Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?

Stacey B. Lee, Johns Hopkins University Carey Business School

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

Stacey B. Lee **

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 10th 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 re-aligns 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.


**Assistant Professor, Johns Hopkins Carey Business School, J.D., University of Maryland School of Law.
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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’ patent protection on pharmaceuticals. 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. Under the TRIPS compulsory license provisions governments can disregard a patent in order to produce locally a low cost generic version of a patent drug. In practice, however, the majority of developing countries lacked the requisite domestic generic manufacturing capacity to use these provisions.

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2 Id. at art. 27. Other TRIPS flexibilities include: member countries’ ability to “exclude from patentability (a) 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 TRIPS Agreement, supra note 1, art. 31(f)
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 Declaration”). In addition to reaffirming the validity of compulsory licenses, Paragraph 6 of the 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.

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. The decision amended the compulsory license provisions by waiving the TRIPS requirement that compulsory licenses be used “predominately for the domestic market.” These Paragraph 6 provisions now enable member countries to export generic medication to countries with insufficient pharmaceutical production capabilities.

Public health advocates hailed the Paragraph 6 provisions as the “solution to developing countries’ most pressing medical needs” and a “remarkable achievement.” To date, however, only one pair of countries has utilized the Paragraph 6 provisions to obtain generic versions of patented drugs. Critics refer to this 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. Indeed, articles commenting on the effectiveness and continued relevance of Paragraph 6 are abundant.

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

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6 Ministerial Declaration, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].
7 Decision of August 30, 2003, supra note 4.
8 Id. at P2.
9 Id.
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 this refocused attention on the Doha Declaration’s Paragraph 6 provisions and generic manufacturers’ role in facilitating affordable access of medicines to developing countries. Beginning in 2016, all developing countries must be TRIPS compliant.\textsuperscript{13} This means 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 availability of India’s low-cost generic versions of antiretroviral medications (“ARVs”).\textsuperscript{14} Medecins sans Frontieres (“MSF”) notes that supply is gradually running out.\textsuperscript{15} India became TRIPS compliant in 2005.\textsuperscript{16} The newer and more effective HIV/AIDS drugs developed after 2005 are patent protected and India cannot copy them. As people become increasing resistant to first-line HIV/AIDS treatments, developing countries will not be able to rely on India to supply cheaper generic alternatives to patented second and third line HIV/AIDS medications patented after 2005.\textsuperscript{17} 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 one of this section describes the background of pre-TRIPS intellectual property protections. Part two 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. In particular, this section explores the attempts by Rwanda and Apotex, the Canadian generic manufacturer, attempts to comply with TRIPS to deliver essential medicines under Paragraph 6. Part two of this section broadens its scope to explore other generic manufacturers’ attempts to use the Paragraph 6 compulsory license process. 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 by examining the current and future health challenges facing sub-Saharan Africa. Part two 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 Paragraph 6 process. The article concludes that through proper incentives, generic manufacturers are in a

\textsuperscript{13} 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/20 (July 1, 2002) (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.) Available at http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm.


\textsuperscript{15} Id.

\textsuperscript{16} Id.

\textsuperscript{17}
unique position to change the dynamics in the use by developing countries of Paragraph 6 compulsory licenses to access affordable medicines.

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

A. THE PRE-TRIPS LANDSCAPE

1. Countries’ Pre-TRIPS Relationships with Patented Drugs

While international agreements addressing intellectual property rights date back to the late 1800s, TRIPS is the first to extend such protections to pharmaceutical products. Even on a domestic level, prior to the creation of TRIPS, a majority of developed countries did not include patent protection of pharmaceutical products. According to a 1988 WTO study, of the 98 state parties to the Paris Convention for the Protection of Industrial Property, 49 excluded pharmaceutical products from patent protection.

Among the countries that recognized patent protection for pharmaceuticals, there was no universal approach. Due to the relative weakness of international agreements regarding intellectual property in general, the strength of pharmaceutical patent protection was largely a territorial determination. For example, India offered a weaker patent protection for drugs than it did for other inventions. Manufacturers could legally reverse engineer a patented chemical compound for use in a generic form, as long as the generic manufacturer did not appropriate the branded drug’s manufacturing process. In addition, Indian law limited patent terms for processes that involved social concerns, including the manufacturing of pharmaceutical drugs, to seven years, as opposed to fourteen years afforded other inventions. The patent processes in Brazil, while also recognizing patent protections for pharmaceuticals, took another approach.

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18 International Convention for the International Protection of Property (1883); see also The Berne Convention for the Literary Protection of Artistic Works (1886).
20 Id.
22 Id.
24 Id.
The Brazilian government routinely awarded compulsory licenses to local manufacturers to create generic versions of drugs that were not produced locally for domestic supply.26

Angola, Ghana, and Malawi are among the developing countries that possess relatively weak patent regimes, and prior to, TRIPS did not extend intellectual property protection to pharmaceuticals.27 Unlike more developed economies, these countries historically lacked the necessary resources to devise the elaborate legislation and proactive enforcement mechanisms to create stringent patent protections.28 Arguably, because these countries lagged behind developed countries in terms of technology and innovation, they had less incentive to devote precious resources to create such structures.29

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.30 They also had the ability to issue compulsory licenses as they saw fit regarding their scope, duration, and requirements.31 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.32 As discussed in Section III, this ability to access affordably priced generic versions of patented drugs was instrumental in developing countries fight against HIV/AIDS.33 Without the competitive presence of generic drugs, essential ARV treatments are prohibitively expensive and inaccessible to much of the developing world.34

