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“That which one man has invented, all the world can imitate. Without the assistance of the laws, the inventor would almost always be driven out of the market by his rivals, who finding himself, without any expense, in possession of a discovery which has cost the inventor much time and expense, would be able to deprive him of all his deserved advantages, by selling at a lower price.”

- Jeremy Bentham

“Maintaining monopolies for medicine for poor countries during a worldwide health catastrophe is unethical and immoral”

- Paul Davis, Health GAP Coalition

I. INTRODUCTION

The AIDS epidemic turned the world’s attention to the problem of high drug prices in developing countries and the numerous barriers to access to essential drugs in these countries. The AIDS epidemic also triggered an extensive debate on the relationship between patents, global trade agreements, particularly the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS Agreement”), and public health.


2 Paul Davis is a spokesperson for Health Gap, an organization of U.S.-based AIDS and human rights activists who campaign against policies that deny treatment to millions and increase the spread of HIV. See http://www.healthgap.org/hgap/about.html.

3 A patent can be simply defined as “an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem. A patent provides protection for the invention to the owner of the patent. The protection is granted for a limited period, generally 20 years.” See World Intellectual Property Organization (WIPO), Inventions (Patents), available at http://www.wipo.int/about-ip/en/patents.html.


and raised important questions about the role of the World Trade Organization ("WTO")\textsuperscript{5} in promoting access to medicine in developing countries. Before November 2001, the core questions were: whether the TRIPS Agreement retarded access to essential medicine in developing countries by raising the cost of patented pharmaceuticals,\textsuperscript{6} whether compulsory licensing in developing countries was needed to address the problem of access in these countries, and whether the TRIPS Agreement permitted countries to resort to compulsory license to address public health problems.\textsuperscript{7}

At the 2001 Ministerial Conference\textsuperscript{8} in Doha, Qatar, WTO Members adopted the "Declaration on the TRIPS Agreement and Public Health" ("Doha Declaration").\textsuperscript{9} The Doha Declaration was groundbreaking in the sense that it appeared to unequivocally recognize the primacy of public health over commercial interests.\textsuperscript{10} The Declaration answered in the affirmative the question whether WTO Member States can resort to compulsory licensing to address a public health crisis. However, the Declaration left one

\textsuperscript{5} The WTO is an organization established in 1994 to provide a common institutional framework for the conduct of trade relations among Member States. One of the basic functions of the WTO is to facilitate the implementation, administration and operation of multilateral trade agreements. See Agreement Establishing the World Trade Organization, in General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations (Marrakesh, April 15, 1994), 33 I.L.M. 1125, 1144 [hereinafter WTO Agreement].
\textsuperscript{7} When a government grants compulsory license, the patent holder retains intellectual property rights and is generally entitled to an adequate remuneration. In the pharmaceutical sector, a generic drug is a bioequivalent of a patented drug and is usually intended to be used interchangeably with the original patented drug. A generic drug is not produced under a patent. Under most domestic patent law, governments can issue compulsory license to allow a competitor to produce a patented product or process under license and subject to conditions aimed to safeguarding the legitimate interests of the patent owner.
\textsuperscript{8} The Ministerial Conference is the highest forum in the structure of the WTO. The Ministerial Conference is composed of representatives of all the WTO Members and meets at least once every two years. Since the establishment of the WTO, the Ministerial Conference has been held five times: Singapore (December 1996), Geneva (May 1998), Seattle (November – December 1999), Doha (November 2001), and Cancun (September 2003).
\textsuperscript{10} Sun, supra note 4, at 104 (noting that the Doha Declaration “marked a turning point for political and legal relations at the WTO.”).
thorny question unresolved, the question whether WTO Members with insufficient or no manufacturing capabilities in the pharmaceutical sector and who are thus unable to make use of compulsory licensing can import generic drugs manufactured under compulsory license from other countries (the so-called Paragraph 6 question).

Between November 2001 and September 2003, fresh debates ensued over the Paragraph 6 question. To allay the fears of developing countries, two decisions were made by the TRIPS Council and the General Council respectively in 2002. On June 27, 2002, the Council on TRIPS, acting under paragraph 7 of the Doha Declaration, made a decision to grant the least-developed country Members of the WTO an extension on the time within which they have to comply with some of the provisions of the TRIPS Agreement. On July 8, 2002, the General Council adopted a decision waiving the obligation of least developed countries (“LDC’s”) under Article 70.9 of the TRIPS Agreement with respect to pharmaceutical products. Finally, on August 30, 2003, at a

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11 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, Decision of the Council for TRIPS of June 27, 2002, PRESS/301 (July 1, 2002), available at http://www.wto.org/english/news_e/pres02_e/pr301_e.htm [hereinafter Extension Decision 1]. Paragraph 1 of the decision states: “Least-developed country Members will not be obliged, with respect to pharmaceutical products, 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 1 January 2016.” Paragraph 2 provides that, “[t]his decision is made without prejudice to the right of least-developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.”

On the adoption of the TRIPS Agreement, all WTO Members except developing countries and least-developed countries had one year after the entry into force of the Agreement to comply with the provisions of the Agreement. Except for obligations relating to national treatment and most-favored nation which became applicable after the expiration of one year, developing countries received an additional transition period of four years. Under paragraph 1 of Article 66 of the TRIPS Agreement, least-developed countries had received a ten-year extension on the date stipulated for WTO Members to implement the TRIPS Agreement. This meant that they were not expected to implement most provisions of the TRIPS Agreement until 2005. With the June 27, 2002, Decision of the Council for TRIPS, the least developed countries do not have to implement the TRIPS Agreement until 2016.

12 Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, Decision of the Council for TRIPS of July 8, 2002, available at www.wto.org/english/news_e/pres02_e/pr301_e.htm [hereinafter Extension Decision 2]. Paragraph 1 states that “[t]he obligations of least-developed country Members under paragraph 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until
meeting of the WTO General Council\textsuperscript{13} world trade ministers adopted the \textit{Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health} ("2003 Decision on Implementation" or "Decision")\textsuperscript{14} that appears to finally lay to rest the lingering questions regarding the relationship between patent rights, the TRIPS Agreement and access to medicine.

The different battles over the relationship between patents and public health now appear to be over. This article takes a close look at the battlefield more than three years after the war began. It is an attempt to access gains and map progress. In this paper, I argue that although the several battles over access may have ended, determining what exactly has been achieved and forecasting the potential impact of the Doha Declaration and the 2003 Decision on Implementation on access to medicine in developing countries may not be easy. It may therefore be a long time before the suffering masses in the Third World derive any tangible benefit from the two texts. There are several reasons for this. First, both the Doha Declaration and 2003 Decision on Implementation have major loopholes that could still be used to curtail the rights of developing countries in the future. Second, for countries with insufficient or no manufacturing capacity, the 2003

\textsuperscript{13} The WTO General Council is composed of representatives of all the Member States. The General Council meets as appropriate and conducts the functions of the Ministerial Conference in the intervals between meetings of the latter. \textit{See} WTO Agreement, \textit{supra} note 5, Article IV.2.

Decision of Implementation contains conditions that are somewhat burdensome and that could discourage the emergence of a robust generic industry in needed pharmaceuticals. Third, it is doubtful that developing countries will begin to grant compulsory license as envisaged in the two texts. For one thing, developed countries could still use covert threats of economic sanctions and other forms of political pressure to compel developing countries to respect the intellectual property rights (“IPR’s”) of patent holders. In addition, quite apart from political pressures from developed countries, the reality is that “[f]ew compulsory licenses have ever been granted in developing countries.”

The most important but hitherto overlooked problems, however, are the problems of abuse of patent rights and anticompetitive practices by pharmaceutical companies and the absence of comprehensive rules at the global level to address these problems. In the United States (“U.S.”), brand-name pharmaceutical companies, in their attempt to maintain their dominant market share, are increasingly resorting to a host of abusive and anticompetitive practices. Despite the existence of strong antitrust laws in the U.S. and a multitude of laws and regulations directed at protecting U.S. consumers from false business practices, pharmaceutical companies find ingenious ways to evade the law and prey on vulnerable consumers. A study of unfolding law suits in the United States teaches that in the absence of strong antitrust rules at the domestic level and a multilateral agreement on competition law at the global level, pharmaceutical companies will find ways to avoid the consequences of the Doha Declaration and the 2003 Decision on Implementation. In other words, the nature of competition in the pharmaceutical industry and the capacity of states and/or the WTO to regulate competition in the industry may

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ultimately determine the overall effect the Doha Declaration and the 2003 Decision on Implementation will have on access to medicine in poor countries absent the development of a strong ethical code of conduct to guide practices in the pharmaceutical industry.

In pursuing my argument, I examine and attempt to draw lessons from the present war against abuse of patent rights and anti-competitive practices in the U.S. pharmaceutical industry. The U.S. experience suggests that in the absence of strong public and private oversight, a host of abuses are possible in the pharmaceutical industry. One such abuse is in the form of collusive settlement agreements between brand name drug manufacturers and generic drug manufacturers that have the effect of delaying the entry of generic drugs into the market. These cases suggest the need, beyond well-intended legal solutions, for public oversight and vigilance by consumer groups and non-governmental organizations.

Undoubtedly, there are strong and compelling reasons why IPR’s must be respected and accorded maximum protection; there are, however, other values worth protecting besides intellectual property rights. IPR’s operate as an incentive for the development of new and useful technology, including pharmaceuticals.16 IPR’s, particularly patents, are important to the pharmaceutical industry for two reasons. First, frequently the industry has to invest considerable amount of time and resources into researching and developing new drugs.17 Second, “pharmaceuticals are generally relatively easy to reverse-engineer and thus are open to easy copying in the absence of …

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17 *Id.* at 373 (observing that research into new drugs is risky, expensive and time consuming).
For developing countries, the protection of IPR’s can also encourage the transfer of technology from developed countries. Because IPR’s are commercial rights essentially driven towards economic gains, they can and do frequently affect the welfare of the general public. This means that when IPR’s are discussed, the emphasis must not be exclusively on the rights of producers of intellectual property (“IP”), particularly patent holders. Rather, IPR’s must be discussed and examined also from the perspective of consumers and the general welfare of a nation.

Overall, I conclude that the battle over access to medicine was not a waste. It is necessary that the WTO clarify the flexibilities countries enjoy under the TRIPS Agreement to address their domestic problems. Even if developing countries do not fully exercise their right to grant compulsory license in the future, the existence of such a right can function as a powerful weapon for bargaining lower prices from brand-name pharmaceutical companies. Compulsory license can be a solution to the problem of patent exclusivity; it is frequently used to remedy certain antitrust violations involving IPR’s. However, compulsory licenses can also trigger or encourage a range of abusive practices in the pharmaceutical industry as affected companies struggle to maintain their market share and dominant position.

The debate over access to medicine underscored the fact that there are obvious political, social, economic and policy implications when states decide to adopt strong

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18 Id.
19 Id. at 364 (arguing that “a strong patent protection regime has a net global social gain, as well as a net social gain to developing countries”).
20 Id.
21 OSTERGARD, JR., supra note 4, at 12.
22 As a result of threat by the Brazilian government to issue a compulsory license, Roche, the Swiss pharmaceutical company, agreed to a substantial price cut for Nelfinavir, a patented AIDS drug. See DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT 115 (2002).
intellectual property protection,\textsuperscript{23} and the fact that “all states are not equal in their level of political and economic development”\textsuperscript{24} – something that was ignored during the negotiations that produced the TRIPS Agreement.\textsuperscript{25} The TRIPS Agreement was the product of aggressive negotiation by developed countries governments and “bound all signatory states to implementing a full Western-style IP regime.”\textsuperscript{26} Unwittingly, developing countries signed on to the TRIPS Agreement largely as a result of intense pressure from developed countries but without addressing the potential social and economic costs of their action.\textsuperscript{27}

In the final analysis, the pharmaceutical industry cannot be the enemy for three reasons. First, the battle over access to medicine arose primarily because medicines are essential goods and yet their production does require substantial and very expensive technological in-put. The nature of drugs inevitably means that pharmaceutical companies have a unique type of financial and social responsibility – they provide important public goods.\textsuperscript{28} Second, although WTO Members now appear to have the freedom to issue compulsory license to address their health problems, the cooperation of

\textsuperscript{23} OSTEGARD, JR., supra note 4, at 2 (observing that states do not adopt strong intellectual property rights policies as a matter of rationale economic policy only, but also as a matter of rationale political policy).
\textsuperscript{24} Id. at 3.
\textsuperscript{25} Id. at 7 (observing that the US argued forcefully that there were international benefits to be derived from global protection of intellectual property rights without regard for where countries were in their development process).
\textsuperscript{26} OSTEGARD, JR., supra note 4, at 1 (observing that the TRIPS Agreement was a result, in part, of the strong lobbying effort by the United States). Developed countries were the strongest proponents of the TRIPS Agreement because of changes in their industrial base and the rise of intense global competition. Essentially, as the comparative advantage of Western nations shifted from agricultural products and manufacturing to sectors that require high technological in-put, these countries became anxious to see intellectual property rights globalized. Id. at 7.
\textsuperscript{27} Id. at 7 (noting that the United States pressured governments of developing countries into accepting stringent intellectual property rights regulation).
\textsuperscript{28} Anna Thomas, Street Price: A Global Approach to Drug Pricing for Developing Countries 5, a Position Paper for the Voluntary Service Organization or “VSO” (Ken Bluestone et al eds.), available at http://vso.org.uk/publications/positionpapers/pdfs/street_price.pdf. See also Singham, supra note 16, at 365 (noting that patents enable the industry to provide a very important public good).
patent holders will still be crucial for countries to obtain the technology needed to effectively work the patent. Third, given my predictions that it is not likely that many developing countries will actually issue compulsory licenses in the future, countries may still have to rely on the goodwill of pharmaceutical companies to meet their pharmaceutical needs through alternative channels.

This paper is in five sections. Section II offers a background to the Multilateral Trading System (“MTS”), the TRIPS Agreement, and the compulsory licensing debate as it has unfolded since the explosion of the AIDS epidemic. Section III introduces the reader to the 2003 Decision on Implementation and highlights the main provisions of the Decision. In Section IV, I engage in a critical analysis of the 2003 Decision on Implementation. Section V focuses on pharmaceutical abuses in the United States and the current efforts by the FTC and the private sector to fight these abuses. In Section VI, I examine current efforts to establish a multilateral framework on competition law and policy and the obstacles to these efforts. Paradoxically, although many developing countries do not have any competition law and are likely to benefit from such a framework, developing countries have strongly opposed the idea of a multilateral rule on competition policy. I conclude in Section VII by noting that although welcomed, despite the flexibilities afforded by the Doha Declaration and the Decision, few compulsory licenses will be issued.

I advance seven reasons for my position. First, very few countries have the capacity to effectively exploit a compulsory license should one be issued; also very few countries have internal procedures for granting compulsory licenses. Second,

29 Matthews, supra note 22, at 114.
developing countries that are starved of foreign exchange and desiring to attract foreign
direct investment would most likely refrain from liberally utilizing the flexibilities.  
Third, developing countries that desire to encourage inventive activity locally may also
not want to liberally use compulsory licenses as this “could work against the interests of
new domestic actors and have adverse demonstration effect on other potential
investors.” Fifth, in situations where the cooperation of the right holder is needed to
acquire the technology needed to work with the protected invention, such cooperation
may not be forthcoming.

The intersection of patent rights, global trade, public health and ethics unearthed
many thorny issues. For example, is a balance between intellectual property rights, state
sovereignty and ethics possible? Should ethical concerns and human rights norms trump
over property (patent) rights? Do the sovereign rights of states allow them the option of
“opting out” of onerous and “mischievous” international obligations? Does the TRIPS
Agreement prevent Members from taking measures to protect public health?

II. THE GLOBALIZATION OF INTELLECTUAL PROPERTY
LAW: BACKGROUND TO THE TRADE-RELATED ASPECTS
OF INTERNATIONAL PROPERTY (“TRIPS”) AGREEMENT
AND THE COMPULSORY LICENSING DEBATE

The last three hundred years has witnessed tremendous evolution in our notion of
property. From its once humble beginnings focused on tangibles, the notion of property
has broadened to include intangible products of the human mind such as patents,

30 In effect, the granting of compulsory license has its drawbacks and should not be seen as the preferred
option for countries. See Matthews, supra note 22, at 114 (noting that “foreign companies may be
reluctant to invest in developing countries with a propensity to grant compulsory licenses.”).
31 Watal, supra note 15, at 382.
32 Id.
trademarks and copyrights. For the most part, this development in the notion of property occurred primarily in Europe and North America. As long as information could be contained within national borders, domestic law was considered sufficient in regulating dealings in intellectual property. Intangible property are however much more fluid than tangible property and transverse national boundaries much more readily. By the end of the 19th century, counterfeiting and piracy in the global marketplace had become a strong concern of many countries; in the industrialized world, there was a growing realization that multilateral efforts were needed to address these concerns. This triggered a century-long effort directed at expanding and universalizing intellectual property laws (what I refer to as “the globalization project”) culminating in the adoption of the TRIPS Agreement in 1994.

A. The TRIPS Agreement

Initial efforts to globalize and harmonize intellectual property law produced two significant international treaties: the Berne Convention for the Protection of Literary and Artistic Works (“Berne Convention”) and the Paris Convention for the Protection of Industrial Property (“Paris Convention”). However, January 1, 1995, marked a major turning point in the globalization project with the entry into force of the TRIPS Agreement.
Agreement.\textsuperscript{37} Negotiated as part of the Uruguay Round of Multilateral Trade Negotiations,\textsuperscript{38} the TRIPS Agreement comes as a package-deal meaning that all WTO Members are automatically bound by the agreement.\textsuperscript{39}

In terms of coverage, the TRIPS Agreement is the most comprehensive multilateral instrument on intellectual property rights.\textsuperscript{40} The TRIPS Agreement is innovative in at least five ways. First, the TRIPS Agreement represents the first time in the history of multilateral trade negotiations that intellectual property has been integrated into an international trade agreement. Second, compared to preexisting instruments, the TRIPS Agreement contains a detailed provision on enforcement and imposes detailed obligations on States.\textsuperscript{41} Third, the TRIPS agreement establishes a strong monitoring and supervisory scheme through the machinery of the TRIPS Council, a marked departure from the norm in previous conventions.\textsuperscript{42} Fourth, the TRIPS Agreement addresses


\textsuperscript{38} The TRIPS Agreement was negotiated as part of the Uruguay Round of multilateral trade negotiations. The agreement is annexed to the final Act embodying the results of the Uruguay Round of multilateral trade negotiations. \textit{See Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations,} Punta del Este, Uruguay (September 20, 1986), \textit{reprinted} in \textit{Raj Bhala, International Trade Law Handbook} (2d ed. 2001) [hereinafter \textit{Ministerial Declaration on the Uruguay Round]}.

\textsuperscript{39} With the exception of four “plurilateral” agreements, all the WTO agreements apply to all WTO members. With one signature, WTO members each accepted all the Uruguay Round agreements as one single package. \textit{See World Trade Organization, Legal Texts: The WTO Agreements, available at http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#Introduction} (“The WTO framework ensures a ‘single undertaking approach’ to the results of the Uruguay Round – thus, membership in the WTO entails accepting all the results of the Round without exception.”).

\textsuperscript{40} The TRIPS Agreement deals with all types of intellectual property rights. The agreement covers: Copyright and Related Rights (Section 1); Trademarks (Section 2); Geographical Indications (Section 3); Industrial Designs (Section 4); Patents (Section 5); Layout-Designs (Topographies) of Integrated Circuits (Section 6); Protection of Undisclosed Information (Section 7); and Control of Anti-Competitive Practices in Contractual Licences (Section 8).

\textsuperscript{41} TRIPS Agreement, \textit{supra} note 4, Articles 41 – 49.

\textsuperscript{42} \textit{Id.} at Article 68 (“The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights.”).
compliance and enforcement questions through its automatic linkage with the WTO dispute settlement system; this ensures a permanent quasi-judicial, dispute resolution mechanism to address intellectual property controversies.\textsuperscript{43} Finally, WTO Members cannot enter a reservation in respect of any of the provisions of the Agreement without the consent of the other Members.\textsuperscript{44} Overall, the TRIPS Agreement offers an institutionalized, multilateral, and comprehensive mechanism for addressing intellectual property-related issues and disputes.\textsuperscript{45}

The success of the globalization project is reflected in the minimum substantive and procedural standards of protection for intellectual property protection that the TRIPS Agreement establishes. With respect to patents, the agreement lays down standards relating to patentability, scope of patent protection, limitations on patent rights, and enforcement. Article 27 stipulates that patents shall be available “\textit{for any inventions, whether products or processes, in all fields of technology}, provided that they are new, involve an inventive step and are capable of industrial application”\textsuperscript{46} and that “\textit{patents shall be available and patent rights enjoyable \textit{without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”}\textsuperscript{47}

\textsuperscript{43} The dispute settlement mechanism was established pursuant to a separate agreement. \textit{See The Uruguay Round Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), available at http://www.wto.org/english/docs_e/legal_e/28-dsu_e.htm.}
\textsuperscript{44} TRIPS Agreement, supra note 4, Article 71.
\textsuperscript{45} Debroy, supra note 6 (noting that WTO is “a better forum for establishing global norms in IP, not only because more countries are members of the WTO, but also because the WTO system ensures enforcement and compliance through the dispute resolution and retaliation provisions.”).
\textsuperscript{46} TRIPS Agreement, supra note 4, Article 27 (emphasis added).
\textsuperscript{47} \textit{Id.} (emphasis added).
B. Globalization Amidst Growing Discontent

The TRIPS Agreement exposes the North-South asymmetries in global trading arrangements. To developed-country governments, the TRIPS Agreement was conceived primarily as an instrument to combat global counterfeiting and piracy, eliminate distortions in and barriers to global trade, allow the industry to recoup research and development (“R&D”) costs, and guarantee a fair return on investment in innovative research. These goals, they argued, must be met within the context of limited monopoly granted by patents. During the negotiation for the TRIPS Agreement, multinational corporations and developed-country governments also argued that an enhanced global IP regime would facilitate long-term economic development in developing countries by fostering technology and investment flow to the later.

