

FINDING FLAWS: THE LIMITATIONS OF COMPULSORY LICENSING FOR IMPROVING ACCESS TO MEDICINES – AN INTERNATIONAL COMPARISON

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1. Introduction

In August 2003, the General Council of the World Trade Organization (WTO) unanimously adopted a Decision¹ (“2003 WTO Decision”) to allow compulsory licensing of patented medicines for the purpose of exporting the generic versions to those countries with little or no pharmaceutical manufacturing capacity. This interim decision was lauded by many as a breakthrough in the efforts to improve access to medicines in developing countries.² However, as of August 2008, only a handful of WTO Members³ have adopted domestic legislation, regulations or other instruments that in some way implement the 2003 WTO Decision. More concerning, only one export licence has been granted under the General Council 2003 WTO Decision,⁴ and as of the time

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1 *Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/C/W/405, online: WTO <<http://docsonline.wto.org>> [2003 WTO Decision].

2 World Trade Organization, Press Release, “Decision removes final patent obstacle to cheap drug imports” (30 August 2003), online: WTO News <http://www.wto.org/english/news_e/pres03_e/pr350_e.htm>.

3 As of August 2008, Canada, EU, Norway, India, China, South Korea and the Netherlands have amended their respective domestic legislations or other relevant legal instruments to implement the 2003 WTO Decision.

4 On 4 October 2007, Canada became the first country to notify the WTO of its decision to grant a compulsory licence to make a generic version of a patented medicine for export to Rwanda. For more information, see World Trade Organization, “Canada is first to notify compulsory license to export generic

of writing, only one shipment of anti-retroviral drugs has been exported to Rwanda.⁵ It has been argued that the underutilization of the 2003 WTO Decision illustrates the flawed nature of the WTO mechanism.⁶ This paper does not attempt to confirm nor refute the claim that the Decision is unworkable, but rather examines the different domestic legislative amendments made by WTO Members in order to illustrate some aspects that both facilitate and hinder utilization of the General Council Decision. In particular, we focus on Rwanda's attempt to import under Canada's implementation of the 2003 WTO Decision and compare it to an Indian generic company's ongoing application for the grant of a compulsory licence under India's implementation of the 2003 WTO Decision. This is the only other example outside of Canada of an attempt to export compulsory licensed medicines under the 2003 WTO Decision. Finally, we offer some conclusions based on lessons learnt from these experiences.

drug," online: WTO News <http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm>.

- 5 On September 25, 2008, the Government of Canada reported that the first shipment of the generic triple combination HIV medication Apo-TriAvir produced under Canada's Access to Medicines Regime arrived in Rwanda. See "Canada sends Rwanda life-prolonging HIV drugs" (25 September 2008), online: Canadian High Commission in Kenya <<http://www.dfait-macei.gc.ca/world/embassies/nairobi/news-2008-09-25-en.asp>>.
- 6 For a more detailed discussion, see Richard Elliott, "Will they deliver treatment access?: WTO rules and Canada's law on generic medicine exports" (2006) 11:2/3 Can. HIV/AIDS Pol'y & L. Rev. 13. For a detailed analysis of MSF's effort to use the Canadian legislation, see Médecins Sans Frontières, *Neither Expedition, Nor A Solution: The WTO August 30th Decision is Unworkable: An Illustration through Canada's Jean Chretien Pledge to Africa* (Geneva: Campaign for Access to Essential Medicines, 2006), online: Campaign for Access to Essential Medicines Medicins Sans Frontieres <http://www.accessmed-msf.org/fileadmin/user_upload/medinnov_accesspatents/WTOaugustreport.pdf> [MSF 2006 Report]. For a proposal of sample statutory amendments to CAMR, see Canadian HIV/AIDS Legal Network, *Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export: Brief to the House of Commons Standing Committee regarding Canada's Access to Medicines Regime* (Toronto: Canadian HIV/AIDS Legal Network, 2007), online: Canadian HIV/AIDS Legal Network <<http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=10587>>.

2. The WTO's response to the Doha Declaration on the TRIPS Agreement and Public Health

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁷ requires all WTO Members to adopt minimum standards of intellectual property rights. In essence, TRIPS provides heightened standards for all member countries. Still, it does provide some flexibility for use of a patent without the patent holder's authorization, either through government use or through a compulsory licence issued to a third party, with payment of adequate remuneration to the patentee.⁸ At the WTO's Fourth Ministerial Conference in Doha, Qatar in November 2001, WTO Members affirmed that the TRIPS Agreement should be interpreted in a "manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."⁹ It was envisioned that patent exception provisions such as the compulsory licensing provisions contained in the TRIPS Agreement could be used by governments to facilitate access to essential medicines in a time of public health crisis or circumstance of national emergency by allowing for production of cheaper generic drugs.

WTO Members further recognized in the Doha Declaration (paragraph 6) that the TRIPS Agreement limited the effective use of compulsory licensing in those countries with "insufficient or no manufacturing capacities in the pharmaceutical sector." Originally TRIPS Article 31(f) provided that compulsory licensing could only be used "predominantly" for the purposes of supply of the domestic market of the country in which the licence was issued. This posed a problem for those poorest countries which did not possess sufficient manufacturing capacity to produce their own generic pharmaceuticals and therefore needed to import medicines. In response, WTO Members committed to finding an "expeditious solution" to the "Doha paragraph 6 problem" by the end of 2002.¹⁰ However, it was not until after much debate and almost two years later, in August 2003, that the WTO General

7 *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, L/UR/A-1C/IP/1, online: WTO <<http://docsonline.wto.org>> [TRIPS Agreement].

8 *Ibid.* at art. 31.

9 *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. 01-5860, 4th Sess., at para. 4, online: WTO <[http://docsonline.wto.org:80/DDFDdocuments/t/WT/min01/DEC2.doc](http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDdocuments/t/WT/min01/DEC2.doc)> [Doha Declaration].

10 *Ibid.* at para. 6.

Council finally reached a Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health ("2003 WTO Decision").

The 2003 WTO Decision was the outcome of difficult negotiations in which several countries tried to limit the scope of the "solution" to the problem of importing and exporting compulsory licensed medicines. WTO Member countries home to research-based pharmaceutical companies – including the European Union (EU) states, Japan and Switzerland – joined with the United States in seeking to limit the solution to paragraph 6 in terms of scope of diseases, eligible countries, and the articles of the TRIPS Agreement to be addressed by the solution.¹¹ Health activists and developing countries argued for the use of TRIPS Article 30¹² which allows for "limited exceptions" to patent protection as the basis for a solution to permit compulsory licensing predominantly for export. In the end, WTO Members focused their efforts on amending the source of the problem, Article 31(f) itself. The 2003 WTO Decision took the form of an interim waiver that, among other things, waived the requirement in Article 31(f) that compulsory licensing be used predominantly for the supply of the domestic market. The 2003 WTO Decision allowed for any least-developed country Member or Member with insufficient pharmaceutical manufacturing capacity to make use of the Decision to import any pharmaceutical product needed to address public health problems.¹³ A "Chairperson's Statement," whose legal significance is unclear, was adopted in conjunction with the 2003 WTO Decision. The separate statement by the General Council chairperson sets out WTO Members' "shared understandings" of the Council decision and was designed to

11 Frederick M. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" (2005) 99 Am. J. Int'l L. 317; see also Richard Elliott, "Delivering on the Pledge: Global Access to Medicines, WTO Rules, and Reforming Canada's Law on Compulsory Licensing for Export" (2007) 3 McGill J.S.D.L.P. 23.