2. Pre-TRIPS Objectives of the United States and PhRMA

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31 TRIPS, art. 31.
33 Parameswaran Narayanan, PATENT LAW at 3-4 (4th ed. 2006) see also J.W. BAXTER, WORLD PATENT LAW AND PRACTICE 73-76 (2d ed. 1968) (discussing countries which do not provide pharmaceuticals full patent protection) (explaining the patent systems of various countries).
Beginning in the 1980s, the United States shifted from an industrial to knowledge-based economy.\textsuperscript{35} By the mid 1980s, over 25\% of American exports contained a high intellectual component including patented drugs manufactured by multi-billion dollar pharmaceuticals companies.\textsuperscript{36} With these advances, American corporations saw an increase in reverse engineering, copying, and unauthorized use of technologies abroad.\textsuperscript{37} Lead by the Pharmaceutical Research and Manufacturing Association (“PhRMA”)\textsuperscript{38} and other groups, the U.S. government was under increasing pressure to strengthen intellectual property protections to reduce foreign competition “free riding” on their research and development.\textsuperscript{39} Chief among PhRMA’s concerns was the competitive threat brand name manufacturers were facing from generic manufacturers’ lower cost products.\textsuperscript{40} 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.\textsuperscript{41}

In the years, leading up to TRIPS, PhRMA and other key industries played an influential role in shaping the United States’ international intellectual property priorities.\textsuperscript{42} Brand name manufacturers wanted to expand intellectual property protections to include pharmaceutical products and processes. Global enforcement of their pharmaceutical patents would eliminate generic competition and increase brand name manufacturers’ market control in WTO member countries.\textsuperscript{43} With this exclusive control, brand name manufacturers could set their prices above marginal costs.\textsuperscript{44} This virtual monopoly would also have the added effect of limiting foreign governments’ ability to ensure affordable access to medications and to regulate health conditions.\textsuperscript{45} Finally, PhRMA advocated extending the international patent term to 20 years. This would increase the timeframe in which generic drugs are unavailable to those in developing countries.\textsuperscript{46}

Ultimately, the United States pursued a strategy that was heavily influenced by American law and that would require countries to comply with patent protections that incorporated strong private

\textsuperscript{35} Deere-Birkbeck, supra note 29 at 38-40.
\textsuperscript{36} Id.
\textsuperscript{37} Id.
\textsuperscript{38} \url{http://www.phrma.org/about/about-phrma} (PhRMA represents the interests pharmaceutical companies devoted to innovation and strong intellectual property protections)
\textsuperscript{39} Deere-Birkbeck, supra note 29 at.
\textsuperscript{40} Carlos M. Correa, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (2007) at 19.
\textsuperscript{42} Id.
\textsuperscript{43} Correa, supra note 40 at 271.
\textsuperscript{44} TRIPS affords patent holders the exclusive use of their medication for twenty years with no limit on price. TRIPS, supra note 1, art. F8.
\textsuperscript{45} Id.
\textsuperscript{46} TRIPS art. 27
property rights. By advancing an international agenda that linked these intellectual property protections to WTO membership, the U.S. further ensured worldwide adoption of these practices.

B. Evolution of Intellectual Property Protections under TRIPS

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

TRIPS requires all member countries to provide a minimum of 20 years patent protection to all pharmaceutical products and processes. The aim of this provision was to eliminate the “free riding” scenarios that flourished in countries that did not protect intellectual property rights. TRIPS gave pharmaceutical patent holders the exclusive right to prevent unauthorized third parties from making, using, offering for sale, selling or importing their drugs. The Agreement also included a number of transitional provisions. Developing countries like India had until January 2005 to implement the pharmaceutical provisions, while least developed countries like sub-Saharan Africa were not required to extend patent protections to pharmaceutical products until 2005.

The WTO further obligated all member countries, regardless of their level of development, to apply these same TRIPS’ standards to their domestic laws. 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. In exchange, member countries have access to global markets and the free movement of technology and innovation in an environment that ensured the uniform protection and enforcement of intellectual property rights.

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

47Correa, supra note 40 at 40.
48Id.
49TRIPS, art. 7
50TRIPS, art. 27 (1)
51Id. at pmbl.
52Id.
54Id. Art 1, para. 1.
55While the obligations to comply with TRIPS apply equally to all members, developing countries were given a transitional period to come into compliance. See TRIPS, supra note 1, art. 65; see also WTO Overview.
56Id.
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. In other words, the Agreement recognizes that public health problems may exist and includes “flexibilities” members can use to address those problems. 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. In the context of access to medicines, a compulsory license allows a developing country’s government to suppress legally a patent as a means of making medicines more affordable in its country. Because these provisions allow a country to bypass the exclusive rights of the patent holder, Article 31 outlines restrictive conditions that must be satisfied before granting a compulsory license. Prior to issuing a compulsory license, countries must provide a reasonable period to negotiate a voluntary license with the patent holder based on reasonable commercial terms. If good faith negotiations with the pharmaceutical patent holder fail, then countries are able to issue compulsory licenses provided they are limited to situations “predominantly for the supply of the domestic market of the member authorizing such use.”

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. 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. This essentially made compulsory licenses useless to countries that lacked the pharmaceutical infrastructure to manufacture the generics within its own borders. At the time, only about a dozen countries, among them China, India, Brazil, Argentina and South

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57 TRIPS at art. 8
58 Id.
59 Id.
60 Id. at art. 31(b)
62 Id.
63 TRIPS, art. 31.
64 Id. at art. 31(f).
66 Id.
Africa had a functional domestic pharmaceutical sector capable of producing significant quantities of generic drugs.  

Article 31’s domestic use requirement laid bare the unnecessary supply and demand problem created by TRIPS. WTO countries were prohibited from issuing compulsory licenses to supply low cost generic medicines to member countries afflicted with grave public health problems. 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. Accordingly, these member countries’ demand for vital medicines went unmet.

Article 31(f) essentially placed developing countries in an untenable position. The provision ignored the fact that the countries most in need of the drugs did not have the adequate manufacturing capabilities. The provisions wrongly presumed that patents primarily were the obstacle prohibiting developing countries’ access to drugs. The WTO appeared to reason that simply removing the patent restriction was sufficient to resolve the access problem. This shortsighted approach failed to consider that the majority of developing countries lacked the requisite manufacturing infrastructure to produce safe and effective generic drugs. Further, by prohibiting these countries from turning to other WTO members to supply the necessary generic medicines, the TRIPS compulsory license provisions were useless.

