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Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?

*Jennifer Bjornberg**

I. INTRODUCTION

In June 2005, Brazil threatened to infringe the patent of an anti-AIDS medication, Kaletra, patented and produced by a U.S. based pharmaceutical company, Abbott Laboratories. The resulting controversy necessarily implicated the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property ("TRIPS Agreement") as Brazil was a Member Nation under the agreement and Abbott's product was protected under that agreement. Ultimately, the threat came to a voluntary resolution between both parties, but the dispute raised a number of unique questions relating to international trade and public health concerns.

This article will discuss the recent controversy between Abbott and Brazil and its resolution in light of the TRIPS Agreement. The article will also discuss amendments to and interpretations of the TRIPS Agreement. Part II will describe the background and development of the TRIPS Agreement as applied to the international pharmaceutical industry, specifically, pharmaceutical patent protection. This section will also outline and discuss the relevant articles in the TRIPS Agreement and related amendments, and will briefly address the current ability of developing countries to utilize TRIPS Agreement provisions to break pharmaceutical patents. Part III will delve into the events surrounding and leading up to the Kaletra controversy with an emphasis on the positions of both Brazil and Abbott. Part IV will use the TRIPS Agreement provisions discussed in Part II to support the arguments of both Brazil and Abbott. This section will also include an analysis of the policy arguments for and against international pharmaceutical patent protection. Part V will discuss the resolution of the dispute between Brazil and Abbott and the events contributing to the agreement between both parties. It will also analyze the relative position of each party following the resolution, weighing the costs

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and benefits to each. Part V will also explore the larger effects of the resolution between Brazil and Abbott on the developing world. Finally, Part VI will briefly conclude on the resulting relationship between the recent events and the TRIPS Agreement.

II. OVERVIEW OF RELEVANT TRIPS AGREEMENT PROVISIONS AND AMENDMENTS

A. Background to the Agreement

The system of patent protection established in the World Trade Organization's ("WTO's") Agreement regarding Trade Related Aspects of Intellectual Property is modeled after the U.S. patent system.¹ Pharmaceutical companies played an important role in the development of the TRIPS Agreement. Lobbying by the pharmaceutical industry beginning in the 1980s led to the introduction of intellectual property issues on the international trade agenda and the eventual adoption by the WTO of the U.S. model of intellectual property protection.² The U.S. model was officially adopted with the enactment of the TRIPS Agreement as an annex of the Marrakesh Agreement Establishing the WTO.³

Membership in the WTO is conditioned on compliance with the TRIPS Agreement.⁴ For poor and developing nations, WTO membership is crucial and necessary to any hope of economic growth. Some argue that the TRIPS Agreement requires all WTO member countries to prematurely adopt intellectual property standards appropriate for wealthier countries, "irrespective of their level of development or the social importance of particular products, or to risk trade sanctions."⁵ This controversy frames the present problem, that is, how to balance the property interests of patent holders with the needs of developing countries, both economically and in terms of public health. Any interpretation of the TRIPS Agreement and its application to the dispute between Brazil and Abbott Laboratories necessarily involves an analysis of these issues.

¹ Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103, 108 (2003).

² *Id.* at 109.

³ *Id.*

⁴ Peggy V. Sherman & Ellwood F. Oakley III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353, 361-62 (2004).

⁵ Ruth Mayne, *The TRIPS Agreement and Access to Medicines: An NGO Perspective*, in THE WTO AND DEVELOPING COUNTRIES, 146, 154-55 (Homi Katrak & Roger Strange eds., 2004).

B. Areas of Restriction

The TRIPS Agreement prevents the unauthorized use, production, sale, import, or distribution of patented products for the duration of the patent (now a mandatory twenty years) with very specific and limited exceptions.⁶ When an exceptional case occurs, the TRIPS Agreement places limits on the production⁷ and exportation⁸ of cheap generic versions of patented products, and provides for compensation⁹ to the patent holder.

C. Relevant Articles and Provisions

The preamble states the purpose of the TRIPS Agreement is to “reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measure and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”¹⁰

Article 7 sets out the objectives of the agreement. The objectives reflect more than an interest in protecting intellectual property rights. Article 7 protects these rights in a way that is mutually beneficial to both producers and the consumers. These rights are to be enforced “in a manner conducive to social and economic welfare, and a balancing of rights and obligations.”¹¹

Article 8 establishes the principles of the agreement. It states that “[m]embers may, in formulating, or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”¹² Article 8 also states that nations may take steps to prevent the “abuse” of intellectual property rights or practices that “unreasonably restrain trade or adversely affect the international transfer of technology.”¹³ Any action taken, however, must again be consistent with the agreement.¹⁴

⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 28, para. 1, Apr. 15, 1994, 33 I.L.M. 81, available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS] (The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization); Lazzarini, *supra* note 1, at 109.

⁷ TRIPS, *supra* note 6, art. 28.

⁸ *See id.* art. 31(f).

⁹ *Id.* art. 31(h).

¹⁰ *Id.* pmbl.

¹¹ *Id.* art. 7.

¹² *Id.* art. 8(1).

¹³ TRIPS, *supra* note 6, art. 8(2).

¹⁴ *Id.*

Article 27 of the TRIPS Agreement provides the basic parameters of patent protection. This article provides that all parties must make patents “available for any inventions, whether products or processes, in all fields of technology” subject to standard intellectual property requirements.¹⁵ Article 27 also includes some basic exceptions to the grant of such protection.¹⁶ One such exception effectively allows countries to deny patent protection in circumstances where such denial would be necessary to protect public health and the environment.¹⁷ The scope of this exception is not clear from the language, however, and may be read broadly or narrowly in its application.

Article 28 describes the rights conferred by a patent. This article provides specifically that a patent holder shall have the exclusive rights “to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product.”¹⁸

Article 30 is entitled “Exceptions to Rights Inferred” and, as the title suggests, describes the type of limited exceptions allowed by the TRIPS Agreement to the rights conferred by a patent.¹⁹ Effectively, this article creates “limited exceptions”²⁰ to patent rights so long as the country is able to show that the patent holder’s interests are not unreasonably infringed upon.²¹

Article 31 is entitled “Other Use Without Authorization of the Right Holder” and is commonly referred to as the “Compulsory Licensing” provision. This article, along with Articles 27 and 30, describes an exception to rights conferred by a patent issued by a party to the TRIPS Agreement.²² Compulsory licensing recognizes the government authority of a party to the agreement to force the licensing of a patent that would otherwise be protected by intellectual property laws.²³ Government licensing effectively allows for distribution of a patented product to its citizens.²⁴ The article dictates that payment should be made to the patent

¹⁵ *Id.* art. 27(1); see Sherman & Oakley, *supra* note 4, at 363.

¹⁶ See TRIPS, *supra* note 6, art. 27(2).

¹⁷ Lazzarini, *supra* note 1, at 112.

¹⁸ TRIPS, *supra* note 6, art. 28(1)(a).

¹⁹ *Id.* art. 30.

²⁰ *Id.*

²¹ Lazzarini, *supra* note 1, at 112.

²² See TRIPS, *supra* note 6, at arts. 27, 30–31; see also Dora Kripapuri, Note, *Reasoned Compulsory Licensing: Applying U.S. Antitrust’s “Rule of Reason” to TRIP’s Compulsory Licensing Provision*, 36 NEW ENG. L. REV. 669, 676 (2002).