12 *Supra* note 7 at art. 30: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

13 See *supra* note 1 at paras. 1(a)-(b).

appease those who feared that the decision might be abused and used to undermine patent protection.¹⁴

The 2003 WTO Decision was intended only to be an interim measure and the TRIPS Council was mandated to find a more permanent solution. In December 2005, WTO Members adopted a Protocol to amend the TRIPS Agreement (“2005 WTO Agreement”) by making permanent the provisions of the August 2003 WTO Decision.¹⁵ The agreed text of the 2005 WTO Agreement is to be formally incorporated into the TRIPS Agreement when two-thirds of the WTO’s Members have ratified the amendment. The original deadline of 1st December 2007 for implementing this permanent amendment was extended in October 2007 by another 2 years, to 31 December 2009, because only 11 WTO Members had ratified the amendment (7 other Members have signed up since, bringing the total to 18 WTO Members¹⁶). Tellingly, until the TRIPS amendment is adopted, the 2003 waiver remains in place.

3. Amending domestic legislation

Although the WTO has seemingly self-servingly lauded the 2003 WTO Decision as a significant breakthrough in facilitating access to essential medicines, its impact will be negligible unless WTO Members amend their domestic legislation in order to allow for the issue of compulsory licenses under the conditions envisaged in the 2003 WTO Decision. As explained by Carlos Correa in his report to the WHO,¹⁷ the ability of generic drug manufacturers to export compulsory licensed medicines without interference from the patent holders is subject to the extent to which a Member’s domestic legisla-

14 WTO, General Council, *Minutes of Meeting* (held on 25, 26 and 30 August 2003), WTO Doc. WT/GC/M/82 at para. 29, online: WTO <http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDdocuments/t/WT/GC/M82.doc> [Chairperson’s Statement].

15 *Amendment of the TRIPS Agreement – Decision of 6 December 2005*, WTO Doc. WT/L/641, online: WTO <<http://docsonline.wto.org>> [2005 WTO Agreement].

16 For a list of WTO Members accepting amendment of the TRIPS Agreement, see World Trade Organization, “Members accepting amendment of the TRIPS Agreement,” online: WTO <http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm>.

17 Carlos M. Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (Geneva: World Health Organization, 2004), online: World Health Organization <www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf>.

tion has been amended to implement the terms of the 2003 WTO Decision. Countries may implement the Decision without first ratifying the 2005 WTO Agreement, or may ratify the amendment without implementing the Decision.¹⁸

In September 2003, a few weeks after the August 2003 WTO Decision, Canada became the first country to announce its intention to adopt legislation to implement the August 30th Decision.¹⁹ Norway, who played an active role in the negotiating process of the Decision, was the first country to actually amend its legislation in December 2003 by adding a new paragraph to section 49 of its *Patents Act* that came into effect in February 2004.²⁰ Canada soon followed with its own detailed legislation, the *Jean Chretien Pledge to Africa Act* (JCPA), that amended its *Patent Act* and *Food and Drugs Act* to facilitate the export of compulsory licensed pharmaceutical products to countries in need.²¹ The JCPA Act and accompanying Regulations became effective on 14 May 2005 and 1 June 2005, respectively, and are now generally referred to as “Canada’s Access to Medicines Regime” (CAMR). As of August 2008, the EU, India, China, Korea and the Netherlands have joined Canada and

18 Sweden, National Board of Trade, *The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems?* (Stockholm: The National Board of Trade, 2008), online: Kommerskollegium <http://www.kommers.se/templates/Standard___3127.aspx> [National Board of Trade (Sweden) Report].

19 MSF Report, *supra* note 6.

20 Although Canada’s Act has been more widely publicized, Norway was the first country to adopt implementing legislation. On December 19, 2003, Norway amended s.49 of its *Patents Act* (entered into force February 1, 2004) by adding a new fifth paragraph stating: “A compulsory licence shall be issued mainly with a view to supplying the domestic market. The King may by regulations prescribe rules that deviate from this.” See Norway, *The Norwegian Patents Act*, online: Patentstyret <http://www.patentstyret.no/upload/Filarkiv/regelverk/Norwegian_Patents_Act.pdf> [*Norwegian Patents Act*]. Accompanying Regulations in accordance with the 2003 WTO Decision entered into force on 1 June 2004. See Norway, *The Patent Regulations*, online: Patentstyret <http://www.patentstyret.no/upload/Filarkiv/regelverk/Patent_Regulations.pdf> [Norway, *Patent Regulations*]. For more information, see Abbott, *supra* note 11.

21 Canada, Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, 3rd Sess., 37th Parl., 2004, online: Parliament of Canada <www2.parl.gc.ca/content/hoc/Bills/373/Government/C-9/c-9_4/C-9_4.pdf>.

Norway and implemented domestic legislation allowing for compulsory licensing of pharmaceuticals primarily for export.²²

Effective implementation of the 2003 WTO Decision will require more than simply making amendments to national legislation.²³ Although it has been almost five years since the WTO issued its Decision, so far Canada has been the only country to grant a compulsory licence for export to Rwanda using the WTO scheme.²⁴ Even if countries amend their laws to permit compulsory licenses for export, additional hurdles are often in place as countries are pressured to adopt “TRIPS-plus” or “Decision-plus” obligations, primarily through bilateral and regional trade agreements. Civil society organizations have criticized implementing regimes for creating cumbersome processes that limit the usefulness of the 2003 WTO Decision. In particular, critics of the Canadian legislation (CAMR) have called for numerous reforms to streamline the process.²⁵ Members should comply with the obligations cre-

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- 22 See the collection established by Consumer Project on Technology, “Legislation to Allow for the Export of Pharmaceuticals Under Compulsory License,” online: CPTEch <<http://www.cptech.org/ip/health/cl/cl-export-legislation.html>>. Switzerland has proposed a draft amendment dated November 23, 2005 to revise Swiss patent law, but has not yet enacted any legislation. See Switzerland, *Confirmation of Swiss Law to the WTO Decision of 30 August 2003 concerning the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, online: Swiss Federal Institute of Intellectual Property <<http://www.ige.ch/e/jurinfo/documents/j10019e.pdf>>. See also Government of Canada, “Canada’s Access to Medicines Regime – Consultation Paper, Annex B,” online: Canada’s Access to Medicines Regime <http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult_tab1_e.html>.
- 23 Jillian C. Cohen-Kohler, Laura C. Esmail & Andre Perez Cosio, “Canada’s implementation of the Paragraph 6 Decision: is it sustainable public policy?” online: (2007) 3:12 *Globalization and Health* <<http://www.globalizationandhealth.com/home/>>.
- 24 *Notification under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Canada*, WTO Doc. IP/N/10/CAN/1, online: WTO <<http://docsonline.wto.org>> [Government of Canada Notification].
- 25 *Supra* note 23; Elliott, *supra* note 11. For written submissions regarding CAMR from interested parties made to the Government of Canada, see Government of Canada, “Review of Canada’s Access to Medicines Regime (CAMR),” online: Canada’s Access to Medicines Regime <http://camr-rcam.hc-sc.gc.ca/review-reviser/index_e.html>.

ated by the Decision in good faith and avoid assuming TRIPS-plus or Decision-plus obligations that are not in keeping with the spirit of the 2003 WTO Decision. The next section that follows focuses on the positive and negative aspects of CAMR and compares other implementing legislations to CAMR with a view to illustrating factors that may promote or hinder effective utilization of the 2003 WTO Decision.

4. Statutory review of domestic legislations implementing the 2003 WTO Decision

4.1 Eligible importers

The 2003 WTO Decision applies when an importing country facing a public health problem requires a pharmaceutical product that cannot be produced domestically and is subject to one or more patents in the exporting country. The Decision applies whether or not the product is patented in the importing country.²⁶ If the product is patented in both the exporting and importing country both countries must issue a compulsory licence. If the product is only patented in the exporting country then only the exporting country must issue a compulsory licence. The 2003 WTO Decision is not needed if a compulsory licence has been issued (1) to remedy anti-competitive practices in the exporting country²⁷ or (2) predominantly for the supply of the domestic market and the licensee only seeks to supply a non-predominant share of its production to an importing country.²⁸ According to paragraph 1(b) of the Decision, an “eligible importing Member” includes:

- a) Any least developed country WTO Member or
- b) Any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer.

