

CAN INCENTIVES TO GENERIC MANUFACTURERS SAVE THE DOHA DECLARATION'S PARAGRAPH 6?*

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ABSTRACT

A primary objective of the Doha Declaration was to create a process for member countries with insufficient manufacturing capabilities to access generic versions of patented drugs without violating TRIPS intellectual property standards. This year marks the tenth anniversary of the process. Referred to as the “Paragraph 6 compulsory licenses provisions,” this first and only amendment to TRIPS was intended to ensure developing countries access to affordable medicines. Over the past decade, these provisions have failed to provide the gains initially anticipated. This Article explores the reasons for this failure and suggests that an under-examined approach to reaching the Doha Declaration’s goal lies in reframing the role of generic manufacturers in the Paragraph 6 process. More specifically, the current health challenges facing many developing countries call for a compulsory licensing framework that realigns legal and business incentives to encourage generic manufacturers to become primary drivers in delivering necessary medicines to developing countries through Paragraph 6 provisions. This Article proposes such a framework.

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* Selected for the 2012 ABLJ Invited Scholars Colloquium, sponsored by the American Business Law Journal. Thank you to my reviewer, Professor Robert Bird.

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I. INTRODUCTION

The effect of the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement on the generic pharmaceutical industry has always been contentious. TRIPS established a comprehensive set of global standards of intellectual property protection, including a minimum of twenty years of patent protection on pharmaceuticals.¹ This change in intellectual property rights significantly altered generic manufacturers' ability to provide WTO member countries affordable medicines. TRIPS also contained various flexibilities, including compulsory licenses, to counterbalance the adverse effect of patents on member countries' ability to access generic medicines.² Under the TRIPS compulsory license provisions, governments can disregard a patent to produce locally a low cost generic version of a patented drug.³ In practice, however, the majority of developing countries lacked the requisite domestic generic manufacturing capacity to use these provisions.⁴

Ultimately, member country dissatisfaction over the lack of access to generic medication under TRIPS resulted in the WTO adopting the Declaration on the TRIPS Agreement on Public Health (Doha Declara-

1. Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 28, 33, Apr. 15, 1994, 33 I.L.M. 1197, 1869 U.N.T.S. 299 [hereinafter TRIPS].

2. *Id.* at art. 27. Other TRIPS flexibilities include: member countries' ability to "exclude from patentability . . . diagnostic, therapeutic and surgical methods for the treatment of humans or animals . . ." and the discretion in the protection of patented products when there is concern for the "public or morality, including to protect human, animal, or plant life or health." *Id.*

3. *Id.* at art. 31 (f).

4. See Decision of the General Council, *Implementation of Paragraph of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003) [hereinafter Decision of August 30, 2003].

tion).⁵ In addition to reaffirming the validity of compulsory licenses, Paragraph 6 of the Doha Declaration tasked the TRIPS Council with finding a way for countries with insufficient or no manufacturing capabilities to gain access to generic medications through TRIPS' compulsory license provisions.⁶

The TRIPS Council responded with the Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.⁷ The decision amended the compulsory license provisions by waiving the TRIPS requirement that compulsory licenses be used "predominately for the domestic market."⁸ These Paragraph 6 provisions now enable member countries to export generic medication to countries with insufficient pharmaceutical production capabilities.⁹

Public health advocates hailed the Paragraph 6 provisions as the "solution to developing countries' most pressing medical needs"¹⁰ and a "remarkable achievement."¹¹ To date, however, only one pair of countries has utilized the Paragraph 6 provisions to manufacture and purchase generic versions of patented drugs.¹² Critics refer to the infrequent use and the lackluster results as evidence that Paragraph 6 compulsory licenses offer little to the international community in terms of meeting developing countries' health needs.¹³ Indeed, articles com-

5. See *The Doha Declaration on the TRIPS Agreement and Public Health*, http://www.who.int/medicines/areas/policy/doha_declaration/en/ (last visited Mar. 30, 2013) [hereinafter World Health].

6. World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2001) [hereinafter Doha Declaration].

7. Decision of August 30, 2003, *supra* note 4.

8. *Id.* at 2.

9. *Id.*

10. Bermudez, Jorge AZ, Maria Auxiliadora Oliveira & Gabriela Costa Chaves, *Intellectual Property in the Context of the WTO TRIPS Agreement: What is at Stake*, in INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH 23, 23-61 (2004).

11. Paul Vandoren & Jean Charles Van Eckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 J. WORLD INTELL. PROP. 779, 780 (2003).

12. *Members Ask: Is the 'Par. 6' System on Intellectual Property and Health Still Working?*, WTO 2010 News Item, WORLD TRADE ORG. (Mar. 2, 2010), http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm; *Canada's Intervention to TRIPS Council: Experience Using the System (Apotex—Rwanda Case)*, Thiru's Blog, KNOWLEDGE ECOLOGY INT'L, <http://keionline.org/node/1000>.

13. Vanessa Bradford Kerry & Kelley Lee, *TRIPS, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines*, 3 GLOBALIZATION & HEALTH 3 (2007); 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

menting on the effectiveness and continued relevance of Paragraph 6 are abundant.¹⁴ While these publications frequently mention generic manufacturers, there is an absence in the literature of a detailed analysis demonstrating how altering the role of generic manufacturers could increase the utility of the Doha Declaration's Paragraph 6 compulsory license provisions. This Article addresses that gap in the literature.

Specifically, this Article examines the functionality of compulsory licenses as authorized by Paragraph 6 of the Doha Declaration through the lens of generic manufacturers. This examination reveals that generic manufacturers are underutilized resources in the current discussion regarding the viability of Paragraph 6 compulsory licenses. Set against the current health challenges faced by Africa, this Article explores how legal and economic incentives aimed at generic manufacturers could increase the effectiveness and usage of Paragraph 6 provisions.

Two factors are motivating the urgency of refocused attention on the Doha Declaration's Paragraph 6 provisions and generic manufacturers' role in facilitating affordable access to medicines for developing countries. First, beginning in 2016, all developing countries must be TRIPS compliant.¹⁵ This means that Paragraph 6 compulsory license provisions will serve as the primary mechanism for these countries to access generic versions of patented drugs. Second, Africa and other developing countries owe much of their progress in fighting HIV/AIDS to the

ECON. L. 1, 73 (2007); Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects*, 37 J. L. MED. & ETHICS 2, 209 (2009); Cecilia Oh, *Compulsory Licenses: Recent Experiences in Developing Countries*, 1 INT'L J. INTELL. PROP. MGMT. 1, 22 (2006).

14. Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J. L. MED. & ETHICS 2, 184 (2009); 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. 4, 921 (2007); Jessica J Fayerman, *Spirit of TRIPS and the Importation of Medicines Made under Compulsory License after the August 2003 TRIPS Council Agreement*, 25 NW. J. INT'L L. & BUS. 1, 257 (2004); Reed, Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis*, 9 PLOS MED. 1, 1 (2012).

15. Council for Trade-Related Aspects of Intellectual Property Rights, *Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (July 1, 2002), available at http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm (noting that with respect to pharmaceutical products, least-developed country Members are not required to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until January 1, 2016).

availability of India's low-cost generic versions of antiretroviral medications (ARVs).¹⁶ *Medecins sans Frontieres* (MSF) notes that supply is gradually running out.¹⁷ India became TRIPS compliant in 2005.¹⁸ The newer and more effective HIV/AIDS drugs developed after 2005 are patent protected and India cannot copy them. As HIV/AIDS patients become increasingly resistant to first-line HIV/AIDS treatments, developing countries will not be able to rely on India to supply cheaper generic alternatives to second- and third-line HIV/AIDS medications patented after 2005.¹⁹ It is against this backdrop that the need for an effective compulsory framework takes on new significance.

Section I provides an overview of the compulsory licensing practices under TRIPS. Part 1 of this section describes the background of pre-TRIPS intellectual property protections. Part 2 addresses the evolution of TRIPS and discusses the Doha Declaration's Paragraph 6 provisions. Section II examines the inadequacies of the current compulsory licensing scheme by, in particular, exploring the attempts by Rwanda and Apotex, a Canadian generic manufacturer, to comply with TRIPS to deliver essential medicines under Paragraph 6. From this examination, the Article offers possible explanations for the limited use of the Paragraph 6 process by generic manufacturers and developing countries. Section III places the need for a new framework in context through examining, in Part 1, the current and future health challenges facing sub-Saharan Africa. Part 2 of this section describes necessary revisions to the existing compulsory licensing framework. These changes center on expanding legal, business, and economic incentives for generic manufacturers to participate in the Paragraph 6 process. The Article concludes that, through proper incentives, generic manufacturers are in a unique position to change the dynamics of developing countries' use of Paragraph 6 compulsory licenses to access affordable medicines.

16. Sangeet Shashikant, *More Countries Use Compulsory License, But New Problems Emerge*, TWN THIRD WORLD NETWORK (May 19, 2005), <http://www.twinside.org.sg/title2/health.info/twninfohealth004.htm>.

17. *Id.*

18. Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281 (2008).

19. Stine Jessen Haakonsson & Lisa Ann Richey, *TRIPS and Public Health: The Doha Declaration and Africa*, 25 DEV. & POL'Y REV. 71, 79 (2007).

