Affairs and Trade <http://www.dfat.gov.au/ip/trips_update.html>.

¹⁴ Susan Sell, “Post-*TRIPS* developments: The Tension between Commercial and Social Agendas in the Context of Intellectual Property” (2002) 14 *Florida J. Int’l Law* 193 at 194-95.

¹⁵ U.S. General Accounting Office, *Report to Selected Congressional Subcommittees: International Trade: Strengthening Worldwide Protection of Intellectual Property Rights*, (NSIAD-87-65) (Washington, D.C.: United States General Accounting Office, April 1987), online: GAO <<http://archive.gao.gov/d2t4/132699.pdf>>.

¹⁶ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 2nd ed. (London: Sweet & Maxwell, 2003) at 220 [Gervais]. According to article 27(1), patents are to protect products and processes, with no discrimination as to the field of technology, places of invention or production. For a more extended discussion on this issue, please see Fanni Weitsman, “*TRIPS*, Access to Medicines and the ‘North-South’ Conflict after Doha – the End or the Beginning?” (2006) 6 *Asper Rev. Inter. Bus. & Trade L.* 67.

The impact of this new level of protection is felt especially on pharmaceutical patents; before *TRIPS*, a number of developing and least-developed countries had not granted patent protection for pharmaceuticals, preferring to leave medicines for public domain. See 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.* at 2-3 and 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*, c.17 at 356, online: IPRsonline.org <<http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>> [Roffe *et al.*].

the problem of access to medicines in developing countries. A challenging task was to find a balance between making cheaper versions of life-saving medicines available to people in need in poor countries and preserving incentives (particularly, strong patent protection of pharmaceuticals) to invest in costly R&D to create new drugs.¹⁷ This controversy was further deepened by an obligation to implement stronger IP rules in the national laws of WTO member countries.¹⁸ Stronger patent protection increases the price of drugs which limits access to medicines. If it is a life-saving drug, such as HIV/AIDS medicine, the dilemma is even more profound: should the encouragement of incentives to create new drugs outweigh the current need of people who are unable to afford existing medicine because of patent protection?¹⁹

The impact of *TRIPS* on the pharmaceutical industry was one of the major concerns of developing countries during the Uruguay Round.²⁰ However, *TRIPS* itself has offered few exceptions from patent protection.

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) refuse to grant a patent in order “to protect human, animal or plant life or health, or to avoid serious prejudice to environment.”²¹ Article 27(3) makes it possible to exclude from patentability certain categories of inventions;²² conversely, Article 27(2) excludes specific inventions whose commercial exploitation imperils public interests.²³ Article 27(2) covers the way inventions are applied, as opposed to Article 27(3), which covers

¹⁷ According to the US Department of Health and Human Services Food and Drug Administration Report, the estimated costs of bringing new drugs into market are between \$0.8-1.7 billion. See “Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products” US Department of Health and Human Services Food and Drug Administration (March 2004), online: FDA <<http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html#intro>>.

¹⁸ Adam Lewinberg, “Access to Medicines Guide,” online: Center for Innovation Law and Policy <<http://www.innovationlaw.org/English/Access-to-Medicines-Guide.html>>.

¹⁹ *Ibid.*

²⁰ Commission on Intellectual Property Rights, “Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights,” (September 2002) at 29, online: Commission on Intellectual Property Rights <http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf>.

²¹ Roffe *et al.*, *supra* note 16, c.19 at 375.

²² These categories of inventions include diagnostic, therapeutic and surgical methods for the treatment of humans and animals, as well as for plants and animals, with some exceptions. See *TRIPS*, *supra* note 2, art. 27(3).

²³ Roffe *et al.*, *supra* note 16, c.19 at 377-78.

products and processes themselves.²⁴ Another type of exception provided in Articles 30-31 of *TRIPS* is the exception from patent protection. Unlike Article 31, which offers specific conditions for the use of patented invention without right holder's authorization, Article 30 could theoretically be interpreted as authorizing the issuance of a license to manufacture drugs for export to another country that issued a compulsory license for importing these drugs under Article 31.²⁵ In fact, there were several attempts to use such a broad interpretation of Article 30 as an alternative mechanism for granting compulsory licenses to export generic versions of patented drugs.²⁶

Another way to interpret *TRIPS* so that it would allow generic drugs to be exported under compulsory licenses is to apply the 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".²⁷ 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," if such measures are consistent with *TRIPS*.²⁸ It has been suggested that in cases involving the supply of life-saving drugs to people

²⁴ *Ibid.*, c.20 at 384.

²⁵ Article 31(f) limits the use of patented invention under a compulsory license "predominantly for the supply of the domestic market" of the country issuing a 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. See *TRIPS*, *supra* note 2, art. 31(f). See generally Gervais, *supra* note 16 at 242.

²⁶ 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 952-53, 965-966 [Haag]. However, the scope of article 30 was interpreted narrowly in the WTO's panel decision in the EU-Canada case. See WTO, *Canada - Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their member States*, WTO Doc. WT/DS114/R (17 March 2000), online: WTO <<http://docsonline.wto.org>>. For an extended discussion, see Chapter 3(a) of "TRIPS, Access to Medicines and the 'North-South' Conflict after Doha - the End or the Beginning?" *supra* note 16.

²⁷ *TRIPS*, *supra* note 2.

²⁸ It has been argued that these two provisions reflect the strain between developing and developed countries during the GATT negotiations. Developing countries argued time and again that *TRIPS* reflects only the interests of developed nations to raise the standards of IP protection, while the interests of developing countries in promoting technology transfer and development were ignored. See Roffe *et al.*, *supra* note 16 at 119.

in need, the public interest should prevail over preserving a monopoly intended to create incentives for inventors, so that the balance mentioned in Article 7 could be reached.²⁹ However, the same public interest could suffer if, as a result of the exclusion from patent protection, the patent as an incentive for investments in R&D would be rendered ineffective. There would be fewer new technologies that would become a part of the public domain, which could, in turn, delay the promotion of innovations and a transfer of technologies.³⁰

In paragraph 19 of the Doha Ministerial Declaration, Articles 7-8 were granted a special status: the TRIPS Council was to be guided in its Work Program by the objectives and principles determined in these articles, pointing out that the development dimension should be taken into consideration.³¹ Therefore, it has been argued that Articles 7-8 could be used as a basis for the interpretation of different *TRIPS* provisions, such as Articles 30-31.³²

While all exceptions described above were used in different circumstances to justify exporting generic versions of patented drugs to developing countries in need, the most effective but controversial provision seems to be Article 31 of the *TRIPS Agreement*.

b. Article 31 – A Problematic Solution for Developing Countries

Article 31 of *TRIPS*, a compulsory license mechanism, is usually used to allow the import of generic versions of patented pharmaceuticals.³³ This mechanism allows a government or a governmental agency to grant a license to exploit a patented invention without the patent holder's authorization.³⁴

²⁹ Gervais, *supra* note 16 at 119.

³⁰ *Ibid.* at 119-20.

³¹ *Supra* note 7 at para. 19 & *ibid.* at 120.

³² Gervais, *supra* note 16 at 120. However, we should bear in mind 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 8 of *TRIPS* requires that the measures undertaken for the protection of public health and nutrition, the promotion of the public interest be consistent with *TRIPS*. By that, art. 8 restrains the discretion of the member-countries to adopt the measures they consider necessary for the protection of public health. See Roffe *et al.*, *supra* note 16 at part 1.20 at 126-27.

³³ 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 131-33.

³⁴ 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.

Similar to Article 30's general definition, Article 31(a) provides that there will be no specific grounds for issuing a compulsory license, leaving it to the members to decide in which circumstances the license will be issued.³⁵ However, it would be safe to say that this is the single similarity between the two articles.

Meanwhile, the distinctions between them are obvious. Article 30 expands the scope of exception by a requirement to take into consideration legitimate interests of third parties. Article 31, on the other hand, states that a compulsory license is to be determined as "another use,"³⁶ *i.e.*, different from the one mentioned in Article 30, and, therefore, can only be granted under specific conditions. In other words, compulsory licenses can be granted for a specific patented invention, while Article 30's exception can apply to more general action, such as legislation or amendments.³⁷

Article 31 is paradoxically restrictive, considering the fact that it is designed to provide flexibility. This Article reflects a desperate attempt to balance a need for flexibilities in *TRIPS* to allow developing and least-developed countries to adjust to stronger standards of IP protection, with a desire of developed nations to prevent massive patent infringement.

