

BETTER ACCESS TO MEDICINES:
WHY COUNTRIES ARE GETTING “TRIPPED” UP
AND NOT RATIFYING ARTICLE 31-BIS

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I. INTRODUCTION

The TRIPS agreement does not and should not prevent members from taking measures to protect public health.¹

--- World Trade Organization, Doha Summit 2001.

With the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”)², advocates for patent protection rejoiced, while those concerned about world health and access to medicines lamented. One of the most visible results following the enactment of TRIPS in 1995 was higher drug prices for health programs in developing and least developed countries (“LDCs”).³ At the same time, the poorest regions of the world, mostly encompassing sub-Saharan Africa, had the highest concentrations of people with treatable diseases such as AIDS/HIV, tuberculosis, and malaria.⁴

TRIPS sought to balance patent protection and access to medicines, but the results indicate that TRIPS has only decrease access to affordable medicines. Numerous factors contribute to the lack of access, but one of the largest barriers is the medicines’ exorbitant cost. High costs are a direct result of TRIPS patent protection, which prevents the production of generic drugs that can be sold at a lower cost.⁵ For example, the

¹ World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, ¶ 4, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

³ Jennifer May Rogers, Note, *The TRIPS Council’s Solution to the Paragraph 6 Problem: Toward Compulsory Licensing Viability for Developing Countries*, 13 MINN. J. GLOBAL TRADE 443, 443 (2004).

⁴ Erin M. Anderson, Note, *Unnecessary Deaths and Unnecessary Costs: Getting patented Drugs to Patients Most in Need*, 29 B.C. THIRD WORLD L.J. 85, 85 (2009).

⁵ Jessica L. Greenbaum, Comment, *TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of the Paragraph 6 Waiver*, 25 J. CONTEMP. HEALTH L. & POL’Y 142, 142–43 (2008); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the DOHA “Solution,”* 3 CHI. J. INT’L L. 47, 47 (2002); See Joint U.N. Programme on HIV/AIDS, *2008 Report on the Global AIDS Epidemic 157* (Aug. 2008), available at http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp.

United Nations Commission on Human Rights reported that the HIV drug Fluconazole costs \$55 in India, where the drug does not enjoy patent protection. This same drug costs \$697 in Malaysia, \$703 in Indonesia, and \$817 in the Philippines, all places where the drug is patented.⁶ Unfortunately, “an abundance of poor health contributes to status as a poor country, just as a poor country translates into high concentrations of poor health.”⁷ Additionally, restrictions on compulsory licensing under Article 31(f) kept developing countries and LDCs from actually manufacturing necessary medicines for exportation or importation, further inhibiting access to life saving pharmaceuticals.⁸ Thus, the practical effects of TRIPS (e.g., increased drug costs with restrictions on obtaining affordable generic versions)⁹ prompted the World Trade Organization (“WTO”) to issue a declaration at the 2001 Doha Ministerial, stressing the importance of taking the necessary “measures to protect public health.”¹⁰ One measure subsequently taken was the amendment Article 31-bis.¹¹ This amendment modifies some of the restrictions originally placed on the compulsory licensing scheme. While WTO members officially accepted the amendment on December 6, 2005, the amendment will not become part of TRIPS until two thirds of the WTO countries ratify it.¹² The WTO first imposed a December 2007 deadline for ratification,¹³ but then extended it to December 2009,¹⁴ and

⁶ U.N. Econ. & Soc. Council [ECOSOC], Sub-Comm’n on the Promotion and Prot. of Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, ¶ 44, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001), available at [http://www.unhcr.ch/Huridocda/Huridocda.nsf/e06a5300f90fa0238025668700518ca4/590516104e92e87bc1256aa8004a8191/\\$FILE/G0114345.pdf](http://www.unhcr.ch/Huridocda/Huridocda.nsf/e06a5300f90fa0238025668700518ca4/590516104e92e87bc1256aa8004a8191/$FILE/G0114345.pdf).

⁷ Anderson, *supra* note 4, at 86 n.8.

⁸ CARLOS M. CORREA, IMPLEMENTATION OF THE WTO GENERAL COUNCIL DECISION ON PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 1 (2004) (Health Economics and Drugs, EDM Series No.16).

⁹ Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, 3 CHI. J. INT’L L. 27, 27 (2002).

¹⁰ Doha Declaration, *supra* note 1, ¶ 4.

¹¹ Amendment of the TRIPS Agreement, WTO Doc. WT/L/641 (Dec. 8, 2005) [hereinafter Article 31-bis].

¹² Press Release, World Trade Org., Members OK Amendment to Make Health Flexibility Permanent (Dec. 6, 2005) [hereinafter Amendment Press Release], http://www.wto.org/english/news_e/pres05_e/pr426_e.

