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*PATENTS AND PILLS, POWER AND PROCEDURE:
THE NORTH-SOUTH POLITICS OF PUBLIC HEALTH IN THE WTO*

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**Patents and Pills, Power and Procedure:
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ABSTRACT

This article uses the contemporary international politics of intellectual property rights (IPRs) as a lens to examine North-South conflicts over international economic governance and the possibilities of institutional reform. Although developing countries have limited control over the distributional and substantive dimensions of international institutions, they retain an important stake in a rule-based international order. Because international institutions provide small states with a potential mechanism to bind more powerful states to mutually-recognized rules, developing countries may seek to strengthen multilateral institutions. Lacking the power to revise the substance of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), developing countries subsequently designed strategies to operate within the constraining international political reality they faced. They sought to clarify the rules of international patent law, to affirm their rights established during the TRIPS negotiations and to minimize their vulnerability to opportunism by powerful states. Rather than undermine TRIPS, then, the developing countries strengthened global governance in IPRs.

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**Patents and Pills, Power and Procedure:
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Why would developing countries seek to strengthen international institutions? Moreover, why would developing countries seek to strengthen international institutions that are clearly contrary to their interests? This article addresses these questions through analysis of the international politics of intellectual property rights (IPRs) in the World Trade Organization (WTO). To understand North-South conflicts over international economic governance and the possibilities of institutional reform, it is necessary to distinguish between the *substantive* and the *procedural* dimensions of international governance. Developing countries may have limited control over the substance of international institutions, but they nevertheless retain an important stake in creating and sustaining a rule-based international order.

Most work on developing countries' efforts to reform international institutions has focused on the substantive and distributional aspects of international governance. Scholars have focused on developing countries' generally unsuccessful efforts to redesign international institutions as part of broader strategies to alter the distributional effects of the international economy (e.g. Finlayson and Zacher 1981 and 1988; Hart 1983; Ruggie 1983; Rothstein 1984; Krasner 1985; Lake 1987; Ferguson 1988; Sell 1998). These studies revealed an international economic order that was relatively unresponsive to demands for substantive change from below. Indeed, one prominent and comprehensive analysis of North-South relations argued that if developing countries insisted on pressing collective demands in global forums, they would do so at their own peril by reducing developed countries' commitment to multilateral institutions (Krasner 1985: 29-30).

In contrast to the extensive documentation of developing countries' challenges to the substantive dimension of institutions, comparatively little has been written about these countries' efforts to reform the procedural aspects of international governance. Even where weak actors do not

control institutions, they can still benefit from the predictability and stability introduced by multilateralism. Thus, because international institutions provide small states with a potential mechanism to bind more powerful states to mutually-recognized rules, developing countries may seek to strengthen multilateral institutions.

The paradox, then, is that developing countries may become protagonists of institutions that disfavor them substantively. They may participate in and attempt to strengthen international institutions, so to insulate themselves from the discretionary actions of more powerful states. Though the anarchic nature of the international system means that stronger states can continue to act unilaterally and flaunt collectively-recognized rules, institutions that clearly define states' expected rights and obligations can raise the associated political costs of unilateralism. In the simplest terms, multilateral institutions can provide developing countries with a form of limited political protection against opportunistic behavior on the part of developed countries (see Haggard 1995). This article examines developing countries' efforts within the WTO to strengthen global governance in the area of IPRs. Special emphasis is placed on the relationship between pharmaceutical patents and public health.

The Uruguay Round of trade negotiations, which concluded in 1994, established a new and important organization for regulating the international economy – the WTO. One of the three agreements within the WTO is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹ By linking IPRs to trade and formally integrating the global governance of IPRs into the WTO, the Uruguay Round brought the issue-area to the forefront of international relations.

¹The other two agreements are the General Agreement on Trade in Services (GATS), which like TRIPS was new, and the General Agreement on Tariffs and Trade (GATT), which prior to the conclusion of the Uruguay Round had been the principal institution for regulating international trade. There are, of course, numerous additional sets of trade and investment rules monitored by the WTO, though these fall within one of these three principal agreements. Hoekman and Kostecki (2001) provide a thorough overview of the WTO.

A landmark of TRIPS was to include pharmaceutical products among the range of industrial and commercial products for which countries must make patents available. Because pharmaceutical patents can increase the price of drugs, most developing (and many developed) countries did not grant pharmaceutical patents prior to the conclusion of the Uruguay Round. TRIPS, then, has major implications for public health in the developing world.² As discussed below, the problems associated with the high price of drugs in poor countries is most pronounced with regard to the treatment of patients with HIV/AIDS.

Few issues would appear so ripe for North-South conflict as IPRs, in general, or the narrower issue of pharmaceutical patents. Most copyrights, patents, and trademarks are developed, claimed, and owned by firms in the more developed countries. Developing country consumers, firms and governments, in contrast, are largely importers and users of intellectual property. Since patents provide market exclusivity to owners, strong enforcement of IPRs at the global level implies significant resource transfer from developing countries to developed countries (Maskus 2000; May 2000; CIPR 2002; Bronckers 1994; World Bank 2001: Chapter 5). And while patents, in general, constitute an issue-area marked by structural asymmetry, the specific area of pharmaceutical products is marked by even starker asymmetries. Table 1 presents data on patents granted in the United States over the five-year period, 1997-2001. The top fifteen developed countries received nearly sixteen times as many patents as did the top fifteen developing countries (compare the sub-total of the upper-left column to that of the lower left). With regard to medical patents, however, the developed countries' sub-total is thirty-four times greater. What this means is that the positive effects of strengthened IPRs – rewarding innovation – will be captured almost exclusively by firms in a handful

²For analyses of how developing countries' new obligations regarding patents on pharmaceutical products might affect public health, see, among others, Abbott (2001); CIPR (2002: Chapter 2); Correa (2000); Mrazek (2002); Scherer and Watal (2001); WHO (1998); WHO (2001); WTO/WHO (2002).

of countries, while the negative effects of stronger IPRs – higher costs for medicines – are absorbed internally by developing countries.

-- Insert Table 1 --

Notwithstanding the myriad reasons to seek either revision or elimination of the international rules on IPRs, the developing countries did not attempt to introduce fundamental changes in the substance of TRIPS. Rather than use the mandated review of TRIPS in 2000 (part of the Uruguay Round's "built-in agenda") to reopen negotiations and correct the imbalances between the rights of patent producers and obligations of patent consumers (e.g. remove the obligation to grant pharmaceutical patents), developing countries spearheaded a series of high-level discussions on the more narrow and immediate issue of the relationship between TRIPS and public health. The WTO's TRIPS Council dedicated special sessions to the issue throughout 2001, and the relationship between patents and public health would constitute one of the most important topics addressed at the WTO's Fourth Ministerial Meeting in Doha, Qatar, in November 2001. The central theme of these sessions regarded how to interpret TRIPS – how to deliver the level of intellectual property protection demanded by the developed countries while also leaving developing countries' sufficient capacity to respond to public health crises. Specifically, developing countries sought to maximize their ability to take advantage of TRIPS' flexibilities to control healthcare costs and respond to public health crises.

Contemporary conflicts over IPRs shed critical light on the politics of global governance. Though the structural asymmetry of the issue-area may give developing countries ample motivation to seek to change the substantive dimensions of TRIPS, they lack the power to do so. The margin for action on the part of developing countries was constrained by a core set of developed countries' insistence that the substance of TRIPS would not be revised. Throughout the course of these discussions, for example, the U.S. subjected all measures proposed to address the issues concerning the developing countries to a litmus test of how they would affect the IPR obligations established in

the Uruguay Round. With the weakening of patent protection a non-starter, developing countries designed strategies to operate within the constraining international political reality they faced: they sought to clarify the rules in the “gray areas” of international patent law to affirm their rights established under the Uruguay Round. Rather than undermine TRIPS, then, the developing countries sought to strengthen global governance in IPRs and thereby secure limited political protection.

The first section of this article underscores the different perspectives of strong and weak states towards participation in international institutions. I argue that for developing countries the “price” of multilateral rules is that they must accept rules written by – and usually for – the more developed countries. Here I build upon the institutionalist approach, which emphasizes states’ demand for international institutions, by showing how developed and developing countries are likely to have fundamentally different sources of demand. The second section examines the introduction of IPRs into the GATT/WTO during the Uruguay Round. This period essentially witnessed the U.S. setting the price of multilateralism. The third section examines IPR conflicts in the aftermath of the Uruguay Round, when developing countries found themselves subject to external pressures to provide a greater level of intellectual property protection than stipulated by TRIPS. The fourth section links extra-institutional vulnerability to public health challenges in developing countries, with particular emphasis on the treatment of HIV/AIDS. The problem for developing countries in the late 1990s was not TRIPS, but unilateral and bilateral pressures outside the WTO that prevented them from using TRIPS and that pushed them to exceed their Uruguay Round obligations. This problem was particularly acute for developing countries struggling to meet their new obligations compatible while confronting the global HIV/AIDS epidemic. The fifth section examines the developing countries’ efforts within the WTO to affirm and secure their rights under TRIPS, focusing on the movement within the WTO to explicitly clarify the rights of Members with regard to patents and

public health. The concluding section considers the opportunities and limitations of changing international governance on IPRs.

Developing Countries and the Price of Multilateralism

Scholars of international political economy have long focused on the political underpinnings of international economic relations. Institutions structure interaction among actors in the global political economy, and in doing so they provide predictability and reduce uncertainty. International institutions, thus, are the cornerstone of multilateral rule-based international environment.