Article 31(b) obliges a potential license holder to attempt to obtain a voluntary license from the patent holder on reasonable commercial terms and conditions.³⁸ 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 general amount of remuneration to be paid; instead "the circumstances of each case" should be considered.³⁹ Although Article 31(h) requires that, in assessing adequate remuneration, the licensee or the granting authority take "into account the economic value of the authorization", it does not oblige a granting authority to establish a rate of compensation for this value.⁴⁰

However, the main problem for developing countries wishing to grant a compulsory license to import generic versions of patented drugs results from Article 31(f),⁴¹ which authorizes the use of compulsory licenses

³⁵ Roffe *et al.*, *supra* note 16, c.25 at 462.

³⁶ According to article 31's footnote, the definition of "other use" refers to use other than that allowed under article 30." See *TRIPS*, *supra* note 2, art. 31.

³⁷ Roffe *et al.*, *supra* note 16, c.25 at 462.

³⁸ A more extended discussion on art. 31(b) can be found in the article "TRIPS, Access to Medicines and 'North-South' Conflict after Doha – the End or the Beginning?" *supra* note 16.

³⁹ Roffe *et al.*, *supra* note 16, c.25 at 475.

⁴⁰ *Ibid.*

⁴¹ This article was one of the primary reasons for adopting the separate Doha Declaration on TRIPS and Public Health. See "The separate Doha Declaration explained," http://www.wto.org/english/tratop_e/trips_e/healthdecexpln_e.htm. WTO

“predominantly for the supply of the domestic market” of the authorizing member. This requirement basically excludes exporting drugs produced under a compulsory license rendering some developing countries, with insufficient manufacturing capacities in the pharmaceutical field, incapable of using the compulsory license mechanism without infringing the agreement.⁴² To find an expeditious solution for this problem was one of the main goals of Paragraph 6 of the Doha Declaration on TRIPS and Public Health (the Paragraph 6 problem).

In the pre-TRIPS period, countries were not obliged to provide patent protection for pharmaceuticals. Therefore, they could export generic drugs at lower prices as long as the drugs were not patented in the importing country, or a compulsory license was issued in the importing country, in case the product was patented there.⁴³ After *TRIPS* was implemented, this option was no longer available.⁴⁴ Therefore, countries that possess pharmaceutical manufacturing capacity and can produce generic drugs locally will not be able to export them because of the

⁴² See Fanni Weitsman, “TRIPS, Access to Medicines and ‘North-South’ Conflict after Doha – the End or the Beginning?” *supra* note 16 at 99-100. See also *TRIPS*, *supra* note 2, art. 31(f). The only case where members are not obliged to abide by article 31(f) is where a compulsory license is granted to remedy an anti-competitive practice. See *TRIPS*, *supra* note 2, art. 31(k). 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. In other words, the export under a compulsory license is allowed as a marginal 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. See Gervais, *supra* note 16 at 252 and Roffe *et al.*, *supra* note 16 at 474.

⁴³ Carlos M. Correa, “Implementation of the WTO General Council decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,” WHO/EDM/PAR/2004.4 (April 2004) at 1, online: WHO <http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf>.

⁴⁴ Considering the transitional periods, this will not happen in least-developed countries, for example, until 2016. Developing countries were given a four-year extension in implementing *TRIPS* and in providing patent protection in areas of technology not so protected beforehand. Such developing countries were allowed to delay implementation of *TRIPS* patent section for 10 years after signing the agreement. See *TRIPS*, *supra* note 2, arts. 65(4), 66 and WTO, Press 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>.

Article 31(f) restriction. On the other hand, countries lacking manufacturing capacities that could grant a compulsory license to import a needed generic drug will not be able to find an exporting country.⁴⁵

c. Paragraph 6 of the Doha Declaration and its Implementation in the WTO General Council's Decision

The problems arising from the *TRIPS* flexibilities, especially the anticipated problem of the inability to use a compulsory license clause under Article 31, brought some developing countries, specifically the African Group,⁴⁶ to request that the *TRIPS* requirements be clarified at the Doha Ministerial Conference. Badly affected by the HIV/AIDS pandemic,⁴⁷ South Africa, among other developing countries, initiated a series of high-level consultations on the authoritative interpretation of *TRIPS* in order to find a solution to the public health controversy.⁴⁸

In response, a separate Doha Declaration was adopted.⁴⁹ Paragraph 1 of the Doha Declaration recognizes 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 “national emergenc[ies] or other circumstances of extreme urgency”.⁵⁰ As it was said earlier, the Doha Declaration required the TRIPS Council to find a prompt solution to the Paragraph 6 problem. It has been argued that

⁴⁵ *Supra* note 43 at 1-2.

⁴⁶ The African Group consisted of all the African members of the 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#parall_elimports>.

⁴⁷ 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 195-96.

⁴⁸ 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.

⁴⁹ *Supra* note 4.

⁵⁰ *Supra* note 4, paras. 1 and 5(c) and Richard Elliot, “TRIPS from Doha to Cancún . . . to Ottawa: global developments in access to treatment and Canada’s Bill C-56” (2003) 8:3 *Can. HIV/AIDS Pol’y & L. Rev.* 1 at 9 [Elliot]. A more extended discussion on this issue can be found in the article “TRIPS, Access to Medicines and ‘North-South’ Conflict after Doha – the End or the Beginning?” *supra* note 16.

while giving a mandate to find a solution to the inability of some countries to use *TRIPS* flexibilities, Paragraph 6 attempts to level countries with insufficient manufacturing capacities that cannot use the compulsory license mechanism with countries that can use it.⁵¹ The argument is that all Paragraph 6 really does is counterbalance the disadvantage that some developing countries experience because of Article 31.⁵²

In 2002, the *TRIPS* Council commenced finding a solution to the Paragraph 6 problem.⁵³ The solution was expected to encompass the views of all parties, and it had more chances to reach a proper balance between the two struggling elements: strong IP protection and access to medicines at affordable prices for patients in developing countries.

Unfortunately, the solution adopted by the *TRIPS* Council⁵⁴ was far from balanced. Out of four suggested solutions,⁵⁵ the Council adopted an interim waiver of obligations under Article 31(f) pending an amendment of *TRIPS* within the first half of 2004.⁵⁶

According to the WTO General Council's decision, the definition of pharmaceutical products eligible to be exported under a compulsory license is rather broad and includes not only patented pharmaceuticals themselves, but also products produced through a patented process.⁵⁷

⁵¹ Amir Attaran, "Assessing and Answering Paragraph 6 of the Doha Declaration on the *TRIPS* agreement and Public Health: The Case for Greater Flexibility and a non-justiciability Solution" (2003) 17 *Emory Int'l L. Rev.* 743 at 745.

⁵² *Ibid.*

⁵³ Haag, *supra* note 26 at 952.

⁵⁴ The solution was based mostly on five communications from the U.S., the EU, Kenya on behalf of the African Group, the Group of Developing Countries (Brazil on behalf of the delegations of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela) and the United Arab Emirates. See WTO, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation*, WTO Doc. IP/C/W/363 (11 July 2002), online: WTO <<http://docsonline.wto.org>>. A more extended discussion on this issue can be found in my article, "TRIPS, Access to Medicines and 'North-South' Conflict after Doha – the End or the Beginning?" *Supra* note 16.

⁵⁵ Suggested solutions included: a broad interpretation of article 30 authorizing export of patented products under a compulsory license; an amendment of article 31 to allow such an export; waiver of article 31(f) requirements and dispute settlement moratorium to determine non-compliance with article 31(f). See Haag, *supra* note 26 at 953-54.

⁵⁶ *Supra* note 5 and also WTO, Press Release, Press/350/Rev.1, "Decision removes final patent obstacle to cheap drug imports" (30 August 2003), online: WTO <http://www.wto.org/english/news_e/pres03_e/pr350_e.htm>.