To some non-governmental organizations and some developing-country governments, however, the TRIPS Agreement is but one component of a broader policy of technological protectionism “aimed at consolidating an international division of labour whereunder Northern countries generate innovations and Southern countries constitute the market for the resulting products and services.” The real motivation for TRIPS, some have argued, was to “freeze the comparative advantages” that had ensured Northern

49 CORREA, supra note 48, at 4.
50 MATTHEWS, supra note 22.
51 CORREA, supra note 48, at 5 (arguing that the TRIPS Agreement aims at stifling imitative paths to industrialization).
technological supremacy and counter Northern countries’ declining competitive position in the global market.\(^{52}\)

Viewed also from the perspective of developing countries, critics also argue that the trend is not really towards a globalization of intellectual property rights or IPR’s (suggesting a convergence of norms and harmonization of standards), but really a universalization of standards of protection that is Northern-grown\(^{53}\) and suitable for industrialized countries.\(^{54}\) In other words, given developing countries’ dependence upon innovations made in the North\(^{55}\) and their negligible share of the world market in medium- and high-tech goods,\(^{56}\) it is believed that industrialized countries have the most to benefit from the TRIPS Agreement.

Finally, there is also the perception in the developing world that the TRIPS Agreement could be used to prevent poor countries from achieving important social and developmental goals. The fear is that by ignoring the profound differences in economic

\(^{52}\) Id. (noting the TRIPS Agreement was “an expression of an aggressive action by the United States to establish international rules that counter their declining competition in world markets.”).

\(^{53}\) Id. (noting that in negotiating the TRIPS Agreement, industrialized countries had the objective of universalizing the standards of intellectual property protection that they had incorporated into their legislation. He notes further that the emerging framework of intellectual property protection in the TRIPS Agreement “basically universalizes standards of protection that are suitable for industrialized countries.”). See also, United Nations, United Nations Commission for Human Rights 8 (“[T]he protection contained in the TRIPS Agreement focuses on forms of protection that have developed in industrialized countries. For example, in the case of patents, the protection in the Agreement is most relevant to the protection of modern forms of technology, such as biotechnology, and most relevant to innovators situated in a selected number of industrialized countries.”).

\(^{54}\) Some scholars question whether developing countries are really ready to have strong intellectual property rights. They point to the fact that industrialized countries were also able to establish higher standards for intellectual property protection after they had attained a certain level of technological and industrial capacity. Correa, supra note 48, at 5.

\(^{55}\) Id. (citing studies by Nagesh that estimate that of the patents granted in the United States between 1977 and 1996, developing countries accounted for less than 2%, while 95% of 1,650,800 patents granted were conferred on applicants from 10 industrialized countries). See Kumar Nagesh, Technology Generation and Technology Transfers in the World Economy: Recent Trends and Implications for Developing Countries 5-9 (1997).

\(^{56}\) Id. (citing estimates by Alcorta and Peres to the effect that of the exports of the Group of 7 (G7) to OECD countries, 56.7% consist of medium- and high-tech goods). See Ludovico Alcorta and Wilson Peres, Innovation Systems and Technology Specialization in Latin America and the Caribbean 5-6 (1995).
and technological capabilities between the North and the South and by offering a one-
size-fits-all approach to intellectual property protection, the TRIPS Agreement will be
progressively used to curtail policy options in developing countries and hamper States in
their efforts to address serious health emergencies.

C. The Pharmaceutical Industry, AIDS Epidemic and the Compulsory
License Debate

The pharmaceutical industry is at the center of the debate about the relationship
between patent rights, the TRIPS Agreement, and public health. Until recently, “the
patent law of most poor countries exempted pharmaceutical products from patents.”57 As
a result of the TRIPS Agreement, however, many countries amended or are in the process
of amending their patent law to comply with TRIPS. In the wake of huge AIDS
epidemics decimating millions of lives in the developing world, how to balance the patent
right of pharmaceutical corporations against the sovereign rights of states to determine
their internal health policies and ensure that essential drugs are available and accessible
to their citizens surfaced. Also, the question how to balance the patent rights of
pharmaceutical corporations against core internationally guaranteed rights such as the
right to “the highest attainable standard of physical and mental health,”58 assumed a
central place in this debate.59 Essentially, developing countries governments, civil society

57 Julian Morris, TRIPS and Healthcare: Rethinking the Debate, Introduction and Summary (July 2001),
available at http://www.policynetwork.net/pring/morris.htm. See also MATTHEWS, supra note 22, at 114
(observing that for many developing countries “the underlying rationale for excluding pharmaceutical
products from patent protection in the pre-TRIPS era was to enhance access to medicine and healthcare.”).
58 See International Covenant on Economic, Social and Cultural Rights, G.A. 2200A (XXI), 21
(Article 12 provides: “The State Parties to the present Covenant recognize the right of everyone to the
enjoyment of the highest attainable standard of physical and mental health.”).
59 For a human rights analysis of the TRIPS Agreement, see United Nations Commission on Human Rights,
The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights:
groups and AIDS sufferers feared that the TRIPS Agreement could be used to disrupt the availability of cheap generic pharmaceutical products and that developing countries would be forced to obtain brand-name pharmaceutical products from multinational companies at exorbitant prices.

i. The AIDS Epidemic: As of December 2001, the total number of people (adult and children) living with HIV/AIDS (“PLHA”) was estimated at 40 million60 and the total number of children orphaned by AIDS and living was estimated at 14 million.61 Of the total number of PLHA, 95% live in the developing world.62 Five million people became newly infected with HIV in 2001 and 3 million AIDS deaths were recorded in the same year.63

The discovery of Highly Active Antiretroviral Therapy (“HAART”) as a treatment for AIDS led to a paradigm shift in most of the industrialized world because HAART brought about significant reduction in the prevalence of AIDS-related morbidity and mortality in the West. In the West, it became possible to view AIDS not as a death sentence but as a manageable chronic disease.64 However, in most of the developing world the story was different. As a result of the absence of HAART, instead of

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62 Access to Treatment for HIV/AIDS, supra note 60, at 1.
64 Access to Treatment for HIV/AIDS, supra note 60, at 3 (“…in the United States, the number of PLHA increased from 174,244 in 1993 to 317,368 in 1999, while mortality associated with AIDS decreased from 45, 494 to 16, 767 in that same period.”).
treatment, the focus of national programs and international support was on prevention, the treatment of opportunistic infections, care, and support. The principle barrier to treatment frequently cited by national governments and donor agencies was the cost of HAART (estimated at US$10-$15,000 per person per year in 2001). Thus, as of 2001, despite breakthroughs in medicine, only 230,000 of the 6 million people who were sick enough to require HAART were receiving it. Of these, half lived in Brazil. This meant that at least 96% of people in developing countries who needed treatment were not receiving it.

ii. Does TRIPS Provide an Answer? Against the backdrop of a massive HIV/AIDS epidemic and reported welfare effects of pharmaceutical product patents in developing countries, some governments in the developing world began to explore the possibility of using compulsory licenses to lower drug prices. These countries acted on

65 Id.
66 Id. (other reasons cited included the capacity of health care delivery systems and the ability of patients to adhere to lifelong treatment regimens).
67 In Brazil, the government instituted a universal access to AIDS treatment program. This led to a 54% reduction in AIDS-related mortality between 1995 and 1999. Treatment provision has resulted in overall cost-savings for the government, in terms of avoided hospitalization and reduction in the burden of opportunistic infections, totaling US$677 million between 1997 and 1999. Some observers attribute the success in Brazil to the government’s aggressive involvement in the manufacture of generic versions of several HIV drugs in its own government laboratories. See INTERNATIONAL COUNCIL OF AIDS SERVICE ORGANIZATIONS, THE INTERNATIONAL GUIDELINES ON HIV/AIDS AND HUMAN RIGHTS: AN ASSESSMENT OF NATIONAL RESPONSES IN IMPROVING ACCESS TO HIV/AIDS TREATMENT IN THE FRAMEWORK 11 (2002) [hereinafter GUIDELINES ON AIDS & HUMAN RIGHTS].
68 Poor developing nations appear to be the most affected by global patent protection laws. In many countries, welfare losses which economists attribute to heightened patent protection are beginning to appear. Nogués, a World Bank economist, estimates that minimum welfare loss to developing countries of patent pharmaceutical products would amount to a minimum of US$3.5 billion and a maximum of US$10.8 billion, while the income gains by foreign patent owners would be between US$2.1 billion and US$14.4 billion. . Julio Nogués, Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries, 24 J. OF WORLD TRADE L. 6 (1990) (cited in CORREA, supra note 48, at 35) Several studies in developing countries support Nogués conclusions. These studies point to the appearance of about a six-fold increase of drug prices with the introduction of product patents compared to non-patented products, a strong correlation between the introduction of pharmaceutical product patents and significant (as much as 45%) reduction in the consumption of medicine, and wide disparities in prices of drugs between countries where patent protection exists and countries with no protection. Id.
the assumption that the TRIPS Agreement allowed governments to address critical
shortages in essential drugs through compulsory license. However, countries that
attempted to address domestic health crisis through compulsory licensing came under
heavy attack from the pharmaceutical industry\(^6^9\) and from some governments in the
developed world, particularly the U.S. government.\(^7^0\)

The problem was that even though the TRIPS Agreement addresses conditions for
the grant of compulsory licenses and does appear to allow governments some flexibility
to enable them address domestic crisis, the entire agreement is riddled with ambiguities
and permits multiple interpretations. What flexibilities does the TRIPS Agreement afford
governments? First, governments can exclude certain inventions from patentability.\(^7^1\)
Second, pursuant to Article 30, governments can place some exceptions on the rights of a
patent holder provided such exceptions do not “unreasonably” conflict with the normal
exploitation of the patent.\(^7^2\) Third, WTO Members are allowed to control anti-

\(^6^9\) In 2001, a group of multinational drug companies took the South African government to court for
attempting to import generic versions of AIDS drugs from India. The multinational companies were forced
to withdraw their suit after adverse media attention. See USA Today, Drug companies Drop Lawsuit
drugsuit.htm.

\(^7^0\) Past attempts by South Africa, Thailand, and Brazil to compulsorily license the manufacture of critical
drugs for treating HIV/AIDS resulted in threatened economic sanctions from the U.S. Government and
invocation of the WTO dispute settlement procedure by the U.S. Government. See generally, OSTERGARD,
Patent Dispute,” Ostergard Jr. discusses attempts by the United States to get the South African government
to adjust its patent laws to enhance protection for pharmaceutical patents).

\(^7^1\) TRIPS Agreement, supra note 4, Article 27 (2) (“Members may exclude from patentability inventions,
the prevention within their territory of the commercial exploitation of which is necessary to protect
ordre public or morality, including to protect human, animal or plant life or health or to avoid serious
prejudice to the environment, provided that such exclusion is not made merely because the exploitation is
prohibited by their law.”).

See also, Article 27(3) of TRIPS under which WTO Members are permitted to exclude from
patentability: “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” and
“plants and animals other than micro-organisms, and essentially biological processes for the production of
plants or animals other than non-biological and microbiological processes.”

\(^7^2\) TRIPS Agreement, supra note 4, Article 30 (“Members may provide limited exceptions to the exclusive
rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal
competitive practices and prevent abuse of rights by patent holders.\(^{73}\) Fourth, parallel importing is very possible under the TRIPS Agreement.\(^{74}\) Most important, the preamble,\(^{75}\) Article 7 (“Objectives”)\(^{76}\) and Article 8 (“Principles”)\(^{77}\) of the TRIPS Agreement provide a broad framework for interpretation that, if followed, would have allowed for a balanced result in the debate.

Regarding compulsory licenses, although Article 31 of the TRIPS Agreement appeared to accord WTO Members broad rights to grant compulsory licenses,\(^{78}\) a debate ensued regarding the precise scope of the flexibility permitted governments and the precise grounds for which compulsory license may be issued.\(^{79}\)

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\(^{73}\) TRIPS Agreement, supra note 4, Article 8(2) (“Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”).

\(^{74}\) Parallel import permits countries to search for the lowest price for patented products worldwide and import from the lowest source. It is based on the principal that once a patent-holder sells goods, he has lost his right to control the resale of those goods; in other words, he is said to have “exhausted” his property rights in the product. The TRIPS Agreement is vague on the subject and arguably left the issue of parallel importing unaddressed. See TRIPS Agreement, supra note 4, Article 6 (Article 6 provides: “For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”).

\(^{75}\) In the preamble of the TRIPS Agreement, Members recognize "the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives." Members also recognize "the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base," and the fact that “patent rights cannot be paramount to overarching public policies, in particular health policies.”

\(^{76}\) TRIPS Agreement, supra note 4, Article 7 (“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”).

\(^{77}\) TRIPS Agreement, supra note 4, Article 8(1) (“Members 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.”).

\(^{78}\) Article 31 outlines the conditions a government must meet when issuing a compulsory license. What conditions? First, there must be a prior effort to negotiate a voluntary license with the patent holder on “reasonable commercial terms” and within a reasonable period. This requirement is waived in the case of a “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” See Article 31(b). Second, “the scope and duration of such use shall be limited to the purpose for which it was authorized.” See Article 31(c). Third, the patent owner is to be paid “adequate remuneration …taking into account the economic value of the authorization.” See Article 31(h).
The pharmaceutical industry argued that the relationship between TRIPS, patents and access to medicine was tenuous at best.\textsuperscript{80} According to the industry, the causes of lack of access to essential drugs in developing countries were legion and generally included official corruption, misguided taxation, systemic poverty, exorbitant retail markups and the general lack of infrastructure.\textsuperscript{81} The argument, thus, was that patent protection is but “a very small part of a much bigger issue”\textsuperscript{82} and that compulsory license should be allowed only in very limited circumstances. Essentially, while welcoming the TRIPS Agreement, the industry called for a tightening of the provisions of the Agreement.\textsuperscript{83}

Developing countries, on the other hand, view compulsory license as a critical pathway to ensuring low-cost drugs. By facilitating generic entry and generic competition, they argued, it would be possible to ensure that essential drugs are accessible, available and affordable. While avowing commitment to the TRIPS Agreement, developing countries were of the view that nothing in the TRIPS Agreement reduced the range of options available to governments to promote and protect public

\textsuperscript{79} In the light of efforts by countries such as United States to “punish” countries that attempted to exercise their rights under Article 31 and a lawsuit filed against the South African Government by a group of pharmaceutical companies, developing countries began to push for a clarification of Article 31. Developing countries wanted a common understanding that confirm the right of governments to make use of the provisions in the TRIPS Agreement whenever the exercise of intellectual property rights result in barriers to access to essential drugs. At a TRIPS Council meeting of 2-6 April 2001, the decision was made to hold a special session to initiate discussions on the interpretation and application of the relevant provisions of the TRIPS Agreement based on a proposal by the Africa Group. See World Trade Organization, Council for Trade-Related Aspects of International Property Rights, Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/296, June 29, 2001, available at http://docsonline.wto.org [hereinafter Submission by the African Group].

\textsuperscript{80} Debroy, supra note 6, at 3.

\textsuperscript{81} \textit{Id.}

\textsuperscript{82} \textit{Id.}

\textsuperscript{83} The following websites have helpful information: www.ifpma.org (International Federation of Pharmaceutical Manufacturers Association) and www.phrma.org (Pharmaceutical Research and Manufacturers of America).
health nor placed a restriction on the purposes for which compulsory license could be issued. Developing countries also pointed to the fact that some developed countries were great users of compulsory licenses.

Domestic and international Non-Governmental Organizations ("NGO’s") and AIDS support groups also argued that TRIPS put profit over human lives in the developing world. By forbidding the easy and cheap copying of patented drugs, these groups argued, the TRIPS Agreement constrained the ability of developing-countries to address immediate loss to the welfare of domestic consumers. The solution, they argued, was compulsory licensing.

III. THE DOHA DECLARATION AND THE 2003 DECISION ON IMPLEMENTATION: A REVOLUTION IN INTERNATIONAL TRADE LAW?

The Doha Declaration and the 2003 Decision on Implementation now appear to lay to rest the different debates regarding compulsory licensing. The 2003 Decision on Implementation was adopted by the General Council in the light of a “Statement of Understanding” read out by the Chairperson of the General Council of the WTO. In this

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84 Submission by the African Group, supra note 79, at 5.
85 Several scholars support the position that the TRIPS Agreement does not limit the grounds upon which compulsory license may be issued. See CORREA, supra note 48, at 89-90 (arguing that although the TRIPS Agreement refers to five specific grounds for the granting of compulsory license, the Agreement did not limit the members rights to establish compulsory license on other grounds not mentioned). See also WATAL, supra note 15, at 380 (observing that the final text of Article 31 places no restrictions on the purposes for which compulsory license could be authorized).
86 Submission by the African Group, supra note 79, at 28.
87 Debroy, supra note 6, at 3.
88 See supra note 9 and accompanying text.
89 See supra note 15 and accompanying text.
section, I shall briefly highlight the key provisions of the Doha Declaration, bring readers up to date on the Paragraph 6 question – the question that was left unaddressed in the Doha Declaration, and extensively examine the 2003 Decision on Implementation. In Part A, I examine the main provisions of the Doha Declaration. In Part B, I highlight the main issues that arise in the Paragraph 6 question. In Part C, I highlight and critically examine the main provisions of the 2003 Decision on Implementation. In Part D, I examine the main contours of the Statement of Understanding issued by the Chairperson of the General Council. A more detailed evaluation of the merits and demerits of the 2003 Decision on Implementation will be undertaken in Section IV.

A. The Doha Declaration

The Doha Declaration reiterates the importance of an effective intellectual property regime for the development of new medicines while recognizing the concerns about the effect of intellectual property on drug prices. The Doha Declaration also stresses the need for the TRIPS Agreement to be part of wider national and international action to address the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Paragraph four, one the most ambitious provisions in the declaration, provides:

We agree that the 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

\[91\] Doha Declaration, supra note 9, at para. 3.
\[92\] Id. at para. 1-2.
manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.\textsuperscript{93}

Regarding the flexibilities permitted members under the TRIPS Agreement to promote access to medicine, the Doha Declaration, reaffirms “the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”\textsuperscript{94} More specifically on compulsory licenses, the Doha Declaration states that, “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”\textsuperscript{95} and that in deciding to grant compulsory license “[e]ach 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.”\textsuperscript{96}

The Doha Declaration was undoubtedly a victory for developing countries. The declaration is most useful to countries with local technological, productive and regulatory capacity to support generic industries.\textsuperscript{97} Moreover, even if a country has sufficient capacity to support local production, it may be economically inefficient “to require domestic production for every medicine a country may need.”\textsuperscript{98} For countries with insufficient manufacturing capacity and countries whose generic industries may not operate on an economy of scale for every drug required domestically, the obvious

\textsuperscript{93} Id. at para. 4.
\textsuperscript{94} Id.
\textsuperscript{95} Id. at para. 5(b) (emphasis added).
\textsuperscript{96} Id. at para 5(c) (emphasis added).
\textsuperscript{97} Sun, supra note 4, at 107.
\textsuperscript{98} Id.
solution is to import generic drugs manufactured under compulsory license from other
countries. However, the Doha Declaration did not decide the question whether such
importation of generic drugs manufactured under compulsory licenses was permitted.
Rather, Paragraph 6 reads:

> We recognize that WTO Members with insufficient or no manufacturing
capacities in the pharmaceutical sector could face difficulties in making
effective use of compulsory licensing under the TRIPS Agreement. We
instruct the Council for TRIPS to find an expeditious solution to this
problem and to report to the General Council before the end of 2002.99

The Paragraph 6 issue triggered another year of debates, discussions and
negotiations in the WTO. Although the TRIPS Council considered a draft decision at the
end of December 2002, and despite approaching the year-end deadline stipulated in the
Doha Declaration, the issue remained unresolved as a result of the inability of WTO
Members to reach a consensus on the issue.

B. The Paragraph 6 Question

The Paragraph 6 question arises because of a restriction contained in Article 31(f)
of the TRIPS Agreement.100 Article 31(f) appears to prohibit the export of products
manufactured under a compulsory license by specifying that a compulsory license shall
be authorized predominantly for the supply of the domestic market authorizing such use.