A key question regards the dynamics of change in international institutions – not just what institutions do, but rather where they come from and how they change³ One approach, focusing on states' demand for institutions, maintains that states seek institutions to obtain predictability and minimize uncertainty (Keohane 1982 and 1984; Abbott and Snidal 1998). To institutionalize interactions gives actors greater confidence that conflicts will be resolved according to known and recognized procedures. Actors may not know what the precise outcome will be, but the array and probability of different scenarios can be anticipated. Knowing the “rules of the game” provides the stability essential for actors to devise strategies to realize their goals.

Though certainty and predictability may be desirable, participation in international institutions also implies that states sacrifice some degree of sovereignty. A country's commitment to make its policies conform to international obligations reduces the capacity to act unilaterally – to do what it wants, when it wants, and how it wants. At the most general level, then, increasing predictability and reducing uncertainty explain why states might want to create institutions to regulate interactions, and the sacrifice of sovereignty explains states' reluctance.

³See Martin and Simmons (1998) and Haggard and Simmons (1987) for comprehensive reviews of this literature.

The relative weights of the underlying tradeoffs of participation in international institutions are likely to appear differently to different sorts of states. The degree to which we should expect a country to be willing to sacrifice some sovereignty typically has to do with that country's ability to achieve its goals on its own. A state for which unilateralism is fruitful is less likely to want or need to sacrifice sovereignty by committing to multilateral institutions. That is, a more powerful state that can better control its external environment and achieve its goals unilaterally can obtain predictability and certainty with a smaller sacrifice of sovereignty. However, even stronger states may demand institutions that reduce transaction costs (Keohane 1984).

Weaker states, in contrast, are more likely to be willing to tie their own hands. As much as sovereignty may be valued at a symbolic and rhetorical level, developing countries may be willing to sacrifice sovereignty and commit to multilateral institutions – so long as there is an expectation that the powerful countries will do the same. Multilateralism comes at a high price for developing countries, however. To obtain the benefits of multilateralism – developed countries' commitment to mutually-recognized rules and thus protection against unilateralism – developing countries have to accept and adapt to rules and regulations that are generally not of their making.

The price of multilateralism, and the subsequent opportunities and challenges for developing country participation in international institutions, provides key insights for understanding the contemporary international politics of IPRs. Developing countries argue that they “paid” for multilateralism in the Uruguay Round with substantive concessions in the form of TRIPS, but that they have not enjoyed the benefits of a rule-based system in the post-Uruguay Round environment.

For all of the problems posed by new obligations under TRIPS, developing countries retained necessary flexibilities to address public health crises (Correa 2000; Scherer and Watal 2001), and the WTO promised to deliver the predictability and stability essential for long-term public health

planning.⁴ Yet the predictability and stability was not forthcoming. As we will see, the obstacles developing countries faced were not derived from TRIPS and the WTO, but rather from the extra-institutional pressures – diplomatic, economic, and legal – that developed country firms and governments applied. These pressures limited developing countries’ ability to use the flexibilities granted to them under TRIPS.⁵ Thus, the problem for developing countries was not so much developing countries’ substantive obligations under TRIPS, but rather the weakness of TRIPS’ procedural dimensions that in many ways made the agreement effectively irrelevant. Subsequently, the developing countries sought to eliminate the ambiguities in TRIPS and clarify their rights. Though altering the substance of the agreement was politically infeasible (though perhaps desirable), they managed to strengthen important procedural dimensions of international governance.

Intellectual Property Rights in the Uruguay Round: The Price of Multilateralism

Prior to the Uruguay Round, international governance in the issue-area of IPR was weak, both procedurally and substantively. Because IPRs were not considered “trade-related,” they were not regulated by multilateral trade institutions (e.g. GATT). Instead, the principal international covenant for patents was the 1883 Paris Convention for the Protection of Industrial Property, an international treaty monitored by the WIPO. WIPO, like many international organizations, lacks enforcement mechanisms. The Paris Convention allowed countries a significant degree of flexibility in designing their IPR regimes. Though the parties to the Paris Convention pledged to abide by the norm of non-discrimination (i.e. they would not treat patent applications and patents differently depending on the country of origin), they could impose different standards and obligations on foreign, as opposed to

⁴For a similar argument with regard to trade and investment measures, see Amsden and Hikino (2000).

national, patent holders. And because the Paris Convention allowed countries to establish the “scope” of their patent regimes, countries varied the standards and levels of patent protection by type of products. Many countries, in fact, simply declared certain products, such as pharmaceuticals, outside of the scope of patentability.⁶

In the 1980s and 1990s the developed countries, led by the U.S., pushed for stronger enforcement of a less flexible set of regulations regarding intellectual property protection.⁷ The increased prominence of IPRs in U.S. foreign policy is a well-known story of sectoral politics. Well-organized industry groups representing the chemical, entertainment, pharmaceutical, and software industries pushed the U.S. government to use trade sanctions against countries that were argued to be lax in protecting their copyrights, patents, and trademarks (Ryan 1998: Chapter 4; Sell 1998: Chapter 4; Ostry 1999; Ellsworth 1993).⁸

American firms’ initiative for patent protection yielded results. In 1984 congress amended Section 301 of Trade Act of 1974 to make violation of intellectual property rights “actionable.” As the business constituency for stricter enforcement of IPRs grew, the same coalition succeeded in obtaining another amendment to Section 301 in 1988 – “Special 301,” which heightened the USTR’s powers to act against countries that provided insufficient intellectual property protection. Though clearly at the forefront of drive to link IPRs to trade, the U.S. did not act alone. The EU’s 1984 “New

⁵Throughout this paper reference is made to the *flexibilities* afforded countries by TRIPS, not “safeguards.” Safeguards suggest exemption – they establish the conditions by which countries are released, temporarily, from their obligations. According to TRIPS, however, measures that Members take to protect public health or promote economic development must be “consistent” with other obligations in the agreement. Thus, they should not be regarded as safeguards (see Bronckers 1994: 1260).

⁶See Gadbow and Richards (1988) for a review of pre-Uruguay Round patent policies in a range of developing countries.

⁷It is worth noting that the U.S.-led offensive followed an earlier attempt in the 1970s by a coalition of developing countries, working through the United Nations Conference on Trade and Development (UNCTAD), to reform international governance in IPRs. UNCTAD sought to codify developmentalist rules for patent regulations and technology transfer, and to make developed country obligations legally binding (Miller and Davidow 1982; Sell 1998).

Commercial Policy Instrument,” which is like Section 301 in authorizing trade sanctions against countries involved in acts of “illicit trading,” also includes inadequate protection of EU firms’ intellectual property as an actionable offense (van Bael and Bellis 1990: 336-339).

From Special 301 to TRIPS

In addition to unilateral strategies of IPR enforcement, the U.S. and the EU also insisted on integrating IPRs into the Uruguay Round negotiations . An important goal for the Uruguay Round became the establishment of a new set of global standards to guide countries’ IPR regimes. Such standards would stipulate what items were eligible to receive copyright and patent protection, institute guidelines for copyright and patent application and granting, and establish minimum periods of protection. The standards would also include entail new obligations with regard to enforcement and de facto protection of intellectual property. The institutionalist perspective helps us understand the movement to seek higher global standards at the multilateral level, for doing so potentially spreads the burdens of monitoring and enforcement, and thus reduces the costs that would otherwise accrue to the handful of dominant countries in the issue-area.

To be sure, many middle-income developing countries were opposed to the integration of IPRs into the GATT, and a coalition of ten countries attempted to block the developed countries’ project. As indicated, developing countries had only recently been defeated in their effort to weaken international protection of IPRs. From these countries’ perspective, what the U.S. was proposing was even more problematic than the status quo. Yet the developing countries were no more successful in keeping IPRs off the agenda in the Uruguay Round than they had been in reforming the Paris Convention. Business lobbying made TRIPS a high priority for the U.S. in the Uruguay Round negotiations, and considerable pressure was used to generate consent. Indeed, the unilateral strategy

⁸Aggarwal (1992) analyzes a similar process by which services gained prominence on the U.S. trade agenda, with key business constituencies playing a key role in defining services as “trade-related.”

was used as a tool to gain acceptance of the multilateral strategy, as the U.S. explicitly used Special 301 provisions to coerce larger developing countries such as Korea and Brazil into accepting the inclusion of IPRs in the Uruguay Round negotiations. As one participant in the negotiations has since written, “given a choice between American sanctions or a negotiated multilateral agreement, the TRIPS agreement began to look better” (Ostry 1999: 195).⁹

There is little disagreement that the TRIPS agreement produced in the Uruguay Round reflects the interests of the powerful set of developed countries that motivated the negotiations. With regard to patents, for example, on virtually every issue – e.g. the scope of patentability, the length of patent terms, the provisions for regulating and revoking patents – the developed countries prevailed.¹⁰ The agreement extends patent protection into new areas that were left uncovered by many countries’ IPR regimes, requires uniform twenty-year patent terms, and greatly restricts states’ ability to compel regulate patent-holders and thereby compel licensing. One area where the developing countries did attain a significant concession regarded transition periods for implementation: while all countries were required to introduce national treatment and non-discrimination immediately into their existing IPR laws, developing countries had until January 2000 to bring their IPR regimes into full conformity with the WTO, and the least developed countries were given until 2006.¹¹

One of the most important changes introduced by TRIPS was to include pharmaceutical products among the range of industrial and commercial products that could be patented. Article 27.1 stipulates that “patents shall be available and patent rights enjoyable without discrimination as to [1]

⁹The author was a negotiator from Canada. Ryan (1998: 108) shows how unilateral pressures were used as a mechanism to ensure developing countries’ acquiescence to multilateral negotiations.