The 2003 WTO Decision was adopted in light of a Chairperson’s Statement which states that certain high-income countries have “agreed to opt

²⁶ *Supra* note 17.

²⁷ *Supra* note 7. Art. 31(k) states that art. 31(f) does not apply if a compulsory licence has been issued to remedy anti-competitive practices.

²⁸ *Ibid.* Art. 31(f) only requires that generic pharmaceutical products made under compulsory licences be “predominantly” for the supply of the domestic market.

out of using the system as importers” and that a number of other countries would “only use the system as importers in situations of national emergency or other circumstances of extreme urgency.”²⁹

Although the 2003 WTO Decision only contemplates WTO Members as importers, the Canadian legislation sets a positive precedent by extending the Decision to include countries recognized as least-developed countries (LDC) by the United Nations (UN), regardless of WTO membership. Countries eligible to import under CAMR are listed in Schedules 2, 3 and 4 of the *Patent Act*. Schedule 2 is composed of least-developed WTO and non-WTO members. Schedule 3 is composed of developing country WTO Members and Schedule 4 is composed of WTO Members not listed in Schedule 2 or 3 or non-WTO Members that have signalled their intention to use the waiver only in cases of national emergency or extreme urgency.³⁰ As a result of civil society advocates who argued that access should not depend on WTO membership, CAMR was amended to allow developing countries who were neither WTO Members nor LDCs to import generics produced under CAMR as long as they have been identified by the Organization for Economic Cooperation and Development (OECD) as eligible for “official development assistance.”³¹ However, these non-WTO developing countries can only be added to Schedule 4 as long as they declare a “national emergency or other circumstance of extreme urgency.”³² Despite the fact that WTO Members rejected efforts to limit use of the Decision to “emergency situations,” the Canadian government insisted on this “emergency” limitation.³³ This “emergency” provision is at odds with the Decision and fortunately has not been replicated by other jurisdictions.

29 See *supra* note 14.

30 Government of Canada, *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act* (Ottawa: Multimedia Services Section Communications and Marketing Branch, 2007), online: Canada’s Access to Medicines Regime <http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_report_rapport-eng.pdf> [Government of Canada Statutory Review].

31 Richard Elliott, “Pledges and pitfalls: Canada’s legislation on compulsory licensing of pharmaceuticals for export” (2006) 1 *International Journal of Intellectual Property Management* 94. According to Elliott, the result of this amendment is that five developing countries cannot import under CAMR: Russian Federation, Ukraine, Belarus, Bahamas and Libya.

32 *Patent Act*, R.S.C. 1985, c.P-4, s. 21.03(1)(d)(ii).

33 *Supra* note 31 at 105.

Article 4 of the *European Union Regulation 816/2006* on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems also allows for non-WTO members eligible for OECD assistance as importers.³⁴ However, it remains unclear whether a developing country who is neither a WTO Member nor a LDC can import under Norway's,³⁵ China's³⁶ or the Netherlands'³⁷ imple-

34 EC, *Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*, [2006] O.J. L157/0001, online: Eur-Lex <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0001:01:EN:HTML>> [*EU Regulation 816/2006*].

35 In the explanatory note that accompanies Norway's *Regulations* amending the *Patent Regulations* in accordance with the 2003 WTO Decision, it appears that for the purposes of the *Regulations*, an eligible importing State is any State that is "designated by the UN as a LDC" or "that has insufficient manufacturing capacity in accordance with the Annex to the General Council Decision." Because the Annex refers only to WTO Members, it is unclear whether Norway's implementation allows developing countries who are neither WTO Members nor LDCs to import.

36 In the unofficial translation of China's State Intellectual Property Office Order #37 implementing the August 30th decision, Article 9 only allows for non-WTO Members of LDCs as eligible importers. See People's Republic of China, *State Intellectual Property Office Order #37*, online: CPtech <<http://www.cptech.org/ip/health/cl/china-order37.html>> [China SIPO Order #37]. However, in Dec 2007, a draft revision of art. 50 of the Patent Law proposes that any "developing country or LDC" with insufficient manufacturing capacity be eligible to import from China. See State Intellectual Property Office of the People's Republic of China, *SIPO's Proposals on the Third Revision of the Chinese Patent Law* (Beijing: State Intellectual Property Office of the People's Republic of China, 2007) at 48, online: <[http://www.uibm.gov.it/roving2/Introduction%20to%20SIPO%20Proposals%20on%20Patent%20Law%20Revision%20\(Part%20II\).ppt](http://www.uibm.gov.it/roving2/Introduction%20to%20SIPO%20Proposals%20on%20Patent%20Law%20Revision%20(Part%20II).ppt)> [China SIPO Proposals].

37 Under art. 3 of the Netherlands' Policy Rules on issuing compulsory licensing pursuant to the 2003 WTO Decision, it appears that only LDCs (WTO or non-WTO Members) are eligible importers. See Netherlands, *Policy rules on issuing compulsory licences pursuant to WTO Decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, under section 57, subsection 1 of the Kingdom Act on Patents of 1995*, online: CPtech <<http://www.cptech.org/ip/health/cl/netherlands-export-rules.html>> [Netherlands' Policy Rules].

mentation of the 2003 WTO Decision. Under Korea's amendment of its compulsory licence rules, non-WTO members who are not LDCs must establish that they have insufficient or no manufacturing capacity³⁸ – it is unclear from the legislation what constitutes sufficient evidence. India's legislation appears to be the broadest, allowing for *any* country having "insufficient manufacturing capacity in the pharmaceutical sector." India's approach is preferable to other implementing laws in terms of not creating a double standard between developing countries who are WTO Members and those who are not. It has been argued that nothing in the WTO law (including the 2003 WTO Decision) prohibits WTO Members from authorizing compulsory licensing for export to non-WTO developing countries as well.³⁹ Eligibility should be based on public health needs and pharmaceutical manufacturing capacity. Access to medicines is regarded as a fundamental element of the human right to health and the General Assembly of the United Nations has reaffirmed "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."⁴⁰ This human right to the highest attainable standard of health should not be determined according to membership status in the WTO.

4.2 Non-governmental organizations as eligible purchasers

The 2003 WTO Decision does not explicitly contemplate non-governmental organizations as purchasers of generic medicines produced under compulsory licence. This in fact hinders effective use of compulsory licensing as civil society organizations often play an important role in contributing to better access to essential medicines for developing countries. Responding to concerns by NGOs, the Canadian government amended its legislation to allow generic producers to sell directly to NGO purchasers for use in eligible countries. However, s.21.04(2)(f) of CAMR requires that the third party purchaser obtain the "permission" of the government of the importing country.

38 See Korea, *Patent Act of Korea, as amended December 31, 2004*, art. 107(7)(ii), online: Korea IP Law Blog <<http://iplawyer.wordpress.com/intellectual-property-laws-of-korea/patent-law-of-korea/patent-act-of-korea/patent-act-of-korea-as-amended-december-31-2004/>>.

39 *Supra* note 31 at 104.

40 *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, GA Res. 58/173, UN GAOR, 58th Sess., Supp. No. 49, UN Doc. A/RES/58/173 (2003), online: UN Resolutions <<http://www.un.org/Depts/dhl/resguide/r58.htm>>.