⁵⁷ This definition reflects the proposals of the EU, the African Group and the group of developing countries. See WTO, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation*,

Eligible importing countries include any least-developed country (automatically) and any other country, following notification to the TRIPS Council. Eligible exporting members can be any countries that produce a needed drug within their territory.⁵⁸

The adopted solution itself — the waiver of members' obligations under Article 31(f) — incorporated the position of developing countries. However, the number of safeguards meant to lessen the probability of any abuses and trade diversions can certainly render the solution unfeasible.⁵⁹

II. BILL C-9 AS A FIRST MODEL OF THE NEW MECHANISM FOR EXPORT OF GENERIC DRUGS TO DEVELOPING COUNTRIES UNDER COMPULSORY LICENSE

CANADA WAS THE FIRST COUNTRY TO AMEND ITS *PATENT ACT*⁶⁰ and *Food and Drugs Act*⁶¹ to allow generic pharmaceutical companies to export patented drugs to developing countries under a compulsory license.⁶² On 14 May 2005, Bill C-9, *an Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to*

WTO Doc. IP/C/W/363 (11 July 2002) at 4, online: WTO <<http://docsonline.wto.org>>.

⁵⁸ Numerous countries (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 the U.S.) declared that they will not use the system under any circumstances. Some countries stated that they will use the system only in 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, United Arab Emirates. *Supra* note 5 at para. 1(b) and “Intellectual Property: The General Council Chairperson’s statement” (30 August 2003), online: WTO <http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm>.

See Fanni Weitsman, “TRIPS, Access to Medicines and ‘North-South’ Conflict after Doha – the End or the Beginning?” *Supra* note 16 at Chapter (III)(b).

⁵⁹ 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 country other than a least-developed importing country to establish lack or insufficiency of manufacturing capacities, with no detailed instructions as to the kind of evidence that would satisfy this requirement; various notifications, *etc.* See *supra* note 5.

⁶⁰ *Patent Act*, R.S.C. 1985, c. P-4.

⁶¹ *Food and Drugs Act*, R.S.C. 1970, c. F-27.

⁶² Jim Keon, “Editorial: Canada first to pass legislation on delivering generic medicines to developing countries” (2004) 1:4 *Journal of Generic Medicines* 292

Africa), came into force.⁶³ The Bill was meant to establish an effective operating system that would eliminate barriers to the export of cheaper generic versions of patented drugs to developing and least-developed countries unable to manufacture the drugs locally, and facilitate access to safe and effective pharmaceuticals.⁶⁴

Bill C-9 was the second attempt of the Canadian Government to pass such legislation. Its predecessor, Bill C-56, had not had an opportunity to progress beyond the First and Second Readings⁶⁵ because Parliament was prorogued on 12 November 2003.⁶⁶ Bill C-9 was reintroduced in the new Parliament's session on 12 February 2004, and was immediately referred to the Standing Committee on Industry, Science and Technology (INST Committee).⁶⁷

a. Reasons for the Bill's Creation

The need to facilitate access to affordable, much needed drugs in countries afflicted with diseases such as AIDS, tuberculosis or malaria is unquestionable. According to the WHO's World Health Report (2004), about "34-46 million people are living with HIV/AIDS. Already, more than 20 million people have died from AIDS, 3 million in 2003 alone."⁶⁸ Africa, which is home for 11 percent of the world's population, has two-thirds of the HIV/AIDS infected people in the world, meaning that about one in 12 adults in Africa lives with HIV/AIDS.⁶⁹ The interaction of HIV/AIDS with other infectious diseases is worrying as well. Such diseases as malaria, tuberculosis and other bacterial infections were

at 292, online: WHO
<<http://www.who.int/intellectualproperty/events/CGPAPER.pdf>>.

⁶³ Bill C-9, *supra* note 6.

⁶⁴ Hon. Ujjal Dosanjh, Minister of Health, News Releases, "Coming into force of the Jean Chrétien Pledge to Africa" (13 May 2005), online: Industry Canada <<http://www.ic.gc.ca/cmb/welcomeic.nsf/261ce500dfcd7259852564820068dc6d/85256a5d006b972085257000006c78bf1OpenDocument>>.

⁶⁵ On 6 and 7 November 2003. See Canada Bill C-56, *An Act to amend the Patent Act and the Food and Drugs Act*, 2nd Sess., 37th Parl., 2002-2003, 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>>.

⁶⁶ *Ibid.*

⁶⁷ *Supra* note 6.

⁶⁸ WHO, *The World Health Report of 2004: "A Global Emergency: A Combined Response"* at 1, online: WHO <http://www.who.int/whr/2004/en/03_chap1_en.pdf>.

⁶⁹ *Ibid.* at 1-2.

named as the leading causes of the death toll caused by HIV in Sub-Saharan Africa.⁷⁰

It is a known fact that most of these deaths are preventable, that life-saving drugs do exist, and that the major problem for patients in poor countries afflicted with the diseases is the inaccessibility of these drugs. High drug costs and inadequate infrastructure are among the main reasons why pharmaceuticals are unaffordable in poor countries.⁷¹ For example, the minimum annual costs of antiretroviral (ARV) treatment for AIDS, even if generic, exceeds the annual health expenditures per person in developing countries.⁷²

Canada's initiative to amend its *Patent and Food and Drugs Acts*⁷³ following the WTO General Council's decision comes as a response to this data. Even before the WTO General Council reached a decision on the implementation of Paragraph 6 of the Doha Declaration, Canada's Prime Minister, Jean Chrétien, at the G8 Summit in June 2002, stressed that the nations of the world have a moral obligation and an economic interest in Africa's future development, including Africa's coping with issues of poverty, AIDS and socio-economic challenges.⁷⁴ In December 2001, the Canadian Government established the Canada Fund for Africa that allocated \$500 million to fight HIV/AIDS and promote economic growth, etc.⁷⁵ Canada was the first country to legislate a Bill allowing the export of generic drugs under compulsory license because Canada has experience with the compulsory license system in the pharmaceutical field.⁷⁶

⁷⁰ In 2000, about 17 million people in Africa were infected with both TB and AIDS. See *ibid.* at 7.

⁷¹ *Supra* note 20 at 30-31.

⁷² According to the IPR Commission Report for 2002, current per capita health expenditures in poor countries are standing on \$23 per year, while the cheapest AIDS treatment costs are about \$200 per year. According to the WHO, only about 230,000 of six million people in need of ARV treatment in the developing world receive the drugs. *Ibid.* at 31.

⁷³ *Supra* notes 60 and 61.

⁷⁴ "The Road to Kananaskis: Africa at the Heart of the G8 Summit" *Canada World View* 15 (Spring 2002), online: Foreign Affairs Canada <<http://www.dfait-maeci.gc.ca/canada-magazine/issue15/15t5-en.asp>>.

⁷⁵ Canada Fund for Africa, "The fund: new vision, new partnership," online: Canadian International Development Agency <<http://www.acdi-cida.gc.ca/canadafundforafrica>>.

⁷⁶ Canada had a law allowing compulsory licenses for domestic production of patented pharmaceuticals to be granted since 1923, and only in 1987 had the system begun to weaken (when a seven to ten year exclusivity period was granted to patentees), until it was eliminated in 1992. See F.M. Scherer, "The Economics of Compulsory Drug Patent Licensing" (May 2003), extracted from F.M. Scherer & Jayashree Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2001) Paper written for Working Group 4 of the

Finally, in the Speech from the Throne in the opening of the Third Session, 37th Parliament of Canada in 2004, The Right Honourable Adrienne Clarkson, Governor General and Commander-in-Chief of the Canadian Forces 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."⁷⁷

It seems that one of the most significant arguments in favour of adopting Bill C-9 was that Canada had an opportunity to take initiative and be the first country to implement the WTO General Council's decision.⁷⁸ However, being the first country to do so presented the inevitable challenges as well. The Government had no other jurisdictions to learn from, had no precedent to rely upon. On the other hand, the Government's intent was to pass legislation that would not be considered a "dead weight" for being unfeasible and impractical.⁷⁹

Bill C-9 was meant to allow generic versions of drugs patented in Canada to be exported.⁸⁰ However, the Bill also 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 not forfeiting compliance with Canada's other obligations under *TRIPS*.⁸¹

Commission for Macroeconomics and Health of the WTO at 8-9, online: Patentmatics <<http://www.patentmatics.org/pub2005/pub5f.pdf>>.

⁷⁷ 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>> (The Right Honourable Adrienne Clarkson).

⁷⁸ 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, 37th Parliament, 3d Session (24 February 2004), Hon. Pierre Pettigrew, online: Parliament of Canada <<http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=72244>>.

⁷⁹ *Ibid.*, Opening Speech of Hon. Lucienne Robillard.

⁸⁰ "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>>.