99 *Doha Declaration, supra* note 9, at para. 6.
100 *Article 31(f) states, “Where the law of a Member allows for other use of the subject matter of a patent
without the authorization of the right holder, including use by the government or third parties authorized by
the government, the following provisions shall be respected:... Any such use shall be authorized
predominantly for the supply of the domestic market of the Member authorizing such use” (emphasis
added).*
The rationale behind Article 31(f) “lies in the territorial nature of patent law and in the need to avoid circumvention of patent rules.”101

As a result of Article 31(f), uses permitted by a compulsory license are limited to those aimed at predominantly supplying the domestic market of the WTO Member granting such a license. Although Article 31(f) does allow a non-predominant part of the pharmaceutical product manufactured under compulsory license to be exported, difficulties arise where a country lacking domestic manufacturing capability is seeking to import massive quantities of generic drugs from the manufacturing country. As stated by the United States in its communication to the WTO:

Difficulties could arise, therefore, when a country with insufficient domestic manufacturing capacity and experiencing grave health problems seeks to import a needed pharmaceutical from a manufacturer in a WTO Member where a patent exists on that pharmaceutical. In this situation, it currently would be inconsistent with Article 31(f) for that WTO Member to grant a compulsory license to its manufacturer to produce the drug solely for export to the country that has insufficient or no manufacturing capacities in the pharmaceutical sector. It is this situation that the TRIPS Council must address.102

WTO Members disagreed on the procedural mechanism needed to address the problem as well as the substantive solution that was needed to address the problem. At a March 2002 TRIPS Council meeting, four different solutions were proposed: (i) an authoritative interpretation of Article 30 of the TRIPS Agreement;103 (ii) an amendment


103 Article 30 provides that “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” An authoritative interpretation of Article 30 would have recognized the
to Article 31 in order to overcome the Article 31(f) restriction;\textsuperscript{104} (iii) a moratorium on dispute settlement with regard to the non-respect of the restriction under Article 31(f);\textsuperscript{105} and (iv) a temporary waiver with regard to Article 31(f).\textsuperscript{106}

C. The 2003 Decision on Implementation

The 2003 Decision on Implementation takes the form of a provisional waiver to Article 31(f) and allows countries to export generic drugs to third countries with no manufacturing capacity in the pharmaceutical sector.\textsuperscript{107} The Decision pertains only to pharmaceutical products.\textsuperscript{108} It lays out the obligation of exporting members, eligible importing members, other members of the WTO, and the TRIPS Council. The Decision includes safeguards against abuse and trade diversion and lays down rules to ensure transparency. The Decision also contains provisions on transfer of technology and regional cooperation. In the following section I shall outline the main provisions of the Decision.

\textsuperscript{104} An Amendment to Article 31 would have been in the form of a new paragraph which would carve out exceptions to the restrictions imposed by Article 31(f). The European Communities (“EC”) supported this solution arguing that “[t]he insertion of a textual provision into the TRIPS Agreement itself has the advantage of providing for a straightforward, clear, legally secure, effective and permanent solution within an existing legal framework, i.e. Article 31 of the TRIPS Agreement.” EC, \textit{Communications Relating to Paragraph 6, supra} note 101. See also, EC Communication to the TRIPS Council of March 4, 2002 (IP/C/W/339).

\textsuperscript{105} A moratorium on dispute settlement would have operated as a pledge by WTO Members not to challenge any member that fails to comply with the letter and spirit of Article 31(f). The United States initially proposed and strongly supported this solution.

\textsuperscript{106} See EC, \textit{Communications Relating to Paragraph 6, supra} note 101, at para. 5.

\textsuperscript{107} Paragraph 1 provides that “[t]he obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s).”

\textsuperscript{108} \textit{2003 Decision on Implementation, supra} note 1, at para. 1.
1. Qualifying Countries: Which countries will benefit from the system? Which countries are excluded?

Only “eligible importing Members” can utilize the 2003 Decision on Implementation. Eligible importing members means “any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer.” The category of importing members is potentially broad. The only requirement is that a country wishing to use the system files a notification of intent with the TRIPS Council. Some countries, mostly industrialized, have voluntarily decided not to use the system as importing Members.

An “exporting Member” simply means “a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.” It appears to mean that any country with manufacturing capacities, including industrialized countries, can export under this system.

2. Qualifying Products: Which products are covered by this system? What about vaccines?

The Decision is strictly limited to pharmaceutical products which are defined in paragraph 1 to mean “any patented product, or product manufactured through a

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109 Id. (emphasis added).
110 Paragraph 1 notes that “some Members will not use the system set out in this Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency.” Id. See also footnote 3 to paragraph 1(b) (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.). See also, Statement of Understanding, supra note 90 (“Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers . . . some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.”).
111 2003 Decision on Implementation, supra note 14, at para. 1
patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration.” 112 Active ingredients necessary for the manufacture of the pharmaceutical products and diagnostic kits needed for its use are also included in this definition. The definition of patented products appears to be broad enough to allow countries to address legitimate public health needs and would extend to vaccines.

3. Qualifying Diseases: What is the Disease Scope of the Decision?

The Decision does not contain a list of qualifying diseases for which the waiver may be used – a major victory for developing countries. An effort by the U.S. to limit the disease coverage led to a major deadlock in negotiations and made it impossible for WTO Members to meet the 2002 year-end deadline stipulated in the Doha Declaration. In a January 7, 2003 letter to Ministers of the WTO, the European Union (“EU”) Commissioner for Trade, Pascal Lamy, suggested a compromise deal. 113 The EU proposed that the mechanism apply to an initial list of infectious epidemics “which are generally recognised by health experts as those which have the most damaging impact on developing countries,” with an added suggestion that Members wishing to import medicines to meet a public health concern not explicitly covered in an initial list be encouraged to seek the advice of the World Health Organization (“WHO”). 114 The proposal by the European Communities (“EC”) was subsequently rejected.

114 Id. See also, EU seeks to break the current deadlock on WTO access to medicines: a multilateral solution is needed Brussels (January 9, 2003), available at http://www.europa.eu.int/comm/trade/csc/pr090103_en.htm. The proposal submitted by the EU outlined 23 infectious diseases that the EC believed had the most damaging impact on developing countries. In addition to HIV/AIDS, malaria, and tuberculosis, the following additional diseases were suggested: Yellow fever, plague, cholera,
4. **Condition Precedent to Using the System: Will Beneficiary Countries Need Prior Authorization From the WTO to Use the System?**

Generally, prior authorization of the TRIPS Council is not required before a member can utilize the mechanisms established by the Decision. However, the Decision does require that both importing and exporting countries file some notification with the Council for TRIPS. Countries, other than least-developed countries (“LDC’s”), intending to use the system as importers must establish that they have no manufacturing capacity and notify the WTO accordingly.

The Decision also lays down specific requirements that both importing and exporting countries utilizing the system must satisfy. Essentially, all countries have an obligation to ensure that medicines produced under the system are used for their intended purpose and are not diverted to other countries where they could compete with brand-name drugs manufactured by the original patent owner.

a) **Obligation of Importing Countries:** An eligible importing Member must make a prior notification to the Council for TRIPS specifying the names and expected quantities of the product(s) needed, confirming that the eligible importing Member in question “has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question,” and confirming that, “where a meningococcal disease, African trypanosomiasis, dengue, influenza, leishmaniasis, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, haemorrhagic fevers, and arboviruses.

115 *2003 Decision on Implementation*, supra note 14, foot note 2 (“It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.”).
116 *Id.* at para. 2(a).
117 *Id.* This requirement is waived for least-developed countries (“LDC’s”). The Annex to the Decision sets out two ways that a country can establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector. For the purposes of the Decision on Implementation, LDC Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector. For other eligible importing
pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision.”\textsuperscript{118}

Importing Members have an obligation to prevent re-exportation of the products that have being imported into their territory under the system. To ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members are required to “take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system.”\textsuperscript{119}

b) Obligation of Exporting Countries: Several obligations are imposed on exporting countries utilizing the system. First, such an exporting country must first issue a compulsory license in accordance with Article 31 of the TRIPS Agreement. Second, the compulsory license issued by the exporting Member must contain certain conditions. It must stipulate that “only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS.”\textsuperscript{120} It must also stipulate that “products produced under the licence shall be

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Members, insufficient or no manufacturing capacities for the product(s) in question can be established in either of two ways. One way is for the Member in question to establish that it has no manufacturing capacity in the pharmaceutical sector. Where the Member has some manufacturing capacity in the pharmaceutical sector, it has to examine this capacity and determine that, “excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs.” In the later case, the system ceases to apply when it is established that such capacity has become sufficient to meet the Member’s needs.

\textsuperscript{118} Id.
\textsuperscript{119} Id. at para. 4.
\textsuperscript{120} Id. at para. 2(b)(i).
clearly identified as being produced under the system set out in [the Decision on Implementation] through specific labelling or marking.”\textsuperscript{121} The exporting country must also require that “[s]uppliers …distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.”\textsuperscript{122} Finally, an exporting country must require that before shipment begins, the licensee shall post on a website “the quantities being supplied to each destination”\textsuperscript{123} and “the distinguishing features of the product(s).”\textsuperscript{124}

A third requirement placed on an exporting member pertains to notification. An exporting Member is required to notify the Council for TRIPS of the grant of the license and the conditions attached to it.\textsuperscript{125} Finally, an exporting member who has granted a compulsory license under this system has an obligation to pay “adequate remuneration” to the patent holder pursuant to Article 31(h) of the TRIPS Agreement.\textsuperscript{126}

c. Obligations Imposed on Other WTO Members: All WTO Members are required to take necessary measures to prevent diversion. Members also agree not challenge actions taken by countries under this Decision. Paragraph 10 stipulates that “Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.”

\textsuperscript{121} 2003 Decision on Implementation, supra note 14, at para. 2(b)(ii).
\textsuperscript{122} Id.
\textsuperscript{123} Id. at para. 2(b)(iii).
\textsuperscript{124} Id.
\textsuperscript{125} Id. at para. 2(c) (“The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence.”).
\textsuperscript{126} Id. at para. 3.
5. **Safeguards against Diversion:**

Measures against diversion are directed at preventing goods from being diverted from their intended purpose. In the course of negotiations on the Paragraph 6 issue, pharmaceutical companies expressed fear that cheaper drugs produced under compulsory license may be diverted to rich country markets where a different pricing system exists. To address this, all WTO Members are obliged to “ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.”\(^{127}\)

6. **Surveillance and Review Mechanism**

The Council for TRIPS assumes a new monitoring role under the Decision. Paragraph 8 stipulates that the Council for TRIPS “shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council.”\(^{128}\) The notifications required of exporting and importing countries also go to the Council for TRIPS.

7. **Technology Transfers**

The Decision recognizes the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Doha Declaration. Consequently, the Decision calls on eligible importing Members and exporting Members to use the system in a manner that would promote the objective of technology transfer. Paragraph 7 contains a vague

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\(^{127}\) *2003 Decision on Implementation, supra* note 14, at para. 5.

\(^{128}\) *Id.* at para. 8.
undertaking by Members “to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector.”129

D. The Statement of Understanding

The original draft of the Decision was unacceptable to the U.S. and to the pharmaceutical industry.130 To achieve a much needed consensus on the paragraph 6 question, it became necessary for the Chairperson of the General Council to adopt a statement to accompany the Decision. The Statement of Understanding was issued essentially to placate the United States and the pharmaceutical industry and to ensure that WTO Members arrived at a consensus before the biennial meeting of the WTO Ministerial Conference. The Statement of Understanding has four important clauses: a good faith clause, an anti-diversion clause, a transparency clause, and a peaceful and expeditious settlement of dispute clause.

According to the Statement, WTO Members “recognize that the system that will be established by the Decision should be used in good faith to protect public health” and

129 Id. at para 7.
130 When a draft of the Decision (known as the “Motta text”) was circulated in December 2002, the United States was the only country that refused to endorse the text. On top of the Motta text, the U.S. government demanded: that any solution be restricted to “humanitarian use” (a vague clause that many feared could disqualify normal generic production); an “opt-out” clause that will hinder the economic viability of the solution; heavier burdens on suppliers to change the packaging of products made under this system; and a “review mechanism” to monitor the diversion of generics back into wealthy markets. See Oxfam, US seeks further restrictions on generic medicines for developing countries (August 25, 2003), US seeks further restrictions on generic medicines for developing countries, available at http://www.oxfam.org/eng/pr030825_TRIPS_health.htm (discussing how several NGO’s involved in the Paragraph 6 question – Médecins Sans Frontières (MSF), Oxfam, Health Action International (HAI), Third World Network (TWN) and the Consumer Project on Technology (CPTech) – have found additional demands by the U.S. to be a threat to the access of poor countries to needed medicines because they are, in effect, a “redundant layer of bureaucracy that can easily be manipulated to pressure countries out of the system.”).
“not be an instrument to pursue industrial or commercial policy objectives.” 131 The
Statement also contains an understanding among Members that the purpose of the
Decision would be defeated if products supplied under the Decision are diverted from
their intended market. Consequently, Members agree that “all reasonable measures
should be taken to prevent … diversion in accordance with the relevant paragraphs of the
Decision.” 132 The Statement, however, specifically states that “[i]t is the understanding of
Members that in general special packaging and/or special colouring or shaping should not
have a significant impact on the price of pharmaceuticals.” 133

The Statement also calls on Members to “seek to resolve any issues arising from
the use and implementation of the Decision expeditiously and amicably.” 134 To ensure
transparency, the Statement of Understanding requires that notifications made under
paragraph 2(a)(ii) of the Decision pertaining to eligibility of importing country include
information on how the Member in question established that it has insufficient or no
manufacturing capacities in the pharmaceutical sector.

The Statement of Understanding also confirms the new monitoring role of the
TRIPS Council. Essentially, “[a]ny Member may bring any matter related to the
interpretation or implementation of the Decision, including issues related to diversion, to
the TRIPS Council for expeditious review, with a view to taking appropriate action.” 135

Any WTO Member who has concerns that the terms of the Decision have not been fully

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131 Statement of Understanding, supra note 90.
132 Id. The Statement notes that the provisions of paragraph 2(b)(ii) pertaining to the obligations of
exporting countries with respect to labeling “apply not only to formulated pharmaceuticals produced and
supplied under the system but also to active ingredients produced and supplied under the system and to
finished products produced using such active ingredients.”
133 Id. Regarding special packaging and labeling, the Statement notes the fact that in the past and for
different reasons, companies have developed procedures to prevent diversion of products. Attached to the
Statement, is a “Best practices” guideline that draws upon the experiences of companies.
134 Id.
135 Id.
complied with, “may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.”

E. Conclusion

After all the battles over access to medicine and the relationship between patent rights, the TRIPS Agreement and public health, what exactly has been achieved? What can countries that are members of the WTO legitimately do to ensure that essential medicines are available and affordable?

WTO Members have at least five options. First, where patent exists on a desired medicine, developing countries can still attempt to meet their needs by dealing directly with the patent holder through normal commercial arrangements and through aid programs such as donations and discounts. Second, also where patents exist on a desired medicine, a WTO Member with manufacturing capacity has the flexibility under the TRIPS Agreement and the Doha Declaration to grant compulsory license to permit the manufacture of generic versions of the same product. Third, where a WTO Member has insufficient or no manufacturing capability, such a Member can, without compulsory license, import generic pharmaceutical products manufactured in another country provided there are no patents on the pharmaceutical in question in the importing

136 Id.
137 Second Communication from the U.S. on Paragraph 6, supra note 102, at para. 7 (“First, difficulty would be expected to arise only in situations where the supply of the pharmaceutical in question has not been provided by the patent holder through normal commercial arrangements or through discount, donation, or other aid programs. A TRIPS-based solution can also only be expected to be effective where Members have, or are provided, the resources necessary to procure pharmaceuticals under the terms of a TRIPS-consistent compulsory licence, which includes the provision of adequate remuneration to the patent holder.”).
138 Id. at para. 8.
country and in the prospective exporting country. Fourth, where there are patents in both the importing and exporting country, compulsory license would need to be issued in both countries before medicines could be exported.

Although the 2003 Decision on Implementation appears to be a victory for developing countries, its usefulness is yet to be tested. During negotiations the World Health Organization (“WHO”) and civil society groups had recommended a much simpler, workable, and economically viable solution: allowing generic production for export as a limited exception to a patent right. There are fears that the Decision creates a costly and cumbersome process that could ultimately discourage generic production.

IV. ACCESSING GAINS; MAPPING PROGRESS: THE MERITS AND DEMERITS OF THE 2003 DECISION ON IMPLEMENTATION

The objective of both the Doha Declaration and the 2003 Decision on Implementation was to ensure speedy and low priced supplies of essential medicines to those in countries in need of them, while maintaining a legal environment that rewards inventors for their investment and encourages research and development into new products. Several questions inevitably arise. Will the adoption of the Decision enable countries in need of affordable medicines to import them quickly and easily from generic manufactures in other countries? Is the solution transparent and economically feasible?

Will the Doha Declaration and the Decision ensure that needed drugs are available on a

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139 In general, developing countries are not required to establish a patent protection regime under the TRIPS Agreement until January 1, 2005. Thus, a developing country with manufacturing capacity and no patent laws can manufacture and export patented drugs without a compulsory license.
sustained basis? Altogether, is the solution crafted in the Decision expeditious, workable, transparent, sustainable and legally certain?\textsuperscript{140}

The questions are pertinent because although the 2003 Decision of Implementation is seen in some quarters as a balanced solution to the Paragraph 6 question,\textsuperscript{141} many NGO’s are critical of the Decision.\textsuperscript{142} Critics argue that the Decision is

\textsuperscript{140} Second Communication from the U.S. on Paragraph 6, supra note 102, para. 29 (arguing that “[w]hile each option suggested by Members has some merit, at this stage we believe an expeditious, workable, transparent, sustainable and legally certain solution may more likely be achieved through either a moratorium for dispute settlement or a waiver of the obligation in TRIPS Article 31(f).”).

\textsuperscript{141} On August 30, 2003, Shannon Herzfeld, Senior Vice President, International Affairs of the Pharmaceutical Research and Manufacturers Association (“PhRMA”), issued a statement that read in part:

With the unanimous adoption of the Menon Statement and the Motta text, we are pleased that these negotiations have come to a conclusion…. The two decisions that the General Council reached today – the Motta text and the Chairperson’s statement – will ensure that the system will not be abused. The additional clarifications contained in the Chairperson’s statement add strong provisions to prevent diversion, and increase the likelihood that the solution will benefit patients in the world’s poorest countries as envisioned in the Doha Declaration. Taken as a whole, this solution reaffirms the critical role of patents in the development of new medicines.

\textsuperscript{142} In a Joint NGO Statement issued on September 10, 2003, twenty-one NGOs criticized several aspects of the 2003 Decision on Implementation. According to the Joint NGO statement:

These are the main problems with the rules:

1. The WTO is requiring the issuance of two compulsory licenses when the new mechanism is used.
2. The WTO has added many constraints on the business practices of the generic companies.
3. The WTO deal introduced an extra layer of uncertainty by stating that the system should not be an instrument to pursue industrial or commercial policy objectives, creating uncertainty over the role that will be played by the businesses that manufacture and sell generic drugs.
4. The decision leaves unclear whether or not economic efficiency is a grounds for determining a lack of manufacturing capacity in the importing country. The lack of clarity on this issue has been defended as a matter of "creative ambiguity", but already the US is telling the Philippines and other countries that they will oppose "economic efficiency" as grounds for allowing a country to import generics.
5. The deal gives the WTO itself new authority to second guess and interfere in the granting of individual compulsory licenses to generic companies.
6. The United States and other Developed Economies now have greater opportunities to pressure and stop developing countries from issuing compulsory licenses.

Joint NGO Statement on TRIPS and Public Health WTO Deals on Medicine: A “Gift” Bound in Red Tape (September 10, 2003), available at http://www.cptech.org/ip/wto/p6/ngos09102003.html [hereinafter Joint NGO Statement]. The statement was signed by the following organizations: ACT Up Paris; Consumer Project on Technology; Consumers International; Essential Action; European AIDS Treatment Group;
intended to “[l]imit the importance of the Doha Declaration,” “[p]rejudice more fundamental and sustainable fixes to the 31.f problems,” “[c]reate more and not less uncertainly regarding what can and cannot be done,” and “[g]ive the US and the EU a big public relations bonanza which will be cruelly use [sic] as the basis for more bilateral pressure against the use of compulsory licenses and against better export strategies, as well as a basis to leverage additional concessions from developing countries in other WTO negotiations.” Overall, the belief is that “[t]he new agreement has very modest benefits,” and that “it has very substantial costs, risks and uncertainties.”

In this Section, I focus specifically on the 2003 Decision on Implementation in part because The Doha Declaration has been the subject of a good many law review articles. I shall review the Decision in the light of some of the perceived concerns of some of the NGO’s. Three main issues will be taken up. First, I shall examine the viability and sustainability of the waiver mechanism as a solution to the paragraph 6 question. Second, I shall examine the nature of obligations imposed on prospective importing and exporting countries to see if they are unnecessarily burdensome, onerous and an imposition on sovereignty. Third, I shall examine the gaps in the Decision – areas where the Decision is vague and could potentially create problems in the future for countries desiring to utilize the system.
A. The Waiver Solution

Was the waiver solution the best possible solution to the Paragraph 6 question? The 2003 Decision on Implementation, which operates as a temporary waiver, offers a quick solution to a thorny problem but carries with it a lot of legal uncertainty. Compared to a more formal amendment, a temporary waiver carried the advantage of speed and simplicity.

Although the waiver solution had its advantages, an amendment would have offered the advantage of permanence, sustainability and legal certainty, although undeniably more time consuming to achieve than a waiver. The United States had opposed an amendment to Article 31(f) on the grounds that actions of countries acting under an amendment would have been susceptible to legal challenges which would have marred the legal certainty of the solution.