¹⁰Though this paper addresses only patents, it should be emphasized that in addition to patents TRIPS also establishes minimum standards for IPR protection and enforcement in the areas of copyrights, trademarks, geographical indications, industrial designs, and integrated circuits.

¹¹Article 66.1 gives the least developed countries the right to request a ten-year extension of the transition period.

the place of invention, [2] *the field of technology* and [3] whether products are imported or locally produced” (emphasis and numeration added).¹² By integrating IPR governance into the WTO and by barring sector-based discrimination in granting of patents, TRIPS not only compels countries to raise their IPR regimes, in general, but ultimately it also eliminates countries’ ability to treat pharmaceutical products differently.

To understand the significance of this change, it is important to recall that most developing countries did not grant patents to medicines (nor did most wealthier countries at earlier stages of development). According to the World Health Organization (WHO 2002: 15), prior to TRIPS more than forty countries did not provide any patent protection for pharmaceuticals, while many that did so issued patents only for processes and not for products. And where pharmaceutical patents were granted, for products and/or processes, patent terms tended to be for significantly less than the uniform 20-year minimum stipulated by TRIPS. Given the magnitude of the change and sensitivity of the issue, Article 65.4 allows countries that did not previously grant patents to pharmaceuticals prior to the introduction of TRIPS in 1995 to delay patentability until 2005. Yet few countries took full advantage of this exception.¹³

Notwithstanding the asymmetries of the agreement, developing countries accepted TRIPS as the price of multilateralism. The U.S.’ insistence that the Uruguay Round be an all or nothing affair – a “single undertaking” – meant that developing countries could not approve the Final Act, with its

¹²The first condition conforms to the GATT/WTO norm of country-based non-discrimination. The second condition operationalizes non-discrimination in a new way. The third condition addresses a long-standing debate in the international politics of IPR governance over the meaning of “working” a patent. I discuss the broader implications of this in the concluding section of the paper.

¹³Argentina, Brazil, and Turkey, for example, did not grant patents to pharmaceuticals as of 1995 but were doing so by 2000. In fact, by 2000 even most of the least developed countries, which had until 2006, had made pharmaceuticals patentable. Among the countries that continued using the extra transition period granted by Article 65.4 are Cuba, Egypt, India, Kuwait, Madagascar, Pakistan, Paraguay, Tunisia, the United Arab Emirates, and Uruguay (WTO 2001b). Even if not granting patents on pharmaceutical goods, however, TRIPS required WTO members to establish a “mailbox” system, by which they accept patent applications and grant exclusive marketing rights. Failure to implement such a system was the subject of the WTO case that the United States brought against India (and won) in 1997.

promises of increased access to the U.S. and European markets, the final elimination of the onerous Multi-Fiber Arrangement (MFA), and, critically, a global trading system regulated by the rules-based World Trade Organization, without also accepting TRIPS. It is also worth noting that integrating IPRs into a multilateral forum at least introduced the possibility of a move from status quo reciprocity, in which developing change their IPR policies in exchange for status quo, to real reciprocity, in policy change in IPRs is exchanged for substantive concessions in other issue-areas, such as increased market access (Subramanian 1990). The ultimate post-Uruguay Round problem for developing countries was not just that the expected substantive concessions were not forthcoming, but that the stability and predictability to be produced by a multilateral agreement did not materialize either.

Beyond the Uruguay Round: Accelerated Implementation and TRIPS Plus

In the aftermath of the Uruguay Round, developing countries faced considerable external pressure to conform rapidly to TRIPS. The U.S. policy was to push for *accelerated* implementation, discouraging countries from taking advantage of the transition periods allowed under TRIPS and holding many to higher standards than established in the Uruguay Round. As indicated, TRIPS establishes minimum standards for patent regimes. Countries may of course introduce higher standards (e.g. reducing exceptions to patentability, extending patent terms beyond twenty years) as they wish, and they may meet their obligations in full prior to end of their transition periods – but they have no WTO-based obligations to do so.

The U.S. push for accelerated implementation is illustrated by considering the treatment of developing countries in the USTR's annual Special 301 Reports on IPR enforcement. Throughout the 1990s developing countries were routinely placed on the Watch List and Priority Watch List for what the U.S. regarded as insufficient protection of intellectual property. For the U.S., the Special 301

annual review became a key mechanism to pressure countries. It was, in the words of Trade Representative Charlene Barshefsky, “much more than an in-depth review. It provides a direct route to press countries to improve their IPR practices” (USTR 1997).¹⁴ As Table 3 indicates, in the seven years after the WTO entered into effect, more than half of the countries subject to this pressure were developing countries. And developing countries accounted for nearly two-thirds of the countries identified on the Priority Watch List.

-- Insert Table 2 --

The USTR listed many countries for failing to implement their TRIPS obligations, including both developed and developing countries. Because January 2000 was the deadline for *full* compliance and developing countries had some immediate obligations, it was possible for a country to be out of compliance prior to the end of the transition period. Indeed, where the USTR adjudged other WTO Members – developed or developing – to be in violation of TRIPS, the U.S. typically pressed its case in the WTO. By 2001 the U.S. had initiated fifteen IPR-related cases with the WTO’s dispute settlement boards, including cases against developing countries such as Argentina, Brazil, and India.¹⁵

As problematic as the potential to be punished for not adequately implementing TRIPS was that developing countries found themselves under threat even when in compliance with the Uruguay Round’s IPR obligations. Indeed, the Uruguay Round Agreement Act of 1994 had amended U.S. trade statutes to ensure that countries in compliance with TRIPS could still be targeted under Special 301. Subsequently, the USTR consistently emphasized that ensuring full and rapid compliance with TRIPS – not just by the end of the transition periods granted stipulated by TRIPS but *before* such

¹⁴As part of the Special 301 process, the U.S. also used visible and publicized “out-of-cycle reviews.” These special reviews, which saw increased use beginning in 1995 (just as WTO Members’ Uruguay Round commitments were entering into effect), subject countries’ IPR regimes to focused, intensive scrutiny.

periods ended – was one of its highest priorities in the area of intellectual property rights. In April 1995, for example, three months after the WTO’s birth, the USTR stated that “the United States has now fully implemented its TRIPS obligations, in many instances in advance of the required implementation date of January 1, 1996. We look to other countries to do the same. We will continue to press all WTO member-countries to implement their TRIPS obligations in the shortest possible time” (USTR 1995). And the Fact Sheet accompanying the USTR’s 1996 Special 301 report underscores U.S.’ commitment “to encourage other countries to accelerate implementation of the WTO TRIPS agreement and move to even higher levels of IPR protection” (USTR 1996).

The use of the Special 301 process to push for accelerated TRIPS Plus is made evident by a careful reading of the annual reports. Many of the developing countries targeted by the USTR were in compliance with TRIPS: they had implemented the necessary immediate measures required, and in many cases they had fully implemented new legislation along with administrative and judicial practices, making their IPR regimes fully TRIPS-consistent in advance of the 2000 deadline. But the U.S. sought full and accelerated implementation, and in many instances the U.S. also sought IPR reform that went beyond what was required by TRIPS. To that end the U.S. singled out countries that were in compliance with TRIPS, but in taking advantage of the agreement’s flexibilities had introduced IPR regimes that did not meet U.S.’s higher standards for intellectual property protection. Thus, developing countries often found themselves subject to penalties not just for violating TRIPS, or for being too slow in making their IPR regimes TRIPS-compliant, but rather for using the flexibility that TRIPS formally preserves – for not adapting “TRIPS Plus” regimes. For developing countries, then, the problem was not TRIPS itself, but the weakness and seeming irrelevance of TRIPS.

¹⁵In fact, as part of the push for full compliance, the US sought a revision that would make it easier use the WTO’s dispute settlement mechanism to challenge countries for inadequate enforcement. “Status Report Shows Deep Divisions on Agenda for New WTO Round,” *Inside US Trade*, Vol. 19, No. 30, July 27, 2001.

It is worthwhile to contrast, briefly, developing and developed countries' abilities to pursue extra-institutional strategies to secure their implementation goals with regard to Uruguay Round commitments in IPRs and apparel. The Uruguay Round replaced the MFA with an Agreement on Textiles and Clothing (ATC), which was to phase out the quota regime over a ten-year period, ending in 2005. Like TRIPS, the ATC has built-in transition periods; and the schedule for quota reduction allows products accounting for up to 49 percent of the value of 1990 imports into developed country markets to remain subject to quota restrictions until the end of December 2004. The developed countries took full advantage of the transition periods in ATC, reserving the most significant quota reductions until just before the 2005 deadline.

Of course, delayed implementation of ATC obligations on the part of the developed countries is similar to developing countries taking advantage of the various transition periods in TRIPS. In both instances, Members are taking advantage of the WTO's flexibilities and are WTO compliant; neither the developed countries' dragging their feet on opening their markets to developing countries' textile products nor the developing countries' moving slowly in protecting developed countries' intellectual property are subject to legal challenges within the WTO. As we have seen, however, the U.S. (and EU) used their power outside the WTO to push for accelerated implementation of TRIPS obligations and adoption of TRIPS Plus standards. Developing countries lack this recourse. To be sure, the developing countries would stand to benefit from accelerated implementation of ATC obligations, and they would benefit from the removal of other restrictions to market access that go beyond what the ATC requires – they would, in short, like “ATC Plus.” Yet the developing countries are powerless to pressure the developed countries in this way. Indeed, developing countries have used the WTO's dispute settlement mechanism to challenge countries that violate the rules established in the Uruguay Round, but they lack the resources to pressure countries into going beyond such obligations. Lacking the ability to pursue their own extra-institutional

strategies, and with limited capacity to change the substance of the agreements, developing countries sought to clarify the procedural dimensions of TRIPS. In doing so, the developing countries strengthened international governance in IPRs.