⁸¹ See generally *supra* note 78.

b. The Bill and the Balance of Interests Stated in TRIPS and Doha

Creating minimum international standards of IP protection and incorporating stronger levels of IP protection in WTO member-countries' national laws were definitely the major goals of the *TRIPS Agreement*. While setting relatively clear rules of IP protection, *TRIPS* connected IP issues with relatively effective WTO enforcement and dispute settlement mechanisms.⁸² Despite the fact that *TRIPS* is often criticized for being ineffective and for allowing developing and least-developed countries to “free-ride” on the economic and technological advantages provided by industrialized members,⁸³ its mechanisms are also named a “cornerstone of today’s globalized research, development, production, and trade.”⁸⁴

The Doha Declaration, on the other hand, emphasized humanitarian aspects that were, for the most part, neglected in *TRIPS*.⁸⁵ The attempts to balance patent rights of drug manufacturers with public interest in access to affordable drugs are evident in the Declaration.⁸⁶ The vague language of the Doha Declaration was preserved as a response to demands of developing countries to retain the spirit of humanitarian aid and shift an emphasis to public health issues.⁸⁷

⁸² Gervais, *supra* note 16 at 287, and also J.H. Reichman & 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 13-14 [Reichman & Lange].

⁸³ Reichman & Lange, *ibid.* at 20-21.

⁸⁴ 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, Vanderbilt University” (1998-1999) 9 *Duke J. Comp. & Int’l L.* 91 at 95.

⁸⁵ The WTO members agreed in the Doha Declaration 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 and justified using the flexibilities of *TRIPS* to that end. *Supra* note 4, para. 4 and Elliot, *supra* note 50 at 7-8. Also see Jean Bizet, “The TRIPS Agreement and Public Health” (Report at the Cancún Session of the Parliamentary Conference on the WTO, 9-12 September 2003) at 2, online: Inter-Parliamentary Union <<http://www.ipu.org/splz-e/cancun/5b.pdf>> [Bizet].

⁸⁶ Richard Elliot, “Steps forward, backward and sideways: Canada’s bill on exporting generic pharmaceuticals” (2004) 9:3 *HIV/AIDS Policy & Law Review* 15 at 18.

⁸⁷ For example, the broad definition of the diseases to be considered for a compulsory license that includes “HIV/AIDS, tuberculosis, malaria and other epidemics” or a definition of public health crisis. See *supra* note 4, paras. 1 (a) & 4. Also see Bizet, *supra* note 85 at 3.

Where does Canada's Bill C-9 stand in terms of balancing these interests? To address this question, a profound analysis of the Bill's provisions is needed.⁸⁸ Obviously, the title of the amendment to the *Patent Act*,⁸⁹ "Use of Patents for International Humanitarian Purposes to Address Public Health Problems," as well as its purpose,⁹⁰ are supposed to attest to the humanitarian nature of the Bill. However, do the contents of the amendment agree with its title?

One of the most criticized provisions of the Bill (in its initial version) was the so-called "right of first refusal" provision.⁹¹ According to the Bill's first version, if the product intended to be produced under a compulsory license is patented, a generic company must seek either authorization from the patentee to use the invention or the patentee can notify the Commissioner that he/she would supply the needed drugs on terms no less favourable than those negotiated by the generic company with the future importing country. In other words, the generic company could find itself in a situation where, after successfully negotiating terms and conditions of the supply of pharmaceuticals and after investing time and resources, the patentee would be able to replace him in the contract. Eventually, it would be the patentee who would enjoy the profits. Therefore, such a scheme could deter generic manufacturers from participating in this initiative and render the mechanism unworkable.⁹²

This provision was not included in the final version of the Bill, and the only requirement that remains is that the generic manufacturer attempts to seek a voluntary license from the patentee "on reasonable terms and conditions" to manufacture and export the patented product.⁹³ The fact that the "right of first refusal" was eliminated from the Bill's final version attests to the humanitarian nature of the amendment. While the brand-name industry proposed that the Bill provides "an equal opportunity" for the research-based and generic manufacturers to participate in the system, generic companies and civil society organizations, such as Médecins Sans Frontières (MSF), argued that any

⁸⁸ In this paper we analyze the Royal Assent version of the Bill. See *supra* note 6.

⁸⁹ The Bill amended the *Patent Act* by adding ss. 21.01-21.20 and the *Food and Drugs Act* by amending ss. 30 and 37. *Ibid.*

⁹⁰ The declared purpose 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." *Supra* note 6, s. 21.01.

⁹¹ Canada Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, First Reading Version, 3rd Sess., 37th Parl., 2004, online: Parliament of Canada <http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_1/90247bE.html#1> at ss. 21.04(6) & (7).

⁹² *Supra* note 62 and note 78.

⁹³ Bill C-9, *supra* note 6, s. 21.04 (3)(c)(i-ii).

provision that resembles the “right of first refusal” clause would prevent generic companies from participating in the system and eventually end competition. According to this argument, research-based companies can supply drugs to developing countries in need whenever they wish, with no need to use a compulsory license system because they are the right holders.⁹⁴

Another obvious feature of the Bill’s humanitarian nature is that the Bill waives one of the fundamental requirements included in paragraph 1(b) of the WTO General Council’s decision — that the members should use the system only in cases of “a national emergency or other circumstances of extreme urgency . . .” Although the purpose of the Bill is to facilitate access to medicine to address public health problems, this does not limit the use of the Bill for the cases of public health emergencies. The only case in which the requirement of “a national emergency or other circumstances of extreme urgency” is invoked is when an importing country is not a WTO member and is not listed in the Schedules of eligible importing countries.⁹⁵ 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, waiving the requirement that the importing country must face a national emergency in order to be eligible to import medicines under a compulsory license 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 determines a limited list of medicines covered by the Bill.⁹⁶ Civil society organizations called for the removal of this provision from the Bill’s final version because of its inconsistency with the Doha Declaration that had not in any way

⁹⁴ Rachel Kiddell-Monroe & Jim Keon, Canada, House of Commons, Standing Committee on Industry, Science and Technology, 37th Parliament, 3rd Session (26 February 2004), online: Parliament of Canada <<http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=73324>>.

⁹⁵ Bill C-9, *supra* note 6, s. 21.03(1)(d)(ii)(A).

⁹⁶ The definition of “pharmaceutical product”, as stated in the Bill, is a patented product listed in the Schedule 1. The list is an initial grouping of drugs patented in Canada and based on the WHO’s model list of essential medicines, which 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, the Governor in Council is authorized to approve additional pharmaceuticals to be added to the Schedule 1, with no requirement of Parliamentary decision. See Bill C-9, *supra* note 6, s. 21.03(1)(a).

restricted the definition of eligible pharmaceutical products.⁹⁷ A proposal to include the same provision in the WTO General Council's decision was rejected during the consultations held prior to the August 30 decision. Eventually, the decision defined "pharmaceutical products" as "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems."⁹⁸ Nevertheless, the provision that determined a limited list of medicines was included in the amendment and was named "a TRIPS-plus" provision by civil society organizations.⁹⁹

Regarding the nature of the Bill, *i.e.*, whether it is humanitarian or TRIPS-like legislation, there are two possible approaches. According to one, the Bill was 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. Therefore, the Bill should comply with the provisions of Article 31 of *TRIPS* that were not waived in the August 30 decision.¹⁰⁰ As was stated by Hon. Lucienne Robillard, Minister of Industry, in her opening speech in the INST meeting on 24 February 2004: "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."¹⁰¹

Another approach, advocated mostly by civil society organizations, was to view the proposed amendments as a part of a more general

⁹⁷ 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> at 18-19 [HIV/AIDS Legal Network Submission].

⁹⁸ *Supra* note 4, para. 1(a). Also see Canadian HIV/AIDS Legal Network, MSF, CCIC, Oxfam Canada, 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>.

⁹⁹ HIV/AIDS Legal Network Submission, *supra* note 97 at 18.

¹⁰⁰ Only 2 provisions of article 31 were waived in the WTO General Council's decision: art. 31(f) allowing use "predominantly for the supply of the domestic market" and art. 31(h) was changed to determine the percentage of royalties. The provisions, such as an attempt to obtain voluntary license (art. 31(b) of *TRIPS*), suitable royalties to the patentee (art. 31(h)), limited scope and duration of a compulsory license (art. 31(c) of *TRIPS*) — the Bill limits it to two years with an option to renew if the affirmed quantity has not been exported during this period — should have been abided according to this approach. *TRIPS*, *supra* note 2, arts. 31(b), 31(c), 31(f) and 31(h).