Given the rigidity of the patent protections and the uselessness of the compulsory license provisions, one questions why a developing country would sign on to TRIPS. In what some critics described as economic warfare, during TRIPS negotiations, the United States and the European Community announced their plan to withdraw from the 1947 GATT Agreement. The United States and Europe made the continued access to their markets that had been available as a

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69 TRIPS, art. 31.
71 Id.
72 TRIPS, art. 31(f)
75 Id; see also Matthew Royle, Compulsory Licensing and Access to Drug, PHARMA MARKETLETTER (U.K.), Dec. 17, 2007
76 TRIPs, art. 31(f)
GATT member contingent on signing TRIPS. The nature of the Hobson’s choice foretold the result. At the conclusion of the Uruguay Round negotiations, despite inequitable terms, all the developing countries joined the WTO and agreed to TRIPS.

The inclusion of strong pharmaceutical patent protections into TRIPS developed primarily by United States and heavily influenced by PhRMA is not surprising. James R. Enyart, Director of International Affairs at Monsato, justified the aggressive lobbying efforts noting, “The rules of international commerce are far too important to leave up to government bureaucrats and their academic advisors. But governments, not businessmen make rules and they only listen when the chorus gets big enough and the singing gets loud enough.” Ultimately, the PhRMA chorus helped enact TRIPS including the heightened intellectual property standards that came with it.

2. DOHA Declaration’s Paragraph 6 Provisions

History would suggest that developing countries had little chance of the WTO revising 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. The entire world took note of developing countries’ inability to use compulsory licenses to access affordable medicines to combat the deadly disease.

In 2001, nearly 20 million people in sub-Saharan Africa were living with HIV. In 1998, an estimated million people became infected with HIV, a number that represented 70% all people infected that year. In 2001 alone, 2.3 million Sub-Saharan Africans died of AIDS-related causes. Due to AIDS related deaths, the life expectancy in Swaziland fell by half between 1990 and 2007, to 37 years. Since the beginning of the AIDS epidemic, African has been its

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78 Id.
79 Id. The Spectator, No.509, Oct. 14, 1712.(The phrase refers to a free choice in which only option one option is offered. As a person may refuse to take that option, the choice is therefore between taking the option or not; "take it or leave it")
80 Steinberg, 56 INT’L Org. at 342 (cited in note 30)
84 Id.
88 United Nations Development Programme, 2008; Whitesiade et al., 2006).
epicenter. During this time 14.8 million children in sub-Saharan African have lost one or both parents to HIV/AIDS.

ARVs are one of the most effective treatments to prolong and improve the quality of life for those infected with HIV. Hoffman-La Roche, a Swiss pharmaceutical company, discovered a protease inhibitor that formed the basis of the first effective treatment against AIDS. These ARV treatments reduced the mortality rate of AIDS by 84% within the first four years of their introduction in developed countries.

Developed countries had access to this treatment beginning in 1996. In the countries where people had access to ARV, treatment mortality rates of AIDS significantly declined. In 1996, 65% of HIV patients receiving clinical care in the U.S. received ARV treatment. Despite the existence of this effective treatment, in the years leading up to the Doha Declaration, developing and least developed countries did not widely use AVRs. Five years after ARVs were available in developed countries, only 2% of people in developing were receiving them. Chief among the reasons cited was that the price was prohibitively expensive for public sector budgets in low-income countries.

In 1999, approximately South Africans carried the HIV virus, and approximately 600 people were dying from AIDS each day. For years, pharmaceutical manufacturers held discussions with South Africa and other African countries regarding the sale of lower priced

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90 2009 AIDS Epidemic Update, supra note 86
93 AVERT, AIDS, Drug Prices and Generic Drugs, AVERT available at http://www.avert.org/generic.htm
94 Id.
95 Id.; see also The Washington Post(1996) With fanfare, Global AIDS Conference gets underway in Vancouver
96 Id.
99 See AVERT, supra note 92 (explaining the cost of AIDS treatment in Sub-Saharan Africa)
pharmaceuticals. By January of 2001, South Africa still had not reached an agreement with the pharmaceutical drug companies.

In February of 2001, Cipla, an Indian manufacturer of generic drugs, offered to supply a triple-therapy AIDS drug cocktail for $350 per year to MSF, a nonprofit medical group. During this same period, Cipla also began offering African countries ARV treatments at prices far below the rates of their brand name competitors. 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 a compulsory licenses to make and sell eight different drugs that were currently protected by patents. Acting under the South African Medicines and Related Substance Control Amendment Act (“South African Medicines Act”) which empowered the Minister of Health to issue compulsory licenses during health emergencies, he granted Cipla’s request.

Prior to executing the deal, 39 pharmaceutical manufacturers filed suit against the South African government. 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. Because of the international public outcry over the lawsuit, the pharmaceutical companies eventually dropped their suit. The debate within the international community regarding the TRIPS Agreement and countries’ access to medicines had reached a fevered pitch.

At the request of the African group, the TRIPS Council held a special discussion on intellectual property rights and access to medicines. 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. Because of the lawsuit against South Africa, developing

103 Id.
104 Id.
106 Id. at 88-89
108 Miller, supra note 105 at 91.
109 Deere, supra note 35 at 227-28.
110 Id.
111 Miller supra note 105 at 90.
countries also wanted a WTO declaration that clarified provisions and protections afforded under TRIPS.\textsuperscript{114}

In response to these concerns, in November 2001, the WTO Ministerial Conference met in Qatar, Doha and adopted the Declaration on the TRIPS Agreement and Public Health.\textsuperscript{115} 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.”\textsuperscript{116} The Doha Declaration solidified the right of member states to use compulsory licenses to obtain generic drugs in response to health needs.\textsuperscript{117} In addition, the WTO extended the transitional period for developing countries to implement the TRIPS pharmaceutical patent provisions to 2016.\textsuperscript{118}

In addition to reiterating TRIPS’ goal of promoting the availability of medicines, the WTO conceded the ineffectiveness of Article 31.\textsuperscript{119} 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.”\textsuperscript{120} The WTO also admitted that other pre-compulsory license requirements hampered developing countries’ ability to use the process.\textsuperscript{121} 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.\textsuperscript{122}

After two years of vigorous debate, the WTO General Council issued a decision that specifically addressed Article 31’s domestic use restrictions.\textsuperscript{123} The WTO’s 2003 Decision is commonly refer to as the “Paragraph 6 provisions” because the sixth paragraph of the Doha Declaration specifically addresses the domestic use requirement.\textsuperscript{124} Generic manufacturers, such as Cosmos Industries and Cipla, joined with developing countries and humanitarian organizations to argue for increased flexibilities in the compulsory license scheme.\textsuperscript{125} In pertinent part, Paragraph 6

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\textsuperscript{115}Doha Declaration, supra note 6

\textsuperscript{116}Id. at para 4.