What constitutes “permission” is undefined in the legislation. This requirement creates another hurdle that is not required under WTO law and can further delay procurement of medicines under the WTO scheme for compulsory licensing. Requiring NGOs to seek permission of the importing country may subject NGOs to political manipulation by governments.⁴¹ This provision allowing for NGOs as purchasers has been replicated in only one other jurisdiction, in Article 3(2) of the Netherlands’ Policy Rules. Unlike CAMR, there is no restriction requiring the NGO to obtain “permission” from the government of the importing country. In order to facilitate procurement and delivery of essential medicines to countries in need under the WTO Decision, implementing domestic legislation should follow the positive precedent set by the Netherlands and allow for NGOs as eligible purchasers.

4.3 Eligible pharmaceutical products for compulsory licensing

Ideally the scope of pharmaceutical products covered by the Decision should be interpreted in a flexible manner.⁴² Correa states: “As the negotiation of the Decision made clear, it applies to pharmaceutical products for *any* disease. The three mentioned epidemics [HIV/AIDS, tuberculosis, malaria] are only special cases...the system established by the Decision is not limited to products related to them” [emphasis in original]. Paragraph 1(a) of the Decision also makes clear that “pharmaceutical products” includes “active ingredients necessary for [their] manufacture” and “diagnostic kits needed for [their] use.”⁴³

Despite the fact that a consensus was reached among WTO Members that there would be no restrictions on the scope of diseases or pharmaceutical products covered by the Decision, Schedule 1 of CAMR⁴⁴ sets out a limited list of specific dosages and forms for specific eligible pharmaceutical products based on the World Health Organization’s (WHO) Model List of Essential Medicines. Schedule 1 can be amended, but this requires a recommendation from the Minister of Industry and the Minister of Health. Another criticism is that CAMR does not make explicit that it applies to “active ingredients” and “diagnostic kits” and not merely the finished pharmaceutical product. China’s implementation, while it does make reference to “active

41 *Supra* note 31 at 106.

42 Abbott, *supra* note 11 at 332.

43 *Supra* note 17 at 11, 10.

44 *Supra* note 32, Sch. 1.

ingredients” and “diagnostic kits” (Article 2), also takes a step backwards in that only pharmaceutical products needed to treat an “infectious disease” are covered.⁴⁵ The draft revision proposed in December 2007 changes the scope to “epidemiological diseases.”⁴⁶ Fortunately, the other jurisdictions do not introduce such restrictions. The pre-approved list of medicines in the Canadian legislation is unnecessary under WTO law and was clearly rejected in the negotiations leading up to the 2003 WTO Decision. Perhaps the best example that is in keeping with the spirit of the 2003 WTO Decision is Norway’s *Regulations*, section 108, which define “pharmaceutical products” as those “covered by paragraph 1(a) of the General Council Decision.”

4.4 Duty to negotiate for a voluntary license from the patentee

Pursuant to TRIPS Article 31(b), which was not waived by the 2003 WTO Decision, a compulsory licence will only be granted after efforts to secure authorization from the patent holder have not succeeded “within a reasonable period of time.” This requirement can be waived “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” Since the purpose of the Decision is to “protect public health” and is not for the pursuit of “industrial or commercial policy objectives,”⁴⁷ then the compulsory licence is being issued for “public non-commercial use” and the requirement to first seek a voluntary licence can be waived in the exporting country.⁴⁸

Despite this, as enacted, the Canadian legislation requires the generic manufacturer to request a voluntary licence from the patentee and wait a minimum of 30 days before applying for a compulsory licence.⁴⁹ However, while TRIPS does not define what constitutes a “reasonable period of time,” CAMR sets a positive precedent by providing a clear statutory definition of 30 days and limits the ability of patentees to drag out negotiations with the generic producer. On the other hand, while Norway does waive the requirement to seek a voluntary licence in emergency situations,⁵⁰ it fails to clarify

45 See China SIPO Order #37, *supra* note 36, art. 2.

46 China SIPO Proposals, *supra* note 36 at 47.

47 See *supra* note 14.

48 Elliott, *supra* note 11 at 31, 34.

49 *Supra* note 32, s. 21.04(3)(c).

50 See Norway, Ministry of Foreign Affairs, *Explanatory notes – Regulations amending the Patent Regulations (implementation of the Decision of the WTO General Council*

what is a “reasonable period of time.” India and China do not make any mention of a duty to seek a voluntary licence, leaving the obligations of a generic producer unclear. Article 107 in Korea’s legislation fails to clarify what a reasonable time period is and whether the requirement is waived in situations set out in TRIPS Article 31(b). Under section 57(1) of the Netherlands *Patents Act* the Minister of Economic Affairs must ascertain that the patent holder is unwilling to issue a voluntary licence before issuing a compulsory licence. The Minister can refrain from such an investigation “in urgent cases.” This may be an unwelcome precedent as this allows discretion on the part of the Minister and the lack of certainty may serve as a disincentive for generic manufacturers.

Perhaps the most positive example is set by the *EU Regulations*. Article 9 sets out a 30 day period of negotiations *and* waives the requirement to seek a voluntary licence in “situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement.” By clarifying what constitutes a “reasonable period of time” and allowing for the requirement to seek a voluntary licence to be waived in accordance with TRIPS Article 31(b), the *EU Regulations* avoid introducing TRIPS-plus obligations and encourage rapid, effective use of compulsory licensing to secure essential medicines.

4.5 Regulatory review requirement

Under Canadian legislation, generally a drug manufactured solely for export does not need to undergo the same regulatory approval process as drugs consumed in Canada. However, if the generic pharmaceutical is produced for export under a compulsory licence in accordance with the 2003 WTO Decision, it must meet the same health and safety standards as drugs destined for consumption in Canada.⁵¹ This mandatory regulatory approval is not specifically required by the WTO Decision and has been criticized by

of 30 August 2003, paragraphs 1(b) and 2(a) (Oslo: Ministry of Foreign Affairs, 2004), online: Ministry of Foreign Affairs

<<http://www.regjeringen.no/en/dep/ud/Documents/Reports-programmes-of-action-and-plans/Reports/2004/Explanatory-notes----Regulations-amending-the-Patent-Regulations-implementation-of-the-Decision-of-the-WTO-General-Council-of-30-August-2003-paragraphs-1b-and-2a.html?id=420374>>.

51 See *Food and Drugs Act*, R.S.C. 1985, c.F-27, s.37(2); *Food and Drug Regulations*, C.R.C., c.870, s. C.07.004.

NGOs as “time-consuming” and “potentially duplicative of other international regulatory review processes.” For once, however, both the innovative and generic pharmaceutical manufacturers are in agreement that the health regulatory review is necessary to ensure that the importing countries receive safe, effective and high quality drugs consistent with Canadian standards.⁵²

In response to criticism that this Decision-plus obligation is “time-consuming,” Health Canada has provided assurances that it would establish a separate “fast-track” procedure for reviewing applications for marketing approval related to drugs produced under the WTO Decision.⁵³ So far there has been only one submission to Health Canada under CAMR, involving a triple fixed-dose combination (FDC) anti-retroviral (ARV). Because there was no already-approved reference product, the product underwent the process required by “new drug submissions” under the *Food and Drugs Act*. According to officials from Apotex, the approval process was timely.⁵⁴ Currently, the process for new drug submissions takes an average of 18 months.⁵⁵ Regulatory approval of the generic FDC product using the separate “fast-track” process took seven months.⁵⁶ Health Canada is, at least in this one example, following through with its assurances of flexibility and speed in reviewing drugs produced for export under CAMR.

Many importing countries require approval from the WHO’s Prequalification Project (PQP). The WHO PQP evaluates pharmaceutical products according to internationally agreed standards for quality, safety and efficacy.⁵⁷ CAMR’s requirement for Health Canada approval has been criticized as duplicating the work of the WHO PQP. However, given that Health Canada has recently reached an understanding with the WHO whereby the WHO will accept the results of Health Canada’s review for the purposes of the PQP,⁵⁸

52 *Supra* note 30 at 12.