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145 EC, Communications Relating to Paragraph 6, supra note 101, at para 6 (The EC observed that, “A waiver or a dispute settlement moratorium could be appropriate and effective mechanisms for a solution, but they may fall short of providing the type of sustainable and legally secure solution that the EC are aiming for.”). See also Attaran, supra note 4, at 767 (noting that a waiver is only a temporary solution).

146 In the TRIPS Council, the United States has argued that “agreement can be reached on a … waiver much more easily and quickly than on an amendment to the TRIPS Agreement and further delay would be required for Members' formal acceptance. Crafting an amendment on which all Members can agree would delay implementation of the 'expeditious solution' beyond the agreed deadline.” See Second Communication from the U.S. on Paragraph 6, supra note 102, para. 29.

147 Id. (“Should an amendment be adopted, it could prove to be either ineffective or seriously harmful in practice. A further amendment of the Agreement would be required to correct this situation.”).

148 EC, Communications Relating to Paragraph 6, supra note 101, at para. 5 (arguing that an amendment “offer[ed] the best guarantees for a sustainable, balanced and workable solution.”). See also EC Communication to the TRIPS Council of 4 March 2002/IP/C/W/339).

149 EC, Communications Relating to Paragraph 6, supra note 101, at para. 7. An amendment to Article 31 would fall under the procedural rules set out by Article X of the Marrakesh Agreement and is time-consuming. Id. The EC noted that an amendment of paragraph 31(f) of TRIPS, as for all amendments of international agreements, is a procedure that takes time. Id.

150 Second Communication from the U.S. on Paragraph 6, supra note 102, para. 29 (arguing that “if a country begins production for export relying on either an authoritative interpretation or an amendment, its actions could be challenged as being inconsistent with the interpretation or amendment,” and such a country would only have full legal certainty after the conclusion of a dispute process.).
Some NGO’s had suggested an authoritative interpretation of Article 30 as a solution. Article 30 of the TRIPS Agreement permits WTO Members to provide limited exceptions to patent rights “provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” Article 30 is seen to be politically more workable. Article 30 does not require a government decision each time a pharmaceutical product is needed and contains no stringent requirements such as the requirement to notify a patent owner of use or to pay reasonable remuneration to the patent holder.

The Article 30 solution was not favored by the United States or the EC. Rejecting this solution, the U.S. argued that Article 30 is “intended to apply to statutory exceptions already provided for in many countries’ laws at the time the TRIPS Agreement was negotiated,” and that “[i]nterpreting Article 30 to allow Members to amend their patent laws to permit compulsory licences to be granted to authorize their manufacturers to produce and export patented pharmaceutical products to other countries would both unreasonably conflict with the normal exploitation of a patent and unreasonably prejudice the legitimate interests of the patent owner.”

The waiver solution is only temporary. Assessment of the wisdom of the solution will depend on how speedily WTO Members can adopt a more permanent amendment to

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151 Id. at para. 31.
152 Attaran, supra note 4, at 870.
153 The EC rejected this idea arguing that “an authoritative interpretation on Article 30 of the TRIPS Agreement may fail to offer the same level of legal security for all parties involved as a textual addition to Article 31(f) would do.” EC, Communications Relating to Paragraph 6, supra note 101, at para. 6. The EC questioned the legal merit of the Article 30 solution and thought it was doubtful whether the criteria of Article 30 offered sufficient scope for such an exception. Id.
154 Second Communication from the U.S. on Paragraph 6, supra note 102, para. 31.
155 Id.
Article 31(f). Although the Decision set a deadline for WTO Members to negotiate and adopt such an amendment,\textsuperscript{156} judging by past negotiating practices at the WTO\textsuperscript{157} and serious debates that preceded the adoption of the Decision, it could predictably take much more time for Members to negotiate and adopt the necessary amendments. Global corporate actors will predictably attempt to influence the negotiating position of developed countries governments, thus prolonging the time amendment process.\textsuperscript{158}

B. The Conditions Attached

Does the Decision provide incentive for manufactures to participate and produce for export or does it de-incentivize generic production? Does the Decision contain onerous conditions that might discourage countries from utilizing the system? Asia Russell of Health GAP (an AIDS Activist Organization) has argued that the solution crafted by the Decision “is a failure for people with AIDS, and people everywhere dying of treatable diseases”\textsuperscript{159} because “[i]n the time it would take a generic company to

\textsuperscript{156} The Decision, including the waivers granted in it, “shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member.” 2003 Decision on Implementation, supra note 14, para. 11. The Decision authorizes The TRIPS Council to “initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration.” Id.

\textsuperscript{157} Attaran, supra note 4, at 708 (predicting that negotiations could drag on for years and that during negotiations, developed countries and pharmaceutical companies will attempt to resuscitate proposals that were rejected).

\textsuperscript{158} MATTHEWS, supra note 22, at 6 (suggesting that global corporate actors will continue to play a pivotal role in any future renegotiation of the TRIPS Agreements and that “[t]heir interests are likely to be at the forefront of developed country perspectives on future requirements of intellectual property protection.”).

\textsuperscript{159} Health GAP Global Access Project, Bush Administration, Big Pharma about to secure disastrous "solution" on access to medicines at the WTO in effort to boost failing pre-Cancun talks, countries are poised for sell-out on public health, Press Release ( August 28, 2003) , available at http://www.healthgap.org/press_releases/03/082803_HGAP_PS_WTO_para6_aug30text.html
comply with all the conditions set out by the U.S., a patent would likely expire anyway.\textsuperscript{160}

Under the Decision, there are at least six steps to acquiring needed medicine through compulsory license:\textsuperscript{161}

- **Step 1**: A prospective importing country must first seek a voluntary license from the patent owner; such a license is supposed to be on commercially reasonable terms and for a commercially reasonable period of time.

- **Step 2**: If attempt to secure a voluntary license fails, an entity must apply for a compulsory license to manufacture the medicine locally.

- **Step 3**: Where the compulsory license is by a country that has no capacity to manufacture the medicine locally and the country is not a least-developing country, such a country must assess its industry’s capacity to produce the medicine locally, notify the TRIPS Council of its determination that it has no or insufficient capacity, and explain and justify its decision regarding capacity.

- **Step 4**: An importing country must identify and notify a willing exporter in a country that has sufficient capacity to manufacture the needed medicine.

- **Step 5**: The prospective exporter must seek a compulsory license from its own government.\textsuperscript{162} In granting the license, the prospective exporting country must ensure that the conditions stipulated in Article 31 of the TRIPS Agreement are met. One important condition is that the exporting country must pay “adequate compensation” to the patent holder.

\textsuperscript{160} Id.
\textsuperscript{161} See 2003 Decision on Implementation, supra note 14.
\textsuperscript{162} It is possible that the exporter may be required first to seek a voluntary license from the patent holder.
• **Step 6:** If and when a license is granted, the exporter must take adequate measures as stipulated in the Decision to prevent diversion. In particular, the exporter must: (a) produce only the amount necessary to meet the needs of the eligible importing Member; (b) export the entirety of the production to the Member(s) which notified its needs to the Council for TRIPS; (c) clearly identify the products produced under the system through specific labeling or marking, special packaging and/or special colouring/shaping of the products themselves; (d) before shipment begins, post on a website, the quantities being supplied to each destination and the distinguishing features of the product(s).

  i. **Notification Requirements:** The Decision creates a somewhat cumbersome procedure for countries with no or insufficient capacity which does not exist for countries with manufacturing capacity.\(^{163}\) Although the system is supposed to be automatic, the TRIPS Council can second-guess a country’s decision to utilize the system and has enough mandate to interfere and scrutinize the granting of compulsory license.\(^{164}\) Some NGO’s have expressed concern that the notification requirements would be used to increase bilateral pressure on weak countries, both exporting and importing.\(^{165}\)

  Additionally, some organizations have argued that the Decision authorizes unnecessary intrusion into sovereignty because it authorizes the WTO Secretariat, the

\(^{163}\) CPTech Statement, *supra* note 144 (“The WTO secretariat, the TRIPS Council and the Chair of the TRIPS council will now begin to routinely review the issuance of individual licenses, and the WTO will now as a matter of expected practice, oversee the use of compulsory licensing in the most intimate terms, looking at the terms of individual licenses, evaluating the basis for deciding manufacturing capacity is insufficient, or reviewing or second guessing any of the new terms and obligations that the new implementation language introduces into the regulation of compulsory licensing of patents on medicines.”).

\(^{164}\) Joint NGO Statement, *supra* note 142 (observing that Decision gives the WTO itself new authority “to second guess and interfere in the granting of individual compulsory licenses to generic companies.”).

\(^{165}\) CPTech Memo, *supra*, note 143.
TRIPS Council and the Chair of the TRIPS Council to review the use of compulsory licensing in the most intimate terms. Currently, scrutiny is required on two levels: to evaluate the basis for a country’s decision that it lacks manufacturing capacity and to evaluate whether the obligations imposed on both the importing and exporting countries have been met. Some loss of sovereignty will be inevitable. The Decision was negotiated on the good faith understanding that it was aimed at addressing the problem of countries with insufficient or no manufacturing capacity. It therefore stands to reason that some kind of review mechanism must be in place to ensure that countries utilizing the system are those for whom it was crafted.

A more troubling concern is the emergence of three classes of states subject to three different rules in multilateral system made up of sovereign states and guided by the principles of equality and non-discrimination. First are states that choose to issue compulsory license under Article 31 of the traditional TRIPS Agreements; these will be subject to very minimal scrutiny but are not immune from legal action via the WTO dispute settlement process. Second are states that issue compulsory license under the Doha Declaration; these will be subject to some measure of scrutiny and are also vulnerable to the possibilities of legal action. Third are states with insufficient or no manufacturing capacity and utilizing the system established under the 2003 Decision on Implementation; these will be subject to more intense scrutiny because the grant of compulsory license under the Decision is far more complicated than is the case under the TRIPS Agreement. In return, however, countries utilizing to system receive some measure of immunity from potential lawsuits.
ii. **Other Conditions**: One problem that arises under the 2003 Decision on Implementation is the need for two separate compulsory licenses to effectuate one import request. Where a pharmaceutical product is patented in both the importing and exporting country, a compulsory license will have to be issued in each country. In other words, compulsory licenses to both exporters and importers would have to be negotiated and issued on a country-by-country and drug-by-drug basis. A manufacture desiring to produce for export must therefore first obtain compulsory license from its home country and ensure that compulsory license is also issued in the importing country. The granting of two compulsory licenses could create delays due to bureaucratic red tape.

iii. **Measures to Prevent Abuses and Trade Diversion**

From the beginning, developed countries expressed concern about abuses and trade diversion\(^\text{166}\) and called for stringent preventive measures. The prevention of trade diversion, the EC argued was “of major importance to guarantee the legal security of the right holders concerned and to preserve the basic principles of the TRIPS Agreement.”\(^\text{167}\) This explains the stringent conditions imposed on the exporting country and generic drug companies in these countries. Under the system, generic manufacturers must differentiate pill size, shape, and color from brand-name products.

Are the safeguards on re-importation inappropriate? There is a legitimate fear that the safeguards may prove too costly for developing countries and generic manufacturers

\(^{166}\) EC, *Communications Relating to Paragraph 6, supra* note 101, at para. 13 (“It will be in the interest of all … that these products would not be diverted from their intended destination and that the system would not be [used] for purposes other than to provide pharmaceutical products … to those in need.”).

\(^{167}\) *Id.*
alike and may altogether discourage the use of compulsory licensing.\textsuperscript{168} Some anti-diversion measures are necessary however. Generic drug companies are not paragons of virtue. To prevent unscrupulous generic producers from exploiting the system for their own personal gain, some safeguards are called for.

In conclusion, some of the conditions appear to be burdensome, may impose unnecessary costs on a country wishing to utilize the system, and may delay the delivery of affordable medicine to people who need it most – the sick and the dying. It becomes a procedural nightmare when each condition has to be fulfilled over and over again for each and every drug and for each and every country to whom the drug will be exported. The Decision appears to take this into account. For example, it provides that “\textquotedblleft[i]n the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.”\textsuperscript{169}

\textbf{C. Dangerous Vagueness}

The fierce negotiation by countries such as the United States, Japan, EU and Switzerland at the TRIPS Council to introduce numerous limitations and conditions to an earlier draft of the Decision suggests that the battle over the precise scope of the Decision may be far from over. In the course of the negotiations, the U.S. government pushed for strong limitations, including a fixed list of diseases, restriction of the use of the system to

\textsuperscript{168}\ CPTech Memo, \textit{supra}, note 143.  
\textsuperscript{169}\ 2003 \textit{Decision on Implementation}, \textit{supra} note 14, at para. 4.
emergency situations and limits on eligible importing countries.\footnote{170} A major concern now is that some countries may attempt to exploit the lacunas in the Doha Declaration and the Decision in furtherance of their narrow interest.\footnote{171}

1. **The Scope of Diseases:** The Decision is silent on disease scope. It is not clear whether the system can be used to address routine public health problems or whether it is limited to epidemics and other major health emergencies.

The preamble to the Decision makes reference to the Doha Declaration.\footnote{172} This could mean that the product scope will be defined by paragraph 1 of the Doha Declaration.\footnote{173} The first paragraph of the Doha Declaration reads: “We recognize the gravity of the public health problems, afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”\footnote{174}

On the other hand, the Statement of Understanding is very telling. The Statement of Understanding explicitly notes that some countries will only use the system for emergencies. It can thus be deduced that the system will normally apply to non-emergencies (including routine public health care). It would be most unwise to restrict the solution to medicines and medical technologies for the treatment of HIV/ADIS,

\footnote{170} Médecins Sans Frontières, Campaign for Access to Essential Medicines, *Doha Derailed: A Progress Report on TRIPS and Access to Medicines*, Briefing for the 5th WTO Ministerial Conference in Cancún 2003 (observing that the proposed list of diseases suggested by the U.S. had no public health rationale), available at http://www.accessmed-msf.org/documents/cancunbriefing.pdf [hereinafter *Doha Derailed*].
\footnote{171} CPTech Memo, *supra* note 143 (“Lack of clarity has not been useful for developing countries, and whatever is unclear will work against the developing countries.”).
\footnote{172} “Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002.” *2003 Decision on Implementation*, *supra* note 14.
\footnote{173} EC, *Communications Relating to Paragraph 6*, *supra* note 101, at para. 10 (suggesting that the product scope is already defined by the Doha Declaration).
\footnote{174} *Doha Declaration*, *supra* note 9.
tuberculosis and malaria because “[w]hile there is no doubt that these epidemics are ravaging developing countries, they cannot be considered the sole public health threats in poor regions – either now or in the future.” 175

2. Eligible Importing Members: It is evident that least developed countries or LDC’s qualify to use the system. The more difficult question arises with respect to other developing countries. Where a WTO Member is a large (disease-burdened), middle-income country such as Brazil, the Philippines and South Africa, problems may arise because it may be difficult for such a country to prove to the satisfaction of the TRIPS Council that it has insufficient or no manufacturing capacity. The Decision also “leaves unclear whether or not economic efficiency is a grounds for determining a lack of manufacturing capacity in the importing country.”176

3. Moratorium on Dispute Resolution? It is not clear whether members who utilize the system are completely immune from lawsuits under the WTO dispute settlement procedure. The Decision appears to create a non-binding moratorium by providing that “Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision.”177 Much will depend on who has the final say on whether measures have been taken in conformity with the Decision and

175 See CPTech, US Government efforts to limit the scope of diseases in the implementation of the Doha Declaration on TRIPS and Public Health have outraged the public health community, and have been presented in a highly dishonest way by the White House and USTR, damaging US reputation abroad (March 5, 2003), available at http://www.cptech.org/ip/wto/p6/cptech03052003.html (quoting Allan Rosenfield, MD, Dean, Mailman School of Public Health, Columbia University, Michael H. Merson, MD, Dean of Public Health, Yale University, Laurence G. Branch, Ph.D, Dean, College of Public Health, University of Southern Florida, Stephen M. Shortell, Ph.D, Dean, School of Public Health, University of California, Berkeley).

176 Joint NGO Statement, supra note 142.

177 2003 Decision on Implementation, supra note 14, at para. 10 (emphasis added).
by what standard such determinations are made. Although the reviewing function rests with the Council for TRIPS,\textsuperscript{178} it bears to remember that membership in the Council is open to representatives of all WTO Members.\textsuperscript{179} The provision on moratorium falls short of an earlier suggestion that what was needed was a legally binding moratorium – a clear determination that actions taken under Article 31(f) would have been non-justiciable.\textsuperscript{180}

Clearly, several provisions of the 2003 Decision could pose major problems for countries wishing to utilize the mechanism established under it because of their ambiguity. The situation is made worse by the fact that the legal status of the Statement of Understanding that accompanies the Decision is not entirely clear. According to the Chairperson of the General Council, the Statement of Understanding “represents several key shared understandings of Members regarding the Decision”\textsuperscript{181} and “the way in which it will be interpreted and implemented.”\textsuperscript{182}

D. Conclusion

On the positive side, the very fact that 146 WTO Members were able to arrive at a measure of consensus in order to address the concerns of countries with no or insufficient

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\textsuperscript{178} \textit{Id.} at para. 8 (“The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council.”).

\textsuperscript{179} WTO Agreement, \textit{supra} note 5, at Article IV:5.

\textsuperscript{180} Attaran, \textit{supra} note 4, at 87 (proposing that the paragraph 6 mandate was better satisfied by a rule of non-justiciability, narrowly tailored to deal with the manufacture and export of generic drugs). The distinction between moratoriums and non-justiciability is clear. According to Attaran:

\ldots whereas moratoriums are unilateral and not legally binding, non-justiciability would be multilateral and fully legally binding. This is because where the moratorium is only a promise not to bring a lawsuit \ldots non-justiciability is a guarantee that those violations do not result in a lawsuit \ldots before the WTO panels in the future.

\textsuperscript{181} \textit{Id.} at 70

\textsuperscript{182} Statement of Understanding, \textit{supra} note 90.
capacity is commendable. Also on the positive side is the fact that the scope of diseases for compulsory licensing does not appear to be limited as the U.S. initially suggested. Some of the conditions attached to the Decision are necessary to ensure that cheaper drugs do not flow back from developing countries to developed countries and to ensure that pharmaceutical companies recoup their returns on investment.

Some of the fears expressed by several NGO’s are unfounded and lack merit. For example, some organizations have argued that the Decision “introduced an extra layer of uncertainty by stating that the system should not be an instrument to pursue industrial or commercial policy objectives, creating uncertainty over the role that will be played by the businesses that manufacture and sell generic drugs.”\textsuperscript{183} Others have argued that the 2003 Decision on Implementation “contradicts the basic principles of the WTO and fair trade”\textsuperscript{184} by prohibiting the export of drugs manufactured under the system to rich countries.\textsuperscript{185} The argument is that by reducing the size of countries that might import generic medicine to meet their public health needs it may not be cost-efficient for any generic manufacturer to participate in the system.\textsuperscript{186} These organizations would want generic producers to be allowed to export drugs produced under the new system to developed countries such as the U.S., Japan, or Australia, on the argument that if such large markets were excluded, drug production will not be economically efficient and

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\textsuperscript{183} Joint NGO Statement, supra note 142.  \\
\textsuperscript{184} Id.  \\
\textsuperscript{185} Id. at footnote 1 (arguing that the Decision “explicitly accepts a protectionist framework, where rich countries can export to poor countries, but 23 rich countries were allowed to bar imports from developing countries.”).  \\
\textsuperscript{186} Brook K. Baker, Health GAP, Vows of Poverty, Shrunked Markets, Burdensome Manufacturing and Other Nonsense at the WTO (September 27, 2003) (noting that 23 rich countries, representing 80% of global drug sales opted out of the export/import option and that ten countries seeking admission to the E.U. have also restricted their option to import”), available at http://www.healthgap.org/press_releases/03/092703_HGAP_BP_WTO_Cancun.html.
\end{flushright}
attractive to generic firms. These lines of argument lack merit and ignore the good-faith understanding on which the Decision was negotiated. Because the Decision was crafted to address the health problems of countries with insufficient or no manufacturing capacity, there is no reason for products manufactured under the system to be shipped to rich countries.

In the future, controversy may arise on the effect of the Statement of Understanding. It is currently not clear if and to what extent it eviscerates the Doha Declaration and if and to what extent it detracts from the terms and conditions of the Decision. Three clauses in the Statement of Understanding could pose a problem in the future: the good-faith clause, the anti-diversion clause, and the transparency clause.

V. ABUSES IN THE PHARMACEUTICAL INDUSTRY: A REVIEW OF EMERGING CASE LAW (THE U.S. EXAMPLE)

In the U.S., a troubling scenario is unfolding in the pharmaceutical sector – the increasing resort by pharmaceutical companies to a range of abusive and anticompetitive practices in an effort to preserve monopoly profits and maintain market

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187 Doha Derailed, supra note 170, at 3 (suggesting that it is essential to include large markets such as South Africa and Philippines in order to make drug production attractive to generic firms). See also, CPTech Statement, supra note 144 (“The persons who have negotiated this agreement have given the world a new model for explicitly endorsing protectionism. The United States, Europe, Canada, Australia, Japan and other developed economies will be allowed to bar imports from developing country generic suppliers – under completely irrational protectionist measures that are defended by the WTO Secretariat and its most powerful members as a humanitarian gesture.”).