²³ TRIPS, *supra* note 6, art. 31.

²⁴ See *id.* art. 31(f).

holder for the relinquishment of his property rights,²⁵ but in reality the sum is generally nominal and is modest in comparison both to the amount invested by the patent-holder and the potential returns available under the usual regulatory scheme.²⁶ Article 31 provides for five types of situations in which granting compulsory licenses would be appropriate: refusal to deal,²⁷ national emergency or extreme urgency,²⁸ anti-competitive practices,²⁹ non-commercial use,³⁰ and dependent patents.³¹

Article 31 defines conditions for compulsory licensing. First, Member Nations must make efforts to obtain permission to use the patent from the patent holder "on reasonable commercial terms and conditions" and show "that such efforts have not been successful within a reasonable period of time."³² An exception to this requirement is provided "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."³³ Second, the compulsory license must be limited only to the purpose for which it was authorized.³⁴ The license may not be exclusive,³⁵ and it is not assignable.³⁶ Also, the license must be predominantly used for the domestic market in which it was granted.³⁷ The license must be revocable.³⁸ There must be adequate remuneration for the use of the patent.³⁹ Finally, the license and its terms are judicially reviewable.⁴⁰

Article 31(f) of the TRIPS Agreement provides a significant restriction on the use of a compulsory license by restricting options for parallel import/export of generic medications.⁴¹ A compulsory license under Article 31 does not grant the license holder the right to export the generic version

²⁵ *Id.* art. 31(h).

²⁶ Kripapuri, *supra* note 22, at 670.

²⁷ TRIPS, *supra* note 6, art. 31(b).

²⁸ *Id.*

²⁹ Subsection (k) of the Article provides that efforts to obtain authorization for use of the patent from the patent holder are not required "where compulsory licensing is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive." *Id.* art. 31(k).

³⁰ TRIPS, *supra* note 6, art. 31(b).

³¹ *Id.* art. 31(l).

³² *Id.* art. 31(b).

³³ *Id.*

³⁴ *Id.* art. 31(c).

³⁵ *Id.* art. 31(d).

³⁶ TRIPS, *supra* note 6, art. 31(e).

³⁷ *Id.* art. 31(f).

³⁸ *Id.* art. 31(g).

³⁹ *Id.* art. 31(h).

⁴⁰ *Id.* art. 31(i).

⁴¹ *Id.* art. 31(f).

of the drug to other countries; conversely, a country granted a compulsory license may not import the generic version of the drug. This provision reduces potential market competition to patent holders, giving a significant advantage to the U.S. and British governments who maintain control over the majority of pharmaceutical companies and subsequently their patents.⁴² This ability to commandeer patents arguably allows these governments to negotiate for reasonable prices with the patent-holders. Developing countries under the TRIPS Agreement remain at the mercy of the pharmaceutical companies.⁴³ However, the WTO has provided an interim waiver of Article 31(f) allowing qualified Member Nations to import generic versions of patented pharmaceuticals produced under compulsory licenses in other countries.⁴⁴ This waiver was meant to benefit poorer countries in the midst of a public health crisis without the means of domestic production.

Article 70(8) makes specific reference to the protection of pharmaceutical patents.⁴⁵ At the time the TRIPS Agreement went into effect, many developing nations did not recognize or enforce patent protection for pharmaceuticals. Article 70(8) attempted to correct this by requiring Member Nations not yet providing “patent protection for pharmaceuticals . . . commensurate with its obligation under Article 27” to do so as part of compliance.⁴⁶

Overall, the TRIPS Agreement does provide some highly limited and poorly defined avenues into the realm of compulsory licensing of patent protected pharmaceutical inventions. Arguably, this vagueness subjects poorer countries to the whim of interpretation and application of the terms of the TRIPS Agreement.

D. Amendment and Interpretation Regarding Public Health Concerns: The Doha Declaration

The WTO held the Ministerial Conference in Doha in November 2001 to address and clarify international trade issues. By the time the conference was held, the WTO was forced to address the increasing number of concerns surrounding the TRIPS Agreement, specifically those relating to public health in developing countries.⁴⁷

Developing countries asserted that the exceptions in Article 27 of the

⁴² See Mayne, *supra* note 5, at 150–51.

⁴³ See *id.* at 151.

⁴⁴ General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WT/L/540 and Corr.1 (Sept. 1, 2003), available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

⁴⁵ TRIPS, *supra* note 6, art. 70(8).

⁴⁶ *Id.*; see Sherman & Oakley, *supra* note 4, at 363–64.

⁴⁷ See Mayne, *supra* note 5, at 149.

Agreement needed further official clarification in order for poorer countries to be able to utilize them free from fear of controversy.⁴⁸ Specifically, developing countries argued that they hesitated to implement “parallel trading or compulsory licensing for fear of trade sanctions or legal actions by Western governments and pharmaceutical industries.”⁴⁹ Predictably, pharmaceutical companies from many of the developed countries lobbied against any amendment to the TRIPS Agreement, arguing that the language already contained therein was sufficient.⁵⁰

In addition to raising issues surrounding domestic production rights, a group of developing countries, including Brazil, lobbied for the ability to export generic versions of pharmaceuticals manufactured domestically under a compulsory license.⁵¹ Perhaps this underscores the economic factors motivating the public health push (to lower pharmaceutical prices for poorer countries worldwide), and it may well validate the concerns of the “greedy” pharmaceutical industry that the TRIPS Agreement would lead to a global collapse of drug prices.

Trade representatives from wealthy developed countries unexpectedly agreed to the developing nations’ proposed public health clarification of the TRIPS Agreement. These propositions were at odds with the property protection concerns generally characteristic of wealthy nations, as the propositions “affirmed the primacy of public health over private patent rights.”⁵² The conference ultimately issued an official declaration (“Doha Declaration”) stating that:

[T]he TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement 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. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.⁵³

This statement, issued at the close of the conference, was intended to close the gap between the TRIPS Agreement’s emphasis on commercial concerns

⁴⁸ Sherman & Oakley, *supra* note 4, at 366.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* at 372.

⁵² See Mayne, *supra* note 5, at 149–50.

⁵³ Declaration on the TRIPS Agreement and Public Health, para. 6, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm [hereinafter Doha Declaration].

of patent owners and public health concerns.

The conference, in addition to addressing Article 27 of the Agreement, also considered the controversial provisions of Article 31. The Doha Declaration included a statement specifically referencing the use of compulsory licenses: "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."⁵⁴

The Doha Declaration also clarified the circumstances that constitute a "national emergency" under Article 31. "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."⁵⁵

The Doha Declaration potentially allows governments of developing countries to use the existing provision of the TRIPS Agreement to protect public health without challenge.⁵⁶ The Doha Declaration did not and could not, however, remove the potential for external pressures. It remains to be seen how effective this kind of official support will be in allowing developing countries to utilize the exceptions provided to them under the TRIPS Agreement.