\textsuperscript{117}Id.

\textsuperscript{118}Id. at para. 4, 6.

\textsuperscript{119}Id.

\textsuperscript{120}Doha Declaration, supra note 6 at para.67

\textsuperscript{121}TRIPS, art. 31 (b) and (h)

\textsuperscript{122}Doha, supra note 6 at para. 6.

\textsuperscript{123}Decision, see supra note 4

\textsuperscript{124}Doha, supra note 6 at para. 6.

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contains three waivers to TRIPS’ Article 31. The first eliminates the “domestic use” provisions under Article 31(f). Accordingly, countries can now import needed generic drugs from any manufacturing nation. The second waiver provides that member countries can now export generic pharmaceutical products made under compulsory licenses to meet the needs of importing countries subject to certain conditions. Third, the Decision also amends Paragraph 6 of the Doha Declaration by waiving the importing country’s remuneration obligations. Accordingly, the cost of compulsory licenses is no longer the responsibility of the country receiving the generics, which may or may not be able to afford remuneration payments. Instead, compensation is the responsibility of the exporting nation.

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. 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. In addition, only two countries have used the Paragraph 6 compulsory license process.

II. ASSESSMENT OF THE DOHA DECLARATION’S PARAGRAPH SIX COMPULSORY LICENSING EFFECTIVENESS

A. 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. The AIDS epidemic had taken a toll on the health and economy of Rwanda. In 2007, there were approximately 150,000 people living with HIV in Rwanda. Between the ages of 15 and 49, 2.8% of the population had AIDS. The majority of Rwandans lived (and still lives) below the poverty line, earning...

126 Doha Declaration, supra note 6 at par. 6.
128 Paragraph 6 Implementation Agreement 2003
129 Id.
130 Id.
131 Id.
135 U.S. Dept. of Health and Human Services, How HIV Causes AIDS, NIAID Fact Sheet (Nov. 2004),
136 Id.
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approximately 250 Rwandan francs per day, which amounts to approximately $157 per year or $0.43 per day. At the time, the cost of generic ARV treatment ranged from $88 to $261 per year. The cost of brand-name antiretroviral treatments cost approximately $10,000 per year or higher. In April 2007, Rwanda notified the WTO of its intent to use Paragraph 6 compulsory license provisions. 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 a 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 importing country. That entire amount must then ship to the importing country. The packaging must clearly specify that the drugs are produced under the Paragraph 6 provisions. Prior to shipment, the exporting country must post on a publicly available website the quantity of drugs supplied and distinguishing features of the product. In addition, the exporting country must provide adequate remuneration to the patent holder, “taking into account the economic value to the importing [m]ember.”

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. 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.” In addition, CAMR sought “to allow generic manufacturers to produce and export medication to developing countries.”

Notwithstanding CAMR’s laudable objectives, Canada forced generic manufacturers to undergo additional and time-consuming requirements not included in TRIPS. For example, before the

139 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)
141 Doha, para 2(b)(i)
142 Id.
143 Id.
144 Id.
145 Id. 2(b)(ii)-(iii)
146 Id. at para 3
147 Christina Cotter, The Implication of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries, 5 LOY. U. CHI. INT'L. R. 177, 185-86 (2008)
149 GOVERNMENT OF CANADA, CANADA'S ACCESS TO MEDICINES REGIME INTRODUCTION http://www.camr-rcam.gc.ca/intro/index-eng.php
150 Richard Elliott, pledges and falls: Canada's legislation on compulsory licensing of pharmaceuticals for
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Canadian government would issue a compulsory license, the generic manufacturer must negotiate for voluntary license from the patent holder. Specifically, CAMR requires generic manufacturers to provide:

- a solemn or statutory declaration . . . that the applicant had, at least 30 days before the 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 export the country where WTO member name in the application on reasonable terms and conditions and that such efforts have not been successful.

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. The practical effect of the voluntary license requirement is that it allows pharmaceutical patent holders to stop the process at any time by the mere offer to negotiate.

Next, the generic manufacturer must obtain a compulsory license release from the Canadian Commissioner of patents. After receipt of the release, the generic manufacturer can formally begin the bidding process with the government of the importing country. Once authorized, CAMR contains additional non-TRIPS specified measures the generic manufacturer must meet. For example, the generic manufacturer 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. Generic manufacturers bear the responsibility of maintaining a dedicated website that discloses the generic product information. The exporting generic manufacturer is also obligated to issue an export notice to every exporting party that will

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151 CAMR, §21.04(3)(c)
152 Id. at §21.04(3)
155 CAMR §21.04(3)(b).
158 Id. §21.06
be handling the generic product.\textsuperscript{159} Canadian law does not require regulatory approval for exporting any other pharmaceuticals.\textsuperscript{160}

In addition to imposing extra costs on the exporting manufacturer, CAMR also limits what a manufacturer can charge for the generic drug.\textsuperscript{161} The Good Faith Clause prohibits a generic manufacturer from charging more than 25\% of the average price of an equivalent drug in Canada.\textsuperscript{162} Should a generic manufacturer violate this requirement, the Federal Court has the authority to revoke the compulsory license.\textsuperscript{163} In addition to paying the existing royalty, the generic manufacturer is subject to pay “an amount that the federal court considers adequate to compensate the patentee commercial use of the patent.”\textsuperscript{164}

In 2004, the Toronto-based generic drug manufacturer Apotex, Inc., began development of a fixed does combination of three HIV/AIDS antiretroviral drugs.\textsuperscript{165} 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.\textsuperscript{166} Apotex informed each of the manufacturers of the amount of drugs it sought to use solely for export and the price ($0.40 U.S. per tablet).\textsuperscript{167} During negotiations, Apotex also indicated that for humanitarian reason, it was supplying the drug at no profit.\textsuperscript{168} The brand name manufacturers refused to give Apotex a voluntary license.\textsuperscript{169} It was only after Rwanda notified the WTO about the stalled negotiations that the companies relented

\textsuperscript{159} Id. §21.07.