Disease, Drugs, and Extra-Institutional Vulnerability

Throughout the latter half of the 1990s, developing countries struggled to meet their new obligations under TRIPS while addressing overwhelming problems of deprivation, disease, and poverty. This section uses the case of patents and responses to the HIV/AIDS epidemic to analyze the problems that extra-institutional vulnerability presents to developing countries.

Treatment of people suffering from AIDS is possible, as made evident by the successful containment of the epidemic in developed countries. Modern drugs, particularly anti-retrovirals (ARVs), make treatment possible and reduce the spread of the disease. To be sure, not even the most sophisticated drug regimens can cure patients with AIDS, but treatment can prolong lives and, critically, reduce transmission. In contrast to the situation in most OECD countries, however, the AIDS epidemic in the developing world is anything but contained. According to UNAIDS (2002a), the number of adults and children living with HIV/AIDS increased from 37 million in 2001 to 42 million in 2002, suggesting not just high levels of prevalence but alarming rates of incidence. Each day, approximately 8,000 people in the developing world die from HIV/AIDS.¹⁶ Nor has the epidemic reached a plateau, as UNAIDS (2002b) predicts that the epidemic may kill up to 68 million people by 2020 if not dealt with effectively.

Not only is HIV infection on the rise in the developing world, but treatment is a rarity. UNAIDS (2002a: 4) reports estimates that less than four percent of the people in need of ARV

¹⁶Of the estimated 3.1 million people deaths due to HIV/AIDS in 2002, 2.4 million (77 percent) were in Sub-Saharan Africa.

treatment in the developing world were receiving treatment.¹⁷ The low level of treatment, in turn, seriously affects the spread of the disease. To the extent that treatment is an incentive for individuals to be tested, the absence of treatment possibilities may reduce the incentive for individuals who are HIV positive – but not yet showing the symptoms of AIDS and thus perhaps unaware of their condition – to be tested. From a public health perspective, then, minimal treatment can undermine prevention campaigns.¹⁸

The challenge of tackling the AIDS epidemic in the developing world is overwhelming indeed. Drugs are expensive, and the delivery of the complex ARV regimens requires that drugs be complemented by sophisticated healthcare systems. Treatment requires proper equipment and facilities for testing and counseling, adequately trained medical professionals (doctors, nurses, and lab technicians), social workers to work with patients (and their families) who are undergoing the difficult treatments, and well-equipped hospitals for medical emergencies. Yet treatment is possible, even in resource-poor settings in the developing world (Rosenberg 2001; Berwick 2002).

The cornerstone to treatment is that the medicines be affordable. In Brazil, for example, the treatment regime is based on twelve medicines, of which eight are not under patent because they were on the market before April 1997, when new IPR legislation entered into effect. Thirty-six percent of the money that the Health Ministry spent on AIDS drugs in 2000 went to purchase two of the patented drugs.¹⁹

Drug prices, of course, are far from being the only relevant issue. Given the complexity of treatment (the ARV regimen and the necessary testing and monitoring), even if drugs were free many countries would still lack the necessary healthcare infrastructure to provide treatment. Yet drug

¹⁷Brazilian patients alone account for half of those receiving treatment.

¹⁸It is also worth noting that for the same reasons low levels of treatment greatly complicates the task of estimating disease prevalence.

¹⁹“Brazil highlights Aids debate,” *FT.com*, June 24,2001 (accessed June 25, 2001). See also, Rosenberg (2001); CIPR (2002: 43).

prices unquestionably play a critical role, for drugs are the key input into any treatment process. Indeed, for public health ministries operating with scarce resources, the high price of drugs can serve as a disincentive to invest in the development of valuable healthcare infrastructure for delivering treatment. When drugs are affordable, in contrast, improving healthcare infrastructure may appear as a more worthwhile task. Thus, lower drug prices create incentives (and free resources) to build necessary infrastructure (Berwick 2002: 214; Abbott 2001; Schwarzlander *et al.* 2001). In sum, the high price of ARVs limits the feasibility of treating AIDS patients – and thus controlling spread of the disease – for poorer countries with limited resources.²⁰

Moreover – and this is the critical point – what matters is not simply the affordability of essential drugs but the reliability of the supply of affordable drugs. That is, to encourage health planning and investment in health care infrastructure, officials need to know that the source of affordable drugs is reliable, that the essential drugs are not simply available today but that they will also be available, at affordable prices, in the future. The importance of this point cannot be understated. To meet the challenges of the HIV/AIDS epidemic, significant resources need to be invested in healthcare infrastructure, but the incentives to invest in infrastructure are reduced without reliable access to affordable medicines. These are long-term investments that require substantial resource mobilization. The decision to build new hospitals and special treatment facilities, the decision to purchase treatment equipment, the decision to train staff, all these are costly and imply costs over long time horizons. Developing countries need to know that there will be a payoff for their investments – that the critical inputs at the center of healthcare will remain affordable.

²⁰Once it is determined that drug prices do indeed matter, a related debate regards the effect of patents on drug prices. By design patents allow producers to keep prices high, though Attaran and Gillespie-White (2001) have argued that in sub-Saharan Africa few of the relevant drugs for AIDS treatment are actually under patent. For three letters critical of this study, and a reply by the authors, see the correspondence, “Do Patents Prevent Access to Drugs for HIV in Developing Countries?” *JAMA*, Vol. 287 No. 7, February 20, 2002. See also Consumer Project on Technology (2001). UNAIDS/WHO (2000) also provides data on pharmaceutical patents in 80 countries. In any case, the concern that patents affect prices and treatment, rightly or wrongly, motivates developing country behavior in the WTO.

The question, then, is how developing countries may secure a steady stream of drugs at affordable prices. Though patented ARVs are prohibitively expensive, producers of generic ARVs can make the drugs available at a fraction of the price. For example, while the market cost in some countries for an ARV regimen using patented drugs can exceed US\$10,000 per patient per year, generic producers can provide bioequivalent treatments for less than \$400 per patient. Importantly, the threat of local production or importation of generic versions of patented ARVs can induce patent holders to lower prices or license production and distribution rights to local entities.

A key tool for inducing such price-reducing behavior on the part of patent-holding pharmaceutical companies is the compulsory license, by which the host government, without the consent of the patentee, allows a local entity (a private firm and/or government agency) to produce and distribute a good under patent. To be sure, the entry of generic drugs is not the only means to lower prices. Many countries have obtained substantial price cuts directly from patent-holding pharmaceutical companies. However, the threat of generic competition serves as a bargaining tool for obtaining price reductions on patented drugs. Compulsory licenses, in short, are measures – historically part and parcel of most countries’ domestic IPR legislation – to increase competition, ensure affordability, and check against patent abuse (Correa 2000; Reichman 2002).²¹ Moreover, while tiered pricing schemes of brand-name pharmaceutical companies leave control over supply in the hands of the drug-donating firms, compulsory licensing is an instrument that states can use to secure reliable access to essential medicines.

²¹In 2001, following concern of anthrax attacks, the United States used a threat of compulsory license to induce Bayer to reduce the price of Cipro to the Department of Health and Human Services.

Despite the extent of public health crises in the developing world and the high price of drugs, no developing country has issued a compulsory license on a pharmaceutical product.²² Moreover, few countries have even threatened to do so. An exception to this broad trend, which affirms the importance of the ability to issue compulsory licenses, is found in the case of Brazil. In August 2001 Brazil announced its intention to issue a compulsory license on an AIDS drug to which the patent was held by Swiss pharmaceutical giant Roche. When Roche responded to the threat by reducing the price of the drug, no license was issued. Importantly, as all parties involved recognize, Brazil's actions were entirely acceptable under TRIPS.²³

Why, then, have developing countries been so reticent to take advantage of TRIPS-acceptable tools to lower drug prices? One explanation is that TRIPS prohibits such actions. To be sure, TRIPS places conditions on countries' ability to issue compulsory licenses – conditions that are significantly more restrictive than pre-Uruguay Round rules.²⁴ But TRIPS does not proscribe such actions (Correa 2000; Scherer and Watal 2000; Abbott 2001; CIPR 2002; Maskus 2000; Tussie 1997).

A more likely explanation of developing countries' reluctance to act more aggressively to lower drug prices were the ambiguous conditions under which countries can avail themselves of TRIPS' flexibilities and fear of external pressure. Indeed, the sheer legal complexity of this relatively new issue can be overwhelming for officials working in poorly funded ministries in developing countries, and this complexity is exacerbated by the uncertainty as to what falls within and outside of

²²It is important to note that not all generic drugs are produced under compulsory licenses. Many generics are simply products that do not have patent protection, either because the name-brands' patents have expired or because no patent was ever attained in a given country. In the case of Brazil, for example, patents were not issued to pharmaceuticals prior to April 1997, and patentability was not made retroactive. In other countries, such as India, until 2005 only pharmaceutical processes, not products, may receive patent protection. In neither country is generic production based directly on compulsory licenses.

²³The U.S. had challenged Brazil's IPR regime in the WTO on a related issue, but the conflict, temporarily settled in 2001, was not reopened by these activities. I discuss the implications of the Brazilian case in the conclusion.