As the existence of this and many other disputes will attest, the Doha Declaration did not solve all of the problems relating to public health arising out of the TRIPS Agreement, but it was a step forward and an important victory for developing countries.⁵⁷

E. Current State of the Ability of Developing Countries to Produce and Export Generic Versions of Patented Medicines

The conflict at the Doha Ministerial Conference, and almost any other regarding the application of the TRIPS Agreement to public health issues, leads to the question of just what does the TRIPS Agreement allow. Taking into account the original document, and its amendments and clarifications, what exactly are developing countries allowed to do? The quick answer is that the application of benefits envisioned by the TRIPS Agreement and its exceptions will vary dramatically from country to country.⁵⁸ Until

⁵⁴ *Id.* para. 5(b).

⁵⁵ *Id.*

⁵⁶ See Mayne, *supra* note 5, at 150.

⁵⁷ See *id.*

⁵⁸ See generally Wesley A. Cann, Jr., *Creating Standards and Accountability for the Use of the WTO Exception: Reducing the Role of Power-Based Relations and Establishing a Balance Between Sovereignty and Multilateralism*, 26 YALE J. INT'L L. 413 (2001).

precedent or amendment further defines the provisions set out in the TRIPS Agreement, the success rate of utilizing the agreement's exceptions to patent rights will depend on how courts interpret those exceptions amidst the balance of public health concerns and the property interests of the patent holders.⁵⁹

The "national emergency" exception allowing compulsory licensing of a product serves as a general example of the uncertain nature of the application of exceptions under the TRIPS Agreement.⁶⁰ Despite the Doha Declaration's attempt at clarification, the WTO has not provided a precise definition of what constitutes a "national emergency" for purposes of the compulsory licensing exception.⁶¹ This type of imprecision may be an inherent byproduct of the relative newness of the TRIPS Agreement, but it is likely to lead to disparate application and general confusion until such vagueness is cured.⁶²

Critics argue that under the current TRIPS Agreement the production of generic medicines will be progressively curtailed.⁶³ The TRIPS Agreement presently restricts both the export of cheap generic drugs and their production.⁶⁴ Restriction of production in combination with the extension of patent protection to a twenty year period in all countries means that "generic production for both domestic use and for export of new medicines will become dependant on a complicated web of compulsory licensing and other exceptions."⁶⁵ This allows pharmaceutical companies to maintain and strengthen their hold over markets in developing countries and consequently to set higher prices for their drugs.⁶⁶ "This points to a need for a much more substantive reform of the TRIP's [sic] Agreement than is currently contemplated by the WTO."⁶⁷

Some argue that the potential success of developing countries in using the TRIPS Agreement exceptions to break pharmaceutical patents and to produce generic versions of patented drugs will depend entirely on the "the willingness of developed countries to respect the flexibility" provided by the TRIPS Agreement.⁶⁸ Furthermore, without assurances of such flexibility by developed countries, developing countries will be unable to

⁵⁹ Lazzarini, *supra* note 1, at 112–13.

⁶⁰ See TRIPS, *supra* note 6, art. 31(f).

⁶¹ Kripapuri, *supra* note 22, at 691; See Doha Declaration, *supra* note 53, para. 5(b).

⁶² See Kripapuri, *supra* note 22, at 692, for a general discussion of the potential breadth of interpretation and application of this phrase.

⁶³ See Mayne, *supra* note 5, at 154.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ Lazzarini, *supra* note 1, at 133.

meet their obligations both to international patent holders and their citizens threatened by impending health crises.⁶⁹ This argument suggests that the TRIPS Agreement, as it exists today, provides the upper hand to patent holders and leaves developing countries to cater to those holding the chips.

III. OVERVIEW AND BACKGROUND ON RECENT CONTROVERSY BETWEEN BRAZIL AND ABBOTT LABORATORIES

A. Background

To understand fully what is at stake in the conflict between Brazil and Abbott Laboratories, it is necessary to consider relevant statistical and factual background relating to the AIDS epidemic generally, the cost of treatment, and the effects of both on Brazil. The year 2006 will mark the twenty-fifth anniversary of the AIDS pandemic.⁷⁰ In 2001, the United Nations calculated the death toll worldwide at twenty-two million.⁷¹ A vaccine is estimated to be ten years away.⁷² In the United States and developed countries, AIDS has become a livable condition through the effective use of a combination of anti-AIDS medications known as antiretrovirals.⁷³ These antiretroviral combinations are expensive and typically cost a patient \$10,000–\$15,000 per year.⁷⁴

Brazil became caught up in the AIDS epidemic in the early 1990s, and faced a projected rate of infection of 1.2 million people by the year 2000.⁷⁵ In reaction to these grim predictions, the Brazilian government adopted a national policy that guaranteed all persons with HIV the right to free access to antiretroviral treatment.⁷⁶ After the implementation of this national policy, the death rate attributed to the AIDS virus fell sixty percent.⁷⁷ By 2002 at least 100,000 of Brazil's citizens were receiving antiretroviral medications from the government in order to combat the virus.⁷⁸ This turning of the tide was almost universally attributed to the antiretroviral program sponsored by the Brazilian government.⁷⁹

The ability of the Brazilian government to provide this kind of access

⁶⁹ *Id.* at 133–34.

⁷⁰ *See* Sherman & Oakley, *supra* note 4, at 353–54.

⁷¹ *Id.* at 353.

⁷² *Id.* at 354.

⁷³ *Id.*

⁷⁴ Sherman & Oakley, *supra* note 4, at 355; Lazzarini, *supra* note 1, at 129.

⁷⁵ Lazzarini, *supra* note 1, at 128.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

to its citizens was a product of "government commitment, the reduced cost of pharmaceuticals made possible by domestic manufacture of generic drugs, and negotiated price discounts for other drugs."⁸⁰ In 2001, the Brazilian government was paying \$4,137 annually to provide medication to each person infected.⁸¹ In comparison to the medication costs of victims living in the United States, Brazil's program had managed to reduce the cost of antiretrovirals to less than half the price being paid in developed countries.⁸²

B. External Events Contributing to and Explaining Brazil's Position in the Controversy

In the time preceding the recent controversy between Brazil and Abbott Laboratories over the production and sale of Kaletra, there were a number of external events that may have contributed to the rising tensions. Each of these occurrences would not alone justify Brazil's position, but the combination of events created an international climate that provides a contextual basis for Brazil's actions.

First, in 2005, the remaining countries whose laws supported generic-producing companies were required to implement the TRIPS Agreement, effectively eliminating the last source for affordable generic versions of much needed medicines.⁸³ Specifically, India, one of the major sources for cheap generic alternatives to otherwise patent-protected products, was given until January 1, 2006 to comply with the TRIPS Agreement.⁸⁴ The pre-TRIPS Agreement production and distribution of generic medicines had many benefits. For example, in 2001, a leading generic pharmaceutical manufacturer in India (who at the time was under no international patent protection restrictions) offered to sell the South African government generic versions of antiretroviral medications at a fraction of the prices offered by the patent holders.⁸⁵ In response to this offer, the large pharmaceutical companies holding the patents to these drugs significantly lowered their prices in Africa.⁸⁶ Not to be outdone, some pharmaceutical companies offered their drugs to the ailing countries at cost.⁸⁷

It can be argued that by barring manufacture by countries that have the technical capacity to produce and distribute generic versions of these expensive medications, a monopoly will be formed. The majority of

⁸⁰ Lazzarini, *supra* note 1, at 129.