¹³ World Trade Organization, Ministerial Decision of 6 December 2005, WT/L/641 (2005), available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

¹⁴ World Trade Organization, Ministerial Decision of 18 December 2007, WT/L/711 (2007), available at http://www.wto.org/english/tratop_e/trips_e/wt-l-711_e.pdf.

subsequently to December 2011.¹⁵ As of February 2010, only fifty-four member countries have ratified the amendment.¹⁶

This Note examines why the amendment, which was created to provide flexibility and better access to medicines, has not yet achieved the necessary signatures for ratification. Part II provides an overview of compulsory licensing schemes and explores how Article 31-bis infuse greater flexibility into the current TRIPS scheme. Part III explores the obstacles many countries face in their efforts to ratify Article 31-bis, including procedural hurdles and ambiguity in defining adequate remuneration under the amendment. Part IV discusses Rwanda's experience in invoking Article 31-bis and the paragraph six waiver. Finally, Part V suggests that pharmaceutical companies may be willing to negotiate lower prices as an alternative to compulsory licensing.

II. WHILE TRIPS ARTICLE 31(F) PREVENTS COUNTRIES FROM GRANTING COMPULSORY LICENSES IN CERTAIN SITUATIONS, ARTICLE 31-BIS ELIMINATES SOME OF THESE RESTRICTIONS

A. A Compulsory License is a Government Grant to Use a Patent Without the Permission of the Patent Holder

One goal of TRIPS was to alleviate the barriers imposed on WTO member countries by patent protections, in cases where a legitimate public need arises.¹⁷ The WTO accomplished this goal by including language in Article 31 permitting countries to issue compulsory licenses.¹⁸ A compulsory license is issued by the government, and allows a competitor of the patent owner to manufacture, produce, process, or sell the patented invention without the patent owner's permission, in order to address a public need.¹⁹ Compulsory licenses historically were issued for purposes such as:

¹⁵ World Trade Organization, Ministerial Decision of 17 December 2009, WT/L/785 (2009), available at http://www.wto.org/english/tratop_e/trips_e/wt-l-785_e.pdf.

¹⁶ WTO Members Accepting Amendment of the TRIPS Agreement [hereinafter Status of Ratification], http://www.wto.org/english/tratop_E/trips_e/amendment_e.htm (last visited Feb. 24, 2010).

¹⁷ Amendment Press Release, *supra* note 12.

¹⁸ TRIPS, *supra* note 2, at 1210.

¹⁹ Mike Gumbel, Comment, *Is Article 31 Bis Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System*, 22 TEMP. INT'L & COMP. L.J. 161, 162 (2008).

to deal with a situation in which a patent owner is unwilling to work his invention[;] to satisfy an unmet demand from the public for a patented product[;] to introduce a price-reducing competition for important but expensive products, e.g. drugs[;] to deal with a situation in which refusal to license a patent, or the imposition of unreasonable terms, is preventing the exploitation of another invention which is of technical or economic importance; to prevent abuses of patent rights . . . [; and] to prevent the creation of *potential* competition-inhibiting monopolies.²⁰

By the 1990's, roughly one hundred countries had incorporated some type of compulsory licensing scheme, though relatively few compulsory licenses have ever actually been issued.²¹

Under TRIPS, the purposes and requirements for issuing a compulsory license are narrow. A government seeking to issue a compulsory license typically must first attempt to negotiate with the patent holder for a potential license.²² However, a government may waive this requirement “in the case of a national emergency or other circumstance of extreme urgency or [when the compulsory license is limited to] public non-commercial use.”²³ “The public interest of achieving broader access to the patented [medicine] is considered more important than the private interest of the [patent] holder in fully exploiting his exclusive rights.”²⁴ Nevertheless, compulsory licensing still requires appropriate remuneration to the patent holder for violating his exclusive rights under the patent.²⁵

Despite the provisions permitting compulsory licensing, few developing countries have actually invoked their rights under Article 31 of the TRIPS Agreement.²⁶ It was not until 2007 that emerging markets found the political will to invoke compulsory licensing. For example, in January 2007 Thailand issued a license for generic manufacturing of a HIV/AIDS drug patented

²⁰ Graham Dutfield, *Delivering Drugs to the Poor: Will the TRIPS Amendment Help?*, 34 AM. J.L. & MED. 107, 110–11 (2008) (emphasis added).

²¹ *Id.* at 111–12 (noting that Canada, who issued 613 compulsory licenses for the manufacture or importation of medicines between 1969 and 1992, represents an anomaly to the infrequent issuing of compulsory licenses).

²² TRIPS, *supra* note 2, at 1209.

²³ *Id.*

²⁴ Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. INT'L ECON. L. 73, 77 (2004).

²⁵ TRIPS, *supra* note 2, at art. 31(h).

²⁶ Gail E. Evans, *Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries*, 34 AM. J. L. & MED. 175, 183 (2008).

by U.S.-based Abbott Laboratories.²⁷ Brazil followed Thailand's lead and issued a compulsory license for a Merck-patented HIV/AIDS drug in May 2007.²⁸

Compulsory licensing inherently seems to advocate a moral and altruistic duty to protect society from unreasonable patent exclusivity.²⁹ However, patent holders and countries advocating for strong intellectual property rights openly repudiate countries that invoke compulsory licensing.³⁰ The United States has "openly expressed its displeasure when developing country governments have brought in measures to prioritize public health in ways that limit the full enjoyment of the intellectual property rights of U.S. businesses."³¹

Despite this public condemnation,³² the United States itself has issued compulsory licenses under its own domestic laws. When there was an Anthrax scare in 2001, the U.S. government sought to stockpile vast quantities of Bayer's ciprofloxacin ("Cipro"), an anthrax antibiotic.³³ It was mostly concerned with acquiring large amounts of the drug, but also wanted it at a reduced price. Secretary of Health and Human Services, Tommy Thompson threatened Bayer, saying that if it did not lower the price of Cipro by fifty-percent, then the government would acquire the drug from other sources.³⁴ This mere threat induced Bayer to strike a deal with the U.S. government. Bayer agreed to supply it with Cipro at a significantly reduced cost.³⁵ The United States' use of compulsory licensing, while hypocritical, is a perfect example of what should be done in a public emergency. It also demonstrates how the provisions in TRIPS can protect all countries in much the same way through a compulsory licensing scheme.