53 *Supra* note 31 at 103.

54 Interview of Jack Kay by Jillian Kohler (7 November 2007).

55 Health Canada, “How Drugs are Reviewed in Canada,” online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php>.

56 MSF 2006 report, *supra* note 6.

57 *Ibid.* at 5.

58 Canada, House of Commons Standing Committee on Industry, Science and Technology Hearings on CAMR, *Canada’s Access to Medicines Regime (CAMR): Summary of Major Issues Raised During the House of Commons Standing Committee on Industry, Science and Technology Hearings on CAMR* (Ottawa: House of Commons, 2007) at

this ensures timely inclusion in the PQP and avoids putting an unnecessary drain on WHO resources. Having a separate “fast-track” domestic review from Health Canada may in fact act as an incentive rather than a deterrent for generic manufacturers because the generic pharmaceutical product would then be eligible for approval within Canada.⁵⁹

No other legislative regime requires a mandatory health and safety review. The EU legislation is the only other legislation that mentions regulatory review as a precondition for obtaining a compulsory licence, and even then the EU legislation only provides for a *voluntary* review. Under Article 18 of the *EU Regulation No. 816/2006*, an applicant *may* submit for approval from the EU scientific opinion procedure for evaluating medicines⁶⁰ or any other similar procedure under national law. If the product is a generic of a reference medicinal product already authorized, the requirement to submit test data filed for the generic product is waived.⁶¹ As there has been no test case of the EU’s regulation on compulsory licensing of pharmaceutical products for export, it remains to be seen whether this voluntary review creates an onerous obligation.

In order to reassure importing countries that the products are safe and effective, the pharmaceutical products should meet some standard of quality. The question is whether it should be left up to the importing country rather than the exporting country to apply the standards it deems appropriate. In the accompanying explanatory notes to Norway’s *Regulations*, Norway states that it is the quality requirement in the importing State that will determine the regulatory approval required, as long as the pharmaceutical product is

F: Health Canada’s Drug Review, online: House of Commons <http://cmte.parl.gc.ca/Content/HOC/committee/391/indu/webdoc/wd2967322/391_INDU_Letter/391_INDU_Summary-e.html> [Standing Committee CAMR Summary].

59 Memorandum from John Hems, Director, Regulatory Affairs, Apotex Inc., to Douglas Clark, Director, Patent Policy Directorate, Industry Canada, and Brigitte Zirger, Director, Therapeutic Products Directorate, Health Canada (23 January 2007), online: CAMR

<http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_apotex_18_e.pdf>.

60 EC, *Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*, [2004] O.J. L136/0001, art. 58, online: Eurlex <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0726:EN:HTML>>.

61 See *supra* note 34, art. 18.2.

manufactured in accordance with Norwegian statutory requirements concerning the manufacturing process. If the importing country wishes to avail itself of the WHO PQP process, then this should be sufficient. Currently many low-income countries with limited capacity to review pharmaceutical products already rely on the PQP as sufficient assurance of product safety and efficacy. In the event that the importing country wishes to use the regulatory approval process of the exporting country, a separate “fast-track” option should be available for compulsory licensed drugs produced for export. Regardless of the requirements in the importing State, in order to provide incentive for generic manufacturers, they should still be allowed to obtain domestic regulatory approval through a “fast-track” option that guarantees that once the patent expires they can immediately enter their own domestic market. Although drug review adds another step to the process, it is a necessary step to ensure that the products exported under the Decision are safe, effective and of high quality.

4.6 Duration of compulsory licence

Article 31(c) of TRIPS, which was not waived by the 2003 WTO Decision, specifies that the duration of a compulsory licence “shall be limited to the purpose for which it was authorized.” Although not required by the Decision, CAMR imposes a two-year cap on the term for which a compulsory licence can be issued. This limit has been criticized as a major disincentive for generic manufacturers as it restricts the ability of generic manufacturers to achieve the economies of scale and generate revenue worth the start-up expense of producing lower-cost generic products.⁶² Under CAMR, this timeframe can be extended for up to two more years, but only for the purposes of completing production and delivery of the original quantity of the product authorized by the licence. There is no option to allow for manufacture of additional quantities of the product.⁶³ This effectively makes it commercially unappealing for potential generic producers.

No other jurisdiction imposes a similar restriction on the duration of a compulsory licence issued for export. While the implementing legislations of Norway, China and the Netherlands do not make any mention as to a time limit, the *EU Regulation*, *Indian Patent Act* and *Korean Patent Act* all leave the

62 *Supra* note 31 at 107.

63 *Supra* note 32, s. 21.12.

duration of the licence up to the discretion of the competent authority.⁶⁴ This latter approach is preferable to CAMR in that it allows for more flexibility and autonomy on the part of the negotiating parties. Imposing a cap with a qualified renewal process acts as a disincentive by limiting the ability of generic manufacturers to compete effectively in the marketplace. The issuing authority should be permitted to grant a compulsory licence for the duration necessary for the purpose for which it was granted. If a time limit is necessary in order to protect the contracting parties from being locked into an agreement that may become uneconomical or outdated, there should be a possibility for renewal that does not require the parties to go through the entire process again.

4.7 Royalties paid to the patentee

Paragraph 3 of the 2003 WTO Decision requires “adequate remuneration” to be paid to the patent holder by taking into account the economic value of the authorization to the importing Member. The 2003 WTO Decision waives importing countries’ obligation under TRIPS Article 31(h) to pay a royalty fee to the patent holder. In order to avoid double payment, only the licensee must pay royalties to the patentee.

CAMR sets a positive precedent by not only setting a limit on the amount payable to the patentee, but establishing a transparent, sliding scale approach based on the importing country’s rank on the UN Human Development Index.⁶⁵ Using a formula, the lowest country on the scale would pay a royalty of approximately 0.02 percent and the highest, 3.5 percent.⁶⁶ This legislatively mandated royalty rate removes any discretion on the part of Canada’s Commissioner of Patents and provides certainty to generic manufacturers. However, s.21.08 of the *Patent Act* also gives the patent holder the right to challenge the royalty rate in the Federal Court. Critics of CAMR emphasize this is an “unnecessary litigation right” that acts as a disincentive to generic

64 *Supra* note 33, art. 10(3); India, *The Patents (Amendment) Act, 2005*, art. 92A(2), online: IP India <http://www.ipindia.nic.in/ipr/patent/patent_2005.pdf>; *supra* note 38, art. 110(2)(i).

65 See *Use of Patented Products for International Humanitarian Purposes Regulations*, S.O.R./2005-143, s. 8, which prescribes the formula to be used for determining the royalty rate: $[(1 + \text{number of countries on UNHDI} - \text{importing country's rank}) / \text{number of countries on UNHDI}] \times 0.04$.

66 *Supra* note 30 at 17.

manufacturers.⁶⁷ Under the *EU Regulation*, remuneration paid to the patent holder is limited by a ceiling of 4% where the product is used in situations of extreme urgency. In situations not constituting a national emergency, the competent authority can either exceed or undercut this ceiling, taking into account the economic value of the use authorized under the compulsory licence and humanitarian circumstances.⁶⁸ Both the Canadian and EU legislations reject a one-size-fits-all approach that is in keeping with the spirit of the 2003 WTO Decision and establish a positive precedent by establishing a ceiling to the royalty rate. Other jurisdictions (Norway, China, Korea and the Netherlands) fail to clarify what constitutes “adequate remuneration”⁶⁹ according to TRIPS Article 31(h), and India does not make any reference to remuneration to the patent holder.

Establishing a ceiling is an important feature of legislation implementing the 2003 WTO Decision. In order to facilitate access to essential medicines to those living in developing countries, it is not enough that the price be reduced, but that the price is reduced substantially to the point that governments in resource-poor countries can afford to purchase the medicines. Applying a formula based on a sliding-scale approach and limiting the amount of royalties paid to the patentee help to reduce the costs to the generic manufacturer, create transparency and provide incentive to generic manufacturers to produce low-cost generics under a compulsory licence.