¹⁰¹ Hon. Lucienne Robillard (24 February 2004), *supra* note 78.

picture, *i.e.*, as a part of Canada's effort to help developing and least-developed countries fight infectious diseases such as AIDS, tuberculosis, and malaria. As the Minister of Health, Hon. Pierre Pettigrew stated, the Bill will go together with Canada's other initiatives that are currently underway, such as Canada's involvement in the WHO's "Three by Five" campaign.¹⁰²

These two different approaches — the narrow one, seeing the Bill as an implementation of 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 countries in need — could possibly explain why the mechanism outlined in the Bill was so controversial. If the Bill is but an attempt to implement the August 30 decision, then the Government is obliged to adhere to the principles of *TRIPS* and can only waive the requirements waived in the decision itself. In this case, the Bill's nature would not be entirely humanitarian. However, if the Bill is a part of Canada's effort to contribute to the global fight against infectious diseases in developing and least-developed countries, then the Bill could be seen as being mostly humanitarian. That way, it will fit into a general framework of exceptions provided in *TRIPS*,¹⁰³ exceptions that are designated to protect, among other things, public health issues.

III. ACHIEVEMENTS AND FAILURES OF THE NEW MECHANISM

a. Main Features of the Mechanism of Export of Generic Drugs under Compulsory License.

The new mechanism of exporting generic drugs under a compulsory licensing system provided in the Amendment to Canada's *Patent Act*¹⁰⁴ is

¹⁰² The "3 by 5" initiative was launched by UNAIDS and WHO in 2003 and designated to provide three million people living with HIV/AIDS in low- and middle-income countries with essential anti-retroviral medicines until the end of 2005. The initiative focuses on simplifying tools to deliver medicines; ensuring effective, reliable supply of medicines and diagnostics; training health workers, developing health systems and building infrastructure for reception of medicines. See "Treating 3 million by 2005: Making it happen," online: WHO <<http://www.who.int/3by5/about/en/>>.

¹⁰³ For example, arts. 7-8 of *TRIPS*, determining that the protection and enforcement of IP should be "in a manner conducive to social and economic welfare" 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". See *TRIPS*, *supra* note 2, arts. 7-8.

¹⁰⁴ *Supra* note 60.

detailed, although, at times, unclear. While the WTO General Council's decision is related only to the WTO member-countries, Canada's Bill C-9, in Sections 21.03(1)(d)(ii) and 21.03(1)(b)(ii), allows least-developed countries that are not WTO members to use the system.¹⁰⁵

Aside from Schedule 1, which determines a list of limited medicines that could be a subject to the compulsory license, the Bill also sets out a list of eligible importing countries in Schedules 2-4.¹⁰⁶ It has been argued that while all least-developed countries are allowed to participate in the system, the only developing countries that can be eligible to import medicines under compulsory license are members of the WTO.¹⁰⁷ The Government counterclaimed that the proposed amendments are an implementation of the WTO's August 30 decision. Hence, it should apply to the WTO members only. However, as a gesture of assistance to underdeveloped countries, Canada included all least-developed countries in its Bill.¹⁰⁸

There are no restrictions on the exporting countries. According to Section 21.04(1), 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 . . ." ¹⁰⁹ However, an applicant must request the permission of the governmental authority in the importing country, where the invention is patented.¹¹⁰ This provision does not allow NGOs, such as MSF, Oxfam and others, to directly contact generic manufacturers in order to import needed drugs, unless the local governmental agency permitted it.¹¹¹ It has thus been argued that a compulsory license mechanism would be used only when a partner is a government. Were this the case, however, governments would be involved

¹⁰⁵ The Governor in Council is authorized to amend the list of eligible least-developing countries (Schedule 2) by adding any country recognized as least-developed by the UN. Moreover, the Governor in Council can also add any developing non-WTO member country, if the country is eligible for a development aid according to the OECD.

¹⁰⁶ Schedule 2 determines a list of 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 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 WTO-member countries that declared that they would use the mechanism as importers only in cases of national emergency or other cases of extreme urgency (s. 21.03(4)(d)).

¹⁰⁷ Andy Savoy (24 February 2004), *supra* note 78.

¹⁰⁸ *Ibid.*, Suzanne Vinet.

¹⁰⁹ Bill C-9, *supra* note 6, s. 21.04(1).

¹¹⁰ *Ibid.*, s. 21.04(2)(f).

¹¹¹ *Supra* note 86.

in the process from the beginning, which would provide political accountability for any potential abuses of this provision.¹¹²

The requirement of Section 21.04(3)(c) to seek a voluntary license from the 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 such an attempt was not successful. Despite an enthusiastic opposition from the NGOs, the research-based pharmaceutical industry was able to include this provision in the final version of the Bill. The brand-name industry’s representatives argued that the need of generic producers to seek a voluntary license first is of the utmost importance because it ensures participation of both a patentee and a generic manufacturer in the system and, therefore, could provide an equal opportunity to supply.¹¹³ Although the Canadian Generic Pharmaceutical Association claimed that the brand-name company owning a patent does not need a compulsory license system to make, sell or donate drugs, generic producers were not opposed so much to the idea of an early-stage negotiations with a patentee, as long as they had legal certainty in the stage of actual development and export of the patented products.¹¹⁴

Another provision that confirmed the Bill’s humanitarian nature was a royalty rate payable to a patentee.¹¹⁵ The royalty rates are determined in the regulations.¹¹⁶ The regulatory formula for calculating royalties must take into account the humanitarian and non-commercial basis for granting a compulsory license.¹¹⁷ According to this formula, the lowest royalty rate possible is 0.02 percent of the value of a supply agreement, while the rate ceiling will be 4 percent, as it appears from the formula.¹¹⁸ A licensee is required to pay royalties within 45 days of the export notice,

¹¹² David Maloney (24 February 2004), *supra* note 78.

¹¹³ Terry McCool, Vice-President, Corporate Affairs, Eli Lilly Canada Inc., *supra* note 94.

¹¹⁴ *Ibid.*, Mr. Jim Keon, President of Canadian Generic Pharmaceutical Association.

¹¹⁵ Bill C-9, *supra* note 6, s. 21.08.

¹¹⁶ “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>>.

¹¹⁷ The formula for calculating royalties is: “multiplying the monetary value of the supply agreement between the licensee and the importing country by an amount which fluctuates on the basis of that country’s standing on the United Nations Human Development Index (UNHDI). The formula to determine the royalty rate is: 1, plus the number of countries on the UNHDI, minus the importing country’s rank on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04.” See *Ibid.*

¹¹⁸ *Ibid.*

which should be provided at least 15 days before the export occurs.¹¹⁹ It has been stated that the relationship between the royalty rates and the importing country's United Nations Human Development ranking is definitely a "positive feature of Canada's law."¹²⁰ 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,¹²¹ this statement seems to be correct.

According to Section 21.09 of the Bill, a compulsory license is limited to two years from the day the license is granted.¹²² However, there is an option for one renewal for an additional two-year period if the medicines authorized for export were not exported in whole during the first two years.¹²³ To justify this provision, the Government argued that the Bill must comply with Article 31(c) of *TRIPS*, which determines 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 limiting the duration of the licenses.¹²⁴

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 being almost purely 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 developing countries. This attests to the extreme difficulty in deciding which purposes the legislation will pursue. Will it be an additional feature of Canada's general humanitarian effort on the global scene or an implementation of the WTO General Council's decision, shifting more to the spirit of *TRIPS*?

b. Is the Solution Adopted in Bill C-9 Feasible for Developing Countries?

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 medicines¹²⁵ and despite the fact that the decision has been reached

¹¹⁹ *Ibid.*

¹²⁰ *Supra* note 86 at 19.

¹²¹ *Supra* note 91.

¹²² Bill C-9, *supra* note 6, s.21.09.

¹²³ *Ibid.*, ss. 21.12(1) – (4).

¹²⁴ Ms. Marie-Josée Thivierge (24 February 2004), *supra* note 78.