²⁷ Elizabeth H. Williams, *Just Say 'No' to Big Pharma*, 170 FAR E. ECON. REV. 43, 43 (2007).

²⁸ Evans, *supra* note 26, at 184.

²⁹ See generally International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 4 (asking State Parties to recognize an individual's right to enjoy "the highest attainable standard of physical and mental health").

³⁰ Sykes, *supra* note 5, at 50.

³¹ Dutfield, *supra* note 20, at 115.

³² See Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1088 (1996).

³³ See Keith Bradsher, *Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine*, N.Y. TIMES, Oct. 25, 2001, at B8.

³⁴ *Id.* The US government seriously considered using the Indian version of Cipro, even though Bayer owned the US patent. See Ellen't Hoen & Pierre Chirac, Op-Ed., *Don't Renege on Doha*, LE MONDE DIPLOMATIQUE, June 25, 2002.

³⁵ Bradsher, *supra* note 33.

*B. Article 31-bis Infuses More Flexibility into TRIPS'
Compulsory Licensing Scheme*

While the TRIPS compulsory licensing scheme articulates a way for developing nations to access patented drugs,³⁶ TRIPS also requires that the compulsory license primarily benefit the domestic market only.³⁷ In other words, a country may issue a compulsory license only to a domestic manufacturer who does not export drugs. However, the countries in most need of the drugs do not have adequate manufacturing capacities to produce them.³⁸ Thus, while the TRIPS compulsory licensing scheme gives developing countries the ability to avoid high costs associated with recognizing pharmaceutical patents, licensing requirements still erect hurdles for these countries that lack sufficient manufacturing capability.³⁹ The domestic restriction unduly burdens importing countries wishing to obtain the drugs. It also hinders exporting countries with the manufacturing capability because it keeps them from selling generic medications to LDCs or other developing countries.⁴⁰

India provided the biggest impetus for review of Article 31(f)'s domestic supply requirement and ultimately for the proposed paragraph 6 waiver / Article 31-bis. During the transitional period after TRIPS' initial implementation, India developed a world-class generic drug production capacity.⁴¹ India did not grant patent protection to pharmaceuticals before TRIPS. Therefore, after the enactment of TRIPS, it would not be required to grant such protection until 2005, when the transition period ended. During the ten-year transition period, India was able to manufacture drugs "that were otherwise on-patent in developed (and many developing) countries."⁴² India's generic industry was so successful that all major drug procurement agencies like UNICEF, IDA, Doctors without Borders, as well as countries like Lesotho and Zimbabwe, purchased generic drugs from the Indian pharmaceutical industry.⁴³ However,

³⁶ Rogers, *supra* note 3, at 447.

³⁷ TRIPS, *supra* note 2, at art. 31(f).

³⁸ Anderson, *supra* note 4, at 96.

³⁹ Gumbel, *supra* note 19, at 162.

⁴⁰ See Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 *IND. INT'L & COMP. L. REV.* 613, 617 (2004).

⁴¹ Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 *J. INT'L ECON. L.* 921, 934 (2007).

⁴² *Id.*

⁴³ ANAND & ANAND ADVOCATES, REPORT ON IMPLICATIONS OF THE PROPOSED ARTICLE 31BIS OF THE TRIPS AGREEMENT xxxiii,

under TRIPS, any drugs developed in India after 2005 would have to be patented. The domestic distribution requirement of Article 31(f) also prevents India from exporting drugs to other countries or world health organizations in need.

The WTO General Council recognized that the domestic distribution requirement made a compulsory licensing scheme useless for many countries. The General Council announced an interim waiver allowing countries to export generic medicines to countries that were issued a compulsory license, and are in need.⁴⁴ The WTO members ultimately negotiated and codified this “paragraph 6” waiver into the amendment Article 31-bis.⁴⁵ While the amendment does not go into effect until two-thirds of the WTO members ratify it, the amendment was accepted by the body and opened for signature on December 6, 2005.⁴⁶

The main purpose of Article 31-bis is to waive the domestic supply requirement under Article 31(f).⁴⁷ Article 31-bis accomplish this in two ways. First, it allows a country to grant a compulsory license to import a particular drug. This allows countries lacking sufficient domestic manufacturing capacity within their own country to still obtain cheaper generic drugs.⁴⁸ Second, the amendment allows a country, such as India, to export a generic drug to a country that has issued a compulsory license.⁴⁹ Other substantive provisions include:

- 1) no restrictions on the types of drugs for which a compulsory license may be granted;⁵⁰
- 2) importing countries (LDCs excluded) must notify TRIPS of their eligibility and desire to use the compulsory licensing under the Article 31-bis scheme;⁵¹
- 3) in determining eligibility for a country to import a

<http://www.nhicindia.org/content/wrindia/Nupur/doc7011131200957.pdf> (last visited May 8, 2010).