II. OVERVIEW OF THE CONTENTIOUS RELATIONSHIP BETWEEN
INTELLECTUAL PROPERTY RIGHTS AND THE RIGHT TO HEALTH

A. *The Pre-TRIPS Landscape*

While international agreements addressing intellectual property rights date back to the late 1800s,²⁰ TRIPS is the first to extend such protections to pharmaceutical products.²¹ Even on a domestic level, prior to the creation of TRIPS, a majority of developing countries did not provide patent protection to pharmaceutical products.²² According to a 1988 WTO study, of the ninety-eight state parties to the Paris Convention for the Protection of Industrial Property, forty-nine excluded pharmaceutical products from patent protection.²³

Accordingly, prior to TRIPS, developing countries had the flexibility to construct their own solutions to acquiring essential medicines. This included the ability to discriminate against patent inventions based on field technology and to deny patent protection to pharmaceuticals.²⁴ They also had the ability to issue compulsory licenses as they saw fit regarding their scope, duration, and requirements.²⁵ Generic companies were able to enter the market and sell medicines at considerably lower prices than brand name manufacturers, while also driving prices of the patented drugs down by the competitive force they exerted in the market.²⁶

Because of these practices, the Pharmaceutical Research and Manufacturing Association (PhRMA)²⁷ and other groups lobbied the U.S. government to strengthen intellectual property protections to reduce foreign competition “free riding” on their research and develop-

20. See Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 25 Stat. 1372, 828 U.N.T.S. 305; Berne Convention for the Literary Protection of Artistic Works, Sept. 8, 1886, S. Treaty Doc. No. 99-27, 828 U.N.T.S. 221.

21. Naomi A. Bass, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 31 GEO. WASH. INT'L L. REV. 191, 191 (2002).

22. *Id.*

23. K. Balasubramaniam, *Access to Medicines and Public Policy Safeguards Under TRIPS*, in TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 135, 140 (Christophe Bellman et al. eds., 2003).

24. TRIPS, *supra* note 1, at arts. 27, 33.

25. *Id.* at art. 31.

26. Elena Ghanotakis, *How the US Interpretation of Flexibilities Inherent in TRIPS Affects Access to Medicines for Developing Countries*, 7 J. OF WORLD INTELL. PROP. 563, 565 (2004).

27. About PhRMA, PHRMA, <http://www.phrma.org/about/> (last visited June 10, 2013) (declaring that PhRMA represents the interests pharmaceutical companies devoted to innovation and strong intellectual property protections).

ment.²⁸ Chief among PhRMA's concerns was the competitive threat brand name manufacturers were facing from generic manufacturers' lower cost products.²⁹ In particular, pharmaceutical companies objected to the narrow scope and short term of patent protection in many developing countries, lack of transparency in the patent granting process, and limited legal security in respect of the enforcement of patent rights.³⁰

PhRMA achieved its goal of strengthening intellectual property protections abroad in 1995 with the creation of the TRIPS Agreement. TRIPS created a broad set of uniform intellectual property rights that all WTO member countries would be required to enforce.³¹ The Agreement and its subsequent clarifying instruments comprise the laws that define developing countries' access to medicine.

TRIPS requires all member countries to provide a minimum of twenty years patent protection to all pharmaceutical products and processes.³² The aim of this provision was to eliminate the "free riding" scenarios that flourished in countries that did not protect intellectual property rights.³³ TRIPS gave pharmaceutical patent holders the exclusive right to prevent unauthorized third parties from making, using, offering for sale, selling, or importing their drugs.³⁴ The Agreement also included a number of transitional provisions. Developing countries such as India had until January 2000 to implement the pharmaceutical provisions, while least developed countries like sub-Saharan Africa were not required to extend patent protections to pharmaceutical products until 2006.³⁵

28. Carolyn Deere-Birkbeck, *Developing Countries in the Global IP System Before TRIPS: The Political Context for the TRIPS Negotiations*, in RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES 22, 39 (Carlos M. Correa ed., 2010).

29. Carlos M. Correa, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (Robert Howse ed., 2007).

30. See INTELLECTUAL PROPERTY COMMITTEE, BASIC FRAMEWORK OF GATT PROVISIONS ON INTELLECTUAL PROPERTY: STATEMENT OF THE VIEWS OF THE EUROPEAN, JAPANESE AND UNITED STATES BUSINESS COMMUNITIES 31-40 (June 1988). The Intellectual Property Committee also raised concerns about safety risks associated with imitations of some products. *Id.*

31. TRIPS, *supra* note 1, at art. 7.

32. *Id.* at art. 27 (1).

33. *Id.* at pmb1.

34. *Id.*

35. DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 27 (2003); *Frequently Asked Questions about TRIPS*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#Transition (last visited June 12, 2013) (noting that WTO "developing country" status is based on self-identification and includes most countries classified as low or upper-middle income by the World Bank).

The WTO further obligated all member countries, regardless of their level of development, to apply these same TRIPS standards to their domestic laws.³⁶ The United States' objective of ensuring that countries uniformly enforced intellectual property rights is evident throughout the TRIPS provisions. For example, any country wishing to conduct international trade through the WTO must adhere to all the Agreement's intellectual property requirements.³⁷ In exchange, member countries have access to global markets and the free movement of technology and innovation in an environment that ensures the uniform protection and enforcement of intellectual property rights.³⁸

Within this broad Agreement, TRIPS also acknowledges the need to "promote access to medicines for all" and includes provisions that explicitly outline the extent of intellectual property rights in public health.³⁹ Article 8 permits member countries to "adopt measures necessary to protect public health and nutrition, and promote public interest in sectors of vital interest to their socioeconomic and technological development," provided that such measures are consistent with the provisions of the Agreement.⁴⁰ In other words, TRIPS recognizes that public health problems may exist and includes "flexibilities" that members can use to address those problems.⁴¹ One such flexibility is the compulsory license mechanism contained in Article 31.

1. Compulsory License Protections

A compulsory license enables a government or authorized third party to manufacture a patented product without the permission of the right's holder.⁴² In the context of access to medicines, a compulsory license allows a developing country's government to legally suppress a patent as a means of making medicines more affordable in its country.⁴³ Because these provisions allow a country to bypass the exclusive rights of the patent holder, Article 31 outlines restrictive conditions

36. TRIPS, *supra* note 1, at art. 1, ¶ 1.

37. While the obligations to comply with TRIPS apply equally to all members, developing countries were given a transitional period to come into compliance. *See id.* at art. 65; *see also Overview: the TRIPS Agreement*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited June 4, 2010).

38. *Id.*

39. TRIPS, *supra* note 1, at art. 8.

40. *Id.*

41. *Id.*

42. *Id.* at art. 31(b).

43. *Id.*; *see also* Matthews, *supra* note 13, at 77.

that must be satisfied before granting a compulsory license.⁴⁴ The most troubling restriction confines a country's authority to issue compulsory licenses to situations "predominantly for the supply of the domestic market of the member authorizing such use."⁴⁵

The intent of Article 31's compulsory license provision was to provide poorer and less developed countries a mechanism to gain access to low cost generic medicines.⁴⁶ In practice, it did not. Due to the Article's "domestic use" restriction, a country could only issue a compulsory license to a domestic manufacturer.⁴⁷ This essentially made compulsory licenses useless to a country that lacked the pharmaceutical infrastructure to manufacture the generics within its own borders.⁴⁸ At the time, only about a dozen countries, among them China, India, Brazil, Argentina, and South Africa, had a functional domestic pharmaceutical sector capable of producing significant quantities of generic drugs.⁴⁹

Article 31's domestic use requirement inadvertently magnified the unnecessary supply and demand problem created by TRIPS. WTO countries were prohibited from issuing compulsory licenses to supply low cost generic medicines to other member countries afflicted with grave public health problems.⁵⁰ Countries with insufficient or no manufacturing capabilities were also prevented from issuing compulsory licenses because they lacked domestically available manufacturers capable of producing the needed generics.⁵¹ Accordingly, these member countries' demand for vital medicines went unmet.⁵²

44. TRIPS, *supra* note 1, at art. 31(b).

45. *Id.*

46. James Packard Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, KNOWLEDGE ECOLOGY INT'L (2007), available at http://www.keionline.org/misc-docs/recent_cls.pdf.

47. *Id.*

48. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the EC and Their Member States to the TRIPS Council: Concept Paper Relating to Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health*, IP/C/W/339 (Mar. 4, 2002).

49. General Council, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Sep. 1, 2003), available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

50. TRIPS, *supra* note 1, at art. 31.

51. Hoachen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT'L L.J. 101, 110-11 (2003).

52. *Id.*

2. Doha Declaration's Paragraph 6 Provisions

History would suggest that developing countries had little chance of convincing the WTO to revise the one-sided nature of the TRIPS Agreement. Prior to TRIPS, no international agreement had been modified in response to humanitarian and ethical pressures. However, the HIV/AIDS epidemic highlighted the inflexibilities of the TRIPS provisions.⁵³ The entire world took note of developing countries' inability to use compulsory licenses to access affordable medicines to combat the deadly disease.⁵⁴

In 1999, approximately 2.3 million South Africans carried the HIV virus,⁵⁵ and approximately 600 people were dying from AIDS each day.⁵⁶ For years, pharmaceutical manufacturers held discussions with South Africa and other African countries regarding the sale of lower priced pharmaceuticals.⁵⁷ By January 2001, South Africa still had not reached an agreement with the pharmaceutical drug companies.⁵⁸

In February 2001, Cipla, an Indian generic drug manufacturer, offered to supply a triple-therapy AIDS drug cocktail for \$350 per year to MSF, a nonprofit medical group.⁵⁹ During this same period, Cipla also began offering African countries ARV treatments at prices far below the rates of their brand name competitors.⁶⁰ While the South African government was considering acquiring the necessary medication through the compulsory license process, Cipla asked the South African government to grant the company compulsory licenses to make and sell eight different drugs that were currently protected by patents.⁶¹ Acting under the South African Medicines and Related Sub-

53. Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, AM. U. INT'L L. REV. 15, 941 (1999).