¹²⁵ WTO, News Release, "The General Council Chairperson's Statement" (30 August 2003), online: WTO <http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm>.

almost three years ago, no country seems to be in a rush to use the mechanism set out in the decision. The same can be said about Canada's Bill C-9. Although the legislation was enacted in May 2005, no developing country has requested a compulsory license through the system yet.¹²⁶ This fact seems to be even more surprising given the magnitude of the access to drugs problem in developing countries afflicted with pandemics. Moreover, ever since the South African *Medicines and Related Substances Control Amendment Act* of 1997¹²⁷ was enacted, the dilemma of gaining access to life-saving drugs, despite strengthened *TRIPS* patent protection, was at the center of the global debate. The *South African Act* authorized granting compulsory licenses to supply cheaper generic drugs in order to protect public health "notwithstanding anything to the contrary contained in the Patents Act" and was challenged by the U.S. for violation of *TRIPS*.¹²⁸ At approximately the same time, the U.S.-Brazil process at the WTO, in which the U.S. challenged the Brazilian compulsory license system, had begun.¹²⁹ Eventually, under the pressure from civil society organizations, the U.S. withdrew its complaint. The question is why, in these circumstances, where a compulsory license seems to be one of the most effective means of lowering prices and facilitating access to essential drugs, developing countries are in no hurry to use the compulsory licensing system intended specifically for this purpose?

To answer that question, it is necessary to analyze the issue from two different perspectives: from the importing countries' point of view and from the side of potential exporters, *i.e.*, generic manufacturers. To illustrate the importing developing countries' perspective, take Guatemala as an example.¹³⁰ Only US\$38 per person per year can be spent on health care; however, the cost of a year of treatment for HIV/AIDS and other associated infections are far beyond this limit.¹³¹ It

¹²⁶ Geoff Blackie, "Breathing Life into the August 30th Agreement" at 1, online: University of Toronto Faculty of Law <<http://www.law.utoronto.ca/accesstodrugs/documents/TRIPS%20geoffblackie%20trips.doc>>.

¹²⁷ *Medicines and Related Substances Control Amendment Act* of 1997, online: Polity.org <www.polity.org.za/html/govdocs/legislation/1997/act90.pdf>.

¹²⁸ *Ibid.*, s.10. Also see *supra* note 47 at 200-201 and Kara M. Bombach, "Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Amendment Act with the TRIPS Agreement" (2001) 19 B. U. Int'l L. J. 273 at 278.

¹²⁹ *Supra* note 126 at 3.

¹³⁰ This example was brought by Mrs. Rachel Kiddell-Monroe (Coordinator (Canada) Access to Essential Medicines Campaign, Doctors Without Borders) and Dr. Virginia Gualarte (MSF Guatemala, Doctors Without Borders) at the INST meeting of 26/2/04. *Supra* note 94.

¹³¹ *Ibid.*

has been argued that Guatemala, a country in need of life-saving medicines, would not be able to use the mechanism suggested in the Bill.¹³² The drug needed for AIDS treatment (a fixed-dose combination of ARVs) was not included in Schedule 1; and the MSF would not be able to directly procure medicines because it is neither a government nor governmental agency. Thus, in a country where the AIDS issue is not on the government's political agenda, the chances of receiving permission from the government to import generic drugs as the Bill requires are very slim.

One of the main obstacles to receiving essential drugs in poor countries is the high price of medicine;¹³³ however, in the last few years, the prices have begun to fall, mostly due to competition from generic producers.¹³⁴ To be able to participate in the system proposed in the Bill, generic manufacturers want the assurance of gaining a return on their investment.¹³⁵ Ideally, effective legislation would provide flexible and efficient processes for exporting medicines under a compulsory license, so that a generic producer would be commercially motivated to apply for a compulsory license.¹³⁶ Although Apotex announced that it would produce a generic equivalent of Retrovir-AZT (Apo-Zidovudine) the day after Bill C-56 (C-9's predecessor) was introduced,¹³⁷ the Bill seems to be too loaded with administrative obstacles and too inflexible toward

¹³² 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.

¹³³ *Supra* note 126 at 2-3.

¹³⁴ Indian generic manufacturer "Cipla" started offering NGOs a package of ARVs for \$350 a year. By 2004, two more Indian companies and one South African company entered the competition and the price dropped to about \$140 a year. See *ibid.* at 1-2.

¹³⁵ *Ibid.* at 12.

¹³⁶ For example, despite the lack of incentives to produce generic drugs for small markets, some generic companies could be induced to produce generic drugs by the huge volumes of pharmaceuticals needed in poor importing countries. Thus, companies might find it rewarding to export even if the prices of the exported medicines in the importing country are extremely low. *Ibid.* at 19-20 and Keith Maskus, "On TRIPS, Drug Patents and Access to Medicines – Balancing Incentives for R&D with Public Health Concerns" *Development Gateway* (4 September 2004) at 1-2, online: Development Gateway <http://old.developmentgateway.org/download/206719/Maskus_on_> [Maskus].

¹³⁷ The Apotex Group, Press Release, "Canadian-Owned Generic Company Prepared To Provide HIV/AIDS Drug to Developing Nations" (7 November 2003), online: Apotex Inc., Canada <<http://www.apotex.com/PressReleases/20031107-01.asp?flash=Yes>> and *supra* note 126 at 20.

an applicant¹³⁸ to provide a commercially worthy deal for a generic manufacturer.

Another critical issue that could impair the effectiveness of the Bill is that for a humanitarian and non-commercial act, the Bill relies too heavily on private parties, *i.e.*, a generic manufacturer and a patentee. Curiously enough, the governments of exporting and importing countries are not so much involved in the proposed mechanism. Aside from complying with all the administrative provisions required to grant licenses, governments are relieved from any other kind of participation in the system under the Bill.

Ideally, a humanitarian Bill would oblige the exporting government to sponsor a generic manufacturer if, for example, his contract with an importing country became too risky. However, instead of involving the government, the Bill solves the problem of a risky contract, or a contract that has somehow strayed off of the right course set up by the Bill, by shifting responsibilities onto the private parties, *i.e.*, patentees. According to Section 21.14(a)-(i), the Bill allows a patentee to apply for the Federal Court's order to terminate the license following 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.

Both a generic manufacturer and a patentee enter the system with the same purpose, but each pursues that purpose in a different way. Unfortunately, this purpose can in no way be named "non-commercial". While a generic manufacturer intends to make profits from supplying drugs to a country in need, even if supplying medicines at extremely low prices, a patentee would want to protect his patented invention from being used in a commercial way when he does not receive an adequate remuneration for such use. Considering this fact, the system that does not rely so much on the governmental involvement to sponsor participating parties, but instead relies mostly on a generic producer and a patentee, could not possibly be called a humanitarian and non-commercial system.

¹³⁸ One of the major factors for legal uncertainties of the Bill is s. 21.14. This section allows a license to be terminated by order of Canada's Federal Court following a patentee's application, provided that the patentee establishes that inaccurate information had been given or the obligations of the licensee were not met or that the product was re-exported from the importing country. See Canada Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act*, Legislative Summary, online: Library of Parliament <http://www.parl.gc.ca/common/Bills_ls.asp?Parl=37&Ses=3&ls=C9#12section2113txt> and Blackie, *supra* note 126 at 22.

c. Possible Impacts of the New Legislation on Canada's Brand-name Pharmaceutical Industry.

Brand-name pharmaceutical companies argue that they are actively participating in the global effort to fight diseases and improve public health in developing countries.¹³⁹ However, their main argument is that such an effort is only one part of the solution; they argue that governments and international aid organizations should make a combined effort to facilitate access to health care.¹⁴⁰ As part of this agenda, Canada's research-based pharmaceutical companies (Rx&D) declared their support for Bill C-9, but stressed that the system should be strictly humanitarian and non-commercial.¹⁴¹ Rx&D suggested that the Bill could be considered successful only if it could ensure that patients are properly diagnosed, patients have access to adequate medical facilities, medicines are administered to patients correctly, and patient compliance with doctors' instructions is monitored.¹⁴²

A research-based company, *i.e.*, a patentee, is mentioned several times in the Bill. A patentee can accept or decline a request for a voluntary license and additionally, if a compulsory license is issued, suitable remuneration will be paid to the patentee.¹⁴³ Importing countries are to prevent trade diversions and the resale of drugs produced under compulsory licenses, while other countries are to prevent the entry of such drugs into their territories.¹⁴⁴ It has been

¹³⁹ Combined initiatives such as Academic Alliance for AIDS Care and Prevention in Africa, funded by Pfizer; Accelerating Access Initiative, a country-led, cooperative initiative of UNAIDS, WHO, UNICEF, the World Bank, and six research-based pharmaceutical companies (Merck, Boehringer Ingelheim, Bristol-Myers Squibb, Roche, GlaxoSmith-Kline and Abbott) and others, attempt to build infrastructure, train medical personnel and also improve access to pharmaceuticals by providing more affordable prices. See *Building Healthier Societies Through Partnership* (August 2003) International Federation of Pharmaceutical Manufacturers Associations (IFPMA) at 5-6, online: IFPMA <http://www.ifpma.org/site_docs/Health/Health_Initiatives_Brochure_0912.pdf>.