⁴⁴ James T. Tsai, Note, *Not Tripping over the Pebbles: Focusing on Overlooked TRIPS Article 66 for Technology Transfer to Solve Africa's AIDS Crisis*, 11 MICH. ST. U. J. MED. & L. 447, 458 (2007).

⁴⁵ Article 31-bis, *supra* note 11.

⁴⁶ See Amendment Press Release, *supra* note 12; Status of Ratification, *supra* note 16.

⁴⁷ Article 31-bis, *supra* note 11.

⁴⁸ Baker, *supra* note 40, at 640–42.

⁴⁹ See Article 31-bis, *supra* note 11, at Annex to the Protocol Amending the TRIPS Agreement ¶ 1.

⁵⁰ Abbott & Reichman, *supra* note 41, at 936-37 (pointing out that many developed nations, including the United States and the EU, wanted to limit the compulsory licenses to drugs for HIV/AIDS, tuberculosis, and malaria or for “grave” public health problems. However, developing countries were able to negotiate so that the Amendment imposes NO restrictions).

⁵¹ Article 31-bis, *supra* note 11, at Annex to the TRIPS Agreement ¶ 1(b).

- specific drug, the importing country must either be an LDC or make a determination in accordance with the Appendix to Article 31-bis that the country lacks the manufacturing capacity for that specific drug;⁵²
- 4) importing countries must issue a compulsory license, but only if there is domestic patent protection OR the country is NOT an LDC;⁵³
 - 5) importing countries must also notify the TRIPS Council, specifying the name of the products and the expected quantities to be imported;⁵⁴
 - 6) exporting countries must also issue a compulsory license;⁵⁵
 - 7) exporting countries may export only the requested amount, must distinguish the drugs by special packaging or labeling, and must record each export shipment on a WTO website;⁵⁶
 - 8) exporting countries must pay remuneration to the patent holder, taking into account the economic circumstances of the importing country;⁵⁷
 - 9) importing countries must “take reasonable measures” to prevent re-exportation of the drug so that the medicines are in fact used for public health purposes;⁵⁸ and
 - 10) no Member state shall challenge any measures taking in conformity with Article 31-bis.⁵⁹

III. ARTICLE 31-BIS FACIALLY CAN IMPROVE ACCESS TO VITAL MEDICINES, BUT TOO MANY OBSTACLES PREVENT ITS EFFECTIVENESS

The procedural requirements of Article 31-bis as outlined above are numerous, and many criticize the amendment for imposing too many unnecessary obstacles.⁶⁰ Controversy surrounds the adoption of Article 31-bis. Particular criticism comes from NGOs and other similar agencies dealing with

⁵² *Id.* at Annex to the TRIPS Agreement ¶ 2(a)(ii), App. to the Annex of the TRIPS Agreement.

⁵³ *Id.* at Annex to the TRIPS Agreement ¶ 2(a)(iii).

⁵⁴ *Id.* at Annex to the TRIPS Agreement ¶ 2(a)(i).

⁵⁵ *Id.* at Annex to the TRIPS Agreement ¶ 2(b).

⁵⁶ *Id.*

⁵⁷ *Id.* at Annex to the Protocol ¶ 2.

⁵⁸ *Id.* at Annex to the TRIPS Agreement ¶ 3.

⁵⁹ *Id.* at Annex to the Protocol ¶ 4.

⁶⁰ Abbott & Reichman, *supra* note 41, at 932. See also MEDECINS SANS FRONTIERES, DOHA DERAILED: A PROGRESS REPORT ON TRIPS AND ACCESS TO MEDICINES, Aug. 27, 2003, <http://www.msf.org.au/uploads/media/cancun.pdf>.

global health.⁶¹ Specifically, Doctors without Borders characterized Article 31-bis as ill-researched and not a viable plan to increase access to medicine.⁶² Doctors without Borders voiced its skepticism to the amendment by stating: “the decision shows that the WTO is ignoring day-to-day reality of drug production and procurement. The amendment has made permanent a burdensome drug-by-drug, country-by-country decision-making process...”⁶³

A. The Many Requirements Under Article 31-bis Make Ratification Unappealing to Many Developing Countries

With only a small number of WTO member states ratifying the amendment, many critics argue that the cross-boundary compulsory licensing procedures outlined in Article 31-bis remain too complex, especially for developing countries to understand.⁶⁴ Some also argue that generic pharmaceutical companies may want to avoid the rigmarole of negotiating with both domestic patent owners and foreign governments before they can provide the necessary medicines.⁶⁵ Furthermore, the process of both the exporting and importing countries obtaining compulsory licenses increases transaction costs and possibilities for delay.⁶⁶

The public notification provision in Article 31-bis that requires a showing of a country’s intent to use a compulsory licensing scheme is unreasonable and unnecessary. Some commentators surmise that no developing country had made the general notification of intent, due to fears of hostile criticism or even retaliatory action from developed countries, including the United States and the E.U.⁶⁷ Developing countries fear implying that they may one day choose to invoke compulsory licensing.