⁸¹ *Id.*

⁸² *Id.*

⁸³ See Mayne, *supra* note 5, at 151.

⁸⁴ Kripapuri, *supra* note 22, at 688.

⁸⁵ Sherman & Oakley, *supra* note 4, at 357.

⁸⁶ *Id.*

⁸⁷ *Id.*

pharmaceutical patents are held by only a handful of countries, including the United States, Great Britain, Germany, Japan, and Switzerland.⁸⁸ If the pharmaceutical manufacturers are also the patent holders, they may choose to extract a monopoly profit from a drug rather than license the patent to allow others to manufacture the drug. Without the competition provided by multiple manufacturers of a drug, the market price will inevitably be higher. The developing countries most in need of inexpensive licenses to patents held by companies in industrialized nations will be left without access or means to obtain affordable medicines.

Second, the WTO recently extended the term of patent protection under the TRIPS Agreement to twenty years.⁸⁹ This increase in the duration of patent protection is exacerbated by the fast moving pace of the AIDS virus itself as well as the pace of research and development. Both factors render most new AIDS medications obsolete after a matter of years, making access to generic versions of those medications impossible. Some argue that this predicament leaves developing countries “dependent on a complicated web of compulsory licensing and other exceptions.”⁹⁰ Brazil’s threatened invocation of those exceptions may not, as the argument goes, be unreasonable under these circumstances.

The third and most basic factor contributing to Brazil’s position is the cost to the government of providing treatment to its citizens. Brazil provides AIDS drugs to its citizens who need them free of charge, but as mentioned before it costs the government roughly \$4,137 per patient.⁹¹ Currently there are an estimated 160,000 patients.⁹² Brazil has managed to keep costs down through various means, including the legal domestic manufacture of generic versions of HIV and AIDS medications existing prior to 1994 as “TRIPS applies only to drugs patented and placed on the market after that date.”⁹³ However, due to the changing nature of the disease and the constant development of new drugs to combat new mutations and strains, the drugs falling within the pre-1994 category will soon be obsolete.⁹⁴

The last and most controversial factor contributing to Brazil’s actions

⁸⁸ Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L. L. 317, 324 (2005).

⁸⁹ See Understanding the WTO, Intellectual Property: Protection and Enforcement, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Feb. 4, 2006).

⁹⁰ Mayne, *supra* note 5, at 154.

⁹¹ Lazzarini, *supra* note 1, at 129.

⁹² *Brazil Reaches With Abbott Labs in AIDS Drug Dispute*, ASSOCIATED PRESS, October 12, 2005, available at <http://abclocal.go.com/wls/story?section=local&id=3528743> [hereinafter *Brazil Reaches*].

⁹³ Lazzarini, *supra* note 1, at 132–33.

⁹⁴ *Id.* at 133.

is the fact that threats to produce generic versions of pharmaceuticals without a license from the patent holder have served Brazil well in the past.⁹⁵ In March 2001, Brazil made a similar threat to Merck regarding their patented anti-AIDS drugs, and Merck responded by reducing prices.⁹⁶ In August 2001, shortly after the Merck success, Brazil threatened the Swiss drug company, Roche, and received a forty percent reduction on the price of their drug, Viracept.⁹⁷ This may validate the idea that threats to manufacture generic medicines without a license from the patentee are an effective way to keep drug prices at an acceptable level, or at least one that the Brazilian government deems affordable.

C. External Events Contributing to and Explaining Abbott's Position in the Controversy

The first circumstance justifying Abbott's resistance to Brazil's requests is the fact that Brazil has a recognized history of abusing intellectual property rights.⁹⁸ Brazil's request in the area of pharmaceutical patents may be characterized as a continuation of a larger trend. At the least it might lead to a suspicion of Brazil's motivations being more economic, and not related solely to public health.⁹⁹ Also, the aforementioned pattern of threats by Brazil to infringe pharmaceutical AIDS patents may reflect this cavalier attitude toward property rights.¹⁰⁰ The very fact that this is not the first time Brazil has made this kind of threat may discredit the urgency of the present situation.

Another factor supporting Abbott's resistance is Brazil's "local working" requirement. In 1996 Brazil adopted the Industrial Property Law, which stated that patent protection would be extended to products developed after the TRIPS Agreement so long as the manufacturer commences conducting some part of the production of the drug in Brazil

⁹⁵ See Ubirajara Regis Quintanilha Marques, Valesak Santos Guimaraes & Caitlin Sternberg, *Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, 60 FOOD & DRUG L.J. 471, 474 (2005).

⁹⁶ See Sherman & Oakley, *supra* note 4, at 357–58.

⁹⁷ *Id.*

⁹⁸ See *id.*; see also Office of the United States Trade Representative, *Brazil Generalized System of Preferences Intellectual Property Rights Review Extended*, 12/06/04, available at http://www.ustr.gov/Document_Library/Press_Releases/2004/December/Brazil_Generalized_System_of_Preferences_Intellectual_Property_Rights_Review_Extended.html (last visited Oct. 25, 2006) [hereinafter Generalized System of Preferences].

⁹⁹ See *infra* Section IV. for a discussion of the economic implications of maintaining public health and the suggestion that matters of economy and public health may hold separate places in Brazil's motivation in pushing for lower costs. See also Generalized System of Preferences, *supra* note 98.

¹⁰⁰ See Sherman & Oakley, *supra* note 4, at 357–58.

within three years.¹⁰¹ The adoption of this law, in addition to the TRIPS Agreement exemption for drugs on the market before 1994, has allowed the Brazilian government to license generic local production of eight of the twelve antiretroviral medications currently being used to treat the AIDS virus.¹⁰² The adoption of this law has led to considerable controversy and in 2001 culminated with the United States filing a complaint with the WTO against Brazil for its use of the law.¹⁰³

D. The Substantive Controversy

The TRIPS Agreement has often been touted as “a compromise between the interests of the developed and developing world.”¹⁰⁴ As such the Brazil/Abbott Labs dispute exemplifies the competing interests at play within the agreement.

In June 2005, Brazil’s Health Ministry threatened to infringe the patent on Kaletra, an anti-AIDS medication owned and developed by Abbott Laboratories; Brazil said that it would produce a generic version of the drug in government laboratories unless Abbott agreed to lower the price or voluntarily grant patent rights to the Brazilian government.¹⁰⁵ Kaletra is one of the medications included in “the so-called drug cocktail used to treat patients with HIV or AIDS;” in justifying its position, the health ministry asserted that the price of Kaletra “previous to the agreement was so high that it endangered the sustainability of Brazil’s AIDS program.”¹⁰⁶

IV. THE EFFECTS OF THE TRIPS AGREEMENT ON THE RECENT DISPUTE AND RESOLUTION

A. Arguments for Abbott Under the TRIPS Agreement

The main argument for Abbott under the TRIPS Agreement is simply that no accepted definition of “national emergency” has been put forth by the WTO,¹⁰⁷ and Brazil has yet to successfully manufacture patented pharmaceuticals under any provision defined in the TRIPS Agreement.¹⁰⁸

¹⁰¹ Lazzarini, *supra* note 1, at 129; Sherman & Oakley, *supra* note 4, at 358.

¹⁰² Lazzarini, *supra* note 1, at 129.