²⁴For example, TRIPS stipulates need for prior negotiations, requires that compulsory licenses be non-exclusive, and that the patent holder receive compensation.

TRIPS.²⁵ For example, Article 31 stipulated that countries could issue compulsory licenses in the case of national emergencies, but it did not make explicit reference to public health as a national emergency. This ambiguity meant that issuing a compulsory license on a patented drug, as part of a treatment campaign, could potentially make the issuing country subject of charges of violating TRIPS.²⁶ To be sure, public health organizations such as the WHO encouraged the use of TRIPS flexibilities (and the WHO has more recently discouraged countries from going beyond TRIPS).²⁷ Yet the relevance of the WHO's advice was not certain either, for not until July 2000 was the WHO granted "observer status" in the TRIPS Council, and the U.S. and representatives from the pharmaceutical industry criticized the WHO for advocating such behavior (Scherer 2000: 2252, note 14). Not surprisingly, one point of concern among many developing countries was to clarify – within TRIPS – the conditions for issuing compulsory licenses by classifying the continuous crisis of AIDS and disease as national emergencies, in the same status as war or natural disaster.²⁸

External pressures also discouraged developing countries from taking TRIPS-acceptable measures. Again, the external pressures are not from the WTO itself. Developing countries' reticence to take necessary and available measures to increase accessibility to drugs was not because of TRIPS but fear of sanctions outside of TRIPS. Many of the countries included on the USTR's Special 301 lists, for example, were there because of the provisions in their IPR legislation regarding compulsory licenses. And because the U.S. and the major pharmaceutical companies expressed disapproval of the use of flexibilities (see Scherer 2000), countries that took advantage of TRIPS' loopholes feared

²⁵Comments of Francisco Cannabrava, Brazilian delegate to TRIPS Council, at the meeting of the Commission on Intellectual Property Rights, "How Intellectual Property Rights Could Work Better for Developing Countries and Poor People," Session 6: Medicines and Vaccines, 22 February 2002.

²⁶This ambiguity and uncertainty was evident, for example, at the July 2000 International AIDS Conference in Durban, where a prominent issue was determining just what precisely the rules were under TRIPS for issuing compulsory licenses. See *Bridges Weekly Trade News Digest*, Vol. 4, No. 28, 18 July 2000.

²⁷See WHO (1998) and WHO (2002).

²⁸See minutes from the TRIPS Council's "Special Discussion on Intellectual Property Rights and Access to Medicines," June 20, 2001, IP/C/M/31.

retaliation. In fact, in some cases where pharmaceutical companies do not even have a local patent, countries still do not import generically produced versions of essential drugs. As indicated, even when compliant with TRIPS, developing countries were frequently placed on the Section 301 Watch List and Priority Watch Lists, they risked losing authorization for borrowing from the IMF or World Bank, and they could have their GSP benefits reduced or suspended.²⁹

The most prominent case of a country being subject to this sort of extra-institutional pressure involves South Africa. The 1997 Medicines Act included provisions for importing generic versions of drugs under patent in South Africa. Although the Act was TRIPS-compliant, the U.S. maintained that the discretion granted to the Health Ministry to issue compulsory licenses was too broad. Seeking to get the South African government to modify the 1997 Act, the U.S. imposed diplomatic pressure, threatened economic sanctions, and lent support to a legal challenge made by a group of multinational pharmaceutical firms.³⁰

Vulnerability to external pressures prompted developing countries to seek reforms that might secure real, and not just formal, flexibility. As we shall see, developing countries used the TRIPS Council in 2001 to strengthen the procedural aspects of the agreement and thus secure political space to take advantage of their rights under the agreement.

To best understand the developing countries' strategy it is important to highlight the inconsistencies in U.S. approach towards intellectual property enforcement. Officially, the U.S. abandoned the high-pressured strategy to secure TRIPS Plus in 2000. According to a May 2000 Executive Order, continued by a similar Executive Order by the Bush Administration in February 2001, so long as countries remain compliant with TRIPS the U.S. promised not to punish them for

²⁹A non-exhaustive list of countries for which the U.S. explicitly linked GSP benefits to intellectual property protection includes Argentina, Costa Rica, Dominican Republic, Honduras, and Turkey.

taking advantage of TRIPS flexibilities in the case of health crises.³¹ Subsequently, the U.S. maintained that “individual countries should have the ability to take measures to address the HIV/AIDS epidemic, provided that such measures are consistent with their international obligations” (section 2.b.9). Yet the U.S. position is tightly limited, with regard to which countries it applies to and which sorts of action would be exempt from U.S. reprisals. For example, the Executive Orders refer specifically to HIV/AIDS in Sub-Saharan Africa, leading many to believe that the new policy may not apply to non-African countries (or African countries taking advantage of TRIPS flexibilities for diseases other than HIV/AIDS). Moreover, while the pronouncement marks an official downgrading of policy from TRIPS Plus to TRIPS, it was insufficient to provide the stability and predictability that might be delivered by multilateral institutions. For example, the U.S. retained the right to monitor, evaluate, and determine if countries have health crises (USTR would consult with Health and Human Services, not WHO) and whether their actions are TRIPS compliant (section 3.b). Thus, many developing countries remained concerned that temporary U.S. benevolence alone would still not deliver the secure flexibility they seek.

The developing countries’ concerns were buttressed by the continued U.S. position for TRIPS Plus in bilateral and multilateral forums. The IPR section of NAFTA (Chapter 17), for example, exceeds the minimal standards of TRIPS.³² And patent protection in the bilateral trade agreements the U.S. negotiated with Chile and Jordan (along with a series of bilateral investment

³⁰South Africa was included on the Special 301 Watch List in 1998 and 1999, and South Africa’s GSP privileges were suspended. The case by the pharmaceutical firms was dropped in April 2001, after first being suspended by South Africa’s Supreme Court. For a strong criticism of U.S. policy in this affair, see Weissman (1999).

³¹Executive Order 13155, “Access to HIV/AIDS pharmaceuticals and medical technologies,” 65 Federal Register, 30521 (2000).

³²See Ryan (1998: 119-124) for an overview of NAFTA’s IPR provisions.

treaties) is modeled on NAFTA's Chapter 17, not the WTO's TRIPS – as is the U.S. position in negotiations for the hemispheric “Free Trade Agreement of the Americas” (FTAA).³³

Faced with contradictory signals – pronouncements that the U.S.' TRIPS Plus agenda was suspended at the same time that the pharmaceutical industry and U.S. negotiators pushed for TRIPS Plus – developing countries attempted to institutionalize their flexibilities in a multilateral forum. They sought assurances that they could use the TRIPS flexibilities for public health purposes without having to worry about reprisals – private or public, bilateral or multilateral.

To summarize, the key contentions of this section are threefold. First, I argue that countries' laws and regulations on intellectual property affect their ability to secure reliable access to affordable drugs, and that the absence of such reliable access serves as a disincentive to invest scarce resources in healthcare infrastructure. Second, I argue that uncertainty around the legality of compulsory licenses, the external pressures to write legislation in such a way as to minimize states' ability to pressure patent holders (i.e. to implement “TRIPS Plus” regimes), and fear of external reprisals contributed to developing countries' hesitation and reticence to take advantage of their rights under TRIPS. Third, I argue that these same factors, in turn, motivated developing countries' to clarify and strengthen the procedural dimensions of TRIPS. That is, they embarked on a campaign to strengthen the WTO and thereby protect their ability to secure reliable access to affordable drugs.

Before proceeding to discussion of the campaign itself, it is important to note the other factors explaining developing countries' generally slow response to the HIV/AIDS epidemic, and the relationship of these factors to procedural-institutional uncertainty. Other factors contributing to policy in this area include simple lack of concern on the part of political leaders, because AIDS sufferers tend to be politically weak and thus easily neglected, and lack of technical capacity, because

³³Moreover, at the same time as the U.S. had officially revised its TRIPS Plus strategy, the pharmaceutical industry continued to push for TRIPS-compliant countries to be targeted by the USTR, and the Special 301 lists of 2000 and 2001 still targeted such countries for not providing *enough* intellectual property protection.

issuing compulsory licenses is administratively complex and costly, as patent holders are likely to challenge the ruling in the courts. To a considerable degree these factors can be thought of as derivatives of the uncertainty and weakness of TRIPS and the fear of external reprisals, the factors considered above. Degree of concern on the part of governments needs to be considered in the context of cost – even governments likely to be concerned with HIV/AIDS may feel compelled to downplay the issue if treatment remains unfeasible due to high drug prices, and even governments unconcerned may be more easily swayed once treatment becomes feasible. Likewise, the complexity and costliness of issuing compulsory licenses is directly related to their legal status, which is affected obviously by TRIPS. In Brazil, for example, the president of Merck's local subsidiary argued that his company would appeal any attempt to declare AIDS as a health emergency.³⁴ The practicality of such an appeal, of course, is a function of the ambiguous phrasing of Brazil's IPR legislation; yet the ambiguity of the legislation, written to comply with TRIPS, is driven in large part by the uncertainty as to what is acceptable under TRIPS. The following section examines the developing countries' efforts to strengthen the procedural aspects of TRIPS, and thereby reduce this uncertainty.