\textsuperscript{161} CAMR §21.17(1).


\textsuperscript{163} CAMR §21.17(3).

\textsuperscript{164} Canada’s Access to Medicine Regime, R.S.C., ch. P-4, §21.17(3)(1985) (Can.) 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 25\%) essentially makes the agreement commercial in nature. \textit{Id.} at §21.17(1)

\textsuperscript{165} Holger, P. Hestetermeyer, Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines, 11 ASIL INSIGHT, Dec. 2007, at http://www.asil.org/insights071210.cfm


and consented to the use of their patented drugs.\textsuperscript{170} 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.”\textsuperscript{171}

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.\textsuperscript{172} Less than two weeks later, Canada notified the WTO.\textsuperscript{173} After fulfilling the requirements of both CAMR and TRIPS, Apotex was able to begin negotiating with Rwanda.\textsuperscript{174}

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 2 shipments of the drug in September 2008 and 2009.\textsuperscript{175} To ensure the second delivery, CAMR required Apotex to file an application for renewal of the compulsory license in 2009.\textsuperscript{176} A process both parties hoped would afford the efficient delivery of life saving generics, in reality proved a time-consuming and cumbersome experience. No additional exports have occurred under this procedure.\textsuperscript{177}

Ironically, while the parties struggled through the ponderous TRIPS and CAMR requirements, a generic Indian company approached the Rwandan government.\textsuperscript{178} Cipla had the generic ARV available for immediate delivery at $0.26 per tablet savings.\textsuperscript{179} Not only was drug cheaper, Rwanda could import it without triggering the TRIPS complexities.\textsuperscript{180}

\begin{footnotes}
\item[170] Cotter, supra note ---at 186
\item[173] Tsai, supra note at 1079.
\item[176] Stirner, supra note 172, at 199.
\item[177] Apotex Press Release, \textit{CAMR Federal Law Needs to be Fixed if Life-Saving Drugs for Children are to be Developed}, May 14, 2009 (stating that "in its current form it's not workable for us," but noting an interest in developing generic HIV treatments \textit{Id}.)
\item[179] \textit{Id}.
\item[180] Apotex Press Release, \textit{CAMR Federal Law Needs to be Fixed if Life-Saving Drugs for Children are to be Developed}, May 14, 2009 (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) http://www.apotex.com/global/about/press/20090514.asp
\end{footnotes}
Apotex indicated the CAMR is too complicated and that developing countries have problems in identifying the proper process to obtain import permission.\textsuperscript{181} Essentially, the manufacturer stated that it is not advantageous for developing countries to “jump through the hoops imposed by CAMR.”\textsuperscript{182} For example, the compulsory license to export under CAMR is only valid for two years. The renewal process is available only to complete the original amount of medications authorized the compulsory license.\textsuperscript{183} In other words, the renewal mechanism is not available to deliver additional quantities.\textsuperscript{184} If an importing country identifies additional need, both the generic manufacturer and the importing country have to initiate a new CAMR process, including steps such as notifying the WTO regarding the intention to use the system and the mandatory negotiations with the patent holding company for a voluntary license.\textsuperscript{185} In this case, Rwanda wanted to double the order. However, there was no efficient way for the generic manufacturer to deliver because of the CAMR requirements. The limitation on the quantities of drugs that can be manufactured and exported under CAMR also are major constraint for generic manufacturer to reach economies of scale for producing medicines.\textsuperscript{186} Exporting a specific number of drugs to one country for a limited time makes it difficult to recoup investments for R&D, legal costs and expenditures to administer the CAMR process.\textsuperscript{187}

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.\textsuperscript{188} For example, the CAMR provisions consist of over 19 sections and 100 subclasses.\textsuperscript{189} To read, interpret, and comply with these provisions necessitates some level of legal training and cost.\textsuperscript{190} Developing countries are typically lacking in these resources.\textsuperscript{191}

\textbf{B. Other Uses by Africa}

At least initially, generic manufacturers appeared interested in using Paragraph 6 provisions to export needed generics to Africa. Political agendas and governmental infighting, however, have derailed these attempts. For example, not long after the Declaration’s passage, Cosmos, a

\begin{footnotesize}
\textsuperscript{183} Striner, supra note 187 at 200
\textsuperscript{184} Id.
\textsuperscript{185} Id.
\textsuperscript{187} Id.
\textsuperscript{189} CAMR, supra note
\textsuperscript{190} Id.
\textsuperscript{191} McHarg supra note 189.
\end{footnotesize}
Kenyan pharmaceutical company, announced its intention to supply generic ARVs to the East African market. Specifically, it requested a compulsory license to produce a generic version of a patented product of Glaxo SmithKline and Boehringer Ingelheim of Germany. After Cosmos submitted its application for a compulsory license, a conflict developed between the Kenyan Ministry of Health and the Ministry of Trade and Industry. The Ministry of Health ordered the company to produce generic drugs, while the Ministry of Trade and Industry refused to issue the license. On realizing that the government was about to issue a license, Boehringer offered a voluntary license, which effectively ended Kenya’s efforts to utilize the Paragraph 6 compulsory license provisions. In June 2005, Aspen Pharmacare experienced a similar type of setback when it attempted to export ARVs to Ethiopia, Nigeria, Tanzania, and Uganda.