¹⁴⁰ *Ibid.* at 3 and "Providing Affordable Medicines to Patients in the Developing World: A Submission to the House of Commons Standing Committee on Industry, Science and Technology regarding Bill C-9", (February 2004) at 12-15, online: Canada's Research-Based Pharmaceutical Companies <http://www.canadapharma.org/Meds/Submission_to_Industry_Committee_E.pdf> ["Providing Affordable Medicines"].

¹⁴¹ "Providing Affordable Medicines," *ibid.* at 3-5.

¹⁴² *Ibid.* at 11.

¹⁴³ Maskus, *supra* note 136 at 2.

¹⁴⁴ *Ibid.*

argued that the system of export under a compulsory license will not decrease incentives to invest in R&D of new medicines. Research-based companies as it is have no viable incentives, or have the weakest incentives, to develop drugs for diseases afflicting mostly poor countries. The reason for the lack of incentives is the lack of potential reward for such an investment.¹⁴⁵

As for the remuneration formula,¹⁴⁶ although it provides certainty for generic manufacturers in that it is relatively clear and simple, the formula presents a problem for research-based companies.¹⁴⁷ Because the formula is related to the UN Human Development Index (UNHDI) and sets the highest rate of remuneration at 4 percent and the lowest at 0.02 percent, the formula could be considered inadequate remuneration, as opposed to the WTO General Council decision's requirement.¹⁴⁸ Rx&D argued that even a fixed rate of 2 percent, proposed in the initial version of the Bill, was inadequate and not TRIPS-compliant.¹⁴⁹ However, according to Section 21.08 (4)-(7), the patentee can request a Federal Court's order to increase a royalty payment, if the royalty "is not an adequate remuneration for the use of invention," taking into account humanitarian and non-commercial grounds for issuing a license and economic value of the use of invention to the importing country. This provision reduces the level of certainty for generic manufacturers in that it increases chances for long and costly litigation; however, it adds to the level of certainty for research-based companies by determining that if remuneration is not adequate, the patentee has means to intervene in the process.

It seems that although research-based pharmaceutical companies played a significant role in designing the legislation, it will bear no major impact on them. It has been said that Rx&D was disappointed that the research-based industry was practically left behind and its expertise was

¹⁴⁵ *Ibid.* See also Frank R. Lichtenberg, "Pharmaceutical Innovation and the burden of disease in developing and developed countries: Study Summary" (2004) Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), [online: WHO <http://www.who.int/intellectualproperty/studies/StudySummaries.pdf>](http://www.who.int/intellectualproperty/studies/StudySummaries.pdf). This study was conducted regarding the relationship between pharmaceutical innovations and the burden of disease in developed and developing countries.

¹⁴⁶ As prescribed by the regulations, s. 8. *Supra* note 116.

¹⁴⁷ *Supra* note 126 at 15.

¹⁴⁸ According to paragraph 3 of the WTO August 30 decision, adequate remuneration is 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 5.

¹⁴⁹ "Providing Affordable Medicines, *supra* note 140 at 20.

not recognized in the Amendment.¹⁵⁰ Suggesting an “equal opportunity to supply the country in need,”¹⁵¹ the research-based industry expressed its desire to fully participate in the system. However, as the president of Canadian Generic Pharmaceutical Association stated, should brand-name companies so desire, they can sell medicines at any price, or even donate them at any time with no need in compulsory license system, because they are the right holders.¹⁵²

IV. LESSONS FOR THE FUTURE

a. What Could be Learned from the Bill in Terms of Amending TRIPS?

On 6 December 2005, the WTO members adopted a waiver of Article 31(f) and a change of Article 31(h) of *TRIPS* proposed in the WTO General Council’s decision of August 2003, finally turning it into a permanent amendment to *TRIPS* (“the Amendment”).¹⁵³ The text of the Amendment is similar to that of the WTO Decision. The General Council Chair’s statement attached to the Amendment stresses 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.”¹⁵⁴

The question is: what changes could be made in the Bill following the Amendment and what changes could be inspired by the Bill to be included in the Amendment? The Amendment is still loaded with vague

¹⁵⁰ Jean-Michel Halfon, Letter to the Editor, *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>.

¹⁵¹ 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 “Providing Affordable Medicines,” *supra* note 140 at 17.

¹⁵² *Supra* note 94, Mr. Jim Keon, President of Canadian Generic Pharmaceutical Association.

¹⁵³ The waiver remains in force until 1 December 2007. Until then, the amendment is open for acceptance by the members, while two-thirds of the WTO member-countries already ratified the amendment. The amendment added art. 31*bis* following art. 31 of *TRIPS*. See WTO, Press Release, Press/426, “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>. Also see WTO, *Amendment of the TRIPS Agreement: Decision of 6 December 2005*, WTO Doc. WT/L/641 (8 December 2005), online: WTO <[http://docsonline.wto.org](http://docsonline.wto.org/TRIPS_Amendment)> [*TRIPS Amendment*].

¹⁵⁴ *Supra* note 125.

definitions similar to the text of the WTO General Council's decision. For example, it requires an importing member to establish that it has "insufficient or no manufacturing capacities in the pharmaceutical sector"; however, there are no clear rules as to the assessment of manufacturing capacities for any other country except a least-developed one.¹⁵⁵ The Bill drops this requirement, making the process easier and more certain for eligible importing countries. It could be argued that by dropping this requirement, the Bill acquires a more humanitarian nature, because it no longer applies one of the important conditions of Paragraph 6 of the Doha Declaration, *i.e.*, the requirement that the compulsory license be created for the countries with insufficient manufacturing capacities.

Another provision that is better defined in the Bill is the formula for calculating remunerations. 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 in the exporting Member."¹⁵⁶ The language of this provision is too vague to provide certainty as to the rate of remuneration to be paid to a patentee. The Bill, on the contrary, sets a precise formula for calculation based on the UNHDI. Again, it could be argued that while the Amendment sticks to the TRIPS provision,¹⁵⁷ the Bill shifts to the humanitarian formula that takes into account an importing member's ranking in the UNHDI.¹⁵⁸

However, in regard to the list of drugs eligible to be subject to a compulsory license, the Amendment includes a more extended range of pharmaceutical products, which makes it more effective compared to the Bill, especially for those countries that are in need of drugs that are not included in the Schedule 1 of the Bill.¹⁵⁹

Additionally, the Bill is burdened with bureaucratic details that make acquiring a compulsory license too inflexible a procedure.¹⁶⁰ However, the actual administrative procedures determined in the Amendment are too vague and unspecific to provide parties with certainty as to what procedures they are required to comply with in order to use the system.

¹⁵⁵ Least-developed countries will be automatically considered as having insufficient capacities in the pharmaceutical field. See *TRIPS Amendment, supra* note 153.

¹⁵⁶ *Ibid.*

¹⁵⁷ Article 31(h) of *TRIPS* uses almost the same vague definition of the required remuneration. See *TRIPS, supra* note 2, art. 31(h).

¹⁵⁸ Bill C-9, *supra* note 6, s. 21.08 and *supra* note 116, s. 8.

¹⁵⁹ 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 a subject to a compulsory license. See *TRIPS Amendment, supra* note 153, art. 31*bis*(a).

¹⁶⁰ See generally *supra* note 126 at 12.

Overall, it could 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. 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.

b. Other Countries' Experience with Implementation of WTO General Council's Decision

Until 1 January 2005, developing countries with no pharmaceutical manufacturing capacities had no need to use compulsory licenses because the transitional periods determined in *TRIPS* allowed an extension in complying with the Agreement.¹⁶¹ Therefore, developing countries, such as India, which is one of the largest generic drugs exporters that had not provided patent protection for pharmaceuticals prior to *TRIPS*, could export generic versions of drugs that were not patented in their territory.¹⁶² However, after *TRIPS* is fully implemented, the need for legislation, such as Canada's Bill C-9, in potential exporting countries will become evident.¹⁶³

Norway enacted its regulations amending the Patent Regulations (in accordance with the WTO General Council's decision) on 14 May 2004.¹⁶⁴ Contrary to Canadian legislation, Norwegian regulations do not require that an importing non-WTO member country declare a health emergency situation in order to be eligible to import generic drugs under a compulsory license.¹⁶⁵ Norwegian legislation follows the WTO's August 30 decision more closely.¹⁶⁶ The same is true about a remuneration formula. Like the WTO decision, the Norwegian legislation does not provide any clear way of assessing the appropriate remuneration. The

¹⁶¹ *TRIPS*, *supra* note 2, arts. 65-66.