4.8 Good Faith Clause

One of the “shared understandings” established in the Chairperson’s Statement is that the system created by the 2003 WTO Decision should be used in good faith to protect public health and should not be an instrument to pursue industrial or commercial objectives. However, the legal status of the statement is unclear as it is not part of the formal agreement. It has been suggested that the statement can be viewed as a sort of “gentlemen’s agreement.”⁷⁰ Thus, it remains unclear to what extent domestic legislations must implement the shared understandings of the Chairperson’s Statement. In

⁶⁷ *Ibid.*

⁶⁸ *Supra* note 34, art. 10(9).

⁶⁹ See *Norwegian Patents Act*, *supra* note 20, s. 50; *Norway, Patent Regulations*, *supra* note 20, s. 108; *China SIPO Order #37*, *supra* note 36, arts. 7, 11; *supra* note 38, art. 106; *supra* note 37, art. 5.

⁷⁰ *Supra* note 18 at 26.

order to provide incentive to generic manufacturers to produce medicines for export to developing countries, they must be allowed to obtain some commercial benefit. This is glaringly absent in the case of the CAMR.

CAMR is the only legislation to give effect to the Chairperson's Statement by allowing a patentee to challenge a licence based on breach of "good faith" provisions contained in its legislation.⁷¹ Under s.21.17, a patentee can challenge a licensee where it believes that the licence is "commercial in nature." CAMR sets out a number of statutory provisions to determine whether the licence is commercial in nature. If the patentee successfully establishes that the licence is commercial in nature, the Federal Court can either terminate the licence or require the licensee to pay, in addition to the royalty rate, an amount adequate to compensate the patentee for the commercial use of the patent. NGOs and generic manufacturers have voiced concerns that CAMR's "good faith" provisions confer unnecessary litigation rights on patent-holders and discourage generic drug manufacturers from producing drugs under CAMR. As there has been only one application to date for a compulsory licence under CAMR, it remains to be seen whether this provision will in fact serve as an opportunity for unnecessary litigation.

India, China and Korea do not include in their implementing legislation any provision to ensure that a compulsory licence is issued in good faith and is not used for industrial or commercial purposes. The *EU Regulation* includes this good faith requirement in the preamble (paragraph 6), but also states that the Regulation is designed "to discourage litigation." The Netherlands does not provide for a good faith obligation in its Policy Rules, but the accompanying explanatory notes to section 57 of its *Patent Act 1995* repeat the Chairperson's Statement. Neither the implementing legislation of the EU nor the Netherlands makes mention of what happens in the event that a compulsory licence is not used in good faith. Section 108 of Norway's *Regulations* allows for termination of the licence in the event that the licensee learns that the products are being used for purposes other than to cover the importing State's current public health needs.

Given that "good faith" provisions are not part of the Decision itself, and only arise from the shared understandings of the Chairperson's Statement, it remains unclear to what extent implementing legislations must reflect the spirit of this statement. Assuming that implementing legislation must give effect to the Chairperson's Statement, then perhaps the example set by Nor-

71 *Supra* note 58 at J: "Good Faith" Clause.

way best reflects the spirit of the Statement and balances both humanitarian and commercial interests. Norway's "good faith" provisions allow the licensee to terminate the licence if it is no longer being used for the protection of the public health needs of the importing country, and avoids including unnecessary "extra-litigation right" provisions that may lead to costly and time-consuming litigation. Generic manufacturers are not non-profit agencies and implementing legislation should avoid creating further disincentives for generic manufacturers to use the Decision by allowing for litigation in the event of "non-commercial" use.

5. Attempts to make use of compulsory licensing under the 2003 WTO Decision

It has now been almost five years since the August 2003 WTO Decision allowing generic versions of patented drugs to be exported under compulsory licence was agreed upon and only one country has received medication under an implementing legislative regime. While a number of jurisdictions (Canada, EU, Norway, India, China, Korea and the Netherlands) have all amended their domestic legislations in accordance with the 2003 WTO Decision, to our knowledge the only attempts to use the Decision have employed the Canadian and, most recently, the Indian implementation of the system. In this section we turn to Rwanda's and Nepal's attempts to import from Canada and India, respectively, in order to illustrate the barriers an importing country may face in making use of the WTO scheme for compulsory licensing.

5.1 The case of Rwanda and Canada

On 19 July 2007, Rwanda became the first country to notify the WTO of its intention to use the August 30th system to import a combination pill of three HIV/AIDS medicines under patent in Canada, zidovudine (AZT), lamivudine (3TC) and nevirapine (NVP).⁷² In their requisite notification, Rwanda announced its intention to import 260,000 packs of Apo-TriAvir, a combination product of 300 mg of AZT, 150 mg of 3TC and 200 mg of NVP, produced by the Canadian generic manufacturer Apotex, Inc. Rwanda

⁷² *Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Rwanda*, WTO Doc. IP/N/9/RWA/1, online: WTO <<http://docsonline.wto.org>>.

reserved the right to modify the quantity to be imported and notified the WTO that it did not intend to issue a compulsory licence, but intended to make use of its right, as a least-developed country, to use the LDC transition period and not enforce any patent rights that may have been granted with regard to the triple FDC anti-retroviral.

After the mandatory 30-day period of attempted negotiations with the three companies holding the relevant Canadian patent rights failed to result in a voluntary licence, on 4 September 2007, Apotex filed an application for a compulsory licence with the Canadian Intellectual Property Office. On 19 September 2007, the Canadian Commissioner of Patents granted a compulsory licence to Apotex to allow for the production of 15.6 million tablets of Apo-TriAvir (260,000 packs x 60 tablets/pack), which, according to one source, would be enough to treat 21,000 patients for one year.⁷³ On 8 October 2007, Canada filed the requisite notification with the WTO, informing them of this compulsory licence having been issued.⁷⁴

Despite being awarded the compulsory licence, Apotex still had to compete in a tender process, as required by Rwanda's domestic law whenever its government purchases medicines. It was not until 7 May 2008 that the Rwandan government awarded the tender to Apotex. According to Elie Betito, Apotex's director of public and government affairs, the first shipment is scheduled for export in September or October 2008.⁷⁵

More than four years have passed since Canada became the first G8 country to amend its national laws to implement the 2003 WTO Decision and not a single pill has been exported under compulsory licence. In May 2004, the same month that the Canadian legislation was passed, the NGO Médecins Sans Frontières/Doctors Without Borders (MSF), attempted to place an order for medicines needed for its field projects.⁷⁶ In December 2004, Apotex agreed to manufacture a combination pill of three anti-retro-

73 "Canada Issues Compulsory Licence For HIV/AIDS Drug Export to Rwanda, in First Test of WTO Procedure" *Bridges Weekly Trade News Digest* 11:32(26 September 2007) 4, online: International Centre for Trade and Sustainable Development < <http://ictsd.net/i/news/bridgesweekly/6556/>>.

74 *Supra* note 24.

75 "Rwanda Should Receive Cut-Price HIV/AIDS Drugs in September, Five Years After 30 August Decision" *Bridges Weekly Trade News Digest* (14 May 2008) 12:17, online: International Centre for Trade and Sustainable Development < <http://ictsd.net/i/news/bridgesweekly/11081/>> [Bridges May 2008].