Compulsory licenses have been not uniformly successful in Africa, nor have they fared much better elsewhere. In 2008, Nepal applied for a compulsory license under the Paragraph 6 provisions. Natco Pharma, (“Natco”) an Indian drug manufacturer, responded and sought to produce generic versions of two anticancer drugs. During negotiations, Natco indicated that it would manufacturer 45,000 doses of the drugs for export. Subject to TRIPS requirements, Natco offered the patent holder, Rouche a 5% royalty. In the case of a compulsory license for domestic use, the Indian Patent Act affords the patent holder a hearing to express its views on the granting of license prior to its issuance. In this case, Natco opposed such a hearing because neither Indian Patent Act nor TRIPS contain similar requirements for compulsory licenses for export. While not expressly provided, the Indian Court held that nothing prohibited such as hearing. After the Indian Court granted Rouche’s the right to the hearing, Natco withdrew its compulsory license efforts.

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193 Id.
194 Id.
195 Id.
196 Id.
197 Id.
199 Id.
200 Indian Patent Act, Section 92 (A) (2005)
201 TRIPS, art. 31 (h); see also Hiddleston, supra note ___ in India, compulsory licenses are governed by S.92A of the Patent Act, which requires that a license will be issued to supply medicines "to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product would address public health problems."S.92 (A)(1), The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005.
202 Striner supra note at 202.
203 Id.
CAN INCENTIVES TO GENERIC MANUFACTURERS SAVE DOHA’S PARAGRAPH 6?

III THE NEED FOR A NEW FRAMEWORK

In its current form, generic manufacturers have had little incentive to serve as a Paragraph 6 exporter. Transactional and economic burdens have rendered the TRIPS compulsory licensing an unattractive business alternative for generic manufacturers. Sources of generic ARVs and other drugs, however, are diminishing over time. The 2016 deadline by which all countries must become TRIPS compliant is steadily approaching. Within a decade, the Doha Declaration’s Paragraph 6 may be the only available mechanism for Africa and developing countries with insufficient manufacturing capabilities to attain 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. In terms of treatment, the region uses four times more ARVs than the rest of the world combined. Yet, 66% (approximately 6,700,000) of the people in sub-Saharan Africa who need ARVs do not receive treatment. Further, until the progress we have seen in curing AIDS becomes readily available, the 2,925,000 people on ARVs can expect to use the treatment for the rest of their lives. Moreover, a large number these patients will develop drug resistance or side effects that require them to switch from first-line treatment to second-line treatment combinations.

According to one study, almost 22% of people in treatment transition to second-line treatment within a five-year period. The second-line combinations for AIDS currently remain substantially more expensive than the first-line combinations. MSF indicates that second-line combinations probably will not decrease 99% in price like their first-line counterparts. Indeed,

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the second-line combinations can cost up to 11 times as much as first-line treatments.216 These second-line treatments and other patented treatment 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 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.217 By the late 20th-century, India was one of the largest suppliers of generic medications in the world.218 From 1970 to 1995, Indian intellectual property law recognized only patents on processes, not actual pharmaceutical compounds.219 As such, generic manufacturers could reverse engineer pharmaceutical products for export to nations where there was no domestic pharmaceutical patent bar.220 As the “pharmacy to the developing world”221 from 2005 to 2006, Indian exports comprised approximately 40% of the total pharmaceutical industry production.222 Roughly, half of all people in the developing world who receive ARV treatment use products produced in India.223 Moreover, MSF uses ARVs manufactured by Indian generic companies to treat 70% of the people in the organization’s HIV/AIDS project.224

Evidence of the significant effect India’s generic manufacturers have had on the affordability of drugs is reflected in ARV prices. In 2000, the lowest global price for first-line combination of stavudine, lamivudine, and nevirapine was $10,439 a year.225 Paying this amount was, and is, completely out of reach for the majority of patients living in the developing world.226 In 2001, MSF negotiated with the Indian generic manufacturer Cipla a price of $350, which represented a

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216 Id.
220 Sudip Chaudhuri, The WTO and India’s Pharmaceutical Industry, Patent Protection, TRIPS, and Developing Countries 1, 52 (2005).
221 Babovic, supra note at 817.
224 Babovic, supra note at 817.
225 MSF Untangling the Web of Antiretroviral Price Reductions 11th edition available at utw.msfaccess.org/downloads/31
226 Id.
30-fold price reduction. By 2008, competition led by Indian generic manufacturers resulted in the price dropping to $87 a year. A 2009 WHO study indicates that this affordably priced ARV is still the most common first-line therapy. This price differential has made a significant impact in saving lives.

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

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. While patents for selected older ARVs have expired, patents on newer second-line medications will expire as late as 2023. Further complicating this scenario is that patients taking the most common first-line therapy require second-line treatment after twelve months. The WHO also found health risks associated with ofvudine, a component in a widely used stavudine-based ARV. Because of these findings, the WHO recommended countries phase out the use of stavudine as a first-line treatment.

Since becoming TRIPS compliant many Indian firms have pursued business strategies to change from primarily generic to innovative companies to survive in the new environment. This shift

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227 Id.
229 MSF Untangling the Web of Antiretroviral Price Reductions, supra note at 5.
230 Id. at 146.
231 Id.
232 Id. at 141.
233 Id. at 142.
234 Striner, supra note at 203-207
235 Babovic, supra note 228 at 816
236 Background Information on 14HIV AIDS Drugs, Consumer Project on Technology (now operating under new name, Knowledge Ecology International). Available at www.cptech.org/ip/health/sa/loveaffidavit/table11.doc
237 Id.
239 MSF Untangling the Web of Antiretroviral Price Reductions, supra note at 75.
240 Id.
241 Id.
in focus could have an adverse affect 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.243

Negotiations with the European Union is further indication that the now TRIPS complaint India may change its pharmaceutical regulatory system.244 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.245 The agreement includes provisions that would delay or prevent generic manufacturers from accessing brand name drug safety and efficiency data for a set period.246 Another provision includes border measures to detain imported or exported drugs suspected of infringing on intellectual property rights.247 A complete discussion of the adverse effects of the free trade agreements and TRIPS-plus measures is beyond the scope of this Article. The potentially devastating affect such agreements have on the availability and affordability of generic drugs, however, is well documented. Another potential limit to Indian generic drugs 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.248 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.249 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.250