54. *Id.*

55. Verity Murphy, *Mbeki Stirs Up Considerable Aids Controversy*, BBC NEWS (Sept. 26, 2003), <http://news.bbc.co.uk/2/hi/africa/3143850.stm>; *Access to Essential Medicines in the Age of HIV, Equal Treatment*, MAGAZINE OF THE TREATMENT ACTION CAMPAIGN, June 2010, at 14, available at <http://www.tac.org.za/community/files/file/etmag/ET33/ET33English.pdf>.

56. David Allen, *Epidemiology of HIV/Aids in South Africa*, S. AFR. J. HIV MED., July 2000, available at www.ajol.info/index.php/sajhivm/article/download/28212.

57. John S. James, *South Africa: Historic "Defiance Campaign" Imports Generic Fluconazole*, THE BODY: THE COMPLETE HIV/AIDS RESOURCE (Oct. 20, 2000), available at <http://www.thebody.com/content/art32050.html>.

58. *Id.*

59. *Id.*

60. Charles Miller & Kenneth Goldman, *Merck, AIDS, and Africa*, in TRIPS AND PHARMACEUTICAL INDUSTRY: IMPACT ON DEVELOPING COUNTRIES 86, 88 (Manish Ashiya ed., 2007).

61. *Id.* at 88-89.

stance Control Amendment Act (South African Medicines Act), which empowered the Minister of Health to issue compulsory licenses during health emergencies, the Minister granted Cipla's request.⁶²

Prior to executing the deal, thirty-nine pharmaceutical manufacturers filed suit against the South African government.⁶³ The patent owners of the HIV/AIDS drugs, primarily United States and European pharmaceutical companies, claimed that the South African Medicines Act violated the TRIPS Agreement.⁶⁴ Because of the international public outcry over the lawsuit, the pharmaceutical companies eventually dropped their suit.⁶⁵ The debate within the international community regarding the TRIPS Agreement and countries' access to medicines had reached a fevered pitch.⁶⁶

At the request of the African group of countries, the TRIPS Council held a special discussion on intellectual property rights and access to medicines.⁶⁷ Developing countries sought assurance that TRIPS would not prohibit members from adopting measures necessary to ensure access to medicines and to satisfy other public health needs.⁶⁸ Because of the lawsuit against South Africa, developing countries also wanted a WTO declaration that clarified provisions and protections afforded under TRIPS.⁶⁹

In response to these concerns, in November 2001, the WTO Ministerial Conference met in Doha, Qatar, and adopted the Declaration on

62. Bass, *supra* note 21.

63. Miller & Goldman, *supra* note 60, at 91.

64. PATRICK LUMUMBA OSEWE, YVONNE KORKOI NKURUMAH & EMMANUEL K. SACKLEY, IMPROVING ACCESS TO HIV/AIDS MEDICINES IN AFRICA: ASSESSMENT OF TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) FLEXIBILITIES UTILIZATION 2-4 (2008).

65. *Id.*

66. See Miller & Goldman, *supra* note 60, at 90.

67. TRIPS Council, *Governments Share Interpretations on TRIPS and Public Health*, WORLD TRADE ORG., http://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm (last visited June 10, 2013).

68. See WORLD HEALTH ORGANIZATION, GLOBALIZATION, PATENTS AND DRUGS—AN ANNOTATED BIBLIOGRAPHY (2001); United Nations Conference on Trade and Development, 1996, *The TRIPS Agreement and Developing Countries*, UNCTAD/ITE/1 (1997).

69. The African Group and the EU submitted papers to the TRIPS Council. See Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the European Communities and their Member States: The Relationship Between the Provisions of the TRIP Agreement and Access to Medicines*, IP/C/W/280 (Jun. 12, 2001); Council for Trade-Related Aspects of Intellectual Property Rights, *TRIPS and Public Health: Submission by the African Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela*, IP/C/W/296 (Jun. 19, 2001).

the TRIPS Agreement and Public Health.⁷⁰ In what became referred to as the “Doha Declaration,” the WTO affirmed that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”⁷¹ The Doha Declaration solidified the right of member states to use compulsory licenses to obtain generic drugs in response to health needs.⁷² The WTO also extended the transitional period for developing countries to implement the TRIPS pharmaceutical patent provisions to 2016.⁷³

In addition to reiterating TRIPS’ goal of promoting the availability of medicines, the WTO conceded the ineffectiveness of Article 31.⁷⁴ Specifically, the Doha Declaration acknowledges that “WTO members with insufficient or no manufacturing capabilities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”⁷⁵ The WTO also admitted that other pre-compulsory license requirements hampered developing countries’ ability to use the process.⁷⁶ Finally, the Declaration called for an “expeditious solution” to ensure countries without domestic pharmaceutical production abilities can make use of compulsory licensing for affordable generics of patented pharmaceuticals.⁷⁷

After two years of vigorous debate, the WTO General Council issued a decision that specifically addressed Article 31’s domestic use restrictions.⁷⁸ The WTO’s 2003 Decision is commonly referred to as the “Paragraph 6 provisions.”⁷⁹ In pertinent part, Paragraph 6 contains two waivers to TRIPS’ Article 31. The first eliminates the “domestic use” provisions under Article 31(f).⁸⁰ Accordingly, countries can now import needed generic drugs from any manufacturing nation.⁸¹ The second waiver provides that member countries can now export generic

70. Doha Declaration, *supra* note 6.

71. *Id.* ¶ 4.

72. *Id.*

73. *Id.* ¶¶ 4, 6.

74. *Id.*

75. *Id.* ¶ 6.

76. TRIPS, *supra* note 1, at art. 31(b), (h).

77. Doha Declaration, *supra* note 6, ¶ 6.

78. Decision of August 30, 2003, *supra* note 4.

79. Doha Declaration, *supra* note 6, ¶ 6.

80. *Id.*

81. WTO General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1 ¶ 2 (Aug. 30, 2003) [hereinafter WTO General Council].

pharmaceutical products made under compulsory licenses to meet the needs of importing countries subject to certain conditions.⁸²

While these increased flexibilities are significant, it is worth noting that the Paragraph 6 provisions were adopted as an interim modification to the TRIPS Agreement.⁸³ In nearly ten years since the Decision, the Paragraph 6 Amendments have failed to garner the requisite approval of two-thirds of WTO members to become permanent.⁸⁴ In addition, only two countries, as a pair, have used the Paragraph 6 compulsory license process.⁸⁵

III. ASSESSING THE DOHA DECLARATION'S PARAGRAPH 6 COMPULSORY LICENSING EFFECTIVENESS: RWANDA AND CANADA

Rwanda and Canada are the only pair of countries that have successfully used the Paragraph 6 compulsory licensing process to import and export generic drugs.⁸⁶ The AIDS epidemic had taken a toll on the health and economy of Rwanda.⁸⁷ In 2007, there were approximately 150,000 people living with HIV in Rwanda.⁸⁸ Between the ages of fifteen and forty-nine, 2.8% of the population had AIDS.⁸⁹ The majority of Rwandans lived (and still live) below the poverty line, earning approximately 250 Rwandan francs per day, which amounts to approximately \$157 per year or \$0.43 per day.⁹⁰ At the time, the cost of generic ARV treatment ranged from \$88 to \$261 per year.⁹¹ In contrast, brand

82. *Id.* ¶ 6.

83. *Id.* ¶ 11.

84. Intellectual Property: TRIPS and Public Health, World Trade Organization, Members Accepting Amendment of the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Mar. 30, 2012) [hereinafter WTO Members Accepting Amendment].

85. John Boscariol, *Canada is First to Grant WTO Compulsory License for Export of Generic Drug*, MONDAQ BUS. BRIEFING, Apr. 17, 2008, available at <http://mondaq-business.vlex.com/vid/wto-compulsory-licence-export-generic-55260128>.

86. Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37 J.L. MED. & ETHICS 222 (2009).

87. Ruth Kornfield et al., *Living with AIDS in Rwanda: A Study in Three Provinces*, JOHNS HOPKINS UNIV. CTR. FOR COMM'C'N PROGRAMS (2002), available at <http://www.jhuccp.org/sites/all/files/Living-w-AIDS%20in%20Rwanda-2002.pdf>.

88. U.S. Dept. of Health and Human Services, *How HIV Causes AIDS*, NIAID Fact Sheet (2004).

89. *Id.*

90. *Rwanda—2007*, CIA World Factbook, GEOGRAPHIC.ORG, <http://www.allcountries.org/wfb2007/rwanda/index.html> (last visited Jun. 13, 2013).

91. *Id.*

name ARV treatments cost approximately \$10,000 per year or more.⁹² In April 2007, Rwanda notified the WTO of its intent to use Paragraph 6 compulsory license provisions.⁹³ In doing so, Rwanda's government hoped it had found an affordable way to bring needed drugs to Rwandans suffering from HIV/AIDS.