Strengthening Governance from Below

The strategy to strengthen TRIPS reached a peak in 2001, with a joint WHO/WTO conference on affordable medicines, two Special Sessions of the TRIPS Council dedicated to the same topic, and the WTO's Ministerial Meeting in Doha, Qatar. A coalition of more than fifty developing countries, led by the Africa group, sought to ensure that their WTO obligations would not undermine public health campaigns. They sought clear signals that they could proceed with strategies to secure access to affordable medicine – signals that were lacking in the post-Uruguay Round environment. To that

³⁴“Brazil highlights Aids debate,” *FT.com*, June 24, 2001 (accessed June 25, 2001).

end, they called for a Ministerial Statement that would clarify TRIPS and, subsequently, protect their right to use TRIPS-acceptable flexibilities from external pressures.³⁵

Throughout the 2001 period the developed countries' position was primarily defensive, seeking to ensure that the substance of TRIPS would not be changed.³⁶ The U.S., in particular, maintained that developing countries' concerns about medicines did not need to be revisited at the Ministerial level, and expressed concern that any solution to the problem of healthcare in the developing world should not reduce states' IPR obligations established during the Uruguay Round.³⁷ Furthermore, the developed-country delegates emphasized that access to medicines was but a single dimension of health policy. The USTR, for example, asserted that countries were inappropriately blaming TRIPS for a crisis with many causes.³⁸ Developed-country delegates, and the WTO Secretariat, repeatedly pointed to a controversial study published in a prominent American medical journal that questions the extent to which patents constitute an obstacle to the delivery of essential medicines for the treatment of AIDS (Attaran and Gillespie-White 2001).³⁹

In a literal sense, the developing countries agreed with elements of the status quo position articulated by the developed countries, that TRIPS provided sufficient flexibility for countries to address public health crises. The problem, according to the developing countries, was not TRIPS but

³⁵The formal proposal for a declaration was made by the Africa Group in alliance with Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, Venezuela. A number of other developing countries articulated similar positions in the WTO Council without formally endorsing the Africa Group's proposal.

³⁶The "developed country" position was articulated most clearly by members of the Quad Group (Canada, EC, Japan, and U.S.), along with Australia, New Zealand, and Switzerland.

³⁷This is consistent with the U.S. position articulated in the Executive Orders discussed above. Throughout the discussions, the U.S. asserted that countries' strategies to address public health concerns must be designed within the parameters established by TRIPS.

³⁸Developing countries, according to the USTR, seek "to justify use of protectionist measures by associating these measures with the AIDs crisis when no such linkage exists" (USTR 2001a: 5).

³⁹Though not published until October 2001, a draft of this article and its conclusions had been widely circulated and debated in the months prior to its publication. For the debate that this report inspired, see earlier note.

rather their being inhibited from using the rights granted under TRIPS on account of the agreement's ambiguities and threats of external sanctions. Thus, where the developing countries departed from the status quo position was in maintaining that international action was necessary to clarify developing countries' rights to issue compulsory licenses and to import generic drugs so to secure access to affordable medicines. Consider, for example, the remarks of Thailand's delegate to the TRIPS Council's June 2001 Special Discussion on Intellectual Property and Access to Medicines (IP/C/M/31):

We are all aware that TRIPS provides built-in flexibilities regarding measures WTO Members can take to obtain medicines, both patented and non patented, from the best and cheapest sources, both foreign and local. However, due to lack of clarity of certain provisions of the Agreement, developing countries seem to be reluctant to take measures that they are entitled to under the Agreement. This is very unfortunate, because one of the purposes of the Agreement was to establish an international benchmark for intellectual property protection and to prevent unilateral pressure, as stated in the Preamble.

To best understand the developing countries' strategy of strengthening the procedures – as opposed to weakening the substance – of TRIPS, it helps to distinguish their position not just from the developed countries, but also from the network of non-governmental organizations (NGOs) that provided active support for the developing countries. Since the late 1990s a network of non-governmental organizations (NGOs) has become increasingly active in their criticisms of TRIPS, drawing particular attention to the implications of stronger patent protection for the treatment of HIV/AIDS.⁴⁰ Both the developing countries and the NGOs express alarm at the crises of disease and the high price of medicines; and both actors attribute the high price of medicines, in part, to patents and IPRs. Yet while NGOs regard TRIPS specifically as the problem, and many advocate a rollback or elimination of TRIPS as the solution, the developing countries have articulated a position that identifies a strengthened and clarified TRIPS as the solution. That is, the developing countries did not

⁴⁰These groups include, among others, Médecins Sans Frontières (MSF), Oxfam, Consumer Project on Technology, Health Gap, Health Action International, and Act-up. See Sell and Prakash (2002). For analysis of similar patterns of NGO activism on behalf of developing countries in international fora, see Callaghy's (2001) analysis of the global movement for debt relief.

attack TRIPS for inhibiting them from acting; they did not argue that IPRs were antithetical to public health campaigns. Rather, the developing countries maintained that they need the ability to interpret and implement TRIPS obligations without fear of litigation and sanctions.

To be sure, many developing countries may wish to reduce their international obligations for patent protection (and copyrights and trademarks), but doing so is not feasible given the international political realities and constraints they face. Substantially revising (or eliminating) the Uruguay Round's agreement on IPRs is not a demand that developing countries articulated in the TRIPS Council and the WTO. Their strategy consisted of a more modest effort to protect the space to utilize the flexibilities granted by TRIPS.

At the Doha Ministerial, the developing countries succeeded in strengthening TRIPS by obtaining a statement that clarified countries' rights to override patents for public health purposes. The WTO's Fourth Ministerial Meeting produced the "Doha Declaration on the TRIPS Agreement and Public Health."⁴¹ The Doha Declaration was brief – a seven-section statement intended to clarify Members' obligations and rights under TRIPS. The fourth section, which noted that TRIPS "does not and should not prevent Members from taking measures to protect public health," includes as a separate paragraph the critical affirmation of developing countries' rights "to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose." The Declaration also clarifies countries' rights under Article 31 to issue compulsory licenses for the promotion of public health and, importantly, the right to make their own determinations as to what constitutes national

⁴¹WT/MIN(01)/DEC/W/2, 14 November 2001, hereafter referred to as the "Doha Declaration." The Ministerial also produced a declaration that addressed issues of implementation, and a declaration establishing a tentative agenda for a new round of negotiations to be launched officially at the November 2003 Ministerial Meeting in Cancún, Mexico.

emergencies (including AIDS and other diseases).⁴² Finally, the seventh paragraph extends by ten years, until 2016, the deadline for the least developed countries to become TRIPS compliant.⁴³

Assessing the Doha Declaration

One interpretation of Doha, common in the press, was that the Declaration *weakened* TRIPS by authorizing developing countries to override pharmaceutical patents. For example, in an otherwise perceptive editorial on the eve of the November 2002 “mini-ministerial” in Sydney, the *Washington Post* wrote that the Doha Declaration “concluded, to the consternation of the pharmaceutical lobby, that developing countries should be able to buy cheap generic copies of patented medicines when battling health crises.”⁴⁴ Yet developing countries were already authorized to override pharmaceutical patents under certain conditions; it was not at Doha where it was determined that developing countries could purchase cheap generic drugs. That was determined at the Uruguay Round. Doha simply confirmed this.

The Doha Declaration clarified the conditions and confirmed the rights that the countries already had, but it did so in a way that also reaffirmed that TRIPS already had those flexibilities. Developing countries were not granted new and more flexible rights to issue compulsory licenses and import generic medicines. In fact, once it became clear in 2001 that there would be a ministerial declaration at Doha, the developed countries insisted on language ensuring that any clarification of the rules and strengthening of the procedures did not affect the substance of TRIPS. The Declaration

⁴²The Doha Declaration stipulates that “Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted;” and that “Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”

⁴³This change was officialized at the June 2002 meeting of the TRIPS Council (see http://www.wto.org/english/news_e/pres02_e/pr301_e.htm). To clarify, least developed countries already had the right to apply for extensions at the end of their transition periods, and they will still have that right in 2016.

⁴⁴“*Drugs for the Poor*,” *Washington Post*, November 14, 2002.

emphasizes that countries' commitments under TRIPS are maintained – it explicitly notes that the procedural clarifications need to be interpreted in the context of TRIPS broader objectives and principles, which stress the alleged link between intellectual property protection and innovation, investment, and growth.