76 MSF 2006 Report, *supra* note 6.

viral drugs, AZT/3TC/NVP. Despite the speed at which Apotex developed an active prototype, there were a variety of procedural delays created from the complexities of CAMR, the WTO Decision itself and Rwandan government practice.⁷⁷

First, Apotex had to wait while the government amended the list of products eligible for compulsory licensing under CAMR because it was not originally listed in Schedule 1 of CAMR. Apotex then had to submit to Health Canada for the statutorily mandated regulatory review. However, additional delays were incurred while Health Canada undertook an additional review because the potential importing country MSF was in discussions with wanted WHO Prequalification Project approval.⁷⁸ During this time, the importing country in question had not yet filed the requisite notification to the WTO TRIPS Council, seemingly in part because of concern that this would expose the country to risk of considerable pressure from countries such as the U.S. who actively dissuade countries from granting compulsory licenses.⁷⁹ By early 2007, MSF was not successful in getting the potential importing country to publicly notify the WTO. By this time two Indian companies had received WHO PQP approval for the same combination medicine and MSF started buying these copies instead.⁸⁰ However, a breakthrough for Apotex was achieved in July 2007 when Rwanda came forward and deposited the first notification with the WTO to import under the 2003 WTO Decision. Apotex then engaged in the mandatory negotiations for a voluntary licence. When the discussions failed to produce an agreement, Apotex filed an application for a compulsory licence on 4 September 2007, which was subsequently issued on 19 September 2007. Apotex could not yet begin production, however, as it had to wait several months while the Rwandan government engaged in a competitive tender process. Fortunately, Apotex, which had submitted a bid with the lowest price at US \$0.195/tablet, was eventually awarded the tender on 7 May 2008.⁸¹

77 See Elliott, *supra* note 11 at 25-28 for a detailed overview of MSF's and Rwanda's attempt to import under CAMR.

78 Health Canada has since negotiated an agreement with the WHO whereby the WHO will accept the results of Health Canada's review of CAMR products for the purposes of the WHO PQP. See *supra* note 58.

79 Elliott, *supra* note 11 at 27.

80 *Supra* note 18 at 29.

81 *Supra* note 75.

At the time of writing, no one has completed the process under the 2003 WTO Decision. The first shipment left Canada in the fall of 2008. Hopefully the tender process was the last barrier to completion of the process. As is evident from Rwanda's attempts to use the system, many of the obstacles encountered can be attributed to complexities created both by the WTO Decision itself (e.g. duty to seek voluntary licence and the notification requirement) as well as by "Decision-plus" provisions (e.g. a restricted list of eligible products and a statutorily mandated Health Canada review). Critics of CAMR have repeated their calls to remove unnecessary hurdles from the Canadian legislation.⁸² Apotex has said that it will never participate in the process again unless the federal government simplifies the process and a spokesman for the Canadian Generic Pharmaceutical Association has said that none of its members are willing to go through the CAMR process in its current form.⁸³

Is CAMR's detailed legislative framework its downfall? We now turn to the example of Nepal and India, the only other example to our knowledge of an attempt to use another country's implementing legislation under the 2003 WTO Decision. In contrast to CAMR, which contains 19 sections and over 100 clauses, India's implementing legislation consists of three paragraphs. It appears, however, that the ambiguity created by implementing the Decision in three paragraphs has stalled Nepal's attempt to import essential medicines.

5.2 The case of Nepal and India

As part of its accession to the WTO in 2005, India adopted the *Patents (Amendment) Act* in order to bring its intellectual property law into compliance with WTO standards. Previously, the Indian *Patent Act* only provided for patenting of *processes* for inventions in the pharmaceutical sector. The Indian *Patents (Amendment) Act* introduced pharmaceutical *product* patents in the country for the first time. Under the new Amendment Act, medicines that were granted patent protection in other countries between 1995 and 2005 ("mail-box" applications), as well as medicines patented after 1 January 2005, became eligible for patent protection in India.⁸⁴ As India is a major supplier of

⁸² *Ibid.*

⁸³ *Supra* note 5.

⁸⁴ Health Gap Global Access Project, "The Impact of India's Amended Patents Act

the world's generic medicines,⁸⁵ many voiced concern over the effect of the new regime on access to affordable medicines. The Act has been criticized for incorporating ambiguous language and including loopholes that may benefit litigious patent holders.⁸⁶ The impact of the Amended Act on access to essential medicines is illustrated by the current attempt of Nepal to import two cancer drugs from India.

In September 2007, the Indian generic pharmaceutical company Natco filed an application with India's Patent Controller for a compulsory licence to produce two anti-cancer drugs for export to Nepal, erlotinib (which is patented by the Swiss manufacturer Roche under the brand name Tarceva) and sunitinib (which is patented by the US manufacturer Pfizer under the brand name Sutent). Both drugs were granted patents in India in 2007, after India brought its patent laws in line with the WTO guidelines on intellectual property. Based on an import licence issued by Nepal, Natco intends to produce 30,000 tablets of erlotinib and 15,000 tablets of sunitinib. According to Mr. Adi Narayana, Natco's corporate affairs manager, Natco has offered the patent holders a 5 percent royalty rate.⁸⁷

This is the first test case using section 92A of India's *Patent (Amendment) Act*. Section 92A consists of three paragraphs that were inserted into the

on Access to Affordable HIV Treatment," online: Health Gap Global Access Project <http://www.healthgap.org/press_releases/05/020105_HGAP_FS_INDIA_IPR.pdf>.

85 According to MSF, 67% of medicines produced in India are exported to developing countries. Approximately 50% of the essential medicines that UNICEF distributes in developing countries come from India. 75-80% of all medicines distributed by the International Dispensary Association (IDA, a not-for-profit medical supplier of essential medicines to developing countries) are manufactured in India. 80% of anti-retroviral medicines MSF uses are purchased in India and distributed in over 30 countries. See Médecins Sans Frontières, "Examples of the Importance of India as the 'Pharmacy for the Developing World,'" online: Campaign for Access to Essential Medicines <http://www.accessmed-msf.org/fileadmin/user_upload/medinnov_accesspatents/Overview%20Jan%202007%20FINAL.pdf>.

86 Priti Radhakrishnan, "Some Implications of India's New Patent Act" *Bridges* 9:4 (April 2005) 18, online: International Centre for Trade and Sustainable Development <<http://ictsd.net/downloads/bridges/bridges9-4.pdf>>.

87 Shammad Basheer, "India's First 'Doha' Case: Natco, Pfizer and Roche will be heard soon" *SPICY IP* (24 February 2008), online: SPICY IP <<http://spicyipindia.blogspot.com/2008/02/indias-first-doha-case-natco-pfizer-and.html>>.

Patent Act to allow for export of generic versions of patented medicines to *any* country, provided the country, through either notification or the issuance of a compulsory licence, has allowed importation of the drug. If Natco's application is successful, it will be the second time that a compulsory licence for export has been issued under the 2003 WTO Decision.⁸⁸ Currently, however, the process has stalled due to ambiguity over how to interpret section 92A.

In response to Natco's application for a compulsory licence, both Natco and the patent holders were invited by India's Patent Office for a hearing. Although India's Patent Office has the power to grant a compulsory licence based on the strength of the application alone, it has chosen to hear from the patentees before deciding whether to grant a licence or not.⁸⁹ Natco, by way of an interlocutory petition filed on 25 Feb 2008, has opposed the grant of a hearing to the patentees, arguing that there is no right of hearing expressly provided for.⁹⁰ On 19 March 2008, the Delhi Patent Office held a hearing to determine whether a patent holder has the right to a hearing when an application for a compulsory licence for export is filed under section 92A.