Prior to exporting medications using compulsory license provisions, countries, and their generic manufacturers, must comply with the Paragraph 6 provisions. The generic manufacturer can only manufacture the amount necessary to meet the needs of the importing country.⁹⁴ That entire amount must then ship to the importing country.⁹⁵ The packaging must clearly specify that the drugs have been produced under the Paragraph 6 provisions.⁹⁶ Prior to shipment, the exporting country must post the quantity of drugs supplied and distinguishing features of the product on a publicly available website.⁹⁷ In addition, the exporting country must provide adequate remuneration to the patent holder, "taking into account the economic value to the importing [m]ember."⁹⁸

Canada was one of the first countries to enact legislation for the sole purpose of exporting generic drugs to developing countries using the Paragraph 6 compulsory licensing provisions.⁹⁹ According to the Canadian government, the goal of Canada's Access to Medicines Regime (CAMR) was to "provide a way for the world's developing and least developed countries to import high quality drugs and medical devices at a lower cost to treat the diseases that bring suffering to their citizens."¹⁰⁰ In addition, CAMR sought "to allow generic manufacturers to produce and export medication to developing countries."¹⁰¹

92. Ian F. Ferguson, *The WTO Intellectual Property Rights in the Access to Medicines Controversy, in TRIPS AND PHARMACEUTICAL INDUSTRY: IMPACT ON DEVELOPING COUNTRIES* 26, 28 (Manish Ashiya ed., 2007).

93. Holger P. Hestermeyer, *Canadian-Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, 11 ASIL INSIGHTS 28 (2007), available at <http://www.asil.org/insights071210.cfm>.

94. Doha Declaration, *supra* note 6, ¶ 2(b)(i).

95. *Id.*

96. *Id.*

97. *Id.* ¶ 2(b)(ii)-(iii).

98. *Id.* ¶ 3.

99. Christina Cotter, *The Implication of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 LOY. U. CHI. INT'L. L. REV. 177, 185-86 (2008).

100. *Welcome, CANADA'S ACCESS TO MEDICINES REGIME*, <http://www.camr-rcam.gc.ca/index-eng.php> (2007).

101. *Introduction, CANADA'S ACCESS TO MEDICINES REGIME*, <http://www.camr-rcam.gc.ca/intro/index-eng.php> (2007).

Notwithstanding CAMR's laudable objectives, Canada forced generic manufacturers to undergo additional time-consuming requirements not included in TRIPS.¹⁰² For example, before the Canadian government will issue a compulsory license, the generic manufacturer must negotiate for a voluntary license from the patent holder.¹⁰³ Specifically, CAMR requires generic manufacturers to provide:

a solemn or statutory declaration . . . that the applicant had, at least 30 days before filing the application [for a compulsory license], sought from the patentee or, if there is more than one, from each of the patentees . . . a [license] to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful.¹⁰⁴

CAMR does not provide any guidance regarding how long a generic manufacturer must negotiate with the patent holder. Similarly, CAMR is silent as to what constitutes "reasonable terms and conditions" or reasonable negotiation efforts.¹⁰⁵ The practical effect of the voluntary license requirement is that it allows pharmaceutical patent holders to stop the process at any time by making the mere offer to negotiate.¹⁰⁶

Next, the generic manufacturer must obtain a compulsory license release from the Canadian Commissioner of Patents.¹⁰⁷ After receipt of the release, the generic manufacturer can formally begin the bidding process with the government of the importing country.¹⁰⁸ Once authorized, CAMR contains additional non-TRIPS-specified measures that the generic manufacturer must take. For example, the generic manufac-

102. Richard Elliott, *Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export*, 1 INT'L J. INTELL. PROP. MGMT. 94, 109 (2006) (noting that one of "the chief defect[s] of Canada's law on compulsory licensing of pharmaceuticals for export [is that] . . . [i]t contains some TRIPS-plus features that undermine its functionality").

103. Canada's Access to Medicines Regime, R.S.C. 1985, c. P-4, § 21.04(3) (b).

104. *Id.* § 21.04(3)

105. George Tsai, *Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes Under the WTO DOHA Declaration*, 49 VA. J. INT'L. L. 1063, 1082 (2009).

106. Tanya Talaga, *AIDS Drugs Fiasco a Tale of Red Tape: Generic Pills Could Finally Reach African Patients After Years Lost While Canadian Officials Squabbled*, THE TORONTO STAR (Aug. 9, 2007), <http://www.thestar.com/news/canada/article/244582—aids-drugs-fiasco-a-tale-of-red-tape>.

107. Canada's Access to Medicines Regime, R.S.C. 1985, c. P-4, § 21.04(3) (b).

108. *Requirements for Companies*, CANADA'S ACCESS TO MEDICINES REGIME, <http://www.camr-cam.gc.ca/compan-entrepris/req-exig/index-eng.php> (last visited June 14, 2009).

turer must provide the WTO a certified copy of compliance addressing the quantity and type of pharmaceutical and proof of the importing country's insufficient manufacturing capacity.¹⁰⁹ Generic manufacturers bear the responsibility of maintaining a dedicated website that discloses the generic product information.¹¹⁰ The exporting generic manufacturer is also obligated to issue an export notice to every exporting party that will be handling the generic product.¹¹¹ Canadian law does not require regulatory approval for exporting any other pharmaceuticals.¹¹²

In addition to imposing extra costs on the exporting manufacturer, CAMR also limits what a manufacturer can charge for the generic drug.¹¹³ The Good Faith Clause prohibits a generic manufacturer from charging more than twenty-five percent of the average price of an equivalent drug in Canada.¹¹⁴ Should a generic manufacturer violate this requirement, the Federal Court has the authority to revoke the compulsory license.¹¹⁵ In addition to paying the existing royalty, the generic manufacturer is required to pay "an amount that the federal court considers adequate to compensate the patentee for commercial use of the patent."¹¹⁶

In 2004, the Toronto-based generic drug manufacturer Apotex, Inc. began development of a fixed dose combination of three HIV/AIDS antiretroviral drugs.¹¹⁷ In 2007, Apotex sought to obtain a voluntary license from the brand name manufacturers GlaxoSmithKline, Shire, and Boehringer Ingelheim, each of which owned patents on the three components of the triple dose, antiviral AIDS drug known as Apo-TriAvir.¹¹⁸ Apotex informed each of the manufacturers of the amount of drugs it sought to use for export and the price (\$0.40 U.S.

109. Canada's Access to Medicines Regime, R.S.C. 1985, c. P-4, § 21.04(3) (d) (iii).

110. *Id.* § 21.06

111. *Id.* § 21.07.

112. Richard Elliott, *Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export*, 1 INT'L J. INTELL. PROP. MGMT., 94, 107 (2006).

113. Canada's Access to Medicines Regime, R.S.C. 1985, c. P-4, § 21.17(1).

114. Jillian C. Cohen-Kohler, Laura C. Esmail & Andre Perez Cosio, *Canada's Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?*, GLOBALIZATION & HEALTH (2007) <http://www.globalizationandhealth.com/content/3/1/12>.

115. Canada's Access to Medicines Regime, R.S.C. 1985, c. P-4, § 21.17(3).

116. *Id.* This process is triggered when the patentee applies to the Federal Court for an order stating the generic manufacturer's price of the drug (to the extent that it exceeds twenty-five percent) essentially makes the agreement commercial in nature. *Id.* § 21.17(1).

117. Hestermeyer, *supra* note 93.

118. Cohen-Kohler, *supra* note 114, at 2.

per tablet).¹¹⁹ During negotiations, Apotex also indicated that for humanitarian reasons it was supplying the drug at no profit.¹²⁰ The brand name manufacturers refused to give Apotex a voluntary license.¹²¹ It was only after Rwanda notified the WTO about the stalled negotiations that the companies relented and consented to the use of their patented drugs.¹²² Elie Betito, Director of Public and Government Affairs for Apotex, commented on this frustrating CAMR requirement when he remarked, “nothing will be final until the drugs are delivered, in that patent holding companies can still withdraw permission for the sale to take place even on the day we are shipping.”¹²³

Later that year, the Canadian Commissioner of Patents granted Apotex a compulsory license. The duration of the license was limited to two years, and to the production quantity of 15,600,000 tablets.¹²⁴ Less than two weeks later, Canada notified the WTO of its intent to export medicines using the Paragraph 6 process.¹²⁵ After fulfilling the requirements of both CAMR and TRIPS, Apotex was able to begin negotiating with Rwanda.¹²⁶

In May 2008, nearly a year after announcing its intent to import generic ARVs, Rwanda was finally able to accept Apotex’s bid. Rwanda received two shipments of the drug in September 2008 and 2009.¹²⁷ To ensure the second delivery, CAMR required Apotex to file an application for renewal of the compulsory license in 2009.¹²⁸ Although

119. Cynthia Ho, *Complicated Compulsory Licenses: The Waiver/Article 31 bis “Solution” Access to Medicine*, in THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 215 (2011).

120. Jack Kay, *The Apotex Experience with the Canada’s Access to Medicines Regime*, Canadian House of Commons, Standing Committee on Industry, Science and Technology, 39th Parliament of Canada, 23, 1-27 (Apr. 2007).

121. Press Release, Apotex, *Life Saving AIDS Drug for Africa Gets Final Clearance* (Sept. 20, 2007), available at <http://www.apotex.com/PressReleases/20070920-01.asp>.

122. Cotter, *supra* note 99, at 186.

123. *Canadian Drug Company Awarded Rwandan Contract to Provide Combination Antiretroviral*, KAISER HEALTH NEWS (May 12, 2008), available at <http://www.kaiserhealthnews.org/Daily-Reports/2008/May/12/dr00052071.aspx?p=1>.

124. Beatrice Stirner & Harry Thangaraj, *Learning from Practice: Compulsory Licensing Cases and Access to Medicines*, 2 PHARM. PAT. ANALYST 195 (2013).

125. Tsai, *supra* note 105, at 1079.

126. Jessica L. Greenbaum, *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, 146-147, 159 (2008).

127. *First Generic Drugs En Route to Africa under 5-Year-Old WTO Deal*, 12 BRIDGES WKLY. TRACE NEWS DIG. (ICTSD) Sept. 25, 2008, at 5.