¹⁰³ See Sherman & Oakley, *supra* note 4, at 358 (discussing the elements of the complaint and its outcome).

¹⁰⁴ *Id.* at 362.

¹⁰⁵ Gerald Jeffris & Bernd Radowitz, *Brazil, Abbott Reach Deal On Lowering Price For AIDS Drug*, DOW JONES NEWSWIRES, Oct. 11, 2005, available at <http://news.fxclub.com/forex/news?action=view&id=1111452&key=35e132faa4506630bc7138aea2f8f9cb305e36b0>.

¹⁰⁶ *Brazil Reaches*, *supra* note 92.

¹⁰⁷ Marques, Guimaraes & Sternberg, *supra* note 95, at 477.

¹⁰⁸ *Id.* at 474.

The case of Brazil is certainly not the direst,¹⁰⁹ and therefore Brazil should not be granted a compulsory license to manufacture Abbott's patent-protected medicine. There are additional arguments available to Abbott, however, under several of the various Articles of the TRIPS Agreement.

1. Argument Under Article 70(8)

The most basic argument available to Abbott under the TRIPS Agreement is the specific inclusion of pharmaceutical patents within its provisions. The explicit reference to pharmaceutical patents in Article 70(8), in conjunction with Article 27's basic patent protections, makes clear that the TRIPS Agreement was intended to enforce pharmaceutical patent rights, and this coverage represents one of the largest victories for the pharmaceutical companies developing and producing the drugs.¹¹⁰ In order for this argument to hold, however, Abbott must address the question of whether any exceptions to this basic provision of protection apply in this case. This requires an evaluation of those exceptions and separate arguments refuting the application of each one under the circumstances.

2. Argument Against the Application of Article 27 Exceptions

The Article 27 exception that denies patent protection in order to protect public order and "human life" contains no specific language regarding the interpretation and application of those terms.¹¹¹ Pharmaceutical companies argue against a broad interpretation of this language, because an exception to patent protection whenever human life is implicated would completely eliminate the use of pharmaceutical patents, as pharmaceuticals inherently deal with the promotion and preservation of human life.¹¹² As a corollary argument, a broad interpretation and application of this exception would conflict with the protection provided to pharmaceutical patents under Article 70(8).¹¹³

3. Argument Against the Application of Exceptions Provided in Article 31

Article 31's provision for compulsory licensing is the exception most likely to be sought in any case involving pharmaceutical patents. One way to prevent a compulsory license from being issued under Article 31 is to

¹⁰⁹ *Id.* at 471 (noting the comparison between Brazil's number of citizens infected with AIDS, which currently sits at less than one percent of the total population and the South African infection rate, which is well over twenty percent).

¹¹⁰ Sherman & Oakley, *supra* note 4, at 364; TRIPS, *supra* note 6, art. 70(8).

¹¹¹ Sherman & Oakley, *supra* note 4, at 368.

¹¹² *Id.*

¹¹³ *Id.*

attack the conditions that must be satisfied in order to use the exception.¹¹⁴ The first provision, found in Article 31(b), requires that the proposed user attempt to gain authorization for the use of the patent from the patent holder under “reasonable commercial terms and conditions.”¹¹⁵ It could be argued that Brazil’s efforts to obtain authorization are unreasonable and that the terms and conditions surrounding those demands, namely threats to disregard patent protection for Kaletra, supersede reasonable commercial processes required under Article 31(b). Brazil may certainly counter that the commercially reasonable negotiations under Article 31(b) are not required because this is an exceptional case of “national emergency” or “public non-commercial use.”¹¹⁶ The Doha Declaration’s statement regarding the term “national emergency” aids in its interpretation but falls short of providing a concrete definition.¹¹⁷ Despite the vague nature of that statement, the Doha Declaration’s direct reference to the AIDS epidemic may bolster Brazil’s argument. However, Brazil’s established pattern of threats to pharmaceutical companies under the guise of national emergency may again lessen its credibility.

There are also policy arguments against the use of compulsory licensing of pharmaceutical patents for AIDS drugs. For example, compulsory licensing may create a perverse incentive to not manufacture drugs most likely to be subject to compulsory licensing.¹¹⁸ Generally speaking, this would include drugs needed to treat fatal diseases such as AIDS rampant in developing countries. This chilling effect on drug development also implicates trade relations. Pharmaceutical companies may avoid entering the market of countries that do not have robust protection of intellectual property rights.¹¹⁹ This would lead to losses for both parties.

Another problem with compulsory licensing involves the nature of the diseases these drugs are meant to treat. It is possible that more resistant strains of the AIDS virus will develop, rendering existing drugs useless.¹²⁰ Currently, there are no drugs that cure AIDS or HIV, and the argument goes that providing widespread access to these drugs without strict supervision will only lead to more virulent and drug-resistant strains of the virus that will kill more victims.¹²¹ According to this argument, the loss of profits

¹¹⁴ See TRIPS, *supra* note 6, art. 31(b)–(j).

¹¹⁵ *Id.* art. 31(b).

¹¹⁶ *Id.*

¹¹⁷ Doha Declaration, *supra* note 53, para. 5(b).

¹¹⁸ Kripapuri, *supra* note 22, at 671.

¹¹⁹ *Id.* at 697; see also Richard Adelstein, *Equity and Efficiency in the Market for Ideas*, 17 CONN. J. INT’L L. 249, 260 (2002).

¹²⁰ Kripapuri, *supra* note 22, at 671.

¹²¹ *Id.* at 697–98.

from compulsory licensing and uncontrolled distribution triggers a domino effect crippling, and in a worst case scenario bankrupting, the pharmaceutical companies forced to license their patents and develop drugs for an exploding number of strains of the virus. The argument for recouping costs for AIDS drugs through the use of patent protection and high prices thus becomes more relevant and applicable in the case of a mutating disease.

As a practical matter, there is the fear that cheap generic versions of patented drugs produced as a result of compulsory licensing would possibly infiltrate the more lucrative markets.¹²² The TRIPS Agreement and the compulsory licensing article specifically include a provision meant to guard against just such an outcome. Subsection (f) of Article 31, as discussed earlier, is intended to limit the use of a compulsory license to mainly domestic markets. The language is not absolute, however, and it is again unclear to what extent parallel importing would be allowed should generic versions of patented AIDS drugs be manufactured under a compulsory license.

4. Arguments Supporting the Need for Patent Protection

According to the Pharmaceutical Research and Manufacturers of America, research and development is “the key to pharmaceutical innovation.”¹²³ Furthermore, research and development is a “long, risky and expensive” process.¹²⁴ The average cost of developing a new drug is above \$800 million.¹²⁵ The average time taken in development is 14.2 years, yet the average patent life of a drug is comparatively short (11 to 12 years compared to the 18.5 year patent life in other industries).¹²⁶ As little as 1 in 10,000 candidates screened compounds will result in a medicine that can be sold—patent protection is needed so that the research and development expenses associated with successful and failed efforts can be recovered.¹²⁷ Therefore, patent protection is needed in order to yield any return on investments and thus incentivize the continuing development of new drugs. Also, while pharmaceuticals are incredibly costly to create, they are fairly easy and inexpensive to copy and reproduce.¹²⁸ Thus, even poor,

¹²² *Id.* at 671.