188 Baker, supra note 186 (arguing that the Statement of Understanding eviscerates the historic Doha Declaration).

189 The good faith clause reads, “Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.” Id. (noting that there is great confusion in the international press and NGO community about the text’s good faith requirement of the Statement of Understanding. There are speculations on whether it is designed to limit drug use in the importing country to public, non-commercial use and whether it applies to both locally produced generics and imported ones.).
share. By exploiting loop-holes in a law originally passed to facilitate the speedy entry of
generic drugs into the U.S. markets, some pharmaceutical companies have been able to
either suppress or delay generic competition.

The goal of this chapter is to highlight the different ways pharmaceutical
companies (both brand name and generic) have attempted to “game” a system originally
designed to increase generic competition and improve consumer welfare. By exploring
loop-holes in a law passed to increase generic competition, drug manufacturers in the
U.S. have secured greater profits for themselves without providing any corresponding
benefit to consumers.\footnote{190} The degree of abuse in the U.S. pharmaceutical industry is
reflected in the increasing number of private lawsuits against brand-name companies
and/or generic companies for abuse of patent rights; it is also reflected in the growing
number of antitrust enforcement actions affecting both brand-name and generic drug
manufacturers that the Federal Trade Commission (“FTC”) is pursuing.\footnote{191}

Although the U.S. law in issue is very different from the international agreements
under consideration in this article, nevertheless interesting parallels and useful lessons
may be drawn. Many U.S. pharmaceutical companies operate as giant transnational
corporations and are likely to be affected by the Doha Declaration and the 2003 Decision
on Implementation. Given the tendency of these companies to game a domestic system
designed to improve generic competition despite the strong regulatory oversight of the
FTC and the rigorous anti-trust laws in the U.S., I argue that those pharmaceutical

Committee on Judiciary, United States Senate, Washington, D.C. (June 17, 2003), \textit{available at}

\footnote{191 The Federal Trade Commission (“FTC”) enforces federal consumer protection laws that prevent
deception and unfair business practices and enforces federal antitrust laws that prohibit anticompetitive
practices that restrict competition and harm consumers. \textit{See FTC website at}
www.ftc.gov/bcp/conline/pubs/general/guideto_ftc.htm.}
companies affected by the Doha Declaration and the 2003 Decision on Implementation may also attempt to abuse the system established under these instruments absent strong oversight at the global level.

To appreciate the tactics used by pharmaceutical companies to either delay or suppress generic competition in the U.S., an understanding of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (“Hatch-Waxman Amendments” or “Hatch-Waxman”) is necessary. Enacted in 1984, the Hatch-Waxman Amendments changed substantially the law governing approval of generic drug products by the Food and Drug Administration (“FDA”). One of the goals of Hatch-Waxman was to increase opportunities for market entry by generic drug manufacturers. Although the goal of increasing generic drug entry was achieved, studies now show that two main provisions of Hatch-Waxman governing generic drug approval prior to patent expiration have potential for abuse and are susceptible to strategies that may actually prevent the availability of more generic drugs. In April 2002, the FTC began an industry-wide study that focused on certain aspects of generic drug competition under Hatch-Waxman. The FTC issued its report - Generic Entry Prior to Patent Expiration: AN FTC Study – in July 2002.

194 Id.
195 Id. (“Generic drugs now comprise more than 47 percent of the prescriptions filled for pharmaceutical products – up from 19 percent in 1984, when Hatch-Waxman was enacted.”). See also Families USA, The Drug Industry: Facts and Figures (noting that since the enactment of the Hatch-Waxman Amendment, consumer’s access to lower-priced generics has increased), available at http://www.familiesusa.org/site/DocServer/factsheet.pdf?docID=246 [hereinafter Families USA, The Drug Industry].
196 FTC, Generic Drug Entry, supra note 193, at i.
197 Id.
One popular form of abuse is through anticompetitive agreements between brand-name and generic drug companies. Another form of abuse is the improper listing of patents by brand-name companies coupled with frivolous lawsuits against generic companies that have the effect of delaying FTC approval of a generic drug. Some companies also engage in false and deceptive advertising and marketing practices aimed solely at discouraging use of generic drugs once they are on the market. Part A provides an overview of Hatch-Waxman. Part B analyzes some of the abuses in the drug industry and the anti-trust action the FTC is taking against offending companies. In Part C, I highlight useful lessons that may be drawn from the United States.

A. The Hatch-Waxman Amendment: Statutory and Regulatory Background

The Federal Food, Drug and Cosmetic Act (the “Act”) regulates the manufacture and distribution of pharmaceutical drugs in the U.S. Recognizing that the Act’s “cumbersome drug approval process delayed entry of relatively inexpensive generic drugs into the marketplace,” Congress passed the Hatch-Waxman Amendments to the Act in 1984. One of the rationales behind the Hatch-Waxman Amendments was to make generic drugs more readily available. In fact, the Hatch-Waxman Amendments embody Congress’ attempt to “balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop

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198 The goal of the study was to determine whether some provisions of Hatch-Waxman are susceptible to strategies that delay and deter consumer access to low-cost generic drugs and whether alleged anti-competitive agreements between brand-name and generic drug manufacturers that relied on certain Hatch-Waxman provisions were isolated instances or more typical. Id. at 1.
199 21 U.S.C. § 301 et seq. [hereinafter “the Act”].
201 See Hatch-Waxman Amendments, supra note 192.
new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”

The Hatch-Waxman Amendments established new guidelines that simplify the approval process for generic drugs. Previously, any company wanting to market a new drug had to secure approval from the FDA by filing a New Drug Application (“NDA”), a process that is often “time consuming and costly” because a NDA requires companies to submit specific data concerning the drug’s safety and effectiveness. Under the new guidelines, a generic drug manufacturer can file an Abbreviated New Drug Application (“ANDA”) that incorporates by reference the safety and efficacy data developed and previously submitted by the company that manufactured the original “pioneer” brand-name drug. To obtain FDA approval, the ANDA filer must demonstrate that its product is “bioequivalent” to the pioneer drug. To protect the patent rights of the pioneer drug manufacturer, the ANDA filer must make one of four certifications in its ANDA concerning patents listed with the FDA for the pioneer drug, namely that (1) no patent for the pioneer drug is listed in the Orange Book (“Paragraph I Certification”); (2) the relevant patent listed in the Orange Book has expired (“Paragraph II Certification”); (3) the listed patent will expire on a particular date, and the ANDA filer does not seek FDA approval before that date (“Paragraph III Certification”); and (4) the listed patent “is

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203 *Mylan*, 81 F. Supp. 2d at 32 (citations omitted).


206 The Hatch-Waxman Amendments require a NDA to list any patents “which claim[] the drug ... or which claim[] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1). The FDA maintains and publishes this information in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"). See 21 U.S.C. § 355(j)(7)(A).
invalid or ... will not be infringed by the manufacture, use, or sale of the [generic] drug” (“Paragraph IV Certification”).

From a consumer interest standpoint and the standpoint of competition, an ANDA with a Paragraph IV Certification is dangerous in that it can and does frequently set in motion a process that could ultimately delay access to cheaper generics for three years or longer. The regulatory implication of a Paragraph IV Certification is significant; such an application has the potential to trigger the operation of two provisions of the Hatch-Waxman – the “30-Month stay” and the “180-day period of exclusivity.”

1. The 30-Month Stay: An ANDA containing a Paragraph IV Certification (an “ANDA IV”) has “important legal ramification” because “it automatically creates a cause of action for patent infringement.” An ANDA applicant making such a certification must notify the owner of the listed patent upon the filing of such certification. Thereafter, the patent holder has 45 days to initiate a patent infringement suit against the ANDA applicant. If the patent holder does not commence an action within 45 days, the FDA may approve the ANDA at any time. If lawsuit is filed in a timely manner, the FDA cannot approve the ANDA for at least 30 months. Moreover, the court hearing the patent case may extend the 30-month stay if either party fails to “reasonably cooperate in expediting the action.” However, if the court presiding over

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208 Mylan, 81 F.Supp.2d at 32.
209 Id.
212 Id.
213 Id.
214 Id. See also In re Ciprofloxacin Hydrochloride Antitrust Litig., 166 F.Supp.2d 740, 744 (E.D. N.Y.2001) (“Ciprofloxacin I”). This court noted that:
the infringement action determines before the 30-month period expires that the patent at issue is invalid or not infringed, approval is effective from the date the court decision is made.215

2. The 180-Day Exclusivity Period: Although potentially dangerous for a generic manufacturer because it places the manufacturer at risk for a patent infringement lawsuit, a Paragraph IV Certification carries some advantages. The Hatch-Waxman Amendments provide that the first company to submit an ANDA IV is awarded a 180-day period of exclusive rights to market the generic formula of the pioneer drug.216 Prior to the expiration of the exclusivity period, the FDA cannot approve any other ANDA for the same generic drug.217 The exclusivity period is triggered by either the commercial marketing of the generic drug by the first ANDA filer or the decision of a court finding the pioneer drug’s patent to be invalid, unenforceable, or not infringed, whichever is sooner.218

B. Anticompetitive Practices in the Drug Industry

Paragraph IV Certification has prompted some in the pharmaceutical industry to employ a number of anticompetitive practices that are currently the subject of private

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216 See 21 U.S.C. § 355(j)(5)(B)(iv). The 180 days of exclusivity means that “[n]o other generic can go to market until 180 days after the first generic goes to market or wins the patent lawsuit.” See also David A. Balto, Pharmaceutical Patent Settlements: The Antitrust Risks, 55 FOOD & DRUG L.J. 321, 331 (2000) (“[T]he first generic firm to challenge a patent holder is the only generic firm that can enter; until it enters, no other generic firm can enter the market.”).
217 Balto, supra note 216, at 331.
218 Id.; see also 21 C.F.R. § 314.107.
litigation, FTC investigations and legislative proposals aimed at ensuring fair
competition.

One of these abusive practices is in the form of collusive agreements between
brand-name manufacturers and generic manufacturers aimed at keeping the first generic
off the market, which in turn blocks all subsequent generics from getting to the market.
This arises because as discussed, the first ANDA filer with a Paragraph IV Certification
receives 180 days of exclusivity and sometimes controls the timing of the drugs
introduced into the market.\footnote{See 64 Fed. Reg. 42873, 42874 (“During litigation of many cases related to the 180-day exclusivity, the
parties and courts have recognized the potential for the 180-day exclusivity to substantially delay the entry of competitive
generic drug products into the market. This situation can occur when the marketing of any subsequent drug product is contingent upon the occurrence of an event that is within the first ANDA
applicant’s control.”).} Agreement between the first ANDA filer and a brand name
drug manufacturer “can effectively prevent generic competition for the brand name drug
for an indefinite period.”\footnote{Families USA, \textit{Collusion and Other Anticompetitive Practices: A Survey of Class Action
survey.pdf?docID=247 [hereinafter Families USA, \textit{Collusion}].} In exchange for agreeing not to enter the market, the first
ANDA filer shares in the profits that flow from the brand name manufacturer’s continued
monopoly.\footnote{\textit{Id.} at 8} In one case, a brand-name drug company reportedly paid a generic
manufacturer $4.5 million a month to not market its generic;\footnote{Families USA, \textit{The Drug Industry}, supra note 195.} payments of up to $10
million per quarter are not uncommon.\footnote{\textit{Id.}}

Another form of abuse is the improper Orange Book listings that provide the
opportunity for frivolous lawsuits by brand-name manufacturers who thereby trigger the
30-months stay. Because the filing of a patent infringement lawsuit within 45 days of
notice of a Paragraph IV Certification results in an automatic delay of the FDA approval
of the generic, brand name manufacturers have an incentive to claim, obtain, and list as
many patents as possible in the Orange Book (a practice known as “warehousing” of
patents). This puts brand name companies in a position to bring as many lawsuits as
possible against a Paragraph IV filer. This is possible because “[e]ven a completely
frivolous patent infringement action will preclude FDA approval for up to 30 months,”224
and invalid patents can form the basis for the 30-months stays.

Overall, by illegally manipulating the patent process and the FDA approval
process to delay generic market, brand-name companies sometimes in collusion with
generic companies, accumulate millions in additional sales.225 The ultimate victims in the
patent game are the consumers who are denied access to cheaper drugs.226

1. Collusive Agreements

Allegations that some brand-name companies have paid or attempted to pay
generic companies not to enter and compete are rife. In reaching these agreements, the
companies essentially use the generic company’s rights to the 180-day exclusivity to
impede entry by other generic competitors.227 The FTC has found that frequently a brand-
name drug manufacturer and the first generic company to file an ANDA containing a
Paragraph IV certification pertaining to a brand-name drug both have economic
incentives to collude to delay generic entry. “By blocking entry, the brand-name

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224 Families USA, Collusion, supra note 220, at 7.
225 Id. (observing that for one drug alone, the brand name manufacturer accumulated at least $160 million
in additional sales by delaying generic market entry from November 2000 to March 2001).
226 Id. (“Delaying the introduction of generic competition can protect drug company profits, but it costs
consumers millions.”). Studies show that consumers save considerably when they exercise their option by
buying cheaper generics. Families USA rightly notes that “The first generic on the market is typically
priced 20 to 30 percent below the comparable brand-name drug, but as more generics enter the market,
consumers have more choices, and generic prices drop further.” Families USA, The Drug Industry, supra
note 195.
227 Prepared Statement of the FTC 2003, supra note 190, at 3.
manufacturer may preserve monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product.”228 Also, “by delaying the first generic’s entry - and with it, the triggering of the 180 days of exclusivity - the brand-name and first-filing generic firms can sometimes forestall the entry of other generic products.”229

In this section, I take a look at on-going private litigation as well as FTC enforcement actions against some companies. One leading case230 settled by consent order involved an agreement between Abbott Laboratories (“Abbot”)231 and Geneva Pharmaceutical, Inc (“Geneva”)232 (collectively “Abbott/Geneva”).233 Since 2000, the FTC has settled at least three cases against brand-name companies and generic companies by consent orders.234

a) Private Litigation: In Re Ciprofloxacin Hydrochloride Antitrust Litigation235 (Purchasers vs. Patentee)

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228 Id.
229 Id.
231 Abbott Laboratories was founded by Dr. Wallace C. Abbott over 100 years ago and is considered today one of the world’s top health care companies. Abbott became a public company in 1929 and since then its financial performance has ranked among the best in the world. Company headquarters are in Abbott Park, Illinois. In 2003 the annual sales were $19.7 billion worldwide. It has been named one of “America’s Most Admired Companies every year since 1984 by FORTUNE Magazine. See http://www.abbott.com/news/facts/corp.html.
233 See infra notes 249-63 and accompanying text.
In this case ("Cipro Litigation"), purchasers of antibiotic ciprofloxacin hydrochloride ("Cipro"), and advocacy groups, sued brand name manufacturer, and prospective manufacturers of cheaper generic version, claiming that agreement under which proposed manufacturers of cheaper generic version agreed to defer entry into market until expiration of patent held by brand name manufacturer, in return for payments to be received from brand name manufacturer, was illegal market allocation in violation of the Sherman Act § 1 prohibition on contracts in restraint of trade.236

Plaintiffs brought suit against Bayer AG, a German company, and its American subsidiary, Bayer Corporation (collectively, "Bayer") and Barr Laboratories, Inc. ("Barr"); The Rugby Group, Inc. ("Rugby"); Hoechst Marion Roussel, Inc. ("HMR"); and Watson Pharmaceuticals, Inc. ("Watson") (collectively, "Generic Defendants"), alleging that Bayer and Generic Defendants (collectively, "defendants") entered into agreements that prevented competition in the market for Cipro in violation of federal and state antitrust laws.237

236 The court found that the injury requirement for a restraint of trade claim, under the Sherman Act (15 U.S.C.A. §§ 1, 2) was not satisfied by allegations that buyers of antibiotic ciprofloxacin hydrochloride ("Cipro") were forced to pay inflated prices due to delay of market entry by manufacturers of generic version of drug, resulting from prospective generic version manufacturers’ settlement of brand name manufacturer’s patent infringement suit that would have otherwise resulted in judgment against brand name manufacturer, presenting opportunity to acquire generic version prior to expiration of patent; prospect of resolution of patent suit, by ruling of invalidity or noninfringement, coming before expiration of patent, was too speculative. Id.

237 Plaintiffs’ moved, pursuant to Federal Rule of Civil Procedure 56, for partial summary judgment finding that these agreements are per se unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1, and various state antitrust and consumer protection laws. Id. at 230-32. Defendants have filed a cross-motion seeking to dismiss plaintiffs’ respective complaints pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to plead facts sufficient to sustain a Sherman Act violation. Id. at 197-99. These motions present difficult questions of antitrust law and its interaction with patent rights.
Bayer manufactures and distributes Cipro and holds the patent for the active ingredient in Cipro. In October 1987, Miles, Inc. (the predecessor to Bayer Corporation and the licensee of the 444 Patent) obtained FDA approval to market Cipro in the United States. In a letter dated October 22, 1991, Barr filed ANDA 74-124 for a generic, bioequivalent version of Cipro. Barr’s ANDA included a Paragraph IV Certification seeking the FDA’s permission to market its generic drug before the 444 Patent expired on the grounds that the patent was invalid and unenforceable. As set forth in the Hatch-Waxman Amendments, on December 6, 1991, Barr notified Bayer of its ANDA IV filing and its assertions contained therein regarding Bayer’s 444 Patent. On January 16, 1992, Bayer commenced a timely patent infringement suit against Barr in the Southern District of New York, thereby triggering the 30-month statutory waiting period for FDA approval. Subsequently, in November 1992, Bayer and Barr executed a stipulation whereby the parties agreed to extend the 30-month waiting period until final judgment was entered in the patent infringement action. This stipulation was “so ordered” by Judge Knapp on December 8, 1992. Absent this agreement, the stay would otherwise have expired on April 22, 1995.

While the patent litigation was pending, in a letter dated January 4, 1995, the FDA granted tentative approval of Barr’s ANDA for generic Cipro. As the trial date

238 In its patent application, Bayer AG claimed the active ingredient in Cipro – ciprofloxacin hydrochloride – in Patent No. 4,670,444 (the “444 Patent”), which was issued by the Patent and Trademark Office (“PTO”) on June 2, 1987. Id. at 194. The 444 Patent expires on December 9, 2003. Id.

Cipro has been the best selling antibiotic in the United States for many consecutive years and is described as “the most prescribed antibiotic in the world.” Id. Since 1987, Bayer has been the only producer of Cipro in the U.S., and, since 1997, Bayer has derived over $1 billion in U.S. net sales of all Cipro products. Id.

239 Cipro Litigation, 261 F. Supp. 2d at 195. Plaintiffs contend that this approval was tentative, rather than final, due to the parties’ stipulation to extend the 30-month stay. In fact, in its letter to Barr, the FDA stated that “[i]n certain cases approval can be granted after the expiration of the 30-month period... In this case, the 30-month option is not relevant. The [FDA] was advised that on December 8, 1992, the court ordered...
approached, Bayer and Barr reached a settlement that concluded the patent litigation in the Southern District. In connection with the settlement, on January 8, 1997, Bayer entered into three separate but interrelated settlement agreements with Barr, HMR and Rugby, and Bernard Sherman (“Sherman”) and Apotex, Inc. (“Apotex”) (collectively, the “Settlement Agreements”) and a supply agreement with Barr and HMR (the “Supply Agreement”). The terms of these agreements form the basis of plaintiffs’ allegations of a Sherman Act violation.

Under the Settlement Agreements, Barr, HMR, Rugby, Sherman, and Apotex acknowledged the validity of the 444 Patent and additional U.S. Patents held by Bayer. In the Barr Settlement Agreement, Barr also agreed to amend its ANDA to change its Paragraph IV Certification to a Paragraph III Certification, thereby permitting Barr to obtain FDA approval to market generic Cipro only upon expiration of the 444 Patent. The agreement also provided for an immediate $49.1 million payment from Bayer to the “Barr Escrow Account.”

A year later, in January 1996, Bayer and Barr filed cross-motions for partial summary judgment. Judge Knapp denied the parties’ respective motions in an order and opinion dated June 5, 1996. Upon a motion by Bayer to reconsider that ruling, the court re-affirmed its decision in a separate order and opinion dated September 5, 1996. After some postponements, trial of the patent litigation was finally scheduled to begin on January 27, 1997. See id.

On March 29, 1996, Barr and Rugby entered into an agreement pursuant to which Barr agreed to share equally with Rugby (then a subsidiary of HMR) any rights and profits from the eventual marketing and/or distribution of Cipro, and, in return, Rugby agreed to finance a portion of the costs and expenses of the patent litigation (the “Litigation Funding Agreement”). Id.

These patents claim, among other things, starting materials and intermediaries for use in preparing Cipro, some of the processes for preparing Cipro, and the specific tablet, oral suspension, and intravenous formulations that Bayer uses in its proprietary Cipro products.