⁶¹ E.g., Roger Bate & Richard Tren, *Health Policy Outlook on the WTO and Access to Essential Medicines: Recent Agreements, New Assignments*, AM. ENTERPRISE INST. FOR PUB. POL’Y RES., Feb. 13, 2006, http://www.aei.org/docLib/20060216_19636HPO200604_g.pdf.

⁶² Tsai, *supra* note 44, at 458 (in which Medecins San Frontieres cited the procedural requirements for both importing and exporting countries as overly burdensome and bureaucratic and held that these requirements are a main reason why Article 31-bis will not increase access to medicines). See also *Members Strike Deal on Trips and Public Health; Civil Society Unimpressed*, BRIDGES WKLY. TRADE NEWS DIG. (Geneva, Switz.), Dec. 7, 2005, at 1 [hereinafter *Society Unimpressed with Article 31-bis*].

⁶³ *Society Unimpressed with Article 31-bis*, *supra* note 62, at 3.

⁶⁴ Dutfield, *supra* note 20, at 123.

⁶⁵ *Id.*

⁶⁶ Mark C. Lang, Note, *What a Long, Strange “TRIPS” It’s Been: Compulsory Licensing from the Adoption of TRIPS to the Agreement on Implementation of the Doha Declaration*, 3 J. MARSHALL REV. INTELL. PROP. L. 331, 343 (2004).

⁶⁷ Abbott & Reichman, *supra* note 41, at 938.

The provision requiring general notification to the TRIPS Council serves no purpose other than to publically broadcast desires to use compulsory licensing along with erecting political barriers limiting the usefulness of Article 31-bis.⁶⁸ While this is just one example of an unnecessary procedural requirement, TRIPS and Article 31-bis are replete with administrative headaches. Simplifying the scheme could induce more countries to ratify the amendment.

B. Pressure from Developed Countries and the Pharmaceutical Industry Weigh Heavily in a Developing Country's Decision to Ratify Article 31-bis

Developed countries, known for protecting intellectual property rights, pressure developing countries to refrain from using compulsory licenses. They do this even as they invoke compulsory licenses on their own behalf (e.g., the United States and Cipro in 2001).⁶⁹ In 2001, the U.S. sought sanctions against Brazil for invoking a compulsory license on a U.S. patented drug. This sent a strong message to the rest of the world that the U.S. was willing to take extreme measures to protect its pharmaceutical companies.⁷⁰ The United States' widely criticized actions created legitimate fears that countries could be subject to reprisal in the form of sanctions, litigation, and trade restrictions if they invoke compulsory licenses. While the U.S. eventually withdrew its complaint against Brazil from the WTO panel, the lingering effects chilled efforts by the international community to invoke compulsory licensing.⁷¹

Article 31-bis attempted to rectify this situation by including a provision where WTO members shall not challenge "any measures taken in conformity" with the provisions of Article 31-bis or TRIPS.⁷² However, a lingering fear of sanctions following the 2001 Brazil litigation along with trepidation over angering pharmaceutical companies arguably deters developing countries from ratifying the amendment.⁷³

Pharmaceutical lobbying efforts have also been an obstacle to the ratification of Article 31-bis. From the industry's perspective, it simply is unfair and counterproductive to allow a government to issue a compulsory license. The industry claims that the high cost of research and development (an average of \$500 million per new drug) demands adequate compensation to

⁶⁸ *Id.* at 939.

⁶⁹ Dutfield, *supra* note 20, at 115–16.

⁷⁰ 't Hoen, *supra* note 9, at 32.

⁷¹ Greenbaum, *supra* note 5, at 155.

⁷² Article 31-bis, *supra* note 11, ¶ 4.

⁷³ Weissman, *supra* note 32, at 1079.

both recoup costs and promote the development of new medicines.⁷⁴ Interestingly, however, the pharmaceutical industry was either first or second in Fortune Magazine's rankings of the most profitable sectors of the U.S. economy for the period 1960 to 1991.⁷⁵ Nevertheless, the pharmaceutical industry has been putting "pressure on developing nations to prevent the local manufacture or importation of cheaper versions of the drugs produced in countries where either they cannot be patented or where the patents are not respected."⁷⁶ This pressure could also discourage developing countries from ratifying Article 31-bis or even invoking compulsory licenses under the current TRIPS scheme.

C. Ambiguity Surrounding "Adequate Remuneration" May Discourage Countries from Ratifying Article 31-bis

While Article 31(h) requires adequate remuneration to the patent holder, concerns over double remuneration were alleviated with Article 31-bis, which, requires that the exporting country shall bear the costs of remuneration.⁷⁷ However, the amendment equates the appropriate level of remuneration to the "economic value to the importing member of the use of the patent right that has been authorized."⁷⁸

Developed countries believe that adequate remuneration should equate to full compensation for the product.⁷⁹ They posit that intellectual property rights must be respected and valued, and the high cost of developing drugs warrants such high compensation. Furthermore, if there is no adequate compensation from their perspective, incentives to research diseases, especially those primarily affecting developing countries, are hindered.⁸⁰ While the developed countries' argument is persuasive, it runs counter to the Doha Declaration's humanitarian goal of protecting public health.⁸¹ Additionally, allowing full compensation to patent holders

⁷⁴ Nitya Nanda & Ritu Lodha, *Access to Essential Medicines and Affordable Drugs: Making Essential Medicines Affordable to the Poor*, 20 WIS. INT'L L. J. 581, 581–82 (2002); Peter K. Yu, *The International Enclosure Movement*, 82 IND. L. J. 827, 836 (2007).