It is worth repeating that the debate in the TRIPS Council, and the WTO more generally, was not over TRIPS itself, but the inability of developing countries to manage their IPR regimes according to TRIPS – to use TRIPS' flexibilities without fear of bilateral or multilateral sanctions. Thus, by explicitly establishing the rules and clarifying developing countries' rights, Doha did not weaken but rather strengthened TRIPS and global governance in IPRs. When representatives from the pharmaceutical industry declare that there is “nothing in [the Doha] declaration that undermines or diminishes the intellectual property rights that pharmaceutical companies have,” they are partially correct.⁴⁵ The Doha Declaration might remove the supplemental patent protection that TRIPS Plus gave pharmaceutical companies, but, for better or worse, it does not introduce changes to the formal protection that TRIPS promised to grant pharmaceutical companies (and patent owners more generally). Indeed, that the Doha Declaration left TRIPS unchanged, the point celebrated by the pharmaceutical industry, was also lamented by prominent activist organizations critical of the WTO who sought wholesale institutional change at the Doha Ministerial.⁴⁶

The argument in this paper, then, is that the Doha Declaration reaffirms multilateral rules on patents and public health, and thus protects developing countries from opportunistic behavior of developed countries that seek TRIPS Plus. To be sure, the Doha Declaration cannot directly constrain the developed countries. Because multilateral agreements must be self-regulated and self-enforced by

⁴⁵See the comments of Alan F. Holmer, president of the Pharmaceutical Research and Manufacturers of America (PhRMA), and Harvey Bale, director general of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), in “Drug Makers Now Say Doha TRIPs Pact Does Not Diminish Protection of IP Rights,” *International Trade Daily*, November 16, 2001.

the involved parties, nothing agreed upon at the WTO could guarantee that the U.S. will not continue to subject countries unilaterally to its own TRIPS Plus standards for intellectual property protection. In fact, the U.S. continues to push for IPR regimes that make compulsory licenses exceptional, potentially removing from governments' toolbox a critical instrument – sanctioned by TRIPS and affirmed at Doha – to promote competition and lower prices.⁴⁷ At the same time as the USTR was agreeing to the Doha Declaration, for example, the Bush Administration's bill for Trade Promotion Authority (formerly known as "fast track") declared that a principal negotiating objective of U.S. would be to minimize use of compulsory licenses and to demand accelerated compliance with TRIPS in any agreement negotiated by the U.S. Indeed, the final bill contained two contradictory provisions on IPRs – one calling for the USTR to push for accelerated implementation and TRIPS Plus, and one calling for the U.S. to respect the Doha Declaration.⁴⁸

Yet the Doha Declaration potentially raises the associated political costs of this sort of opportunistic behavior, for it makes it clear that when the U.S. (or other developed countries) act in this way that they, and not the developing countries, are violating the WTO. It promises to make it more obvious that if the U.S. pursues an aggressive TRIPS Plus agenda, it is undermining and violating its multilateral commitments. And while such violations may not be punished at the global level, the agreement provides leverage for domestic political actors who they can attempt to hold government officials to their multilateral obligations (Cortell and Davis 1996). Thus, even though strengthened multilateral institutions do not eliminate power disparities, they potentially offer

⁴⁶See, for example, Focus on the Global South "Revised Ministerial Draft Declaration: Still Harmful to Interests of Developing Countries," Press Release, November 13, 2001.

⁴⁷Provisions that restrict the use of compulsory licenses more tightly than TRIPS, along with increased regulations on data exclusivity to make the development of generic drugs more difficult, were included in the U.S.-Jordan Free Trade Agreement, concluded in 2001, and form part of the U.S. negotiating position in the U.S.-Chile FTA (See "U.S. Push for Patent Rules Meets Resistance from Chile in FTA Talks," *Inside U.S. Trade*, March 22, 2002). Such "TRIPS Plus" provisions are also included in the Bilateral Investment Treaties that the U.S. has signed with over forty developing and transition countries.

mechanisms to bound weaker countries' vulnerabilities. Furthermore, as a "political statement,"⁴⁹ it is also likely that the Doha Declaration will serve as a guide in WTO dispute panels, as there is a precedent for Dispute Settlement and Appellate Boards to use this sort of institutional declaration in such a way (see Abbott 2001: 32).

Although the developing countries succeeded in strengthening TRIPS via clarification, the Doha Declaration suffers from a profound and serious limitation that needs to be noted. The Declaration left unresolved an important issue regarding the exportation of generic drugs to developing countries. According to TRIPS, goods produced in one country under a compulsory license should be "predominantly" for domestic use (Article 31.f). Because few countries have the manufacturing capacity to produce ARVs or other sophisticated pharmaceuticals on their own, however, in order to secure a steady and reliable flow of low-priced drugs they need to be able to import generics from countries with capacity to take advantage of the TRIPS flexibilities and engage in such production.⁵⁰

To address this concern, in October 2001 the developing countries had proposed a reinterpretation of Article 30, on exceptions to patent rights, to include a limited exception for

⁴⁸An Oxfam report shows a post-Doha reduction in the the number of countries listed by the USTR in the 2002 Special 301 report for introducing WTO-compatible provisions in their IPR laws. See Oxfam (2002).

⁴⁹The legal status of the declaration was controversial at Doha, with the developed countries insisting on a limited declaration. A "hierarchy" of statements, in descending order of legal significance, would be an amendment, followed by an interpretation, followed by a declaration.

⁵⁰The handful of developing countries with such capacity includes Argentina, Brazil, China, India, Mexico, and Thailand. With the exception of China and India, these countries entered into full compliance with TRIPS as of 2000. China joined the WTO in December 2001, and the terms of accession stipulated full and immediate compliance with TRIPS. India, which took advantage of the exemption for pharmaceuticals and issues patents for pharmaceutical processes but not products, will be fully compliant as of January 2005. Mexico, as a member of NAFTA, has a TRIPS Plus IPR regime. A number of other developing countries have advanced biotechnological sectors and well-developed pharmaceutical industries (e.g. Cuba, Egypt, Indonesia), but it is unclear if they have sufficient innovative capacity to produce and export bioequivalent products. Of course, there are large generic industries in most OECD countries.

addressing public health emergencies.⁵¹ According to this proposal, a drug firm in one country would be able to supply a generic drug to a developing country unable to produce the drug locally. The exporting firm would be able to do so even if the drug is under patent in the exporting country. For example, a pharmaceutical firm in Brazil (or India) would be allowed to produce a drug to export to Senegal or Nicaragua, even if the firm in question was not the patent holder in Brazil (or India) – and they would be able to do so without the Brazilian (or Indian) government issuing a compulsory license. The Article 30 exception was not integrated into the Doha Declaration, due to opposition from the brand-name pharmaceutical industry and the developed countries. Instead, paragraph six of the Declaration simply acknowledged the problems faced by countries with limiting manufacturing capacity and instructed the TRIPS Council to resolve the issue and report back to the WTO's General Council by the end of 2002. The TRIPS Council has been unable to resolve the issue, however, with meetings throughout 2002 simply reflecting pre-Doha cleavages.⁵² It should be noted that an Article 30 solution, as proposed by the developing countries, could seriously undermine global patent protection in pharmaceuticals. Doing so would alter the substance of the Uruguay Round. Thus, the developing countries' comparative inability to make progress on resolving paragraph six of the Doha Declaration is not surprising.

Conclusion: Post-Doha Challenges and the Developmental Limitations of IPR Governance

The Uruguay Round's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) obligates all WTO members to introduce a set of minimum standards for intellectual property protection. Beyond those standards, TRIPS grants countries significant flexibilities with regard to issuing compulsory licenses. Nothing in TRIPS itself prevented the use of such measures to ensure

⁵¹See paragraph 9 of developing country proposal to TRIPS Council, WTO, IP/C/W/312, WT/GC/W/450, October 4, 2001.

⁵²*Bridges Weekly Trade News Digest*, Vol. 6, No. 41, November 29, 2002.

access to medicines and promote public health. Yet developing countries found themselves generally unable to use TRIPS. Thus, they sought to strengthen the regime to clarify and protect their rights.

This paper has identified the pre-Doha constraints on using TRIPS and how the Ministerial declaration promises to deliver the rules-based protection that weaker countries seek in multilateral institutions. I have argued that the Doha Declaration provides developing countries with limited political protection and thereby promises to make it easier for them to use the flexibilities in TRIPS. It did not weaken the substance of TRIPS or rebalance the obligations and rights established in the Uruguay Round, but, rather, it strengthened the agreement by clarifying the procedures.

To be sure, one might argue that having the developed countries affirm what was already written into TRIPS is hardly a victory. This assertion, though valid, requires us to recall the challenges of multilateralism discussed in the first section of the paper. Multilateral institutions promise to reduce uncertainty and increase predictability, but the price of multilateralism for developing countries is accepting rules written by more powerful actors. Developing countries paid a high price in the Uruguay Round, but were not receiving the goods they had purchased. The Doha Declaration promises to rectify this imbalance. It does not, however, rectify the larger power asymmetries that continue to be salient in international politics, more generally, and in the issue-area of IPRs. TRIPS may still be inappropriate for developing countries (see CIPR 2002), but the Doha Declaration does not offer relief from that.

In fact, the entire set of conflicts over IPRs and public health that occurred within the context of the WTO point to important limitations to developing countries' capacity to change international institutions. Developing countries, with the active support of a mobilized network of NGOs, did strengthen the procedures of TRIPS and thus secure limited political protection from developed country opportunism. But they have been less successful in securing a change to TRIPS that would facilitate the export of generic drugs produced under compulsory license from one developing

country to another. The reason for this is that this change (discussed above with reference to paragraph six of the Doha Declaration) potentially introduces changes to the substantive dimensions of TRIPS.

With regard to the relationship between TRIPS and public health in the developing world, the Doha Declaration should be regarded as providing both opportunities and challenges. Since it was not TRIPS itself that restricted countries' ability to promote public health, but rather extra-institutional pressures that discouraged developing countries from taking advantage of their rights under TRIPS, the Doha Declaration provides opportunities for action. The Doha Declaration may provide the essential stability and predictability for developing countries to increase the resources allocated to healthcare and treatment.

Indeed, in the aftermath of the Doha Declaration, a wide range of developing countries have significantly intensified their treatment campaigns. In many cases the treatment programs are based on the use of generic medicines, domestic and foreign. In other cases the treatment programs are based on brand-name drugs, made available at reduced prices by the patent holding pharmaceutical firms. Yet even in the latter cases, the willingness of the pharmaceutical firms to offer lower prices needs to be considered as a function of developing countries' right to threaten to issue compulsory licenses, a right they always had but that was clarified and affirmed by the Doha Declaration.⁵³

Even in countries prepared to take advantage of the rights affirmed by the Doha Declaration, doing so still presents complex challenges. Many countries already drafted TRIPS Plus legislation, which they may find changing to be politically difficult; and many lack the legal and technical capacity to draft new IPR legislation that is TRIPS consistent and that takes advantage of the public health flexibilities confirmed at Doha. Moreover, issuing compulsory licenses involves expensive

⁵³For a review of developing country responses, see <http://www.unaids.org/nationalresponse>.

and complicated proceedings. Doing so will pit well-financed legal teams representing multinational pharmaceutical firms against governments with limited resources.