¹²³ Wesley A. Cann, Jr., *On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism*, 25 U. PA. J. INT'L ECON. L. 755, 791 (2004).

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.* at 791–92.

¹²⁷ *Id.* at 792.

¹²⁸ *Id.* at 793.

developing countries are able to pirate these products and harm the pharmaceutical companies that originally developed the drug. For these reasons, the Pharmaceutical Research and Manufacturers of America maintain that intellectual property protection is essential for the existence of a pharmaceutical industry.¹²⁹

5. Response to Concerns About the Negative Impact of the TRIPS Agreement

In response to the call for a reduction of patent rights as a means of helping developing countries gain access to much needed medications, “pharmaceutical companies and the governments of [industrialized countries] initially insisted that the issue was a red herring, and that other factors were far more important in explaining the lack of access.”¹³⁰ The same companies and governments also asserted that a reduction of intellectual property rights, even if limited to developing countries, would ultimately inhibit or chill research and development for drugs in the future.¹³¹ In the extreme, supporters of pharmaceutical patent protection put forth the idea that completely dismantling the current system of patent protection to create greater access to medications now may leave pharmaceutical developers without the resources to respond to the “next great global epidemic.”¹³²

Strong supporters of pharmaceutical patent protection argue that the harm caused by higher prices of patented drugs is counterbalanced by the continual expiration of older pharmaceutical patents, because the expiration of a patent causes a drop in the price of the drug it once protected, as the expired patent no longer prevents competitors from manufacturing competing generic versions of the drug.¹³³ The argument is that for every drug a developing country cannot afford, another one once protected by a now-expired patent will become affordable. Unfortunately, this argument assumes that older drugs will meet the needs of developing countries, which is not the case with AIDS drugs. AIDS medications are generally part of a combination therapy. Newer drugs are often necessary as alternatives to regimens that have failed or are no longer effective, or as a cure to serious side effects of the ever-changing regimens.¹³⁴ The present twenty year mandatory protection for each patent under the TRIPS Agreement means that AIDS drugs are likely to be obsolete and ineffective by the time their

¹²⁹ *Id.* at 793–94.

¹³⁰ Mayne, *supra* note 5, at 148–49.

¹³¹ *See id.* at 149.

¹³² Adelstein, *supra* note 119, at 260.

¹³³ *See* Lazzarini, *supra* note 1, at 110–11.

¹³⁴ *See id.*

associated patents expire.

B. Argument for Brazil Under the TRIPS Agreement

1. Argument Under Articles 7 and 8

Articles 7 and 8 suggest that Brazil's use would be within the TRIPS Agreement's objectives and principles.¹³⁵ Brazil's use would be beneficial to social welfare according to the Article 7 balance¹³⁶ and would properly fit into the public health exception provided by Article 8.¹³⁷ This argument is strengthened by the statement included in the Doha Declaration emphasizing the consideration of Articles 7 and 8 when interpreting other provisions of the Agreement.¹³⁸

2. Argument Under Article 27

Under Article 27, Brazil should be able to refuse to enforce any patent protection of the drug because the exploitation of the drug is necessary to protect public health.¹³⁹

3. Argument Under Article 30

Brazil's use of the drug would fall under Article 30's limited exceptions. As the article left the scope of "limited exceptions" undefined, qualifying the situation as such would be simple enough.¹⁴⁰ The problem comes, however, when approaching the other requirements of Article 30. Brazil must then show that their proposed use of Kaletra would not "unreasonably conflict with a normal exploitation" of the drug, and would not "unreasonably prejudice the legitimate interests" of Abbott.¹⁴¹

4. Argument Under Article 31

The most viable argument arises under the compulsory licensing provisions found in Article 31 of the TRIPS Agreement.¹⁴² Article 31 expressly grants the right for governments to seek compulsory licenses for patents, and there are arguments that Brazil could assert rights under this

¹³⁵ See TRIPS, *supra* note 6, at arts. 7, 8 (emphasizing the Agreement's goal of adopting measures to protect the social welfare of members).

¹³⁶ See *id.* art. 7.

¹³⁷ See *id.* art. 8.

¹³⁸ See Doha Declaration, *supra* note 53, para. 5(a).

¹³⁹ See TRIPS, *supra* note 6, art. 27.

¹⁴⁰ See *id.* art. 30.

¹⁴¹ *Id.* art. 30.

¹⁴² See *id.* art 31.

article.¹⁴³

An argument can be made that the use of Kaletra in this instance would fall under the guise of “national emergency” as provided for in Article 31(b)¹⁴⁴ and could thereby be justified. Also, the Doha Declaration’s grant of power to each Member Nation to decide for itself the conditions of a national emergency may bolster this argument.¹⁴⁵ It is not clear, for example, that the WTO requires that Brazil be steeped in disease before declaring the compulsory licensing a necessity. The licensing of a medication against the will of the patent holder may be a necessary means of averting such disaster. It is unclear, however, how well an argument such as this would hold without some clear declaration from the WTO. As the Doha Declaration shows, the WTO has been hesitant to provide a concrete definition of “national emergency” on which an outcome could be easily predicted.¹⁴⁶

5. Debunking the Need for Patent Protection of Pharmaceuticals in Developing Countries

In 2002 the British Government set up an independent Commission on Intellectual Property Rights.¹⁴⁷ The Commission published a report criticizing public health related aspects of the TRIPS Agreement and its application. The report stated that “the evidence suggests that patent protection has an effect on the prices charged for medicines . . . in the absence of patents more people would be able to afford the treatments they need.”¹⁴⁸ The argument this statement would support may be too broad as it suggests a call for the removal of all pharmaceutical patent protection when affordability requires it. The public health crisis exception under the TRIPS Agreement would appear to be a better compromise to address the concern in the report, and the finding empirically supports the need to allow such exceptions.

There is also an argument against the need for patent protection to support the continued existence of research and development. However, the report from the independent Commission on Intellectual Property Rights noted that “the evidence suggests that the IP system hardly plays any role in stimulating research on diseases particularly prevalent in developing countries, except for those diseases where there is also a substantial market

¹⁴³ *See id.*

¹⁴⁴ *Id.*

¹⁴⁵ *See Doha Declaration, supra note 53, para. 5(c).*

¹⁴⁶ *See id.*

¹⁴⁷ *See Mayne, supra note 5, at 150.*

¹⁴⁸ *Id.*

in the developed world.”¹⁴⁹ The question then becomes how much of the market for Kaletra is made up of the “developed world.” If most of the impetus for research and development of Kaletra and other drugs does not come from developing countries, enforcing patent protection in those countries does not significantly impact research and development activity.