⁷⁵ Nanda & Lodha, *supra* note 74, at 583.

⁷⁶ Graham Dutfield, *Introduction to TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 7* (Christophe Bellmann, Graham Dutfield & Ricardo Melendez-Ortiz eds., 2003).

⁷⁷ Lang, *supra* note 66, at 348.

⁷⁸ *Id.*

⁷⁹ Antony Taubman, *Rethinking TRIPS: "Adequate Remuneration" for Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927 (2008).

⁸⁰ Lang, *supra* note 66, at 348.

⁸¹ Amendment Press Release, *supra* note 12.

would create a windfall, because they would be able to collect profits in a previously unavailable market.⁸²

LDCs and developing countries are at the opposite end of the spectrum in terms of compensation—they believe there should be no remuneration, or at most, minimal remuneration, for use of the patent. While this seems laudable from a humanitarian perspective, a complete lack of remuneration does not effectively balance the patent owner's right with the developing country's need to protect public health.

Article 31-bis attempts to strike the middle ground between full compensation and no remuneration. However, the lack of guidelines defining adequate remuneration⁸³ may lead exporting countries to pay prices that are: (1) too high, thereby negating the potential gains they receive as a result of producing low cost medicine; or (2) too low, in which case the patent holder would not receive adequate compensation for use of his patent.⁸⁴ Thus, countries may be wary of ratifying Article 31-bis because there is no clear standard for determining adequate remuneration.

D. Exporting Countries Must Enact Domestic Legislation in Order to Comply with TRIPS and Article 31-Bis – Such Legislation is Politically Difficult to Achieve and Financially Expensive

Each individual exporting member state must enact legislation to ensure that its domestic laws comply with the regulations under TRIPS and Article 31-bis.⁸⁵ This creates a significant financial and political burden on WTO member states who export generic drugs. The legislation must not only meet the requirements imposed by the WTO and provide humanitarian relief to importing countries, but it must also benefit the exporting country.⁸⁶ Currently, no guidelines or model rules exist for a legislative and institutional framework that could be adopted by countries possessing the manufacturing capacity, and the desire to export the generic medicines into developing countries.⁸⁷

⁸² *Id.*

⁸³ *E.g.*, Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 222–223, 242–44 (2004).

⁸⁴ Greenbaum, *supra* note 5, at 157.

⁸⁵ Baker, *supra* note 40, at 672.

⁸⁶ Greenbaum, *supra* note 5, at 157.

⁸⁷ Council for Trade-Related Aspects of Intellectual Property Rights, *Report on the Workshop on the WTO Decision on Access to Medicines at Affordable Prices for Countries with No or Insufficient Manufacturing Capacities*, ¶¶ 26–28, IP/C/W/439 (Feb. 23, 2005).

Drafting the required legislation from scratch without guidelines or model rules is an arduous process. Countries must expend significant resources, both from a financial and a legal expertise perspective, to create sound public policy and legislation.⁸⁸ TRIPS addresses the difficulty of this process, and depending on a country's economic development, articulates different temporal deadlines by which legislation must be passed.⁸⁹ Still, many countries have not yet crafted the required legislation to pass compliance under TRIPS, let alone compliance with the recent Article 31-bis Amendment.⁹⁰

In May 2004, Canada became one of the first countries to implement legislation designed to carry out the amendment's mission.⁹¹ Under the legislative scheme, Canada's Commissioner of Patents could "grant compulsory licenses permitting the manufacture and export of low-cost versions of patented pharmaceuticals."⁹² According to a statement by the Canadian government, "[r]epresentatives of Canada's generic and brand name drug companies, and various non-governmental organizations were consulted during the development of the legislation and regulations. The Regime balances Canada's trade and intellectual property obligations with the humanitarian objective of the [Doha Declaration]."⁹³ It took over nine months for Canada to draft its legislation. If developing countries do not act immediately to implement similar legislation, the results could be tragic. Nine months is too long for a developing country to wait once it has declared a public health emergency.

Canada's legislation seeks "to facilitate timely access to generic versions of patented drugs, especially those needed by least-developed or developing countries to fight HIV/AIDS, malaria, tuberculosis and other diseases."⁹⁴ Canada's Regime ensures that the drugs exported subscribe to the same standards as drugs for the Canadian market. Standards for safety, effectiveness, quality and issuance are the same for all drugs produced in Canada.⁹⁵ Health Canada also reviews products for

⁸⁸ Anderson, *supra* note 4, at 106 (noting that developing countries may lack the legal and technical expertise required to draft appropriate legislation in compliance with TRIPS (citation omitted)).

⁸⁹ TRIPS, *supra* note 2, at art. 65.

⁹⁰ Michael Westerhaus & Arachu Castro, *How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy?*, 3 PUB. LIBRARY OF SCI. MEDICINE 1230, 1232 (2006).