128. Stirner, *supra* note 124, at 199.

Rwanda and Apotex hoped the process would afford the efficient delivery of life saving generics, it proved a time-consuming and cumbersome experience.

Ironically, while the parties struggled through the ponderous TRIPS and CAMR requirements, Cipla, a generic Indian company, approached the Rwandan government.¹²⁹ Cipla had the generic ARV available for immediate delivery at \$0.26 per tablet savings.¹³⁰ Not only was the drug cheaper, Rwanda could import it without triggering the TRIPS complexities.¹³¹ No additional exports have occurred under the CAMR procedure.¹³²

Apotex has noted that the CAMR is too complicated and that developing countries have problems identifying the proper process to obtain import permission.¹³³ Essentially, the manufacturer stated that it is not advantageous for developing countries to “jump through the hoops imposed by CAMR.”¹³⁴ For example, the compulsory license to export under CAMR is only valid for two years, and the renewal process is available only to complete the original amount of medications authorized by the compulsory license.¹³⁵ The renewal mechanism is not available to deliver additional quantities.¹³⁶ If an importing country identifies additional need, both the generic manufacturer and the importing country have to initiate a new CAMR process, including such steps as notifying the WTO regarding the intention to use the system and undertaking negotiations with the patent holding company for a

129. Hestermeyer, *supra* note 93.

130. *Id.*

131. Elie Betito, *CAMR Federal Law Needs to be Fixed if Life-Saving Drugs for Children are to be Developed*, APOTEX (May 14, 2009), available at <http://www.apotex.com/global/about/press/20090514.asp> (stating that “in its current form it’s not workable for us,” but noting an interest in developing generic HIV treatments for children if the Canadian law were simplified).

132. *Id.* As discussed in Section II.B, India was not required to comply with TRIPS provisions until 2006. As a result, India had produced generic versions of many ARVs and was making them available to least developed countries at lower prices. While this avenue to access pharmaceuticals was always available to Rwanda, the hope was that the compulsory license process would work just as well, if not better. In addition, this process could ensure continued access to necessary generics after India became TRIPS compliant. *See supra* § II.B.

133. Letter from John Hems, Dir., Can.’s Access to Medicines Regime, to Douglas Clark & Brigitte Zirger, Dirs., Apotex Inc. (Jan. 23, 2007), available at http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_msf_11-eng.pdf.

134. Press Release, Apotex Inc., Second Shipment of Life-Saving AIDS Drugs Leaving for Africa (Sept. 18, 2009), available at <http://www.apotex.com/global/about/press/20090918.asp>.

135. Stirner, *supra* note 124, at 200.

136. *Id.*

voluntary license.¹³⁷ In this case, Rwanda wanted to double the order. However, because of the CAMR requirements there was no efficient way for the generic manufacturer to deliver that order. The limitation on the quantities of drugs that can be manufactured and exported under CAMR majorly constrains generic manufacturers from reaching economies of scale for medicine production.¹³⁸ Exporting a specific number of drugs to one country for a limited time makes it difficult to recoup the investments in research and development, legal costs, and expenditures required by the CAMR process.¹³⁹

Outside of Apotex, other Canadian generic manufacturers have found the legislation to be overly complex and unusable. They point to the lack of input in the legislative process from the governments of developing countries as one of the main problems.¹⁴⁰ For example, the CAMR provisions consist of over nineteen sections and 100 subsections.¹⁴¹ To read, interpret, and comply with these provisions entails significant legal costs.¹⁴² Developing countries are typically lacking in these resources.¹⁴³

IV. THE NEED FOR A NEW FRAMEWORK

In its current form, generic manufacturers have had little incentive to serve as Paragraph 6 exporters. Transactional and economic burdens have rendered TRIPS compulsory licensing an unattractive business alternative for generic manufacturers.¹⁴⁴ Sources of generic ARVs and other drugs, however, are diminishing over time.¹⁴⁵ The 2016 deadline by which all countries must become TRIPS compliant is steadily approaching.¹⁴⁶ Within a decade, the Doha Declaration's

137. *Id.*

138. Senate of Canada Standing Senate Committee on Banking Trade and Commerce, 40th Parliament, No. 11, second and third meetings, 1-76, Oct. 22, 2009.

139. *Id.*

140. Marilyn McHarg, MEDECINS SANS FRONTIERES CAN., *Review of the Canadian Access to Medicines Regime: Submission to the Government of Canada* (Jan. 24, 2007), available at http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_msf_11-eng.pdf.

141. Canada's Access to Medicines Regime, R.S.C. 1985, c. P-4.

142. *Id.*

143. McHarg, *supra* note 140.

144. Stirner, *supra* note 124.

145. *Id.*

146. UNAID, *Implementation of TRIPS and Access to Medicine for HIV After January 2016: Strategies and Options for Least Developed Countries* (2011) available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf.

Paragraph 6 may be the only available mechanism for Africa and developing countries with insufficient manufacturing capabilities to obtain necessary medicines at competitive pricing. Simply put, these eventualities call for a renewed focus on Paragraph 6.

A. *Africa's Changing Health Needs*

Sub-Saharan Africa continues to be at the epicenter of the AIDS epidemic, with 22.5 million out of the 33 million people worldwide with HIV living in the region.¹⁴⁷ In terms of treatment, the region uses four times more ARVs than the rest of the world combined.¹⁴⁸ Yet sixty-six percent (approximately 6,700,000) of the people in sub-Saharan Africa who need ARVs do not receive treatment.¹⁴⁹ Further, until the progress we have seen in curing AIDS becomes readily available, the 2,925,000 people on ARVs can expect to depend on the treatment for the rest of their lives.¹⁵⁰ Moreover, a large number of these patients will develop drug resistance or side effects that require them to switch from first-line treatment to second-line treatment combinations.¹⁵¹

According to one study, almost twenty-two percent of people in treatment transition to second-line treatment within a five-year period.¹⁵² The second-line combinations for AIDS currently remain substantially more expensive than the first-line combinations.¹⁵³ MSF indicates that second-line combinations probably will not decrease ninety-nine percent in price like their first-line counterparts.¹⁵⁴ Indeed, the second-line combinations can cost up to eleven times as much as first-line treatments.¹⁵⁵ These second-line treatments and other patented treatments have increased the relevance of the Paragraph 6 provisions as a viable option in obtaining large quantities of medicine at a competitive price. Adding to this urgency is Africa's

147. Olulomire Ogunye, Will Smith, Natalie Hays Stewart & Kuna Malik Hamad, *AIDS, Africa, and ARVs: Domestic Production as the Solution to the Treatment Gap*, GLOBAL CHALLENGES: SCI. & SOC'Y (2009).

148. World Health Organization, Joint United Nations Programme on HIV/AIDS & UNICEF, *Towards Universal Access: Scaling up Priority HIV/AIDS Interventions in the Health Sector: Progress Report (2009)*.

149. *Id.*

150. *Id.* at 68.

151. *Id.*

152. Kankkaram Satyanarayana & Sadhana Srivastava, *Patent Pooling for Promoting Access to Antiretroviral Drugs (ARVs)—A Strategic Option for India*, 4 THE OPEN AIDS J. 41, 43 (2010).

153. Shashikant, *supra* note 17.

154. Satyanarayana & Srivastava, *supra* note 152, at 41-53.

155. *Id.*

inability to rely on India for generic versions of patented medicines produced after 2005.

B. *India's Effect on Africa's Access to Medicine*

Throughout the AIDS epidemic, India has played a vital role in providing affordable generic medicines to Africa.¹⁵⁶ By the late twentieth century, India was one of the largest suppliers of generic medications in the world.¹⁵⁷ From 1970 to 1995, Indian intellectual property law recognized only patents on processes, not actual pharmaceutical compounds.¹⁵⁸ As such, generic manufacturers could reverse-engineer pharmaceutical products for export to nations where there was no domestic pharmaceutical patent bar.¹⁵⁹ As the “pharmacy to the developing world”¹⁶⁰ from 2005 to 2006, Indian exports comprised approximately forty percent of the total pharmaceutical industry production.¹⁶¹ Roughly half of all people in the developing world who receive ARV treatment use products produced in India.¹⁶² Moreover, MSF uses ARVs manufactured by Indian generic companies to treat seventy percent of the people in the organization’s HIV/AIDS project.¹⁶³

ARV prices reflect the significant effect of India’s generic manufacturers on the affordability of drugs. In 2000, the lowest global price for first-line combination of stavudine, lamivudine, and nevirapine was

156. Pooja Van Dyck, *Importing Western-style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on AIDS Treatment in Africa*, 6 NWNW. J. TECH & INTEL. PROP. 138, 141 (2007).

157. Press Release, World Health Organization, New HIV Recommendations to Improve Health, Reduce Infection and Save Lives, World AIDS DAY (Nov. 30 2009), available at http://www.who.int/mediacentre/news/releases/2009/world_aids_20091130/en/index.html.

158. Brook K. Baker, *Arthritic Flexibilities: 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, 658 (2004).

159. SUDIP CHAUDHURI, *THE WTO AND INDIA’S PHARMACEUTICAL INDUSTRY, PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES* 1, 52 (2005).

160. Sonja Babovic & Wasan M. Kishor, *Impact of the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement on India as a Supplier of Generic Antiretrovirals*, 100 100 J. PHARM. SCI. 816, 817 (2011).

161. William Green, *The Emergence of India’s Pharmaceutical Industry and Implications for the US Generic Drug Market* (U.S. Office of Economics Working Paper No. 2007-05-A), www.usitc.gov/publications/332/working_papers/EC200705A.pdf.