Many critics question the idea that patent protection is absolutely necessary to incentivize research and development, especially in the case of developing countries. “Patent-driven research is primarily supported by profits derived from the lucrative Western markets and not by any anticipated profits in impoverished nations.”¹⁵⁰ Some critics even suggest that strong patent protection can actually deter further research and development by discouraging potential researchers from pursuing the development of new medications that involve the use of other patent-protected pharmaceuticals.¹⁵¹

It has also been argued that the amount expended on research and development and the amount of income gained from a patented drug are not necessarily directly correlated.¹⁵² Some have even asserted that the research and development costs cited by the pharmaceutical industry are actually inflated because they do not reflect the federal government subsidies the industry receives. Also, the industry receives substantial tax credits for various development costs that may not be reflected in stated research and development costs.¹⁵³

In general, it is questionable to what degree patent protection and the resulting high prices are necessary to support research and development.¹⁵⁴ The pharmaceutical industry is consistently one of the most profitable.¹⁵⁵ Furthermore, the most financially successful pharmaceutical companies use less money for research and development (18.5 %) than they do for marketing and administration (30.4 %).¹⁵⁶

Even if high prices stimulate research and development, they are not the only means of doing so. Supporters of patent protection reform generally argue for alternatives in the form of government involvement, either through direct financial assistance or organization of funding.¹⁵⁷ In countries such as the United States, where pharmaceutical development has remained almost entirely untouched by the government and capitalist

¹⁴⁹ *Id.*

¹⁵⁰ Cann, *supra* note 123, at 796.

¹⁵¹ See Lazzarini, *supra* note 1, at 111.

¹⁵² Cann, *supra* note 123, at 794.

¹⁵³ *Id.* at 794–95.

¹⁵⁴ See Lazzarini, *supra* note 1, at 111.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

principles drive the development of most new products, increased government participation in pharmaceutical research and development is hardly a likely alternative.

As a general criticism, some accuse the current system of intellectual property protection as being a one-sided endeavor. Countries who prioritize “technical discoveries and innovation” and are able to financially support and maintain a “research infrastructure” will inevitably benefit from strong patent protections; whereas, countries who lack these qualities will not.¹⁵⁸ Some critics go so far as to assert that “trade liberalization” (a term used for the introduction of international patent protection) leads to “neocolonialism,” as it disproportionately benefits the wealthy industrialized nations holding all of the patents in need of protection.¹⁵⁹ As a general rule, developing countries generally have far fewer and less valuable patents to protect.¹⁶⁰

V. RESOLUTION AND ANALYSIS: WHO CAME OUT AHEAD?

A. Resolution

In October 2005, Abbott Labs and Brazil’s Health Ministry came to an agreement after nearly five months of highly publicized negotiations.¹⁶¹ Ultimately, Abbott agreed to lower the price of Kaletra from \$1.17 to \$0.63 a pill, saving Brazil \$339 million over the course of six years.¹⁶² This figure is considerable in light of Brazil’s projected savings had they manufactured the drug generically; Brazil’s Health Ministry estimated savings at \$54 million annually.¹⁶³ In return, Brazil agreed not to produce the generic version domestically.¹⁶⁴

B. Pressures on Brazil to Resolve the Issue

Critics have long asserted that in the current system of intellectual property protection public health concerns are systematically losing out to corporate greed. Specifically, some have voiced “concerns about the way in which the United States is using unilateral pressures, and bilateral and regional trade agreements, to ratchet up patent protection on medicines

¹⁵⁸ *Id.*

¹⁵⁹ See Kripapuri, *supra* note 22, at 692–93.

¹⁶⁰ *Brazil Reaches*, *supra* note 92.

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ Marques, Guimaraes & Sternberg, *supra* note 95, at 475 (noting that Brazil’s Health Ministry estimated savings at \$53 million annually).

¹⁶⁴ See *id.*

beyond the standard in the TRIPS Agreement.”¹⁶⁵ These critics deny being against patents or property protection *per se*, but rather they are “against the unbalanced nature of global rules which, they argue, prioritize private patent ‘rights’ over public health goals.”¹⁶⁶ The recent controversy and resolution between Brazil and the U.S.-based Abbott Laboratories raises the question of whether the United States used external political pressure to force a negotiated resolution with Brazil outside of the TRIPS Agreement framework.

The effects of Brazil carrying out its threat and infringing Abbott’s patent on Kaletra could have been potentially devastating to U.S.-Brazil trade relations, and consequently Brazil’s economy. The Brazil/Abbott Labs dispute occurred while a review of the continued inclusion of Brazil under the U.S. Generalized System of Preferences was imminent.¹⁶⁷ It was reported that the final resolution between Brazil and Abbott Laboratories “was reached after threats of commercial retaliations were made by the U.S. government in response to Brazil’s plan to produce locally a generic version of Kaletra.”¹⁶⁸ One may assume that Abbott used its lobbying power to enlist the U.S. government in its battle against pharmaceutical piracy, and that the commercial retaliation most readily available to the U.S. government at the time of the dispute was the removal of Brazil from the Generalized System of Preferences.

This accusation is not terribly far fetched. The U.S. government has generally been openly supportive of protection of pharmaceutical patent rights. For example, in May 1999, officials within the Clinton administration went on record as supporting such protection.¹⁶⁹ These officials explained the reasoning behind the United States’ international trade policy concerning pharmaceuticals, stating that “tampering with AIDS drug patents threatens the intellectual property rights protection which ensures the search for new drugs.”¹⁷⁰ United States involvement in this dispute should not come as much of a surprise considering this official stance on international pharmaceutical patent protection.

C. Argument that the Resolution was Fair

The official stance of both parties is that the resolution reached was

¹⁶⁵ Mayne, *supra* note 5, at 146.

¹⁶⁶ *Id.*

¹⁶⁷ Alan Clendenning, *Brazil Aims for Cheaper AIDS Drug*, ASSOCIATED PRESS, July 3, 2005, available at <http://www.katv.com/news/stories/0705/240483.html>.

¹⁶⁸ *Abbott Labs Signs Deal with Brazil to Cut Price of AIDS Drug*, AFX NEWS LTD., Oct. 12, 2005, available at <http://www.iii.co.uk/news/?type=afxnews&articleid=5432138&action=article>.

¹⁶⁹ See Kripapuri, *supra* note 22, at 698–99.

¹⁷⁰ *Id.*

fair and beneficial to both parties. Brazil's Health Minister, Jose Saraiva Felipe stated that the resolution precluded any need to break Kaletra's patent and that "[t]he price we reached is what the national AIDS program could pay."¹⁷¹

Even if coercion was used, Article 8 of the TRIPS Agreement may justify the actions of both Abbott and the U.S. government in reaching the resolution. Article 8 provides that Member States may "adopt measures necessary to protect . . . and promote the public interest."¹⁷² One could assert that protecting the financial success of a major pharmaceutical company existing in a capitalist market is well within the public interest. The caveat to this grant of discretionary power is that measures used be consistent with the TRIPS Agreement.¹⁷³ The question then becomes whether threatening to remove Brazil from inclusion under the U.S. Generalized System of Preferences is a tactic consistent with the principles of the TRIPS Agreement and the specific provisions found therein.

D. Larger Effects of the Resolution: A Failure to Establish an Important Precedent

1. Background

Brazil is classified by the United Nations as an "upper-middle income country."¹⁷⁴ While Brazil's economy may pale in comparison to that of the United States, it is still far stronger than those of the world's poorest countries. In addition, Brazil has managed to curb the growth of the AIDS epidemic within its borders through the adoption of government programs.¹⁷⁵ The issue at stake in this dispute had international implications, as other countries with domestic pharmaceutical manufacturing capacity might be tempted to infringe the Kaletra patent if Brazil led the way.¹⁷⁶ The success of Brazil's efforts to gain access to patented HIV and AIDS medications, such as Kaletra, "may be interconnected with the potential options of poorer countries."¹⁷⁷ For example, if Brazil infringed the Kaletra patent, poorer countries without domestic pharmaceutical manufacturing capacity might seek to import Brazil's generic Kaletra.¹⁷⁸

¹⁷¹ *Brazil Reaches*, *supra* note 92.