The “Barr Escrow Account” is a bank account established by Barr and HMR to receive payments made by Bayer. On January 9, 1997, Barr and HMR executed an escrow agreement that established this account and provided that Barr and HMR each would receive one-half of all funds paid by Bayer into the account.
In the Supply Agreement, Barr and HMR agreed not to manufacture (or to have manufactured) Cipro in the United States. In addition, the agreement provided that Bayer either will (1) supply Bayer-manufactured Cipro to Barr, HMR and Rugby for distribution in the United States, subject to certain price controls, or (2) make quarterly payments – varying from $15 million to approximately $17 million – to the Barr Escrow Account from January 1998 through December 2003 (when the 444 Patent expires). If Bayer does not license Cipro immediately, it has agreed to do so at a set price if another generic company successfully challenges the validity of the 444 Patent. In addition, defendants claim that Bayer agreed to supply Cipro to Barr for marketing under a generic label beginning six months prior to the expiration of the 444 Patent. To date, Bayer has chosen to make payments to the Barr Escrow Account, which through December 2003 will total approximately $398 million.246

246 On January 17, 1997, Bayer and Barr each issued a news release announcing the settlement and discussing the payment scheme set forth in the Supply Agreement. In fact, the press releases note that the settlement is comprised of two components: (1) an initial cash payment and (2) a Supply Agreement, which sets forth Bayer’s option to make payments to the Barr Escrow Account or to provide Barr with Cipro that Barr would market pursuant to a license from Bayer. Also, on January 22, 1997, pursuant to the Barr Settlement Agreement, Barr filed an amendment to its ANDA 74-124, and in a letter to the FDA dated January 23, 1997, Barr amended its Paragraph IV Certification to a Paragraph III Certification. See id. at 196-97.

Pursuant to the terms of the Barr Settlement Agreement, Bayer and Barr submitted to Judge Knapp a two-page consent judgment (the “Consent Judgment”) that the parties had negotiated and that extinguished all claims raised in the patent litigation. On January 16, 1997, Judge Knapp signed the Consent Judgment in the form submitted by the parties. The Consent Judgment entered judgment for Bayer, providing that the 444 Patent is valid and enforceable as to, and was infringed by Barr. There was no mention in the Consent Judgment of the payments Bayer agreed to make to the Barr Escrow Account or the agreement by Barr, HMR and Rugby not to manufacture and market a generic form of Cipro. The Settlement Agreements and the Supply Agreement were not filed with or otherwise provided to the patent court, but the court was appraised of the material terms of the settlement on January 30, 1997 when Bayer’s counsel forwarded Bayer’s news release to the court. See id.

In July 1997, Bayer voluntarily submitted its 444 Patent to the PTO for reexamination, and, upon reexamination, the PTO reaffirmed the patent’s validity. Since the execution of the Settlement Agreements, four generic companies have filed ANDA IVs for Cipro and have mounted challenges to the 444 Patent similar to the challenge raised by Barr. Id. at 197. One challenge was dismissed, see Bayer AG v. Ranbaxy Pharm., Inc., Docket No. 3:98 Civ. 4464 (D.N.J. Oct. 29, 1999) (dismissing case per stipulation). Id. at 197. Two other challenges were unsuccessful, see Bayer AG v. Schein Pharm., Inc., 301 F.3d 1306 (Fed. Cir. 2002), and Bayer AG v. Carlsbad Tech., Inc., No. 01 Civ. 867- B (S.D. Cal. Oct. 24, 2001)
Regarding the antitrust issue, the court found no violation. The court thought that the Settlement Agreements and Supply Agreement did not warrant *per se* condemnation under Section 1 of the Sherman Act and found that the case “should not be relegated to the *per se* category reserved for the most blatant antitrust violations.” The court thought that the plaintiffs failed to show that the Settlement Agreements and Supply Agreement imposed restraints with anticompetitive effects broader than the exclusionary effects of Bayer's patent. According to the court:

> [w]hile an unfortunate aspect of the Hatch-Waxman Amendments is that pioneer and generic drug manufacturers have often been entering into mutually beneficial agreements that result in delayed entry of generic drugs into the market place, the cases that have found such agreements *per se* illegal involve findings that the agreements at issue restrained noninfringing products, delayed generic entry and perpetuated litigation. Such is not the case here.  

**b) FTC Enforcement Action: Abbott/Geneva**

This case involved an agreement between Abbott and Geneva relating to Hytrin, Abbott's pioneer brand name drug. The FTC complaint alleged that Abbott paid Geneva approximately $4.5 million per month to delay the entry of its generic Hytrin product. According to the FTC complaint, Abbott's initial patent covering the chemical compound terazosin HCL expired in or around 1994. Between 1993 and 1995, Geneva

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247 *Cipro Litigation*, 261 F.Supp.2d at 257.
248 *Id.* at 256.
249 *See supra* note 230 and accompanying text.
250 Hytrin contains Terazosin HCL, a which is used principally to treat benign enlarged prostate and hypertension. *Abbott/ Geneva Complaint, supra* note 230, at para. 10-11. Total U.S. sales of terazosin HCL amount to approximately $540 million per year. *Id.* at para. 11.
251 *Id.* at para. 27.
filed ANDA’s covering a tablet form and a capsule form of generic terazosin HCL\textsuperscript{252} and was the first company to file an ANDA for each form.\textsuperscript{253} Surprisingly, in early 1996, Abbott notified the FDA of a new patent (‘207 patent) relating to its Hytrin product; according to FDA procedure, the patent was listed in the FDA Orange Book. In April 1996, Geneva filed a Paragraph IV certification with the FDA and duly notified Abbott of the Paragraph IV certification.\textsuperscript{254} On June 4, 1996, Abbott promptly sued Geneva, claiming patent infringement by Geneva’s terazosin HCL tablet product.\textsuperscript{255} By filing the lawsuit within the requisite 45-day period, Abbott’s lawsuit triggered a 30-month stay of final FDA approval of Geneva’s terazosin HCL tablet ANDA, until December 1998. However, as the first generic company to submit a Paragraph IV Certification for generic terazosin HCL, Geneva was also entitled to the 180-day Exclusivity Period promised in the Hatch-Waxman Act.

The FTC complaint centered around an April 1, 1998, agreement between Abbott and Geneva. According to this agreement, Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: “(1) the final resolution of the patent infringement litigation involving Geneva’s terazosin HCL tablets product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product.”\textsuperscript{256} At Abbott’s insistence, Geneva also agreed not to transfer, assign, or otherwise relinquish its right to a 180-day Exclusivity Period. In return, Abbott

\textsuperscript{252} Geneva submitted its tablet ANDA to the FDA in or around January 1993, and its capsule ANDA was submitted in or around December 1995. \textit{Id.} at para. 16.

\textsuperscript{253} \textit{Id.}

\textsuperscript{254} By filing a Paragraph IV certification, Geneva was essentially claiming that its generic terazosin HCL tablet and capsule products did not infringe any of Abbott’s patents covering terazosin HCL, including Abbott’s newly listed ‘207 patent. \textit{Id.} at para. 17.

\textsuperscript{255} It is significant that even though Geneva’s capsule and tablet involved the same potential infringement issues, Abbott made no infringement claim against Geneva’s capsule product.

\textsuperscript{256} Abbott/Geneva Complaint, supra note 230, at para. 26.
agreed to pay Geneva $4.5 million per month in non-refundable payments until a district court judgment in the parties' patent infringement dispute.\(^{257}\) Why did Geneva enter such an agreement? To Geneva, the agreement represented the "best of all worlds," because the company obtained a risk-free “monetary settlement on an ongoing basis until the litigation was resolved” and still could market its product exclusively for 180 days after the litigation was over.\(^{258}\)

As a result of the agreement, Geneva began receiving monthly payments of $4.5 million from Abbott and refrained from entering the market with its generic terazosin HCL capsules which was not under litigation. Geneva also refrained from entering the market with its generic terazosin HCL capsules even after September 1, 1998, when the United States District Court for the Northern District of Illinois granted its motion for summary judgment in its patent tablet litigation with Abbott and invalidating Abbott’s patent. Under the terms of its agreement with Abbott, Geneva still could not enter the generic terazosin HCL market until after the Supreme Court either denied Abbott’s petition for certiorari or disposed of the patent infringement litigation.\(^{259}\) In August 1999, Abbott and Geneva canceled their Agreement, perhaps as a result of the FTC investigation; on August 13, 1999, Geneva finally introduced its generic terazosin HCL capsule product to the marketplace.

\(^{257}\) *Id.* at para. 27 (Abbott and Geneva also agreed that if the district court declared that Geneva’s tablet product would not infringe any valid and enforceable claim of the ‘207 patent, Abbott would thereafter pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation. The understanding was that the party prevailing in the litigation would receive the money in the escrow fund.).

\(^{258}\) *Id.* at para. 29.

\(^{259}\) On July 1, 1999, the United States Court of Appeals for the Federal Circuit affirmed, without dissent, the summary judgment in favor of Geneva. The Supreme Court denied certiorari on January 10, 2000. *Id.* at para. 33.
The FTC complaint alleged that the Abbot/Geneva agreement, “acted with the specific intent that Abbott monopolize the relevant market,”\textsuperscript{260} and “engaged in overt acts … in furtherance of a conspiracy to monopolize the relevant market, in violation of Section 5 of the Federal Trade Commission Act, as amended.”\textsuperscript{261} According to the FTC, the acts and practices of Abbott and Geneva “had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of competition in the form of generic versions of Hytrin into the relevant market.”\textsuperscript{262}

The case was resolved by consent order.\textsuperscript{263} The order prohibited Abbott and Geneva from entering into settlement (brand/generic) agreements pursuant to which Geneva agrees not to: (1) enter the market with a non-infringing product, or (2) transfer its 180-day marketing exclusivity rights. The companies were also required to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action, that provided for payments to Geneva to stay off the market, with advance notice to the Commission to allow it time to present its views to the court. Finally, the companies were ordered to give advance notice to the Commission before reaching a similar agreement in non-litigation contexts.

2. Improper Extension of Monopoly

Brand-name manufacturers in the U.S. also delay generic competition through the use of improper Orange Book listing which typically triggers the 30-month exclusivity

\textsuperscript{260} Id. at para. 41.
\textsuperscript{261} Id.
\textsuperscript{262} Id. at para. 34.
\textsuperscript{263} See supra note 234 and accompanying text.
Improper extension of monopoly achieved through the improper Orange Book listing strategy typically “involves abuse of the Hatch-Waxman process itself to restrain trade.” Indeed the FTC has found that sometimes, brand-name drug manufacturers “act strategically to obtain more than one 30-month stay of FDA approval of a particular generic drug.”

Improper Orange Book listing could be characterized as a fraud on consumers and the FDA because oftentimes brand-name companies, motivated solely by the desire to delay generic entry, falsely and knowingly list invalid patents. The problem arises because of a loop-hole in the law. Under the Hatch-Waxman Act not all patents are eligible for listing in the Orange Book and entitled to the special statutory 30-month stay. The Hatch-Waxman Act provides for listing only if two conditions are met. First, listing is called for, if the patent “claims the drug . . . or a method of using such drug.” Second, listing is also called for if the patent is one “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug.” The difference between listed patents and unlisted patents is that only the former triggers the automatic 30-months stay.

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265 Prepared Statement of the FTC 2003, supra note 190, at 3.
268 See Federal Trade Commission, In the Matter of Bristol-Myers Squibb Company File Nos. 001 0221, 011 0046, and 021 0181: Analysis to Aid Public Comment, available at http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm [hereinafter In the Matter of Bristol-Myers Squibb Company] (noting that in the case of patents not eligible for listing in the Orange Book, a branded firm still can sue a generic company for patent infringement, but under ordinary federal litigation procedures and without the benefit of an automatic 30-month stay). In case of unlisted patents, to prevent sale of the
Brand-name companies are increasingly exploiting loop-holes in Hatch-Waxman and the FDA approval processes to the detriment of consumers. This arises because, despite the serious legal and competitive implications of Orange Book listings, “it is private parties, rather than the FDA, that in practice determine whether patents are listed.” Regarding the Orange Book listing, the role of the FDA is solely ministerial. Not only is the role of the FDA ministerial, generic applicants have no right to bring an action to challenge an NDA holder’s Orange Book listing as improper, the Federal Circuit has held. The overall result is that FDA’s listings do not create any presumption a patent is correct. Nevertheless, as long as a patent remains listed, a brand-name company “can continue to benefit from the availability of an automatic 30-month stay of FDA approval of ANDAs, by initiating a patent suit against generic applicants.”

Because the FDA accepts the Orange Book listing at face value, brand name companies can defraud the system through improper listing. The net result is that “brand-name companies are increasingly listing in the Orange Book, and suing on, multiple patents, and that these are frequently patents that have been listed after an

generic product before conclusion of a law suit, “a branded firm must obtain a preliminary injunction, which requires that it demonstrate a likelihood of success on the merits, among other factors.”

269 Id.  
270 Id. (“The FDA has repeatedly stated that its role in patent listings is solely ministerial and that it lacks the resources and expertise to scrutinize patent information in the Orange Book.” Thus, “[e]ven when a generic applicant disputes a patent listing, the FDA merely asks the NDA holder to confirm that the listed patent information is correct. Unless the NDA holder itself withdraws or amends its listed patent information, the FDA will not remove the patent listings from the Orange Book.”).  
271 Id. See also Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1329-33 (Fed. Cir. 2001).  
273 In the Matter of Bristol-Myers Squibb Company, supra note 268.  
274 See, e.g., American Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1080 (D.C. Cir. 2001) (observing that the FDA “has refused to become involved in patent listing disputes, accepting at face value the accuracy of NDA holders’ patent declarations and following their listing instructions.”).
ANDA has been filed. In some cases (where the patent is obtained and listed after the generic applicant has filed its ANDA) multiple 30-month stays were possible; the FTC has found that additional delay of FDA approval (beyond the first 30 months) ranged from four to 40 months.

a) Private Litigation: In Re Buspirone Antitrust Litigation (Generic Company vs. Patentee)

In this case, competitors filed antitrust claims against Bristol-Myers Squibb Company (“BMS”) alleging that the company engaged in anti-competitive conduct by improperly extending its monopoly over buspirone hydrochloride (“buspirone”), an anti-anxiety drug sold under the brand name BuSpar. On February 14, 2002, District Judge John G. Koeltl granted in part and denied in part Bristol-Myers motion to dismiss the plaintiffs’ antitrust and related state law claims.

The competitors allege that BMS attempted to extend and/or extended an unlawful monopoly over the market of buspirone tablets in violation of Section 2 of the Sherman Act. The allegation is that through fraudulent patent filings with the FDA, BMS caused the agency to list the patent in question in the Orange Book and as a result blocked generic competition with its BuSpar product. Essentially, the FDA was precluded from approving the generic version of buspirone once BMS listed its ‘365

275 Id.
276 Id.
278 Bristol-Myers Squibb Company is a pharmaceutical company headquartered in New York City. In 2002 it reported $18.1 billion in global sales. See www.bms.com/aboutbms/data/.
279 Buspirone Patent Litigation – Bristol-Myers, supra note 277.
Patent\textsuperscript{281} in the Orange Book.\textsuperscript{282} Specifically, the plaintiffs allege that BMS made a bad faith attempt to interfere with the generic competitors’ entry into the buspirone market. This is alleged to have been done by asserting to the FDA that the ‘365 patent covered the approved uses of buspirone when BMS knew that these assertions were false. They also claim that BMS pursued patent infringement suits – thereby obtaining an automatic stay of the FDA’s approval of the generic version of buspirone subsequent to 21 U.S.C. § 355(j)(5)(B)(iii), with knowledge that the stay was obtained by making false statements to the FDA.\textsuperscript{283} Currently, this litigation is still in its initial phases and the court has not ruled on any substantive anti-trust or patent issues. While the private lawsuit is still pending, the FTC has commenced enforcement action against BMS and announced that a consent agreement had been reached.

\textbf{b) FTC Enforcement Action:}

\textit{i. Biovail (Tiazac)\textsuperscript{284}}

The first FTC enforcement action to attempt to remedy the effects of an allegedly anticompetitive Orange Book listing was against Biovail Corporation (Biovail).\textsuperscript{285} In the complaint, the FTC charged that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its branded drug Tiazac. As a result of the listing, Biovail was able to commence an infringement lawsuit against Andrx, thus triggering triggered a 30-month

\textsuperscript{281} This, of course, is the patent in controversy within the patent infringement portion of the case.

\textsuperscript{282} In re Buspirone Patent Litigation, 208 F.R.D. 516, 518.

\textsuperscript{283} \textit{Id.} at 520.

\textsuperscript{284} See FTC Complaint Against Biovail Corporation (April 2002), available at \url{http://www.ftc.gov/os/2002/04/biovailcomplaint.htm} [hereinafter Biovail Complaint].

\textsuperscript{285} Biovail Corporation describes itself as a “full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacturing, sale and promotion of pharmaceutical products.” See \url{http://www.biovail.com}.
stay of FDA final approval of Andrx’s generic Tiazac product. According to the FTC complaint, Biovail knew that the new patent did not claim the form of Tiazac that it had been marketing, and Biovail did not need this new patent to continue marketing Tiazac without infringement risk. The FTC further alleged that Biovail misleadingly represented to the FDA that the new patent claimed existing-and-approved, rather than revised-and-unapproved, Tiazac, to avoid de-listing from the Orange Book and termination of the stay against Andrx. According to the complaint, Biovail’s patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of Section 5 of the FTC Act\(^\text{286}\) and Section 7 of the Clayton Act.\(^\text{287}\)

On April 23, 2002, the FTC announced that it had accepted for public comment an agreement and proposed consent order with Biovail Corporation.\(^\text{288}\) The consent order required Biovail to divest the illegally acquired patent to its original owner, dismiss its infringement case against Andrx thus allowing entry of generic Tiazac, and to refrain from further action that may trigger another 30-month stay on generic Tiazac entry. The consent order also required Biovail to give the FTC prior notice of acquisitions of patents that it intended to list in the Orange Book for Biovail’s FDA-approved products.

**ii. In the Matter of Bristol-Myers Squibb Company**

In an April 14, 2003 complaint, the FTC charged that BMS engaged in a series of unlawful acts to delay competition from generic versions of three of its major drug

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\(^{286}\) Biovail Complaint, *supra* note 284, at para. 54-57. Section 5 of the FTC Act is found at 15 U.S.C. § 45.


products. The FTC subsequently announced that it has accepted for public comment an agreement and proposed consent order with BMS which is intended to settle the charges against the company. In its complaint, FTC alleged that BMS abused governmental processes in order to delay generic competition to the three prescription drugs, and, in particular, that it misused the regulatory scheme established by Congress to expedite the approval of generic drugs. In issue was BMS’s activities relating to three of its prescription drug products: BuSpar, an anti-anxiety agent; and two anti-cancer drugs, Taxol and Platinol. The complaint relating to BuSpar is discussed here.

BMS began selling BuSpar in 1986. By 2000, BuSpar sales in the United States were over $600 million. In anticipation of the expiration of its ‘763 patent pertaining to BuSpar in November 2000, the FTC complaint alleged that BMS filed a new patent application with the PTO in 1999, involving the use of buspirone to create the metabolite of buspirone. After repeated rejection of its patent application by the PTO, BMS succeed in obtaining a patent (patent ‘365) only hours before patent ‘763 was about to expire. BMS proceeded to submit the ‘365 patent details to the FDA for listing in the Orange Book. The complaint further alleged that BMS's ‘365 patent “did not meet either of the statutory requirements for listing a patent in the Orange Book, because it does not claim BuSpar or a method of using BuSpar, and it is not a patent with respect to which a claim of patent infringement could reasonably be asserted against someone selling

289 In the Matter of Bristol-Myers Squibb Company, supra note 268.
290 Id.
291 Id.
292 A metabolite is the new molecule created when a pharmaceutical agent breaks down in the body.
293 BMS was repeatedly rejected because the company had been making and selling BuSpar to treat anxiety in the U.S. for nearly 14 years. Patent ‘365 was issued only after BMS request a patent that claimed solely the use of the metabolite of buspirone - not the use of buspirone itself.
Furthermore, the complaint alleged that “[a]lthough BMS knew that it had only obtained a patent claiming a method of using a metabolite, it nonetheless submitted a declaration to the FDA affirming that the ‘365 patent claimed a method of using BuSpar, in order to list the patent in the Orange Book.” 295 Worse, after ANDA filers on BuSpar asserted to the FDA that the ‘365 patent did not meet the criteria for listing in the Orange Book, BMS intentionally made an additional false and misleading statement. 296 The FDA without making any independent determination regarding the scope and coverage of the ‘365 patent, accepted at face value BMS’s statements and, thus, deemed the ‘365 patent listed in the Orange Book as of November 21, 2000. The FTC complaint charged that BMS “knew that its representations to the FDA - to the effect that the ‘365 patent claimed a method of using buspirone - were false and misleading,” but nevertheless “made these misrepresentations purposely and intentionally, to obtain an improper Orange Book listing of the ‘365 patent.” 297 As a result of its wrongful listing in the Orange Book, BMS “illegitimately acquired the ability to trigger a 30-month stay, thereby delaying entry of generic buspirone and depriving consumers of lower prices and other benefits of competition.” 298 It is pertinent to note that generic competition to BuSpar occurred only after the ‘365 patent was removed from the Orange Book in March 2001, following a district court decision ordering BMS to seek de-listing. 300

294 In the Matter of Bristol-Myers Squibb Company, supra note 268.
295 Id.
296 Id. (“The FDA asked BMS to provide a declaration that the ‘365 patent contains a claim for an approved use of buspirone. BMS responded with a declaration expressly affirming that the ‘365 patent does in fact claim the approved uses of buspirone, a statement that was false and directly contradicted representations BMS made to the PTO to obtain the ‘365 patent.”).
297 Id.
298 Id.
299 Id.
300 See Mylan Pharms., Inc. v. Thompson, 139 F. Supp. 2d 1 (D.D.C. 2001). The Federal Circuit later reversed this ruling on jurisdictional grounds. See Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1329-
The FTC also alleged that the patent infringement suits BMS brought against ANDA filers for infringement of the ‘365 patent “were objectively baseless and filed without regard to their merits” and that the intent and effect of BMS’s suits “was to wrongfully trigger the 30-month stay as a means of preventing generic buspirone manufacturers from marketing their products.” Entry of a lower-priced generic version of BuSpar would have resulted in a significant, immediate decrease in the sales of the BMS’s brand-name drug and would have led to a significant reduction in the average price for the products in the relevant market, hence the motivation to game the system. FTC thus charged BMS with engaging in acts that willfully maintained its monopolies in buspirone in violation of Section 5 of the FTC Act.