162. Médecins Sans Frontières, *MSF Prognosis: Short-term Relief, Long-term Pain* (2005), available at <http://www.doctorswithoutborders.org/publications/article.cfm?id=1504&cat=ideas-opinions>.

163. Babovic & Kishor, *supra* note 160, at 817.

\$10,439 a year.¹⁶⁴ Paying this amount was, and is, completely out of reach for the majority of patients living in the developing world.¹⁶⁵ In 2001, MSF negotiated a price of \$350 with the Indian generic manufacturer Cipla, which represented a thirty-fold price reduction.¹⁶⁶ By 2008, competition led by Indian generic manufacturers resulted in the price dropping to eighty-seven dollars a year.¹⁶⁷ A 2009 WHO study indicates that this affordably priced ARV is still the most common first-line therapy.¹⁶⁸ This price differential has made a significant impact in saving lives.¹⁶⁹

In 2005, India completed updating its domestic patent laws to comply with TRIPS requirements.¹⁷⁰ One impact of these changes is that Indian pharmaceutical companies now have a more narrow range of medicines that they may produce legally as generics.¹⁷¹ In particular, it is illegal for manufacturers to produce generic versions of second- and third-generation HIV/AIDS drugs patented after 2005.¹⁷² The role that Indian pharmaceutical companies have played since 1995, as the primary exporter of needed HIV/AIDS medicine, has changed.¹⁷³

Consequently, while India has lowered the cost of first-line ARVs, the changing AIDS landscape requires different and oftentimes patented medical approaches. For example, ARVs to treat HIV are a relatively new class of medications and still under patent in many of the countries with the manufacturing capacity to produce them.¹⁷⁴ While patents for selected older ARVs have expired, patents on newer second-line medications will expire as late as 2023.¹⁷⁵ Further complicating this scenario is that patients taking the most common first-line therapy require

164. Médecins Sans Frontières, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS (2009), utw.msfacecess.org/downloads/31 [hereinafter MSF UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS].

165. *Id.*

166. *Id.*

167. Babovic & Kishor, *supra* note 160, at 816-18.

168. MSF UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS, *supra* note 164, at 5.

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.*

173. Stirner, *supra* note 124, at 203-07.

174. Babovic & Kishor, *supra* note 160, at 816.

175. *Background Information on FDA Approved HIV/AIDS Drugs*, CONSUMER PROJECT ON TECHNOLOGY (now operating under a new name: Knowledge Ecology International), available at www.cptech.org/ip/health/sa/loveaffidavit/table11.doc; Satyanrayana & Srivastava, *supra* note 152, at 41-53.

second-line treatment after twelve months.¹⁷⁶ The WHO also found health risks associated with ofvudine, a component in a widely used stavudine-based ARV.¹⁷⁷ Because of these findings, the WHO recommended that countries phase out the use of stavudine as a first-line treatment.¹⁷⁸

Since India became TRIPS-compliant, many Indian firms have pursued business strategies to change from primarily generic to innovative companies to survive in the new environment.¹⁷⁹ This shift in focus could have an adverse effect on the availability of generic drugs. If Indian pharmaceutical companies decide to court American and European investors, they may choose not to risk tarnishing their image by applying for compulsory licenses.¹⁸⁰

India's negotiations with the European Union are further indication that the now-TRIPS-complaint country may change its pharmaceutical regulatory system.¹⁸¹ India and the European Union have recently entered into talks regarding a free trade agreement that would extend intellectual property protection laws beyond the requirements of TRIPS.¹⁸² The proposed agreement includes provisions that would delay or prevent generic manufacturers from accessing brand name drug safety and efficiency data for a set period.¹⁸³ Another provision includes border measures to detain imported or exported drugs suspected of infringing on intellectual property rights.¹⁸⁴ The potentially devastating effect that agreements similar to this proposal can have on the availability and affordability of generic drugs is well documented.¹⁸⁵

176. MSF UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS, *supra* note 164, at 75.

177. *Id.*

178. *Id.*

179. Médecins Sans Frontières, *You're Trading Away Our Lives! Voices of People Living with HIV Rise Up in Protest in Delhi* (Mar. 12 2010), <http://www.doctorswithoutborders.org/news/article.cfm?id=4372&cat=field-news> [hereinafter *MSF You're Trading Away Our Lives!*].

180. Sampath, P. Gehl, *India's Product Patent Protection Regime: Less or More of the Pills for the Poor*, J. WORLD INTEL. PROP., Vol. 9, 694 (2006).

181. Henning Grosse Ruse-Khan, *The International Law Relationship Between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibility*, 18 J. INTEL. PROP. L. 325 (2011).

182. *MSF You're Trading Away Our Lives!*, *supra* note 179.

183. Babovic & Kishor, *supra* note 160, at 820.

184. *Id.*

185. Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 291 (2004); Samira Guennif & N. Lalitha, *TRIPS Plus Agreements and Issues in Access to Medicines in Developing Countries*, GUJARAT INSTITUTE OF DEVELOPMENT RESEARCH (2007) available at <http://www.gidr.ac.in/pdf/WP-174.pdf>; Charles T.

Another potential limit to India's generic drug production is the acquisition of several Indian drug companies by foreign companies. In the last six years alone, foreign investors have purchased six Indian pharmaceutical firms.¹⁸⁶ This calls into question the future availability of generic drugs from these companies. There is uncertainty as to whether these foreign companies will wish to issue compulsory licenses.¹⁸⁷ In addition, these companies may opt to use Indian marketing channels to sell more expensive patented drugs, instead of the generic drugs currently being sold.¹⁸⁸

C. *The Challenge: Increasing the Role of Generic Manufacturers*

According to the WTO, the objective of TRIPS compulsory license provisions is to increase the world's access to affordable medications. The goal of Paragraph 6 is to enable countries with insufficient manufacturing capabilities to use effectively those provisions.¹⁸⁹ Changing health needs and international obligations, however, have sparked renewed interest in how compulsory licenses can succeed in the future. To date, an under-examined aspect of the Paragraph 6 discussion is the role of the generic manufacturer. More specifically, what changes are necessary to induce generic manufacturers to participate in the Paragraph 6 compulsory license process?

In 2008, Sweden's National Board of Trade issued a report assessing the WTO's decision on compulsory licensing.¹⁹⁰ The report sets forth criteria to determine if it is possible for the Doha Declaration to achieve its goal of improving access to patented medicines.¹⁹¹ This Article uses the report's economic prerequisites as the starting point to analyze how to encourage generic manufacturers to play a more

Collins-Chase, *The Case Against TRIPS-Plus Protection in Developing Countries Facing Aids Epidemics*, 29 U. PA. J. INT'L L. 29 (2007).

186. The six companies are: Dabur Pharma, Ranbaxy Labs, Shanta Biotech, Matrix Lab, Orchid Chemicals, and Piramal Healthcare. See Madhur Singh, *India May Issue Compulsory Licenses to Control Drug Prices*, 27 BNA INT'L TRADE REP. 1349 (2010).

187. *Id.*

188. *Id.*

189. Doha Declaration, *supra* note 6, ¶ 6.

190. The WTO Decision on Compulsory Licensing: Does it Enable Import of Medicines for Developing Countries with Grave Public Health Problems? Kommerskollegium, National Board of Trade (2008), [hereinafter Kommerskollegium] available at http://www.kommers.se/upload/Analysarkiv/Arbetsomr%C3%A5den/WTO/Handel%20och%20skydd%20f%C3%B6r%20immateriella%20r%C3%A4ttigheter%20-%20TRIPS/Rapport%20The_WTO_decision_on_compulsory_licensing.pdf.

191. *Id.*

prominent role in the future use of compulsory licenses.

1. Necessary Prerequisites

Before a generic manufacturer enters a market, it needs the assurance of making a reasonable profit.¹⁹² However, this need must be consistent with what the importing country can afford. The transaction and production costs, the size of the order, and associated risks heavily influence price, and ultimately, a generic manufacturer's profits.¹⁹³ To increase generic manufacturers' involvement, a compulsory licensing framework must enable them to both meet Paragraph 6's requirements and achieve a profit.

a. *Production and Transactional Costs*

Generic manufacturers consider production and transaction costs when determining whether to enter a market.¹⁹⁴ For Paragraph 6 purposes, these production costs include the research and development expenses associated with reverse engineering the patented drug.¹⁹⁵ The generic manufacturer bears the production expenses of physically manufacturing the drug, maintaining the physical plant, staff, and distribution and transportation.¹⁹⁶ In many cases, these costs are theoretically similar to creating any other generic. They take on greater significance, however, when countries impose price constraints, as in the case of a drug produced under CAMR.¹⁹⁷ In addition, U.S. and E.U. trade agreements with least developed countries routinely include more restrictive intellectual property requirements than are prescribed by TRIPS. These "TRIPS-plus" agreements may also increase production costs of creating a generic drug for export under Paragraph 6. For example, data exclusivity provisions can deny generic manufacturers access to vital information and necessitate additional testing.¹⁹⁸ Finally, if the effective length of the license is short and the

192. Niklas Rudholm, *Entry and the Number of Firms in the Swedish Pharmaceuticals Market*, REV. INDUS. ORG. 19, 351 (2011).

193. *Id.* at 46.

194. *Id.*

195. Tsai, *supra* note 105.

196. *Id.*

197. Canada's Access to Medicines Regime, R.S.C. 1985, c. P-4, § 21.04(3) (d) (iii).

198. *Data Exclusivity in International Trade Agreements: What Consequences for Access to Medicines?*, MSF Technical Brief (May 2004), available at <http://www.citizen.org/documents/DataExclusivityMay04.pdf> ("Data exclusivity refers to a practice whereby, for a fixed period of time,

generic manufacturer must produce quickly to fill the order, startup costs may also increase.