¹⁶² "Denmark and Italy: Trade-Related Intellectual Property Rights, Access to Medicines and Human Rights" (October 2004) at 3, online: 3D Trade Human Rights Equitable Economy <http://www.3dthree.org/pdf_3D/3DCESCRDenmarkItalyBriefOct04en.pdf>.

¹⁶³ *Ibid.* at 4.

¹⁶⁴ 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: Informasjon Fra Regjeringen Og Departementene <<http://odin.dep.no/ud/english/topics/trade/p30003923/032121-990069/dok-bn.html>>.

¹⁶⁵ *Ibid.* Also see *supra* note 126 at 10.

¹⁶⁶ The legislation determines pharmaceutical products eligible to be exported under a compulsory license pursuant to the Decision, and it does not limit the list of pharmaceuticals as it is limited in the Canadian legislation. See *supra* note 164, s. 108(1) and also *supra* note 126 at 10.

legislation simply follows the vague language of the WTO General Council's decision on the matter.¹⁶⁷

India has also informed the WTO that its law implementing the Decision is completed.¹⁶⁸ India's generic pharmaceutical industry is the largest supplier of cheap medicines to the developing world.¹⁶⁹ Therefore, the impact of the Indian amendment on the global generic pharmaceutical market was expected to be quite big. However, instead of setting clear rules for granting compulsory licenses, Indian legislation gave only a general permit to export patented pharmaceutical products to countries with inadequate production capacities and in order to cope with public health emergencies.¹⁷⁰

In July 2005, the European Union (EU) Committee on International Trade published a final report on the proposal for regulations 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.¹⁷¹ Contrary to Canadian and Norwegian legislation, the EU's draft regulations only apply to WTO member countries.¹⁷² Also, contrary to Canada's Bill that

¹⁶⁷ *Supra* note 126 at 10.

¹⁶⁸ WTO, Press Release, Press/426, "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>.

¹⁶⁹ Frederick M. Abbott, "The Patents (Amendment) Bill 2003 and future of India's public health" *Pharmabiz.com* (2 December 2004), online: *Pharmabiz.com* <<http://www.pharmabiz.com/article/detnews.asp?articleid=24905§ionid=50>>.

¹⁷⁰ Earlier, in December 2004, the Indian Government issued the Patent (Amendments) Ordinance 2004 that introduced a provision of compulsory license granted to cope with health emergency situations for the first time, but had slightly changed it while introducing the Patent (Amendments) Bill 2005 for the Parliamentary approval. See Embassy of India Washington DC, 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>. Also see *supra* note 126 at 11.

¹⁷¹ 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](http://www.europarl.eu.int/registre/seance_pleniere/textes_deposes/rapports/2005/0242/P6_A(2005)0242_EN.doc)> [European Proposal].

¹⁷² *Ibid.* at 34/82. See also Richard Elliot, "Generics for the developing world: a comparison of three approaches to implementing the WTO (World Trade Organisation) decision (F)" *Pharma & Healthcare Ind News* at 2, online: Canadian HIV/AIDS Legal Network

states a clear procedure for seeking a voluntary license, the EU's draft does not specify the timeframe for the prior negotiation with the patent holder and does not determine the grounds for waiving the obligation to seek a voluntary license.¹⁷³ Similar to the Norwegian legislation, the EU's draft uses the language of the WTO General Council's decision regarding adequate remuneration, and by that decreases predictability and creates uncertainty for the potential users.¹⁷⁴

The Netherlands enacted "Policy rules on issuing compulsory licenses" in December 2004.¹⁷⁵ An interesting and distinguishing feature of this legislation is that for the first time, NGOs are considered potential applicants, if acting for one state or for a group of states.¹⁷⁶

It seems that the Canadian legislation strayed farther away from the WTO August 30 decision than other countries' legislation. While attempting to set up a relatively clear and feasible mechanism, Canada's Bill C-9 dropped the vague language of the Decision and replaced it with more or less accurate definitions. Obviously, it could be argued that providing detailed and often much burdened procedures rendered the mechanism inflexible. However, the vague and unclear regulations definitely add to the uncertainty and unpredictability of the compulsory license granting process. Eventually, the real effect of Canada's Bill will be seen when it is actually used by developing countries in need of generic drugs.

As for today, there is one initiative under way that was founded to apply the mechanism under the Bill to export generic drugs (mostly ARVs) to Ghana.¹⁷⁷ This initiative is mostly a humanitarian act. Besides supplying generic Canadian drugs to Ghana, it includes such measures as drafting patent legislation for Ghana that would integrate *TRIPS* flexibilities; aiding in establishment of domestic manufacturing of ARVs;

<<http://www.aidslaw.ca/Maincontent/issues/cts/Scrip-article-RElliot-241104.pdf>>.

¹⁷³ European Proposal, *supra* note 171.

¹⁷⁴ *Ibid.* at 36/82.

¹⁷⁵ *Supra* note 126 at 11.

¹⁷⁶ 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, art.3(2), online: Consumer Project on Technology <<http://www.cptech.org/ip/health/cl/netherlands-export-rules.html>>. See also *ibid.* at 11.

¹⁷⁷ Following a 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," *University of Toronto Faculty of Law*, online: Access to Drugs Initiative <<http://www.law.utoronto.ca/accesstodrugs/History.htm>> [ADI], and *supra* note 126 at 23.

training Ghanaian medical professionals to ensure the sustainability of treatment sites and building additional medical facilities, *etc.*¹⁷⁸ Whether Ghana is indeed going to become the first country to use Canadian compulsory license mechanism is still unknown.

CONCLUSION

CANADA'S BILL C-9 THAT WAS MEANT TO IMPLEMENT the WTO General Council's decision of 30 August 2003 can certainly be considered a bold attempt to overcome the obstacles created by the decision's vague language that was supposed to solve the problem of exporting generic drugs to developing countries unable to produce the drugs locally.

Driven by the desire to be a leading player in the world's arena of providing aid for developing countries fighting infectious diseases, the Government of Canada tried to create legislation that, aside from serving a humanitarian purpose, would also attempt to find a balance between numerous controversial interests.¹⁷⁹ As a result, the Bill's provisions range from purely humanitarian in nature, such as the formula for calculation of remuneration, to "TRIPS-plus" provisions that are not even mentioned in the WTO decision, such as a limited list of pharmaceuticals eligible to be subject to compulsory licenses. This is to attest to a difficulty to decide what would be the actual character of the legislation. Will it be an additional feature of Canada's effort on the global scene of humanitarian aid to the developing world or will it be an implementation of the WTO General Council's decision, shifting more to the *TRIPS* spirit of stronger IPR protection?

We can probably answer this question while comparing Canada's legislation to other countries' attempts to implement the WTO August 30 decision. Compared to legislation in Norway and India and the EU's draft of regulations, Canada's Bill C-9 goes farther than the language of the WTO General Council's decision prescribes. The Bill sets clearer procedure than the one outlined in the WTO decision, although it is much burdened with the administrative details. It could be argued that the vaguer the provisions, the more flexible the legislation. However, lack of clear definitions of such important provisions as grounds and timeframe for seeking a voluntary license, lack of a formula for

¹⁷⁸ ADI, *ibid.*

¹⁷⁹ These interests are: encouraging the supply of essential medicines to the countries in need in a timely manner; preserving the IP rights of Canadian patent holders; and not forfeiting compliance with Canada's other obligations under *TRIPS*. See generally *supra* note 78.

calculation of remuneration to a patentee, *etc.*, can render legislation unreliable and uncertain in view of its future users.

The actual test for any legislation is the reality test — only time will tell whether it will work.¹⁸⁰ As for today, there is only one ongoing attempt to use the amendment to provide generic ARVs to Ghana. 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 developing countries afflicted with pandemics.

¹⁸⁰ *Supra* note 126 at 22.