The proposed consent order, bars BMS from seeking to list the ‘365 patent in the Orange Book in relation to any NDA in which the active ingredient is buspirone. The proposed order also contains general prohibitions “designed to deter improper listings and to prevent BMS from triggering the Hatch-Waxman automatic 30-month stay in circumstances that could improperly block generic entry.” The consent order also contains a general prohibition on false statements to the FDA. Regarding the

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33 (Fed. Cir. 2001) (the court held that no private right of action existed under the Federal Food, Drug, and Cosmetic Act to seek de-listing).

301 In the Matter of Bristol-Myers Squibb Company, supra note 268.

302 Id.

303 See Biovail Consent Order, supra note 288.

304 Id. (“Paragraph VI would bar BMS from Orange Book listings that are contrary to the statutes and regulations governing such listings. For example, this provision would prohibit listing patents in the Orange Book that do not actually claim the drug product at issue…. In addition, Paragraph VII bars BMS from acting to obtain or maintain a Hatch-Waxman 30-month stay on FDA approval in certain specified situations.”)

305 The purpose was “[t]o ensure that BMS does not seek to obstruct generic competition through false statements to the FDA outside the Orange Book listing context, such as through the citizen petition process.” See In the Matter of Bristol-Myers Squibb Company, supra note 268. (“Paragraph VIII bans false and misleading statements to the FDA that are material to the approvability or sale of a generic version of a BMS brand-name drug product, unless BMS had a reasonable belief that the statement was neither false nor misleading.”). Id.
allegations that BMS engaged in sham litigation, the proposed consent order bars BMS from “asserting any patent infringement claim that is objectively baseless; or seeking to enforce a patent that BMS knows is invalid, unenforceable, or not infringed.”

The Orange Book listing scheme established by the Hatch-Waxman Act naively assumed that brand-name companies (as NDA holders) would act in good faith in listing patents. However, there is mounting evidence that listings are made in bad faith (to block generic competition) and are not based on a reasonable, good faith belief that the patents listed are listable. As the FTC has noted “the Orange Book listing scheme is susceptible to opportunistic behavior” and brand-name companies (as NDA holder) frequently exploit the listing scheme by obtaining patents and listing them in order to block FDA approvals of generic rivals when the NDA holder does not reasonably expect the patents to ultimately hold up in court.

C. Conclusion

The goal of this section was to highlight how a law enacted in part to stimulate generic competition and thereby expand consumer access to cheaper alternative life-saving drugs has been hijacked by brand-name drug manufacturers, sometimes in collusion with generic drug manufacturers. Brand-name drug companies have traditionally been viewed with suspicion. However, as the case studies highlight, generic drug companies are no saints either. Given the proper incentive, some generic drug companies may be willing to delay or disrupt competition and keep drug prices

306 Id.
307 Id.
308 Id.
artificially high. Collusion between the generic companies is also possible and is increasingly the focus of FTC enforcement actions. The FTC has identified two potentially competition-reducing categories of agreements that merit the agencies close attention. 309

It is disheartening that drug manufacturers can brazenly engage in fraudulent, anticompetitive practices in a country like the United States with state-of-the-art antitrust laws, a plethora of consumer protection laws, a sound judicial system that provides avenues for those harmed to seek recourse, and a strong public regulatory and enforcement agency such as the FTC able to monitor the activities of the companies concerned. None of these mechanisms are readily available at the global level. There is at present nothing to stop a pharmaceutical company intent on exploiting loop-holes in the Doha Declaration and the 2003 Decision on Implementation to delay generic competition.

In theory, the combined effect of the TRIPS Agreement, the Doha Declaration and the 2003 Decision on Implementation will be that developing countries will have more opportunities to obtain essential pharmaceutical products at reduced prices. 310

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309 Prepared Statement of the FTC 2002, supra note 264. The first are agreements that involve exclusive distributorship arrangements. Under such an arrangement, a second generic entrant, rather than bringing a competing product to market, might agree to become the exclusive distributor of the first entrant. Essentially, such an arrangement guarantees the second entrant an agreed-upon share of the market. In return the first entrant is against aggressive price competition. The second category of agreements involves division of market segments. Under such an arrangement, the first generic entrant might agree to market its product exclusively in one market, while the second entrant agrees to market its product exclusively in another. The overall objective of such agreements is to impede vigorous competition.

310 Countries facing health emergencies can: (i) acquire needed medicine directly from brand-name pharmaceutical companies; (ii) acquire patented drugs through parallel marketing channels; (iii) ensure availability of generics through compulsory licensing that enables local manufacture; and (iv) procure generics from another country through the compulsory licensing scheme established under the 2003 Decision on Implementation; (v) acquire generic products from licensees of brand-name companies in situations where the company has voluntarily licensed its patent.

As hitherto explained, where the prices of pharmaceutical products are lower in a foreign market, parallel import permits a government to allow the importation of such products into the national market so
However, an examination of the nature and intensity of competition in the pharmaceutical sector in the U.S. suggests that abuse of patent rights is very rife in the industry and that in many instances brand-name pharmaceutical companies will deploy a host of abusive and anti-competitive practices in an effort to protect their market share and maximize their profit. A study of on-going litigation in U.S. courts and antitrust enforcement actions brought by the FTC, including both branded and generic drug manufacturers, indicates that generic drug companies are not paragons of virtue; given adequate incentive, some generic drug companies will engage in anti-competitive practices that ultimately hurt consumers. In the U.S., although the existence of a plethora of anti-trust and consumer protection legislation and the presence of the FTC has helped to keep abuses in the pharmaceutical industry to a bare minimum, companies are still finding ingenious ways to evade the law and the watchful eyes of the FTC. The obvious lesson is that frequently, well-intended laws are not enough to ensure that medicine is available to those who need it most.

With respect to the war over access to medicine in developing countries, therefore, I argue that despite the laudable goals of the Doha Declaration and the 2003 Decision on Implementation, there are serious potentials for abuse in the industry. These abuses could ultimately work to deprive the suffering men and women in the Third World of the intended benefit of the two texts. In other words, as attention moves away from the emotive issue of HIV/AIDS and attempts are made to use compulsory licensing to secure

as to offer drugs at more affordable prices. See Submission by the African Group, supra note 79, at para. 26 (“For developing countries, in particular, least-developed countries and smaller economies, “parallel importation” can be a significant way of increasing access to medications, where the prices charged by patent holders for their products are unaffordable. Moreover, in situations where the local manufacture of the product is not feasible, and therefore compulsory licences may be ineffective, parallel importation may be a relevant tool to ensure access to drugs.”).
the manufacture of drugs needed to treat other diseases, pharmaceutical companies may be tempted to employ a host of abusive practices in an effort to safeguard their turf.

I envisage at least six possible types of abuses. First, collusive agreements between brand-name companies and generic drug companies may begin to emerge; under these agreements, generic companies may agree to refrain from requesting compulsory license to manufacture generic versions of pharmaceutical products in return for payment or exclusive distribution arrangements. Second, collusive agreements between generic companies may also begin to emerge under which the companies agree to inflate prices and engage in other monopolistic practices. Third, abuses in the form of serious attempts by brand-name pharmaceutical companies to influence the decision of eligible importing and exporting countries may begin to emerge regarding whether and when to issue a compulsory license. Fourth, the world may begin to see abuses in the form of attempts by brand-name companies to delay or block generic competition altogether by challenging the bioequivalence of generic drugs. Fifth, brand-name companies may attempt to undermine the 2003 Decision on Implementation by persistently raising questions about whether exporting countries and manufacturers have satisfied all the requirements stipulated in the Decision, particularly requirements relating to safeguard and anti-diversion. Sixth, although a remote possibility, companies may also engage in false marketing practices aimed at either confusing the general public about the safety of generic drugs or discouraging doctors from prescribing generic drugs.

311 Médecins Sans Frontières, Campaign for Access to Essential Medicines, One Step Forward, Two Steps Back? Issues for the 5th WTO Ministerial Conference (Cancun 2003), at 3, available at http://www.accessmed-msf.org/documents/Pre-CancunBriefing.pdf. The system may also be abused by governments. Pressure may be brought on developing countries to forgo their privilege under the Decision. Moreover, in the context of bilateral and regional trade negotiations, developed countries may push for tighter patent protection than is envisaged under TRIPS.
Abusive practices of multinational companies can adversely affect the trading environment in developing countries and burden consumers with inflated prices for pharmaceutical products. In the United States, the Sherman Act has been particularly useful in addressing monopolistic practices in the pharmaceutical sector. If and when pharmaceutical companies resort to practices which unreasonably restrain trade and adversely impede prompt access to generic drugs, what laws are available to address these practices? Do developing countries and least-developed countries have the requisite legal and institutional capacity to deal with domestic and transborder anticompetitive practices? Are there global trade rules that address potential abuses of patents by right holders? Is there a need for a multilateral agreement on competition? Should such an agreement be developed within the framework of the WTO? Will the development of such rules be in the overall interest of developing countries?

The questions are pertinent because the Doha Declaration and the 2003 Decision on Implementation cannot in and of themselves prevent the abuse of patent rights by drug companies. These questions will be briefly addressed in Section VI. As will be seen, many developing countries currently lack the necessary legislation and/or enforcement powers to deal with abusive practices of transnational corporations, and are thus among the most vulnerable to the effects of anti-competitive activities of international cartels. At first glance, therefore, a multilateral rule on competition would appear to be in the interest of developing companies. A multilateral framework on competition policy could ensure that developing countries have the capacity and tools to deter and remedy anti-competitive practices. Paradoxically, developing countries have resisted efforts to negotiate a global competition rule within the framework of the WTO.
VI. BETWEEN THE DEVIL AND THE BLUE SEA: IS A GLOBAL COMPETITION RULE THE ANSWER?

In this section, I examine existing global trade rules that address anti-competitive behavior in the pharmaceutical sector, evaluate current efforts towards the development of a global competition rule within the framework of the WTO, and highlight the special concerns of developing countries regarding these initiatives.

A. The Treatment of Abusive and Antitrust Practices under the TRIPS Agreement

Several provisions of the TRIPS Agreement address anti-competitive practices by private actors. Article 8(2) stipulates that: “[a]ppropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.” In granting compulsory license under Article 31 of the TRIPS Agreement to remedy an adjudicated violation of competition, a WTO Member may ignore some of the conditions stipulated in the Agreement that are intended to safeguard the interests of the patent holder. Furthermore, in determining the amount of remuneration to be paid

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312 Matthews, supra note 22, at 65 (observing that during negotiations for the TRIPS Agreement, developing countries pushed for the inclusion of anti-competitive measures).
313 Id. at 65 (noting that article 8(2) is broad and is designed to address the abuse of contractual licensing agreements.).
314 Article 31(k) exempts Members from applying the conditions in subparagraphs (b) and (f) “where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.”

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a
in such cases “[t]he need to correct anti-competitive practices may be taken into account.”  

Concerned that patent holders may attempt to impose anti-competitive provisions in contractual licensing agreements, Article 40(2) allows WTO Members to specify in their legislation “licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.” Members may also “adopt, consistently with the other provisions of [the TRIPS Agreement], appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.” Article 40 also establishes a mechanism for extraterritorial investigation and enforcement and creates conditions for cooperation through the supply of necessary information.

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315 Article 31(f) of TRIPS Agreement.
316 Article 40(2). A WTO Member who has cause to believe that an intellectual property right owner that is a national or domiciliary of another WTO Member is undertaking practices in violation of the its laws and regulations, and which wishes to secure compliance with such legislation, may request for consultations with the Member whose national is in violation. Article 40(3) stipulates that each Member to whom a request for consultation has been directed, “shall enter, upon request, into consultations” with the State requesting the consultation. It also provides that “[t]he Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.”
317 Matthews, supra note 22, at 65.
The provisions of the TRIPS Agreement give some room for WTO Members to address patent abuses and anti-competitive practices in the pharmaceutical sector. One of the primary mechanisms envisaged in the TRIPS agreement for dealing with anti-competitive practices is compulsory licensing. However, the TRIPS Agreement does not fully deal with problems that could potentially arise after a compulsory license has been issued, that is, practices that operate to delay or suppress the entry of generic competition even after a compulsory license has been issued. Furthermore, a measure of legal and institutional sophistication is required to effectively utilize the existing provisions of the agreement – something that many developing countries currently lack.

B. Is a Global Competition Rule Necessary?

In the last twenty years there has been a growing call for the development of multilateral rules on anti-competitive practices. The General Agreement on Tariffs and Trade did not provide binding rules on restrictive business practices with the result that to date, efforts to establish global rules to deal with restrictive business practices have only resulted in non-binding codes of conduct. In 1995, the then WTO Director-General, Renato Ruggiero, observed that there was “an urgent need for a dispassionate analysis at the multilateral level of the overall links between competition policy and trade policy,


319 *Id.*
notably to identify the problems that may require action and the options for such action.” 320 The EU communication of June 1996 put competition squarely on the international agenda. 321

Until then, the work in the WTO on competition policy had largely taken the form of responses to specific trade policy issues, rather than a look at the broad picture. 322 At the first regular biennial meeting of the WTO at the Ministerial level in 1996 in Singapore, 323 Trade Ministers reached an agreement to establish a WTO Working Group on the Interaction between Trade and Competition Policy (“WGTCP”) to look more generally at the relationships between trade and competition policies. 324 Trade ministers also agreed to establish a working group on trade and investment. 325 The task of the WGTCP was merely analytical and exploratory. 326 The WGTCP was authorized only “to

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323 Trade Ministers met in Singapore from December 9-13, 1996 for a Ministerial Conference as mandated by Article IV of the Agreement Establishing the WTO.
325 Id. at para. 20 (“we also agree to … establish a working group to examine the relationship between trade and investment.”).
326 It was agreed that the Working Group will not negotiate new rules or commitments and that future negotiations, if any, regarding multilateral disciplines in the area of trade and competition policy “will take place only after an explicit consensus decision is taken among WTO Members regarding such negotiations.” Id.
study” the interaction between trade and competition policy. The General Council was mandated to keep the work of the WGTCP under review, and to determine after two years how its work should proceed. In 2001, the mandate of the WGTCP was extended.

Since 1996, the efforts of the EU and countries like Japan to move the agenda towards negotiations on a multilateral framework of competition rules have been largely unsuccessful. While some members call for a multilateral agreement on competition policy, others strongly oppose the idea. Although there appears to be a consensus among WTO Members on the need to address transborder anti-competitive practices, there is a divergence of opinion on how this problem should be addressed. Discussions in the WGTCP have revolved around some core topics that reflect areas where intense study and further discussions are still needed. In the ensuing section, I will discuss three related issues: (i) the pros and cons of a multilateral agreement on competition; (ii) the structure of any proposed framework and the need of such framework to reflect traditional WTO principles such as the principles of non-discrimination, transparency and procedural fairness; and (iii) the elements of progressivity and flexibility that should be included in any multilateral framework on competition policy to be adopted together with questions

327 Id.
328 The Doha Declaration mandated that negotiations on a global competition rule could start after the 2003 Cancún Ministerial Conference, “on the basis of a decision to be taken, by explicit consensus, at that session on modalities of negotiations.” See supra note 9, at para. 20.
329 In 1999 Japan called for a global agreement on competition. See The Ministry of Foreign Affairs of Japan, Preparations for the 1999 Ministerial Conference on Trade and Competition (“Members should agree to put the item of competition law and policy on the agenda of the next WTO negotiations with a view to: establishing a competition regime for each Member; ensuring effective enforcement in order to properly address anti-competitive practices; and promoting international cooperation in this area.”), available at http://www.mofa.go.jp/policy/economy/wto/min99/t -compe.html.
330 World Trade Organization, Trade and Competition Policy http://www.wto.org/english/thewto_e/ inst _e/min99_e/english/about_e/16comp_e.htm (noting that “a number of Members have renewed the call for a WTO framework to support the implementation of effective national competition policies by Members and enhance the overall contribution of competition policy to the multilateral trading system while other Members have expressed continuing objections to negotiations on this matter.”).
relating to technical assistance, capacity building and special and differential agreement for developing countries.

1. **The Pros and Cons of a Multilateral Rule:** Several arguments are frequently advanced to support the call for a multilateral rule on competition including the difficulty of individual countries effectively addressing transborder restrictive practices and the need for a more comprehensive, consistent and coherent approach to anti-competitive practices in the global market place instead of the current case-by-case approach to transborder restrictive practices, the need to ensure that the gains from liberalization are not undermined by anti-competitive behavior of private actors, and the belief that “an international framework of competition rules would contribute to the development of international trade” by removing barriers to access to markets. It is

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331 *Id.* (“In today’s global economy, there are numerous anti-competitive practices which have an international dimension and which therefore come under the jurisdiction of different competition authorities. This may result in conflicts of law and jurisdiction and might make it difficult for competition agencies to deal with transborder restrictive practices.”).

332 2003 Report of the WGTCP, *supra* note 324, at para. 14 (“Experience had shown that liberalizing trade and encouraging foreign direct investment heightened the dangers posed by anti-competitive practices such as cartels. A multilateral framework would reinforce the application of competition law and policy at the national level and thereby strengthen Members’ ability to address these challenges.”).

333 *Id.* (“There is also a general consensus that competition policy is a key factor in supporting the competitiveness of industry, in protecting a sound functioning of the economy, and in maximising consumer welfare.”).

According to Renato Ruggiero, Director-General of the World Trade Organization, in a speech delivered at Harvard University in 1996:

“But if we have succeeded in getting the rules of competition between countries to work effectively, that very success requires us to go further and consider how the behaviour of companies can serve to distort international competition. We will need to see whether there are any areas where explicit competition rules, or specific understandings, are necessary internationally to complement the statutes that many governments already have on their books. I have no doubt that competition rules are essential to the proper functioning of markets - what we need to clarify, however, is how best to promote such disciplines, both nationally and internationally.”

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also argued that the development of a multilateral agreement on competition policy would “act as an impetus towards building a culture of competition;” \(^{334}\) “encourage countries without a competition policy to adopt one;” \(^{335}\) and “ensure that progress made through previous trade and investment liberalization initiatives at multi-lateral, regional and bilateral levels, is not negated by private anti-competitive activities.” \(^{336}\) These arguments are aptly summed up in the 2003 report of the WGTCP. According to this report:

A multilateral framework on competition policy would establish a coherent set of principles for sound competition policy among all Members, without imposing a harmonized approach, and would promote a more transparent and predictable climate to encourage foreign trade and investment. It would also contribute to the building of institutional capacity in developing countries, and would assist Members lacking a competition law in drafting an appropriate law and establishing an enforcement authority. Cooperation in the context of a multilateral framework offered the prospect of shortening the time frames that developing countries would need to build and embed competition laws and policies that would support their development goals; a key consideration in this regard was the more supportive environment it would provide for better-targeted assistance and capacity building. Finally, an agreement would encourage beneficial cooperation among Members which was important given the increasing prevalence of cross-border anti-competitive activities. \(^{337}\)

While acknowledging the need for a global rule on competition, \(^{338}\) developing

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\(^{335}\) Id.

\(^{336}\) Id.


\(^{338}\) Id. at para. 18 (“Most developing countries now acknowledged the need to implement a national competition law or policy, out of their own self-interest.”). *See also* World Trade Organization, Working
countries are reticent about the development of such a framework. There are several reasons for this. First, for many poor countries, competition policy is overshadowed by higher priorities. Second, developing countries are afraid that a multilateral framework may not “allow for the preservation of policy space in regard to developmental objectives.” Third, developing countries are very worried about the direct financial cost associated with implementation of such a framework. Fourth, apart from the financial implications of implementing a global competition rule, developing countries are also concerned about additional difficulties that could arise as a result of “disparities between countries and/or their firms in respect of levels of development and competitiveness, experience in the adoption or implementation of competition laws and the capacity to implement such legislation.” Fifth, some countries are concerned about the potential scope of any proposed framework in terms of the types of abusive practices that would be addressed and the place of existing WTO principles of transparency, non-discrimination and procedural fairness in any proposed multilateral framework on competition policy. Finally, developing countries also fear that a multilateral agreement on competition would be used as a pretext to open markets for Northern-based

Group on Interaction between Trade and Competition Policy, Communication from Malaysia, WT/WGTCP/W/239, July 24, 2003 (“Malaysia acknowledges that a competition policy seeks to ensure efficiency in the market place. There is growing awareness of the need to develop some kind of regulatory control on anti-competitive conduct of firms and multinational companies as the existence of such practices have unnecessarily burdened consumers with not only inflated prices for goods and services but have also adversely affected the trading environment. Concerted efforts need to be undertaken to counter their effects on developing countries.”), available at http://docsonline.wto.org [hereinafter Communication from Malaysia].