Generic manufacturers also incur transaction costs associated with exporting under Paragraph 6 provisions. These costs include issuing an export notice,¹⁹⁹ disclosing private information on a dedicated website,²⁰⁰ and obtaining the compulsory license.²⁰¹ These costs are not exceedingly high and can be recouped by the price of the generic drug. Accordingly, TRIPS production costs, unburdened by TRIPS-plus requirements, should not dissuade a generic manufacturer from being a Paragraph 6 exporter.

To the extent that generic manufacturers encounter high transaction costs, it is due to non-TRIPS requirements imposed by the importing or exporting country. CAMR, for example, requires that a generic manufacturer must negotiate for a voluntary license from the patent holder before obtaining a compulsory license.²⁰² The absence of time limits or guidance as to what constitutes “reasonable terms and conditions” can result in extensive expenditures of time and money merely to meet a non-TRIPS requirement.²⁰³ To the extent that other countries have enacted cumbersome or extraneous requirements, such requirements should be eliminated so that generic manufacturers can produce needed medicines as promptly and economically as possible.

A way to offset these transaction costs is to eliminate the costs associated with the TRIPS requirement to negotiate with the patent holder prior to obtaining a Paragraph 6 compulsory license. While this is likely to cause considerable backlash from patent holders and developed countries, Article 31 already specifies situations when this requirement may be waived.²⁰⁴ Specifically, Article 31 states that “[t]his requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”²⁰⁵ The Doha Declaration recognizes that compulsory licenses for pharmaceuticals to increase countries’ access to ARVs fits firmly within the “national emergency” language of

drug regulatory authorities do not allow the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine.”).

199. Doha Declaration, *supra* note 6, ¶ 2(b) (i)-(iii).

200. *Id.*

201. *Id.*

202. Canada’s Access to Medicines Regime, R.S.C. 1985, c. P-4, § 21.04(3) (c).

203. *Id.*

204. TRIPS, *supra* note 1, at art. 31.

205. *Id.*

Article 31.²⁰⁶ Expanding this interpretation to include situations where the country has insufficient manufacturing capacities is in keeping with TRIPS' objective of "promoting access to medicine for all."²⁰⁷

TRIPS is silent as to how long the compulsory license lasts. Accordingly, there is nothing to prohibit countries from granting generic manufacturers multi-year compulsory licenses. This could provide sufficient time for generic manufacturers to generate a revenue stream sufficient to recoup their TRIPS-related production, transactional, and startup costs.²⁰⁸ Additionally, the exporting country could offer tax incentives for manufacturers to export under Paragraph 6. However, given the political sentiment surrounding Paragraph 6 in the United States, this may not be feasible everywhere. Finally, governments could offer research grants to subsidize the research and development costs of drugs produced under Paragraph 6.

b. *Market Size*

One of the biggest challenges of Paragraph 6 is that it does not provide for economies of scale.²⁰⁹ Simply put, generic manufacturers lack commercial incentive to make drugs under a compulsory license for only a minimal profit.²¹⁰ To counterbalance the previously discussed challenges, generic manufacturers need a large and secure market. Generic manufacturers typically make profits by pricing their product at a low price but selling large quantities.²¹¹ For Paragraph 6 purposes, the importing country (or countries) need(s) to be large enough for the generic manufacturer to offer attractive pricing yet also cover transaction and production costs and risk.²¹²

While TRIPS encourages low prices, it does not readily permit the selling of large quantities because of its stipulation that licenses must be

206. See Doha Declaration, *supra* note 6, ¶ 5(c) ("[I]t being understood that public health crises, including those relating to HIV/AIDS . . . can represent a national emergency").

207. *Id.* ¶ 4.

208. The Decision does not expressly limit how long a compulsory license is valid; however, it does limit production of the generic drug to "only the amount necessary to meet the needs of the eligible porting member." Decision of August 30, 2003, *supra* note 4, at 2(b) (i).

209. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS DEVELOPMENTAL POLICY (2002).

210. Jane Cottingham, Marie Berer, *Access to Essential Medicines for Sexual and Reproductive Health Care: The Role of the Pharmaceutical Industry and International Regulation*, 19 REPROD. HEALTH MATTERS 69 (2011).

211. Daniel R. Cahoy, *Breaking Patents*, 32 MICH. J. INT'L L. 461, 481 (2011).

212. *Id.* at 481-82.

produced on a country-by-country basis.²¹³ There are more than twenty million people infected with HIV throughout the forty-eight countries that comprise sub-Saharan Africa. Viewed as a whole, the size and financial resources of the region present a market where manufacturers could reach their economies of scale. Viewed on a country-by-country basis, however, they lack the size and financial resources to provide the market that generic manufacturers need.²¹⁴ For example, thirty-four of the countries that have health expenditures of less than \$30 per person per year are in sub-Saharan Africa.²¹⁵ This amount includes all health spending, not just pharmaceuticals, and includes expenditures from all sources, including government entities.²¹⁶ As such, generic manufacturers are unable to recoup the lost profits due to a smaller market by charging more for their product.

Notwithstanding the country-by-country requirement, Article 2 of the Doha Declaration acknowledges the option to use a single compulsory license to deliver generics to multiple countries.²¹⁷ In pertinent part, Article 2b states:

[T]he exporting Member shall notify the Council for TRIPS of the grant of the license, including the conditions attached to it. The information provided shall include . . . the products for which the license has been granted, the quantity (ies) for which it will be granted, the country (ies) to which the products is (are) to be supplied in and the duration of the license²¹⁸

This provision permits countries to pool their demand. Developing countries purchasing medicines in bulk could provide the market characteristics that generic manufacturers need.²¹⁹ Bulk production and sale could alleviate the economic difficulties that generic manufac-

213. TRIPS, *supra* note 1, ¶ 2.b(i) (“Only the amount to meet the needs of the eligible importing member(s) may be manufactured under the license and the entirety of this production shall be exported to the members, which has notified each the Council of TRIPS.”).

214. *The World Health Report*, WHO, 2006. By contrast, even the lowest price for the cheapest triple combination ARV is \$99 per person per year. *Id.*

215. *Id.*

216. *Id.*

217. TRIPS, *supra* note 1, at art. 2.

218. Doha Declaration, *supra* note 6.

219. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS DEVELOPMENTAL POLICY (2002); SISULE MUSUNGU, UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS (2004).

turers identify as a primary obstacle to Paragraph 6 exports.²²⁰ For example, it reduces risk, transaction and distribution costs, and uncertainty generic manufacturers could encounter.²²¹

Countries currently use regional and global arrangements to purchase off-patent medicines or for negotiation with patent holders.²²² To date, these pooling arrangements have not been used with a compulsory license. While nothing in TRIPS specifically prevents enlarging the market through pooling arrangements, a majority of exporting countries' laws prohibit such opportunities. For example, these countries have compulsory license legislations that define the importing recipient as "a" or "one" country.²²³ There are options, however, for pooled demand arrangements that are consistent with the Doha Declaration. Countries that are part of qualifying regional trade agreements (RTA)²²⁴ may re-export drugs imported under Paragraph 6, within the RTA, so long as the other country shares the health problem in question.²²⁵

Currently, six African RTAs qualify to pool their demand pursuant to the Paragraph 6 provisions.²²⁶ This makes it possible for these regions to pool their demand for patented products, import them into one member country, and distribute them from there.²²⁷ The absence of a regional patent system does not prevent the African RTAs from pooling their demand under Paragraph 6.²²⁸ It merely requires countries that have a patent on the product to issue a compulsory license. These compulsory licenses would then form a *de facto* regional compulsory license.²²⁹ A similar approach is available to countries that are not

220. *Regional Pooled Procurement of Drugs: Evaluation of Programs*, Center for Pharmaceutical Management (2003).

221. 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, 973-74 (2007).

222. Kommerskollegium, *supra* note 190, at 60.

223. China's State Intellectual Property Office Order 37, art. 9; Amendment to Korean Patent Act, art. 106.7; Norway Regulations Amending the Patent Regulations of December 20, 1996, No 1162; Canada's Bill C-9, 21.04(1).

224. *See* Decision on Differential and More Favorable Treatment Reciprocity and Fuller Participation of Developing Countries, art. XXIV, Nov. 28, 1979, General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194.

225. Doha Declaration, *supra* note 6, ¶ 6.

226. Kommerskollegium, *supra* note 190, at 60.

227. *Id.*

228. *Id.*

229. *Id.*

part of an African RTA.²³⁰ A member country would issue a compulsory license that comprises the demand for all the participating countries.²³¹ The exporting generic manufacturer would fill that one compulsory license. The delivery would then have to be divided among each participating country because there is no re-export waiver. These options offer the most efficient regional use of the compulsory license provisions. They build on previous models for regional procurement and offer economies of scale that may make generic manufacturers interested in becoming Paragraph 6 exporters.²³² This also creates opportunities for the importing country to stimulate direct investment in local production by inviting generic manufacturers to establish production facilities in the region.²³³ So far, however, no regional organization has used the compulsory license provisions in this manner. Despite these attractive options, there are still a number of risks that have prevented countries from pooling.

c. *Risks*

Generic manufacturers engaging in compulsory licensing face more risk than when conducting ordinary production.²³⁴ They risk time and money in preparing to export under a compulsory license that they may not obtain. In the period between the order and the shipment, they run the risk that the importing country may default on the order.²³⁵ A default may occur, for example, if the products are for public use and there is a change of government in the importing country.²³⁶

The transparency of certain TRIPS provisions also exposes the generic manufacturer to risk. Exporting countries are obligated to notify the TRIPS Council when they grant a compulsory license of the quantities to be produced and the conditions attached.²³⁷ These disclosures could enable the brand name manufacturer who holds the

230. *Id.*

231. 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. 4, 921 (2007).