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.251 The ten-year history of Paragraph 6 leaves much room for debate regarding whether it succeeded. 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

244 Henning Grosse Ruse-khan, The International Law Relationship Between TRIPS and Subsequent TRIPS-plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibility, 18 J. INTELL. PROP. L. 325 (2011)
246 Babovic, supra note 228 at 820
247 Id.
248 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).
249 Id.
250 Id.
251 Doha, para 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. The report sets forth criteria to determine if it is possible for Doha to achieve its goal of improving access to patented medicines. This Article uses the report’s economic prerequisites as the starting point to analyze how to encourage generic manufacturers to play a more 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. Yet 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. To increase generic manufacturers’ involvement, a compulsory licensing framework must enable them to meet Paragraph 6’s requirements and achieve a profit.

a. Production and Transactional Costs

Production and transaction costs are among the components generic manufacturers consider when determining whether to enter a market. For paragraph 6 purposes, these production costs include the research and development expenses associated with reverse engineering the patented drug. The generic manufacturer bears the production expense of physically manufacturing the drug, maintaining the physical plant, staff, and distribution and transportation costs. 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. TRIPS-Plus agreements may also increase production costs of creating a generic for export under Paragraph 6. These trade agreements include additional and more

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253 Id.
255 Id. at 46.
256 Id.
257 Tsai, supra note
258 Id.
restrictive intellectual property requirements than prescribed by TRIPS.°°° For example, data exclusivity provisions can deny generic manufacturers access to vital information and necessitate additional testing.°°° Finally, if the effective length of the license is short and the generic manufacturer must produce quickly to fill the order; start up costs may also increase.

Generic manufacturers incur transaction costs associated with exporting under Paragraph 6 provisions. These costs include issuing an export notice, disclosing private information on a dedicated website, and obtaining the compulsory license.°°°° These costs are not exceedingly high and can be recouped by the price of the generic drug. Accordingly, TRIPS production costs 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.°°°°° The absence of time limits or guidance as to what constitutes “reasonable terms and conditions” could result in extensive expenditures of time and money merely to meet a non-TRIPS requirement. 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.

Possible ways to offset these transaction costs is to eliminate the costs associated with the TRIPS’ negotiation requirement 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 is not required.°°°°°°° Specifically, Articles 31’s states, “This 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.”°°°°°°°° Expanding this provision to include situations where the country has insufficient manufacturing capacities, would eliminate the time and costs associated with generic manufactures producing the needed medicines.

°°°° 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, 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.") Id.
°°°°° Doha, para 2(b)(i)-(iii).
°°°°°° Id.
°°°°°° Id.
°°°°°°° CAMR 21.04(3)(c).
°°°°°°°° TRIPS, art. 31
°°°°°°°°° Id.
TRIPS is silent as to how long the compulsory license lasts. Generic manufacturers may be more willing to incur TRIPS related production and transactional costs if they had assurance that the compulsory license was of a sufficient length to generate a revenue stream that allows them to recoup the start-up expense of manufacturing the generic. 268 Another strategy is to have the exporting country offer tax incentives for manufacturers to export under Paragraph 6. Given the political sentiment surrounding Paragraph 6 in the United States, this may not be feasible everywhere. Finally, governments can 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.269 Simply put, generic manufacturers lack commercial incentive to make drugs under a compulsory license for only a minimal profit.270 To counterbalance the previously discussed challenges, generic manufacturers need a large and secure market. Generic manufacturers typically make profits by pricing their product low but sell large quantities.271 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.272

While TRIPS encourages low prices, it does not readily permit the selling of large quantities because of its stipulation that licenses must be produced on a country-by-country basis.273 The majority of developing countries lack the size and financial resources to provide the market generic manufacturers need.274 For example, 34 of the countries that have health expenditures of less than $30 per person per year are in sub-Saharan Africa.275 This amount includes all health spending, not just pharmaceuticals, and includes expenditures from all sources including government entities.276

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268. 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 importing member." Decision, supra note at 2(b)(i).
272. Id. at 481-82
273. TRIPS, at par 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."
274. WHO The World Health Report 2006 , by contrast, even the lowest price for the cheapest triple combination ARV is $99 per person per year.
275. Id.
276. Id.
Notwithstanding the country-by-country requirement, Article 2 of the Doha Declaration acknowledges the ability to use a single compulsory license to deliver generics to multiple countries.\textsuperscript{277} In pertinent part, Article 2b states:

\begin{quote}
the 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 the duration of the license . . . .
\end{quote}

This provision permits countries to pool their demand. Developing countries purchasing medicines in bulk could provide the market characteristics generic manufacturers need.\textsuperscript{278} Bulk production and sale could alleviate the economic difficulties that generic manufactures identify as a primary obstacle to Paragraph 6 exports.\textsuperscript{279} For example, it reduces risk, transaction and distribution costs, and uncertainty generic manufacturers could encounter.\textsuperscript{280}

Countries currently use regional and global arrangements to purchase off patent medicines or for negotiation with patent holders.\textsuperscript{281} To date, these pooling arrangements have not been used with a compulsory license. Several options however, exist for pooled demand arrangements that are consistent with Doha. Countries that are part of qualifying regional trade agreements (RTA)\textsuperscript{282} may re-export drugs imported under Paragraph 6, within the RTA, so long as the other country shares to health problem in question.\textsuperscript{283}

Currently, six African RTAs qualify to pool their demand pursuant to the Paragraph 6 provisions.\textsuperscript{284} 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.\textsuperscript{285} The absence of a regional patent system does not prevent the African RTAs from pooling their demand under Paragraph 6.\textsuperscript{286} It merely requires countries that have a patent on the product must issue a