340 Id.
341 Id.
342 Id.
343 Id.
344 Id.
corporations rather than address the anti-competitive behavior of multinational
corporations and their impediments to development.\(^{345}\)

2. Structure of a Potential Multilateral Framework:

What would be the structure of a potential multilateral framework in terms of the
breadth and depth of possible obligations that members will be expected to assume? Will
harmonization of national competition laws be an objective of the framework? What core
principles would be integrated into the framework? Would there be sufficient flexibility
built into the framework taking into account the differences in the situation of WTO
Members? These questions are pertinent because paragraph 25 of the Doha Declaration –
the paragraph that extended the mandate of the WGTCP – specifically calls attention to
them.\(^{346}\)

Discussions in the Working Group indicate that there is a general consensus that
hardcore cartels must be addressed in any proposed future rule. Developing countries
welcome this focus.\(^{347}\) Hardcore cartels have been described as “the most unambiguously


\(^{346}\) Paragraph 25 of the Doha Declaration reads:

25. In the period until the Fifth Session, further work in the Working Group on the
Interaction between Trade and Competition Policy will focus on the clarification of: core
principles, including transparency, non-discrimination and procedural fairness, and
provisions on hard core cartels; modalities for voluntary cooperation; and support for
progressive reinforcement of competition institutions in developing countries through
capacity-building....

\(^{347}\) *Communication from Malaysia*, supra note 338, at 2 (“There should be no place for hardcore cartels in
any country, irrespective of its level of economic development. Thus, it would be more appropriate for the
Working Group to concentrate its efforts on discussing anti-competitive practices particularly those related
to hardcore cartels.”).
Harmful of competition law violations. Hardcore cartels are bad because they impose heavy costs on the economies of countries, particularly countries that lack effective tools to deal with them. Although discussions at the WGTC suggest that there is a growing consensus that hardcore cartels should be addressed, there is currently, no generally accepted definition of a hardcore cartel. There is therefore a need for a clearer definition of hardcore cartels and further discussions on what approach should be adopted in dealing with them.

The possible inclusion of WTO principles of non-discrimination, transparency and procedural fairness into any proposed framework is a major concern for some developing countries and civil society organization. For example, Malaysia expressed the concern that transparency requirements may be used to impose additional burdens on developing countries. Kenya has questioned the wisdom of universalizing principles developed in the context of trade policy. Martin Khor, Director of Third World Network, argues that increasing advocacy by Northern governments for application of the principles of non-discrimination, national treatment and transparency reflect a hidden agenda to give foreign corporations, whether as suppliers through exports or by local investments and franchising, equal – if not better – treatment than that given to local enterprises.

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349 Id. at para. 41. (noting also that hardcore cartels raise prices, restrict the supply of essential goods, and can have the effect of impeding the transfer of technology to developing countries).
350 Communication from Malaysia, supra note 338, at 1.
351 World Trade Organization, Working Group on Interaction between Trade and Competition Policy, Communication from Kenya, WT/WGTCP/W/238, July 24, 2003 (“The so-called core principles of transparency, non-discrimination and procedural fairness were developed in the context of trade policy and they were not intended as universal principles applicable to all issues including competition policy. It is not self-evident that it is appropriate or desirable to apply these principles to competition policy.”), available at http://docsonline.wto.org [hereinafter Communication from Kenya].
352 Khor, supra note 245.
3. Flexibilities, Progressivity, Technical Assistance, Capacity Building and Special and Differential Treatment

The adoption of a multilateral framework on competition policy would also undoubtedly involve heavy administrative burdens for many developing countries, particularly countries that currently lack competition legislation and institutions.\textsuperscript{353} Consequently, appropriate flexibility and progressivity elements “supported by continuing commitments with regard to technical assistance and capacity building”\textsuperscript{354} would be necessary. It is also important that any multilateral framework on competition policy “take cognisance of, and accommodate, a substantial degree of pluralism in national competition policies, especially among developing countries, in addition to other, sometimes more interventionist, policies that existed to support development.”\textsuperscript{355}

For many countries, the startup process would be beset by numerous financial and administrative problems;\textsuperscript{356} some countries will need technical assistance in establishing an effective regime. It is therefore important that provisions relating to technical assistance and capacity building be fully fleshed out.\textsuperscript{357}

\textsuperscript{353} 2003 Report of the WGTCP, \textit{supra} note 324, at para, 18 (noting that implementing a global rule on competition could “pose significant difficulties for countries that currently lack a domestic competition law and/or policy.”).

\textsuperscript{354} \textit{Id.} at para. 16.

\textsuperscript{355} \textit{Id.} at para. 18.

\textsuperscript{356} \textit{Communication from Malaysia}, supra note 338, at 1 (noting that capacity constraints abound as both the government and private sectors are confronted with the prospect of a new business environment and pointing to the need for the international community to continue to focus and prioritize on providing technical assistance to developing countries).

\textsuperscript{357} While there appears to be a general willingness to provide assistance to countries that need it, developing countries may be forgiven for not taken the promises of assistance seriously. Promises of better-targeted assistance and capacity building in other agreements including the TRIPS Agreements are yet to materialize.
C. Conclusion

Competition laws and policies are necessary both for the overall wellbeing of an economy and for the protection of consumers. In general, effective competition law and policy help ensure efficiency in the marketplace and a robust competitive environment. Arguably, a multilateral rule on competition could be in the interest of developing countries. A global competition rule could contribute to the development of institutional capacity in developing countries, assist developing countries currently lacking competition law in drafting appropriate legislation, and encourage beneficial cooperation among WTO Members. Such a multilateral framework could strengthen the ability of developing countries to address dangerous anti-competitive practices in the pharmaceutical sector and in other sectors.

However, given a myriad of socio-economic problems and developmental objectives, negotiations on competition law-related matters may not be a priority for many developing countries. In the context of limited resources and growing obligations under a host of international trade agreements, the resources of many developing countries may be better directed at more important socio-economic policies. In addressing anti-competitive practices in the pharmaceutical sector, developing countries

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358 WATAL, supra note 15, at 374 (noting that international cooperation in the breaking-up of cartels of multinationals could be in the interest of developing countries).
359 Communication from Malaysia, supra note 338, at 2 (“At this point of time, we feel that negotiations on competition law-related matters are not part of the Doha work programme. Domestic competition policy/law may not be a major consideration for developing countries. National priorities and limited capacity may require that scarce resources are allocated for the implementation of more important socio-economic development policies in the country. Alternative domestic approaches to enhance competition in the form of regulatory reform are some of the measures being undertaken.”).
may be content to simply utilize the tools presently available under the TRIPS Agreement.\textsuperscript{360}

Some of the fears expressed by developing countries regarding any proposed agreement on competition policy are not overstated.\textsuperscript{361} Whether a global competition rule will be in the interest of developing countries will depend on the extent to which the interests of developing countries are fully reflected in any future agreement. It is important that any proposed multilateral framework does not simply become a smokescreen for promoting market access for transnational corporations and imposing on developing countries, anti-trust laws of more developed WTO Members. One of the purposes of any future multilateral agreement on competition should therefore be to address the challenges currently faced by developing countries, for example through a focus on those anticompetitive practices that developing countries are most vulnerable to. Firm and effective commitments regarding capacity building, technical assistance and special and differential treatment provisions would also be necessary.

\textsuperscript{360} \textit{Watal, supra note} 15, at 374 (“[G]iven the freedom presently available under TRIPS on competition policy in general and compulsory license in particular, it may not be prudent to enter the stage of negotiation.”).

\textsuperscript{361} Proponents of a multilateral agreement on competition are of the view that the fears of developing countries are overstated; these fears some argue, could be addressed by the inclusion of transitional periods and flexibility in the rules. According to Mr. Karel Van Miert,

The developing countries may have most to gain from an international framework of competition rules. On the one hand, they would be able to benefit from the multilateral framework right away - by enabling requests for co-operation to combat anti-competitive business practices and by providing for technical assistance regarding the setting up of domestic competition structures. On the other hand, one could envisage transitional periods in the multilateral framework designed to meet certain specific problems of developing economies.

\textit{See} Van Miert, \textit{supra} note 321.
Although important, it is not enough that harmonization will not be the goal of any proposed framework.\textsuperscript{362} While there are convincing arguments for why a multilateral framework on competition policy may be in the interest of developing countries, there is a strong need to take into account a country’s level of development when formulating such an agreement and establishing obligations regarding implementation. Paragraph 25 of the Doha Declaration buttresses this fact by stating that in discussions on the modalities for a potential multilateral framework, “[f]ull account shall be taken of the needs of developing and least-developed country participants and appropriate flexibility provided to address them.”\textsuperscript{363}

Overall, should a multilateral framework on competition be negotiated, there would be a need to consider (i) the different levels of development and economic circumstances of WTO Members; (ii) the different legal, social, and cultural context of Members; (iii) the difference in availability of resources for implementing the terms of any proposed framework; and (iv) the different levels of institutional development and the fact that Members have different administrative systems.\textsuperscript{364} Thus, rather than attempt to impose a one-size-fits-all standard, as is the case with the TRIPS Agreement, a proposed set of principles that “would embody common values and promote cooperative approaches to competition law enforcement” would be a useful starting point.\textsuperscript{365} In the final analysis, it may be important to “preserve the right of a country to choose whether

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\item 362 Id. (“It is likely that any agreement in the WTO on competition would not match the level of competition policy and instruments achieved by countries, which have decades of experience in antitrust activities. But is this really a problem? We are not talking about replacing national law by international rules.”).
\item 363 Doha Declaration, supra note 9.
\item 364 Khor, supra note 245.
\item 365 2003 Report of the WGTC, supra note 324, at para 16.
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and when to have a competition law and the kind of competition policy to adopt.”\footnote{See Communication from Kenya, supra note 351 (also observing that countries should preserve the right to adopt a phased approach in terms of discussion, implementation and enforcement of a competition law because only then can countries adopts competition regimes that support their industrial policy).}

\section*{VII. CONCLUSION}

To a great extent, the war over access to medicine in developing countries was unnecessary because the TRIPS Agreement appeared to provide sufficient policy spaces aimed at attenuating the potential adverse effects of a strong intellectual property regime. The war was inevitable, however, given the numerous ambiguities that existed in the TRIPS Agreement, the negotiating history of TRIPS Agreement,\footnote{Watal, supra note 15, at 382. During the negotiations there was intense pressure on developing countries to accept stronger obligations relating to the protection of intellectual property rights. Not surprising, “[f]rom the outset, the TRIPS agreement has been controversial.” Pascal Lamy, Commissioner of the European Commission, International Trade in Drugs: Its Role in Equitable Development, Speech to the Association of Pharmaceutical Industry Managers, March 21, 2003, available at http://www.europa.eu.int/comm/commissioners/lamy/speeches_articles/spla162_en.htm [hereinafter International Trade in Drugs].} and the understandable efforts by the pharmaceutical industry to safeguard their profit margins using every means possible. The TRIPS Agreement was negotiated at a time when the impact of a strong patent protection was not widely understood in the developing world and at a time when the debate on the necessity of a global intellectual property regime was dominated by global corporate actors and countries with intellectual property expertise.\footnote{Ostergard, Jr., supra note 4, at (noting that debate was dominated by countries “with a negotiating advantage over developing countries in terms of intellectual property expertise.”).} Today, not only is the relationship between patent protection and economic growth more understood, new actors “whose views were peripheral in the Uruguay Round negotiations have now entered the debate on global intellectual property protection more wholeheartedly.”\footnote{Id.}
The battles over the precise relationship between patent rights, public health and state sovereignty reflect the simultaneous convergence of a number of trends that together define the emerging world of the twenty-first century including: the growing convergence of national economic systems, widening disparities of income and development, the rise in the power and influence of transnational corporations and the explosion of diseases that transcend national boundaries.370 In the twenty-first century, drugs matter because of their role in equitable and sustainable development and because many developing countries have little or no manufacturing capacity in the pharmaceutical sector371 and have little resources to devote to R&D in essential medicine.372 Also, in the twenty-first century, as a result of globalization, transnational corporations in general and pharmaceutical companies in particular are having to assume new global responsibility that they did not have before.

Compulsory license gives developing countries tools to address serious health problems by enabling them to obtain generic drugs at an affordable price.373 Although an important instrument in efforts to protect public health, compulsory licenses alone “will

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370 See International Trade in Drugs, supra note 367 (of the trends in the twenty-first century, Pascal Lamy notes, “widening disparities of development, global interdependency of trade movements, acceleration of technological progress which only benefits a minority, the explosion of a deadly disease known as AIDS, the emergence of global civil society, and the inadequacies of national and international governance systems.”).
371 Id. (noting that little medical and pharmaceutical research is carried on in developing countries and that developing countries have next to no facilities for the manufacture of drugs).
372 Id. (“The gap between North and South is a veritable chasm when it comes to drugs. According to the WHO, developing countries are home to 76% of the world’s population, but account for only 20% of world drug consumption. Not only that, but their share has been declining! (In 1976, they represented 24% of world consumption)).
373 Id. (It is not our aim to encourage the widespread granting of compulsory licences by the developing countries. But it is clear that in negotiations with the major pharmaceutical groups, whose revenues often far exceed those countries’ GDP, the fact that the developing countries have the compulsory licence option to fall back on can give them the leverage they need to secure lower prices. In this way, compulsory licensing can operate as an effective form of deterrence.”).
not address all the problems related to public health.” This is because there are many other factors that influence access to medicine in developing countries including: level of research and development; quality of diagnosis; capacities of health systems and budget; the quality of drugs; and adequacy of health care professionals. Given the multiplicity of factors that influence access to medicine, a combination of policies is needed to ensure that drug prices are lowered on a sustainable basis.

The different battles may be over but the war against diseases in developing countries continues. For one thing, it is not clear yet whether developing countries will actually maximize the political space now afforded by the Doha Declaration and the 2003 Decision on Implementation. Furthermore, experts rightly note that “[e]ven with newly discounted price for patented anti-retroviral drugs and even with dramatically cheaper equivalents from generic producers, developing countries and their private citizens will find it impossible to buy significant quantities of life-saving AIDS medicines without significant and sustained support from the international community.” To date, multilateral funding for AIDS treatment has been very poor; very little has changed since the establishment of the Global Fund to Fight AIDS, Tuberculosis, and Malaria (the

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374 Submission by the African Group, supra note 79, at para. 28.
375 International Trade in Drugs, supra note 367 (noting a host of factors that account for the gap between North and South when it comes to drugs. These include, “the near total lack of social security and health insurance systems in the South, inadequate and badly-organised infrastructure, poor hygiene, badly educated and trained staff, and the failure to implement certain disease-prevention measures. The underlying problem is thus the same as for other forms of under-development: a crying deficiency of governance and public policy.”).
376 Médecins Sans Frontières, Campaign for Access to Essential Medicines, What is the Campaign? (suggesting a host of strategies including: encouraging generic competition, voluntary discounts on branded drugs, global procurement, and local production), available at http://www.accessmed-msf.org/campaign/campaign.shtm [hereinafter What is the Campaign?].
377 Brook K. Baker, Health GAP, The Global Fund to Treat AIDS, TB, and Malaria: Fulfilling or Betraying the Promise of Treatment, (July 7, 2002) (noting that during most of the 1990’s, “the actual per person expenditure on all AIDS prevention and treatment programs in Africa dropped to as little as $3 per person per year.”).
“Global Fund”) in 2001. The Global Fund suffers from serious under-funding. Most important, given the possibilities of abuse in the pharmaceutical industry, the future will depend on the type of rules that exist to address abusive and anticompetitive practices by drug companies, the extent of self-regulation that exists in the industry, the role of ethical codes of conduct in the industry, and the extent to which external pressures can be brought to bear on the pharmaceutical industry. In this respect, actors such as civil society groups have a pivotal role to play in any effort to address the growing global influence of transnational pharmaceutical industry, raise awareness about any abuses in the industry and provide countries with timely information that will be needed to address abuses if and when they arise.

Just as many factors influence access to effective medicine, “many actors have a role to play in addressing the access crisis.” At the local and national level, governments clearly “have the responsibility to give priority to public health through strong, pro-health legislation.” Attention must now turn to other issues affecting access such as inadequacies in the health infrastructure of many developing countries. Unless these issues are addressed, many in the developing world will remain without access to essential drugs even if the drugs are offered at extremely low cost or for free.

378 Id. On April 28, 2001, United Nations Secretary General, Kofi Annan, called for the establishment of the Global Funds to Fight AIDS, Tuberculosis and Malaria. Id. Annan estimated that an initial response to AIDS would cost between $7 and $10 billion dollars per year. Id. Although the Global Funds was established, as of mid-May 2002, the Global Fund was funded at $1.9 billion of which only $725 million was available for spending in the year 2002. Id.

379 What is the Campaign?, supra note 376, at 2.

380 Id.

381 International Council of AIDS Service Organizations, The International Guidelines on HIV/AIDS and Human Rights: An Assessment of National Responses in Improving Access to HIV/AIDS Treatment Within the Framework (2002) (observing that the public profile of the global drug pricing issue has been raised but less attention has been paid to other issues affecting access to treatment).

382 Adding Infrastructure to the Advocacy Agenda, supra note --, at iv (observing that there are examples of countries were drugs have been offered at extremely low prices but access to treatment has not increased for people living with HIV).
At the international level, organizations such as the World Health Organization, World Bank and UNAIDS must “adopt and advocate for policies that give the highest level of protection for public health.” Alongside continuing efforts to reduce the cost of medicine through generic competition, concurrent research and advocacy on additional barriers to access is called for. Renewed commitment to support the United Nations Global Funds to Fight AIDS, Malaria, and Tuberculosis is also called for.

The private sector remains very important. Pharmaceutical companies can contribute to long-term solutions by cutting their prices for developing countries in a transparent and predictable way. Differential pricing thus remains a viable option. International donors and foundations remain very important also. In addition to funding disease prevention, international donors can fund drug purchase and other treatment programs. Finally, civil society groups have a continuing responsibility to monitor and hold accountable all the important players – states, international donors, pharmaceutical companies – and to expose abuses and other failures when they occur.

It is important that the integrity of the patent system is preserved through good faith use of the Doha Declaration and the 2003 Decision on Implementation. The patent system is needed to finance new research and development and ensure that drug manufacturers continue to bring newer and better drugs to the market. However, studies in the U.S. and elsewhere show that the industry’s emphasis on R&D is somewhat exaggerated. Data gathered by Families USA, does show that in the U.S. at least, major

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383 Id.
384 Id.
385 Id.
386 Differential pricing allows the pharmaceutical industry to provide drugs to the poorest countries at significantly reduced prices.
387 Id.
pharmaceutical companies “spend significantly more on marketing, advertising, and administration than they spend on R&D.”

The access to treatment debate unearthed many hidden factors that impede access to essential drugs for millions in the developing world. In addition to increasing access to essential drugs in developing countries, the debate brought the human rights to health back into the spotlight. The access to treatment debate raised interesting questions about how to balance ethical concerns and economic concerns. Public health is an ethical and human rights issue, but does it necessarily trump substantial economic and other public interests at stake when patent rights are implicated? What constraints should society impose on the rights of a patent holder? Can the pharmaceutical industry be trusted to develop sound ethical principles to guide the activities of its members?

These questions and more will continue to resonate many years from now.

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388 Families USA, Profiting From Pain: Where Prescription Drug Dollars Go 1 (July 2002), available at http://www.familiesusa.org/site/DocServer/PPreport.pdf?docID=249 [hereinafter Families USA, Profiting From Pain]. In its study of nine U.S. pharmaceutical companies that manufacture or market the 50 top-selling drugs for seniors, Families USA found that on average, the companies spend 11 percent of revenue on R&D and 27 percent on marketing, advertising, and administration. Id. at 5. The study found that “[n]o company spent as much as 20 percent of revenue on R&D, whereas every company except Merck spent more than 20 percent of revenue on marketing, advertising, and administration.” Id. Finally, the report found that the pharmaceutical industry was very generous to its top executives with the result that “[t]he 10 highest-paid executives across the nine companies received a total of $236 million in compensation in 2001, exclusive of unexercised stock options.” Id. at 7 (emphasis in original).

389 In the case of HIV/AIDS, barriers to accessing treatment take many forms, including drug costs, stigma and discrimination, political denial and disinterest and general lack of healthcare infrastructure. See generally, International Council of AIDS Service Organizations, Adding Infrastructure to the Advocacy Agenda (2002).

390 International Council of AIDS Service Organizations, The International Guidelines on HIV/AIDS and Human Rights: An Assessment of National Responses in Improving Access to HIV/AIDS Treatment Within the Framework 8 (2002) (arguing that access to medical treatment of HIV infection is crucial for the respect of the right to health and the right to life). Essentially some local and global NGO’s, drawing on some human rights treaties, argued that access to treatment was a human right issue. The efforts of this organization led to the adoption of the International Guidelines on HIV/AIDS by the Second International Consultation on HIV/AIDS and Human Rights, held in Geneva, Switzerland in September of 1996. See id. at 1.

391 International Trade in Drugs, supra note 367 (observing that although public health is an ethical issue, there are other economic interests at stake).

392 Id. (“There is nothing to be gained by constructing a false opposition between intellectual property, which is essential if we are to have the innovation we need to produce new drugs, and access to care; instead, we should seek ways to make them work together.”).