232. *Id.*

233. This is particularly favorable because TRIPS does not require least developed nations to enforce pharmaceutical patents until 2016. TRIPS, *supra* note 1, at art. 66.

234. Kommerskollegium, *supra* note 190, at 49.

235. *Id.*

236. *Id.*

237. Doha Declaration, *supra* note 6, ¶ 2b(ii).

patent to undercut the price set by the generic manufacturer and keep the market. This competition is consistent with the purpose of the compulsory license and benefits the importing country.²³⁸ However, from the point of view of generic manufacturers, such action by a brand name manufacturer would be costly and could discourage subsequent attempts by the generic manufacturer to obtain compulsory licenses. Additionally, if some of the generic medicines are diverted from the intended country, there is the risk that the brand name manufacturer could sue the generic manufacturer for violating the terms of the compulsory license.²³⁹

A “single license” solution could counteract these risks and increase the utility of the Paragraph 6 process. This type of compulsory license would offer generic manufacturers a streamlined process that promotes maximum flexibility and utility.²⁴⁰ Specifically, the license would be open-ended in terms of the length of the agreement, the quantity of medicines that could be produced, and the number of countries to which the drug could be exported.²⁴¹ In addition, the generic manufacturer could apply for a compulsory license before there is a specific request from an importing country.²⁴²

This type of single request would enable generic manufacturers to benefit from economies of scale by potentially providing for multiple countries. It would also enable generic manufacturers to identify more easily multiple countries interested in continuing use of the Paragraph 6 system.

Provided these measures create an environment in which generic manufacturers are willing to use the compulsory licensing process, what is next? How can generic manufacturers’ active engagement influence developing countries to use the Paragraph 6 process?

2. Re-Defining the Generic Manufacturers’ Role

The most apparent benefit of generic manufacturers’ increased participation in the Paragraph 6 process is continued access to afford-

238. *Id.* ¶ 4.

239. CYNTHIA HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 219-20 (2011).

240. *Id.*

241. Bill S-232, Fortieth Parliament, 2d Sess. (2009); Bill C-393, Fortieth Parliament, 3d. Sess. (2009); *see also* Richard Elliott, Making CAMR Work: Streamlining Canada’s Access to Medicine Regime, Brief to the Senate (This provision was included in a proposal to amend CAMR and promote greater use the Paragraph 6).

242. Stirner, *supra* note 124, at 195-213.

able generic versions of patented drugs for developing countries. To date, only one pair of countries has successfully used the Paragraph 6 provisions to obtain medicine.²⁴³ Lack of economic incentives may explain why generic manufacturers do not initiate the Paragraph 6 process, but why have developing countries been reluctant to use the process? One of the reasons may be fear of political backlash and economic sanctions from developed countries.²⁴⁴ In addition to the suit brought against South Africa when it attempted to import drugs using the Paragraph 6 provisions, Thailand experienced negative reprisals from its issuance of compulsory licenses. In 2007, Thailand issued a compulsory license for a generic version of Kaletra, an ARV marketed by Abbott.²⁴⁵ In response, the pharmaceutical company decided to stop launching new drugs in Thailand, including a heat-stable version of the patented drug that was the subject of the compulsory license.²⁴⁶ Moreover, the U.S. government downgraded Thailand's trade status to a country with poor intellectual property protections.²⁴⁷ Simply put, political pressure from the governments of major pharmaceutical companies discourages the use of compulsory licensing to increase affordable access to medicine in developing countries.²⁴⁸

The active engagement of generic manufacturers could change these power and influence dynamics that currently govern the debate over access to medicine.²⁴⁹ Generic manufacturers have considerable resources available, both politically and economically, to focus public opinion on the health needs of developing countries. In fact, it was at the insistence of the generic manufacturer, Apotex, that the Canadian government initiated the compulsory licensing process with Rwanda.²⁵⁰

243. *Id.*

244. Babovic & Kishor, *supra* note 160, at 819.

245. *Id.*

246. *Id.*

247. *Id.*

248. BRADLEY CONDON & TAPEN SINHA, GLOBAL LESSONS FROM THE AIDS PANDEMIC: ECONOMIC, FINANCIAL, LEGAL AND POLITICAL IMPLICATIONS 17 (2008).

249. This approach builds in part on the concept of narrowly tailoring compulsory licenses to humanitarian goals. Bird discusses that critique in his article on how to maximize access to medicine through compulsory licenses. See Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects*, 37 J. L. MED. & ETHICS 209, 214 (2009).

250. Samuel Mintzer Fuchs, *Intellectual Propriety: Compulsory Licenses Through the TRIPS Agreement and the Doha Declaration on Public Health* (Independent Study Project Collection, Paper No. 854, 2010), available at http://digitalcollections.sit.edu/isp_collection/854.

The shared interests of PhRMA and developing countries exert considerable influence in shaping the international agenda and trade agreements.²⁵¹ Developing countries have, in large part, been without an economic partner. Generic manufacturers and the organizations like the Generic Pharmaceutical Association and the European Generic Medicines Association could serve in that capacity.

This expanded role calls for generic manufacturers to recast the current Paragraph 6 narrative as a process that enables developing countries access to affordable and necessary medicines. Emphasizing the original intent of the Paragraph 6 process is vital to counteract misperceptions about their most common uses. For example, at least a portion of the negative attention and political backlash centered on compulsory licenses stems from a perception that countries have used them indiscriminately.²⁵² A popular example is Egypt's issuance of a compulsory license for a generic version of Viagra.²⁵³ Issuing compulsory licenses in this manner is distinguishable from developing countries with little or no pharmaceutical infrastructure issuing compulsory licenses to obtain ARVs and other needed medicines. Generic manufacturers could reframe the compulsory license discussion by emphasizing the humanitarian importance of the Paragraph 6 provisions and distancing this process from distracting nonessential access to medicine controversies such as the Viagra license. HIV/AIDS and other health pandemics require these WTO members to use any available tool to provide affordable drugs for their citizens. They constitute a special category of countries in terms of access to pharmaceuticals. It is in these unique situations that Paragraph 6 compulsory licenses are necessary. It should not be the goal of a developing country to rely on Paragraph 6 compulsory licenses as the primary and indefinite source for that country's access to necessary medicines.²⁵⁴ However, Paragraph 6 compulsory licenses could provide a crucial short-term solution to a severe health crisis. As evidenced by PhRMA, generic

251. See *supra* Section II.A.

252. Aileen M. McGill, *Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis Under the Doha Declaration*, 10 WAKE FOREST INTEL. PROP. L.J. 70, 90 (2009).

253. A. Allam, *Seeking Investment, Egypt Tries Patent Laws*, N.Y. TIMES, October 4, 2002, at W1.

254. *A Gathering Storm: Drug Companies' Patents Are Under Attack*, ECONOMIST, June 9, 2007, at 100 (noting that even this narrow approach is met with hostility from the pharmaceutical industry and that pharmaceutical executives have expressed outrage at developing countries' use of compulsory licenses).

manufacturers are able to lobby effectively to restrict the scope and use of the Paragraph 6 provision to avoid excessive reliance by countries without real need for generic drugs. By focusing global attention on the humanitarian and health imperatives, generic manufacturers could remove the stigma of Paragraph 6 compulsory license provisions and decrease the animosity directed toward developing countries in need of generic drugs.

V. CONCLUSION

Generic manufacturers and the Paragraph 6 provisions represent an infrequently used partnership between developing countries with little to no manufacturing capabilities and the developed industrial countries. This Article asserts that generic manufacturers need to get assurances of profitability through favorable regulations and streamlined applications to take a more active role in the compulsory license process. For example, domestic laws implementing TRIPS should remove negotiation requirements not required under TRIPS by interpreting circumstances of extreme urgency for public health to include countries with no generic manufacturing infrastructure. In addition, countries should adopt measures to extend the length of compulsory licenses and offer tax incentives and research grants to offset generic manufacturers' transactional and production costs associated with the Paragraph 6 process. Further, amending TRIPS to allow generic manufacturers to produce large quantities of drugs for several countries through a single license would eliminate the economies of scale obstacle.

Generic manufacturers can play a vital role in recasting the purpose and use of Paragraph 6 compulsory licenses. In light of the changing health needs and international obligations of developing countries, active engagement by generic manufacturers requires more than a mere willingness by them to use the compulsory licensing process. Specifically, the need for a Paragraph 6 compulsory license arises in the situations in which countries lack the infrastructure and capacity to provide pharmaceutical care for their citizens. In those circumstances, developing countries must be able to use the Paragraph 6 process without fearing political and economic repercussions. It is here that the role of the engaged generic manufacturer is essential. This role involves serving as the counterbalance to the influence of developed countries and pharmaceutical companies over developing countries' use of Paragraph 6 provisions. It also requires generic manufacturers to

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reframe the debate over the functionality of Paragraph 6 compulsory licenses by emphasizing their humanitarian efforts in the face of a world health crisis. Ultimately, to achieve the Doha Declaration's humanitarian objective, the Paragraph 6 compulsory licensing provisions must be responsive to the commercial objectives of the generic manufacturers it relies on, as well as the practical needs of the developing countries it is designed to help.