⁹¹ Canada's Access to Medicines Regime, Background [hereinafter CAMR Background], http://www.camr-rcam.gc.ca/intro/context_e.html (last visited May 8, 2010).

⁹² Anderson, *supra* note 4, at 101.

⁹³ CAMR Background, *supra* note 91.

⁹⁴ *Id.*

⁹⁵ Canada's Access to Medicines Regime, Features of the Regime, http://www.camr-rcam.gc.ca/intro/regime_e.html (last visited May 15, 2010).

export under the compulsory licensing scheme, just as it does for domestically produced pharmaceuticals. Review is subject to a special fast-track process to avoid delaying drug delivery to countries in need.⁹⁶ The legislation also limits the drugs eligible for manufacture. Only drugs listed on the World Health Organization's Model List of Essential Medicines can be made, although Canada does reserve the right to add drugs to that list.⁹⁷ The Canadian Regime utilizes less restrictive guidelines regarding which countries can import drugs.⁹⁸

Canada's Regime seems straightforward and the legislation appears to strike the proper balance between safety and expediency. Nevertheless, the legislation also "requires the good will of pharmaceutical companies to participate in the Regime to fulfill the humanitarian objective of alleviating public health problems in developing nations."⁹⁹ Before obtaining a compulsory license from the Canadian government, the generic manufacturer must first seek a voluntary license from the patent holder. This voluntary license, which depends on the goodwill of the patent holder, makes Canada's legislative scheme more rigorous than the standards for compulsory licensing under TRIPS.¹⁰⁰ Relying on a patent holder's goodwill has already proven difficult, as evidence by the situation in Rwanda in 2007.¹⁰¹

While it is typically burdensome to draft and enact legislation, there does not appear to be a feasible alternative at the moment. States do not have a perfect legislative model to adopt automatically.¹⁰² Coupling this difficulty with other procedural requirements under Article 31-bis creates a situation

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ Canada's Access to Medicines Regime, Eligibility for Countries, http://www.camr-rcam.gc.ca/countr-pays/elig-admis/countr-pays_e.html (last visited May 15, 2010) ("Canada expanded the list of countries eligible to participate to include least-developed and developing countries that are not members of the WTO.").

⁹⁹ CAMR Background, *supra* note 91.

¹⁰⁰ See Unnati Gandhi, *Supplying Generic AIDS Drugs Called Pricey Process*, THE GLOBE AND MAIL (Canada), May 8, 2008, at A5.

¹⁰¹ See *infra* pp. 180-181 and notes 103-108 (describing how Rwanda, in conjunction with Canada, invoked the compulsory licensing scheme under Article 31-bis).

¹⁰² DOUGLAS CLARK & BRIGITTE ZIRGER, GOVERNMENT OF CANADA, CANADA'S ACCESS TO MEDICINES REGIME—CONSULTATION PAPER 21 (2006), http://camr-rcam.gc.ca/review-reviser/camr_rcam_consult_e.pdf. Since Canada enacted legislation in 2004, Norway, the Netherlands, India, Korea, China, and the European Union also followed suit. Norway passed legislation in June 2004, the Netherlands in December 2004, India in January 2005, Korea in December 2005, China in January 2006, and the EU in June 2006. Switzerland drafted an amendment in November 2005, but it was never enacted. *Id.*

where countries are unwilling to ratify the amendment simply because of the inefficient bureaucratic hurdles.

IV. FEW COUNTRIES HAVE INVOKED ARTICLE 31-BIS OR THE WAIVER TO OBTAIN ACCESS TO PATENTED MEDICINES

Despite difficulty ratifying Article 31-bis, the Paragraph 6 waiver has been in force since 2003. However, no country chose to exercise its compulsory licensing rights until 2007.¹⁰³ This failure to rely on compulsory licensing, even though it is legally permissible suggests that ratification of Article 31-bis would not have a significant effect on developing countries. While the language of TRIPS and Article 31-bis is problematic, implementation of a compulsory licensing scheme also presents issues, as shown by Rwanda's experience with Canada.

On July 19, 2007, Rwanda notified the WTO's TRIPS Council of its intention to import compulsory licensed drugs from Canada for public health reasons.¹⁰⁴ Per the requirements of Canada's Regime, the generic manufacturer actively sought voluntary licenses from GlaxoSmithKline, Shire, and Boehringer Ingelheim, the patent holders for the drugs.¹⁰⁵ Despite efforts to negotiate, the three pharmaceutical companies were unwilling to issue a voluntary license.¹⁰⁶ It was not until Rwanda sent notification to the TRIPS Council requesting a compulsory license that the patent holders changed their mind.¹⁰⁷ The Canadian government issued a compulsory license, and the generic manufacturer began negotiations with Rwanda.¹⁰⁸ However, this long protracted process delayed Rwanda's ability to receive the necessary drugs. While Rwanda filled its original notice of intent with TRIPS in July 2007, its first shipment of drugs from the Canadian generic manufacturer

¹⁰³ *Patents and Health: WTO Receives First Notification Under "Paragraph 6" System* (WTO Trips and Public Health, Geneva, Switzerland), July 20, 2007, http://www.wto.org/english/news_e/news07_e/public_health_july07_e.htm.