According to section 87 of the *Patents Act*, in the event a patent holder opposes the application for a "regular" compulsory licence, the patent holder has the right to be heard before the Patent Controller makes its decision. However, there is no similar provision offering such a provision in the event of a "section 92A" compulsory licence. It is unclear whether this was a deliberate omission or an oversight.⁹¹ Counsel for Natco argued that the history of the Doha Declaration and the 2003 WTO Decision fully justifies the differential treatment of compulsory licenses for export under section 92A. At the hearing held at the Delhi Patent Office, Natco argued that the gravity of public health problems facing developing countries require a rapid response. Intervention of the patentees had already delayed Natco's application by several months. Counsel for Natco also pointed to CAMR, which does not grant the right of a hearing to the patent holder *during* the application pro-

88 Tatum Anderson, "India Considers Compulsory Licence for Exportation of Drugs" *Intellectual Property Watch* (20 February 2008), online: Intellectual Property Watch <<http://www.ip-watch.org/weblog/index.php?p=933>>.

89 *Supra* note 87.

90 Archana Shanker, "India: Compulsory licence debate develops" *Managing Intellectual Property* (1 April 2008), online: Managing Intellectual Property <<http://www.managingip.com/Article.aspx?ArticleID=1902135>>.

91 *Supra* note 87.

cess (section 21.04), but rather allows the patent holder the right to challenge the validity of the compulsory licence *after* it has been issued.⁹²

Counsel for the patentees argued that under fundamental common-law principles of “natural justice,” an opportunity to be heard was required before any action adverse to the patentee’s interest was taken by the State. The patentees also distinguished the comprehensive nature of Canada’s legislation from the sparse nature of section 92A in India’s *Patent Act*, arguing that in the absence of comprehensive safeguards that ensure a patentee is treated fairly, as contained in CAMR, the very least that India’s Patent Controller could do was allow the patentee the opportunity to be heard prior to the issuance of a compulsory licence. Counsel for the patentees also argued that the “notice” given by the Nepal government that Natco was relying upon was insufficient to demonstrate Nepal’s intent to utilize the 30 August mechanism to import drugs produced under a compulsory licence. The patentees contrasted this to the formal notification provided to the WTO by Rwanda.⁹³

Present uncertainty in the interpretation of section 92A of India’s *Patent Act* has resulted in several months of delay in the granting of a compulsory licence to Natco. While the comprehensive nature of Canada’s legislation has been the subject of much criticism for being too cumbersome, the sparse language contained in India’s *Patent Act* has also proven to be contentious. Two main issues have arisen: first, whether a hearing should be granted to the patentee prior to the issuance of a compulsory licence for export and second, what constitutes sufficient “notification” by an importing country of intent to utilize the 2003 WTO Decision to import under a compulsory licence. If India’s government issues a compulsory licence, this would be the second time an export licence has been granted for public health reasons since the August 2003 WTO Decision. Natco’s application is the first ever application under section 92A for an export licence and will set a precedent for how section 92A will be used in the future. The outcome of this test case is important because India is a major producer of generic drugs for developing countries. The notion of compulsory licensing has very little value to public health if the only nations that utilize it are the ones that have little capacity

92 Chan Park, “Natco’s application for CL for Export – Hearing in the Delhi Patent Office” [*Commons – Law*] relay (20 March 2008), online: [Commons-Law] relay <<http://commonslaw.freeflux.net/blog/archive/2008/03/20/commons-law-natco-s-application-for-cl-for-export-hearing-in-the-delhi-patent-office.html>>.

93 *Ibid.*

to manufacture pharmaceutical products. A judgement in favour of Natco could help to ensure the continued availability of low-cost, essential medicines to countries lacking the manufacturing capacity needed in the pharmaceutical sector to address public health problems. In the meantime, Pfizer announced in early April 2008 that it would be implementing a free treatment programme in Nepal for Sutent.⁹⁴ It is unknown what impact Pfizer's free patient assistance programme will have on Natco's application to the Indian Patent Controller's office.

6. Conclusion: Unwrapping the red tape

Domestic legislation implementing the General Council 2003 WTO Decision on compulsory licensing for export varies from country to country. The legislative models among the handful of countries that have amended their domestic legislation in line with the WTO Decision contain features that both facilitate and hinder effective utilization of the 2003 WTO Decision. Other countries seeking to implement the WTO Decision can learn from the experience of these implementing jurisdictions in order to improve access to medicines among those countries with insufficient pharmaceutical manufacturing capacity to make effective use of compulsory licensing.

Based on an examination of current legislative amendments, countries may want to follow India's example and allow for *any* country having insufficient manufacturing capacity in the pharmaceutical sector to serve as eligible importers, regardless of WTO membership. The Netherlands sets a positive example by allowing for NGOs to act for an importing state without requiring some undefined "permission" from the government of the importing country. NGOs, particularly those with operational experience in the procurement of medicines, may be the best bet in terms of getting drugs to those in need expeditiously. Norway does not go beyond the WTO Decision and defines eligible "pharmaceutical products" as those "covered by paragraph 1(a) of the General Council Decision." The EU establishes a 30 day period for negotiating a voluntary licence but waives the need to negotiate with the patentee in the event that the generic product is needed for an emergency or other circumstance of extreme urgency or for public non-commercial use. As importing countries need reassurance that the pharma-

94 C.H. Unnikrishnan, "Pfizer to launch free Sutent access programme in Nepal" *livemint.com* (3 April 2008), online: [livemint.com <http://www.livemint.com/2008/04/03004838/Pfizer-to-launch-free-Sutent-a.html>](http://www.livemint.com/2008/04/03004838/Pfizer-to-launch-free-Sutent-a.html).

ceutical products are safe and effective, there should be a regulatory review requirement. However, because the product is destined primarily for export, it should be up to the importing country to determine whether it wishes to avail itself of the regulatory approval process of the exporting country or of the WHO pre-qualification project. These measures help to ensure a rapid and effective response to global public health crises, while remaining compliant with WTO obligations.

Additionally, commercial incentives must be provided to generic manufacturers as it is unreasonable and misguided policy to effectively compel generic manufacturers to act as non-profit agencies. In order to allow generic manufacturers to achieve economies of scale in producing cheap generics, there should be no arbitrary time limit on the duration of the compulsory licence. If the issuing authority deems it necessary to impose a cap on the duration of the licence, then there should be a mechanism in place to allow for renewal of the compulsory licence without having to go through the entire process again. A two- year cap, such as that imposed by CAMR, hinders the generic producer from achieving the necessary economies of scale and provides less of a market incentive for generics to even negotiate for such contracts. Likewise, countries should follow the example of Canada and the EU and set legislated caps on the royalty rate paid by the licensee to the patentee in order to leave room for enough of a profit margin to provide adequate incentive to generic manufacturers. Creating a formula based on the importing country's rank on the UN Human Development Index is one method to provide clarity and transparency while taking into account humanitarian considerations. In order to give effect to the "good faith" obligations of the Chairperson's Statement and still provide commercial incentives for generic manufacturers to produce drugs for export under the Decision, countries should follow the example of Norway. Under Norway's *Regulations*, the licensee can terminate manufacture and export if it learns that the products are no longer being used to meet the public health needs of the importing country. This avoids creating "extra-litigation right" provisions that serve as disincentives to generic manufacturers.

As of August 2008, only one export licence has been granted under the 2003 WTO Decision and one export licence is being disputed before the courts. The example of Canada and Rwanda illustrates the obstacles faced by countries when implementing domestic legislation becomes too onerous and cumbersome. The example of India and Nepal illustrates the hurdles created when domestic legislation is too vague and non-specific. It is clear from these two examples that there is no easy solution for drafting legislation that fully reflects the intent and functionality of the WTO General

Council Decision and does not impose restrictive Decision-plus obligations. When people are dying from diseases which are treatable with medicines, these delays are inexcusable. There is an unequivocal need for legislative reform among current amending domestic legislations in order to ensure a flexible and rapid response to the public health needs of developing countries. Other countries seeking to implement the WTO Decision should learn from the experiences of WTO Members who currently have amended their respective domestic legislations and create a more user-friendly legal process to facilitate compulsory licensing for export of essential medicines to developing countries.

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