\textsuperscript{277} TRIPS, art. 2
\textsuperscript{279} Regional Pooled Procurement of Drugs: Evaluation of Programs", mimeo. MSH (2003), "Regional Pooled Procurement of Drugs ...
\textsuperscript{281} Kommerskollegium at 60.
\textsuperscript{282} See Article XXIV of the GATT 1994 and the Differential and More Favorable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903) (Nov. 28, 1979).
\textsuperscript{283} Doha, para 6.
\textsuperscript{284} Kommerskollegium, supra note at 60.
\textsuperscript{285} Id.
\textsuperscript{286} Id.
compulsory license. These compulsory licenses would then form a *de facto* regional compulsory license.\(^{287}\) A similar approach is available to countries that are not part of an African RTA.\(^{288}\) A member country would issue a compulsory license that comprises the demand for all the participating countries.\(^{289}\) The exporting generic manufacturer would fill that one compulsory license. The delivery would then have to be divided by 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.\(^{290}\) It 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.\(^{291}\) So far, however, no regional organization has used the compulsory license provisions in this manner.

### c. Risks

Generic manufacturers engaging in compulsory licensing face more risk than when conducting ordinary production.\(^{292}\) 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.\(^{293}\) A default may also occur, if the products are for public use and there is a change of government in the importing country.\(^{294}\)

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, the quantities to be produced, and the conditions attached.\(^{295}\) These disclosures could enable the brand name manufacturer who holds the 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.\(^{296}\) From the point of view of generic manufacturer, such action by a brand name manufacturer would be costly to the generic manufacturer and could discourage subsequent attempts by the generic manufacturer to obtain compulsory licenses. Finally, 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.\(^{297}\)

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287 *Id.*
288 *Id.*
290 *Id.*
291 This particularly favorable because TRIPS does not require least developed nations to enforce enforcement of pharmaceutical patents until 2016.
292 Kommerskollegium, at 49.
293 *Id.*
294 *Id.*
295 Doha, 2b(ii).
296 Doha, para 4.
297
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. 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. In addition, the generic manufacturer could apply for a compulsory license before there is a specific request from an importing country.

This type of single request enables generic manufacturers to benefit from economies of scale by potentially providing for multiple countries. It also enables generic manufacturers to identify more easily multiple countries interested in a 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? In other words, 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 in continued access to affordable generic versions of patented drugs for developing countries. Yet generic manufacturers have the opportunity to provide another important benefit. To date, only one pair of countries has successfully used the Paragraph 6 provisions to obtain medicine. 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. In addition to the suit brought against South Africa when it attempted to import drugs using the Paragraph provisions, Thailand experienced negative reprisals from its effort to compulsory licenses. In 2007, Thailand issued a compulsory license for a generic version of Kaletra an ARV marketed by Abbott. 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. Moreover, United States government downgraded Thailand's trade status to a country with poor intellectual property protections. 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.\textsuperscript{305}

The active engagement of generic manufacturers could change that power and influence dynamics that current govern the access to medicine debate. This approach builds on the “Capturing the High Moral Ground” concept Bird discusses in his critique on how to maximize access to medicine through compulsory licenses.\textsuperscript{306} 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 Canadian government initiated the compulsory license process with Rwanda.\textsuperscript{307} The shared interests of PhRMA and developing countries exert considerable influence in shaping international agenda and trade agreements.\textsuperscript{308} 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 that in that capacity.

Bird also advances the notion of “narrowly tailoring the compulsory license to genuine humanitarian goals.”\textsuperscript{309} He applies the requirement to compulsory licenses in general. Applying that concept to those Paragraph 6 situations where the country is incapable of manufacturing the needed drugs, however, necessitates more detail. Expanding on Bird’s points, the scope, and intended use of this Paragraph 6’s provision needs clarification.

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.\textsuperscript{310} A commonly referred to example is Egypt’s issuance of a compulsory license for a generic version Viagra.\textsuperscript{311} Issuing compulsory licenses in this manner is distinguishable from developing countries with little or no pharmaceutical infrastructure issuing compulsory license to obtain ARVs and other needed medicines. Countries using the Paragraph 6 provisions are unable to utilize compulsory licenses in the traditional sense as provided by TRIPS. 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

\textsuperscript{308} See Section supra
\textsuperscript{309} Bird, supra note 309 at 213
\textsuperscript{310} A. McGill, Compulsory Licensing of Patented Pharmaceuticals: Why A WTO Administrative Body Should Determine What Constitutes A Public Health Crisis Under the Doha Declaration, WAKE FOREST INTELL. PROP. L J Vol. 10, 70, 90 (20109)
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. Similar to PhRMA, generic manufacturers can use their lobbying efforts to advance this proper scope and use of this Paragraph 6 provision. By focusing global attention on the humanitarian and health imperatives, generic manufacturers could remove the stigma and decrease the animosity surrounding developing countries using Paragraph 6 compulsory license provisions.

**CONCLUSION**

Generic manufacturers and the Paragraph 6 provisions represent an infrequently used partnership that could significantly affect developing countries’ access to much needed medicines. This Article outlines how the meeting of certain prerequisites might encourage generic manufacturers to take a more active role in the compulsory license process. In light of the changing health needs and international obligations of developing countries, this Article suggests that 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 a country lacks the infrastructure and capacity to provide pharmaceutical care for its citizens. Developing countries, wary of political and economic backlash, have not used these provisions. 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. Before there can be an accurate assessment of the effectiveness of the Paragraph 6 provisions, developing countries must be able to use the process without fearing political and economic repercussions. Ultimately, this Article asserts a two-part approach to generic manufacturers’ involvement in the Paragraph 6 process. The first includes ensuring developing countries’ access to needed medicines through the production of affordable generics. The second includes ensuring developing countries access to those medicines by reinforcing the intended scope of Paragraph 6 and countries’ right to use it.

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312 A Gathering Storm: Drug companies Patents Are Under Attack, ECONOMIST, June 9, 2007 at 100. (Even this narrow approach is met with hostility from the pharmaceutical industry. Pharmaceutical executives have expressed outrage at developing countries use of compulsory licenses.)