¹⁷² TRIPS, *supra* note 6, art. 8.

¹⁷³ *Id.*

¹⁷⁴ Lazzarini, *supra* note 1, at 130.

¹⁷⁵ *See id.* at 129–30.

¹⁷⁶ Clendenning, *supra* note 167.

¹⁷⁷ Lazzarini, *supra* note 1, at 134.

¹⁷⁸ Clendenning, *supra* note 167.

Other countries are much poorer and have a much larger AIDS epidemic to worry about.¹⁷⁹ Developing countries account for 95 percent of the HIV/AIDS patients, with sub-Saharan Africa claiming 70 percent of the total epidemic.¹⁸⁰ To put those percentages in perspective, the virus is currently estimated to infect thirty-four million people globally.¹⁸¹ This area, not coincidentally, contains a large number of the poorest nations in the world.¹⁸² Sub-Saharan African governments generally spend less than \$10 per person annually on health care; combine that sum with the per capita income of less than \$50 a month and it becomes clear that a government program or individually financed system of treatment is presently impossible in these countries.¹⁸³ According to the World Health Organization, only 10,000 of the twenty-five million estimated African AIDS victims were receiving antiretroviral treatment as of 2001.¹⁸⁴

The TRIPS Agreement, even if effective, may not provide relief to developing countries. While Brazil and other middle income countries have the production capacity to manufacture and distribute drugs domestically, poorer countries lack the economic means necessary to do so.¹⁸⁵ Without the ability to produce and distribute generic versions of licensed drugs within their own borders, a compulsory license awarded under the TRIPS Agreement is useless to these countries. The poorest countries, those most in need of the help that the TRIPS Agreement was designed to provide, are left with an incomplete solution—the right to manufacture drugs that they have no capability to actually produce.

2. *Compulsory Licensing*

Brazil would have been the first country in the world to break an antiretroviral patent.¹⁸⁶ If Brazil had been successful in declaring AIDS a “national emergency” it would have certainly provided an opportunity to interpret, clarify, and apply the compulsory licensing provision in the TRIPS Agreement. Compulsory licensing is a potentially powerful tool for poorer countries with large AIDS-infected populations who often find themselves on the short end of the bargaining stick with wealthier countries and their patent holders. Establishing a precedent for the use of the compulsory licensing exception under the TRIPS Agreement would pave the way for developing countries to achieve affordable access to cutting-

¹⁷⁹ See, e.g., Kripapuri, *supra* note 22, at 689.

¹⁸⁰ See *id.*

¹⁸¹ *Id.*

¹⁸² See Lazzarini, *supra* note 1, at 134.

¹⁸³ See Sherman & Oakley, *supra* note 4, at 355.

¹⁸⁴ *Id.*

¹⁸⁵ See Lazzarini, *supra* note 1, at 134.

¹⁸⁶ See Marques, Guimaraes & Sternberg, *supra* note 95, at 476.

edge, high priced pharmaceuticals that are currently under patent protection.¹⁸⁷ Major patent holders, like Abbott Laboratories, have heavily opposed efforts by developing countries to utilize the compulsory licensing exception for fear of the precedent that would be established, namely one of avoiding the protection of their valuable patents.¹⁸⁸

One might argue that the existence of the compulsory licensing provision mandates its use. Specifically, that compulsory licensing is expressly provided for under the TRIPS Agreement and should, therefore, be used instead of trying to reach a negotiated settlement with the patentee outside of the TRIPS Agreement framework. The question then becomes whether the Brazil/Abbott Labs dispute would have been an appropriate situation to attempt the use of the compulsory licensing provision of the TRIPS Agreement. By negotiating a settlement, Brazil avoided the risk of failing to qualify for a compulsory license under a formal proceeding under the TRIPS Agreement. Furthermore, if Brazil had tried and failed to qualify for a compulsory license, other countries would be less able to use the threat of a compulsory license as a tool to achieve a lower negotiated price for drugs. Since no precedent has been established on the ease of gaining a compulsory license, it remains a powerful negotiating tool for developing nations—pharmaceutical companies might choose to lower prices rather than risk losing in a compulsory license dispute.

3. Export Under the Waiver of Article 31(f)

Had the compulsory license been approved by the WTO, Brazil would have the production capacity to exceed its own need, and under the current waiver of Article 31(f) may have been able to export generic versions of Kaletra to other poorer countries in even greater need.¹⁸⁹ Not only would export of generic medications in excess of the domestic needs benefit poorer countries lacking production capacity, but it would also boost the economy of the exporter-producer.¹⁹⁰

Pharmaceutical manufacturers understandably fear the slippery slope potentially created under Article 31(f) waivers. The argument is that the application of this waiver could create an entire “parallel international market” for generic versions of their valuable patented merchandise, thus substantially reducing profits.¹⁹¹ Perhaps this is what Abbott feared most. The pharmaceutical manufacturer’s fear of Article 31(f) waivers may potentially cause them to more vigorously oppose grants of compulsory

¹⁸⁷ See Lazzarini, *supra* note 1, at 125.

¹⁸⁸ *Id.*

¹⁸⁹ See *id.* at 134.

¹⁹⁰ See *id.*

¹⁹¹ See *id.*

licenses, thus reducing the overall effectiveness of Article 31 for countries in need.

4. Indirect Aid: Affecting the Market

It is possible that in reaching its deal with Abbott, Brazil failed to “share the wealth,” so to speak. Studies have shown that the presence of generic drugs in the market results in lower pharmaceuticals prices overall.¹⁹² If Brazil had not reached a negotiated agreement with Abbott, and instead manufactured a generic version of Kaletra (through a compulsory license, or by violating the TRIPS Agreement), Brazil may have been able to indirectly help other poorer countries purchase Kaletra at a lower price.

Scholars have also concluded that compulsory licensing of new patents will advance a nation's technological growth.¹⁹³ Similarly, compulsory licensing under the TRIPS Agreement may lead to domestic technological advances in pharmaceutical development. In theory, access to pharmaceutical patents would allow for developing countries to catch up, so to speak, to their wealthier patent-holding counterparts. Technological parity would lead to economic competition, and ultimately lower prices on pharmaceuticals.

VI. CONCLUSION

The recent controversy between Brazil and Abbott Laboratories over the patent to Kaletra brings to light one of the more controversial issues surrounding the TRIPS Agreement, compulsory licensing of AIDS medications. Unfortunately, the resolution of the Kaletra controversy left the larger dispute unresolved. Developing countries will have to wait for another opportunity to establish a much needed precedent defining the AIDS epidemic as a “national emergency” under Article 31(b).¹⁹⁴ Until then, pharmaceutical companies holding antiretroviral patents will likely continue to fight application of the TRIPS Agreement exceptions in hopes that compulsory licensing will never be realized.

¹⁹² See *id.* at 108.

¹⁹³ See Kripapuri, *supra* note 22, at 692.

¹⁹⁴ TRIPS, *supra* note 6, art. 31(b).