¹⁰⁴ *Id.*

¹⁰⁵ *Canada Issues Compulsory License for HIV/AIDS Drug Export to Rwanda, in First Test of WTO Procedure*, 11 BRIDGES WEEKLY TRADE DIGEST 32, Sept. 26, 2007, available at <http://ictsd.org/downloads/bridgesweekly/bridgesweekly11-32.pdf>.

¹⁰⁶ *Id.*

¹⁰⁷ *Canadian Drug Company Awarded Rwandan Contract to Provide Combination Antiretroviral*, KAISER DAILY HIV/AIDS REPORT, May 12, 2008, http://www.kaisernetwork.org/DAILY_REPORTS/rep_hiv_recent_rep.cfm?dr_cat=1&show=yes&dr_DateTime=05-12-08#52061.

¹⁰⁸ Gandhi, *supra* note 100.

was not sent until September 2008, almost fifteen months later.¹⁰⁹

While one could argue that the Canadian scheme for compulsory licensing hindered the negotiations and created the time delay, the procedural requirements of TRIPS and Article 31-bis could be equally at fault. These procedural requirements include creating detailed domestic legislation. Countries are not only nervous or unwilling to ratify the amendment, but also uncomfortable relying on compulsory licensing to ensure access to medicines.

V. THE THREAT OF INVOKING COMPULSORY LICENSES CAN MAKE PHARMACEUTICAL COMPANIES MORE WILLING TO NEGOTIATE

Even if countries are not going to issue compulsory licenses, there remains a short-term benefit in maintaining an effective compulsory licensing scheme under Article 31-bis. The mere possibility of compulsory licensing tends to strengthen the bargaining position of governments, even if it is rarely invoked. For example, Brazil has threatened to use compulsory licenses as permitted under the TRIPS Agreement.¹¹⁰ Such overtures influenced numerous pharmaceutical companies, including Abbott Laboratories, Bristol-Myers Squibb, Merck, and Roche Brazil to come to the negotiation table. Many of these companies ultimately made drastic concessions regarding the medications' costs.¹¹¹

Threats of compulsory licensing worked for Brazil during negotiations with drug companies to lower the prices of anti-AIDS drugs. It also worked for the U.S. when negotiating with Bayer for Cipro during the anthrax scare.¹¹² However, the international community should not rely on threats of compulsory licensing to provide developing countries access to medicines. There is a fundamental difference between Brazil or the United States threatening to issue a compulsory license, and a small sub-Saharan country threatening to do the same. Brazil

¹⁰⁹ Press Release from Elie Betito, Director of Public and Government Affairs, Apotex, to City/International Editors, Canadian-Made Life Saving HIV/AIDS Drug Heading to Africa (Sept. 23, 2008), available at <http://www.apotex.com/be/en/aboutapotex/sept23.asp>.

¹¹⁰ OXFAM INTERNATIONAL, PATENTS VERSUS PATIENTS: FIVE YEARS AFTER THE DOHA DECLARATION, Oxham Briefing Paper 95, 24 (November 2006), available at http://www.oxfamamerica.org/files/Doha5_Final_paper_101106_2.pdf.

¹¹¹ *Id.*; see also Jon Cohen, *Brazil: Ten Years After*, 313 SCIENCE 484,486 (2006) (“[T]he average annual cost of antiretroviral therapy in Brazil dropped from \$6240 per patient to \$1336.”).

¹¹² Dutfield, *supra* note 20, at 120.

and the United States have large populations, which constitute a large share of the pharmaceutical consumption market. Pharmaceutical companies are more willing to lose some profits in these large markets than lose all profits to a compulsory license.¹¹³ A small sub-Saharan country with far fewer consumers would not possess the same amount of bargaining power. Thus, threats of compulsory licensing are only a short-term solution for many countries in their attempts to gain access to medicines.

VI. CONCLUSION

Ultimately, there is “neither a strong experiential basis for recommending acceptance of the [Article 31-bis] Amendment, nor of declining to accept it.”¹¹⁴ Most developing countries have yet to ratify Article 31-bis, likely because they fear repercussions from developed countries, or from the pharmaceutical companies themselves.

The procedural requirements necessary to comply with Article 31-bis and the TRIPS compulsory scheme are complicated and unduly bureaucratic. At the end of the day, the purpose of the amendment is to deliver medicines to those most in need. If stringent procedural requirements make compulsory licensing unattractive as a means to obtaining medicines, then the WTO needs to go back to the drawing board and develop a new regime.

WTO General Council Char Mohamed insists that while the waiver and amendment have not been used as often as anticipated, both have still “been effective, since drug prices have fallen significantly since [they were] adopted in 2003.”¹¹⁵ While the lower drug costs may increase a developing country’s access to medicines, the WTO still needs to do more to ensure greater access. After all, the international community cannot allow intellectual property rights to interfere and “prevent [WTO] [m]embers from taking measures to protect public health.”¹¹⁶

¹¹³ Gumbel, *supra* note 19, at 177.

¹¹⁴ Abbott & Reichman, *supra* note 41, at 933.

¹¹⁵ *Society Unimpressed with Article 31-bis*, *supra* note 62.

¹¹⁶ Doha Declaration, *supra* note 1, ¶ 4.