Doha, thus, presents opportunities and challenges, and the opportunities and challenges are just domestic but also international. Increased technical assistance, from the WTO, WHO, and WIPO, is essential. It is important to keep in mind that the WTO itself has a very small budget. In December 2001, the WTO's General Council approved an enlarged budget that established a "Doha Development Agenda Global Trust Fund" to provide increased technical assistance. This gave the WTO its largest budget ever, potentially increasing its capacity to meet Doha commitments.⁵⁴ Yet in 2002 considerable debate emerged with regard to whether "technical assistance" resources should be allocated to help developing countries with their implementation challenges or, as proposed by the developed countries, simply to assist in the negotiation process.⁵⁵

Most critically, even if countries find the international environment permissive of compulsory licenses, and even if countries have the technical capacity, legal instruments, and political interest in issuing compulsory licenses (or threatening to issue compulsory licenses) and thus secure reliable access to affordable drugs, the battle against HIV/AIDS in the developing world will have only just begun. Limited resources will still restrict governments' capacities to treat HIV/AIDS (and other diseases). Indeed, even at US\$1/day per patient, the lowest prices that generic ARVs are available, many developing countries will be unable to afford adequate treatment programs. Thus, more resources are essential.⁵⁶ Without large contributions to the Global Fund for Aids, Tuberculosis, and Malaria (GFATM), for example, most countries will not be able to take

⁵⁴*Bridges*, Vol. 5, No. 42, December 12, 2001.

⁵⁵*Bridges*, Vol. 6, No. 13, April 9, 2002

⁵⁶See *Macroeconomics and Health: Investing in Health for Economic Development*, Report of the Commission of Macroeconomics and Health ("Sachs Commission"), presented to the WHO, December 2001. Schwartlander *et al.* (2001)

advantage of the rights affirmed at Doha.⁵⁷ Unfortunately, donor countries have been slow in rising to the challenge: the first round of contributions to the GFATM were significantly less than necessary, allocations during 2002 were significantly less than either public health experts deem necessary or countries and treatment organizations have requested.⁵⁸

To conclude, any assessment of what happened at Doha (the clarification of developing countries' TRIPS-consistent options) needs to be considered in light of what did not happen at Doha. Whereas the Declaration creates opportunities to lower pharmaceutical prices and make drugs more affordable, it offers limited help for other health-related products (e.g. patented testing equipment and diagnostic tests). Nor does the Doha Declaration address a whole range of more classically development-related IPR issues related to technology transfer.⁵⁹ Traditionally, the key themes underscoring debates between developing and developed countries over IPRs were technological and industrial transformation (see Sell 1998). At Doha and within the TRIPS Council, however, the developing countries narrowed the debate to one over access to medicines and public health. These are critical issues, to be sure, but they are not the same developmental issues of the past.

Without doubt, TRIPS creates a more restrictive environment for technology transfer than that experienced by developed countries at similar stages of industrialization. And more to the point,

⁵⁷It is also important that the GFATM (and other donor agencies, such as the IDA branch of the World Bank) permit that their limited resources be used (1) for treatment (rather than exclusively prevention) and (2) for the purchase of generic drugs (rather than only patented drugs). These changes were introduced into the Global Fund's guidelines in 2002.

⁵⁸*New York Times*, March 28, 2002. According to a report issued at the July 2002 International AIDS Conference, in Barcelona, the GFATM granted US\$616 million, to be spent over two years, to 58 proposals submitted from 30 countries. See David Brown, "AIDS Meeting Ends With Hope: Formerly Inconceivable Programs to Start This Year," *Washington Post*, July 14, 2002. To be sure, the GFATM is not the only form of external financing. Other mechanisms to finance treatment include countries' bilateral assistance programs and, importantly, debt relief.

⁵⁹Although paragraph 7 of the Doha Declaration reaffirmed developed countries' "obligation" under Article 66.2 to encourage technology transfer, for example, as before there is no mechanism to implement the developed countries' obligations. Furthermore, because the text of paragraph 7 concerns itself with the plight of the least developed countries, these obligations, were they somehow implemented, would appear to have limited applicability.

it is a less enabling patent system than that utilized by developing countries that underwent significant industrialization in the post-war period (Amsden 2001). Reverse-engineering, imitation, and many strategies of innovation to develop technology are either outlawed or made significantly more difficult by the high level of industrial patent protection mandated by TRIPS. Thus, TRIPS has significant (and disconcerting) developmental implications for many countries.⁶⁰ These issues were not on the agenda at Doha.

Both the advances and limitations of changing international governance on IPRs are brought to light by an on-going conflict between the U.S. and Brazil over the latter country's 1997 industrial property law. In the section on compulsory licenses, the Brazilian law contains one article that authorizes licenses in the case of national health emergencies and another article that authorizes licenses when manufactured goods are not produced locally. Article 71 regards public health, is consistent with TRIPS, and has been accepted by the U.S. In contrast, Article 68, with its "local working" requirement that potentially contributes to a more developmental investment regime, is potentially in violation of TRIPS and was the subject of a WTO panel dispute brought by the U.S. in 2000.⁶¹ In June 2001, when the two countries signed a joint communiqué announcing the withdrawal of the U.S. challenge in the WTO, they also recognized that the fundamental conflict over Article 68 remains unresolved. The U.S. has made it clear that were the Brazilians to use Article 68 to issue a compulsory license for non-pharmaceutical products, the WTO case would be reinitiated. The signal sent to other developing countries, resonant with Doha, was that emulating Brazil's program for

⁶⁰See Fisch and Speyer (1997); Maskus (2000); May (2000); CIPR (2002). In contrast, Sherwood (1997) argues that TRIPS standards remain too low to encourage investment and spur technology transfer.

⁶¹The question of what constitutes "working" the patent, and whether importation and distribution – but not production – is a long-standing issue of great contention in the international politics of IPRs. In fact, this was one of the major stumbling blocks in the developing countries' efforts to revise the Paris Convention in the 1970s and early 1980s (Sell 1998: Chapter 4). TRIPS appears to speak to the issue, on the side of developed countries, by stating that a "patent shall be available and patent rights enjoyable without discrimination as to ... whether products are imported or locally produced" (Art. 27.1). The Brazilian government does not accept this interpretation of TRIPS. See Shankar (2002); Champ and Attaran (2002).

distributing AIDS medicines was acceptable, but emulating Brazil's efforts to use IPR policy as a tool of industrial strategy would not be acceptable. The opportunities for developing country action secured at Doha, in sum, are about humanitarianism, not industrial transformation.

**Table 1: Patents Granted by USPTO
(1997-2001)**

TOP 15 DEVELOPED COUNTRIES

	All Patents		Medical Patents	
	Number	Percent of Total [#]	Number	Percent of Total [#]
1. USA	398581	54.12%	19865	58.27%
2. Japan	149642	20.32%	3057	8.97%
3. Germany	46934	6.37%	2341	6.87%
4. France	18312	2.49%	1932	5.67%
5. UK	17346	2.36%	1884	5.53%
6. Canada	15604	2.12%	955	2.80%
7. Italy	7738	1.05%	588	1.72%
8. Sweden	6813	0.93%	377	1.11%
9. Switzerland	6390	0.87%	444	1.30%
10. Netherlands	5854	0.79%	247	0.72%
11. Australia	3484	0.47%	266	0.78%
12. Belgium	3268	0.44%	232	0.68%
13. Finland	3046	0.41%	77	0.23%
14. Austria	2336	0.32%	98	0.29%
15. Denmark	2127	0.29%	340	1.00%
Sub-total	687475	93.94%	32703	95.92%

TOP 15 DEVELOPING AND TRANSITION COUNTRIES

	All Patents		Medical Patents	
	Number	Percent of Total [#]	Number	Percent of Total [#]
1. Taiwan	18888	2.56%	85	0.25%
2. South Korea	15564	2.11%	192	0.56%
3. Israel*	3784	0.51%	286	0.84%
4. Russia	898	0.12%	67	0.20%
5. Singapore*	872	0.12%	8	0.02%
6. Hong Kong	812	0.11%	9	0.03%
7. South Africa	557	0.08%	29	0.09%
8. India	552	0.07%	126	0.37%
9. China	538	0.07%	54	0.16%
10. Brazil	435	0.06%	8	0.02%
11. Mexico	335	0.05%	14	0.04%
12. Argentina	227	0.03%	24	0.07%
13. Hungary	210	0.03%	51	0.15%
14. Venezuela	144	0.02%	1	0.00%
15. Poland	74	0.01%	12	0.04%
Sub-total	43816	5.95%	954	2.80%

[#]Total is greater than sum of the two sub-totals, which only include patents from thirty countries.

*High-income country according to World Bank, but classified as “developing country” in TRIPS.

Source: United States Patent and Trademark Office (USPTO 2002a, 2002b).

**Table 2: Summary of USTR's Special 301 Reports, 1995-2001
(by type of country)**

	1995	1996	1997	1998	1999	2000	2001	1995-2001
Priority Watch List	8	8	10	15	16	16	16	89
WTO Developing (%)	4 (50.0%)	5 (62.5%)	7 (70.0%)	10 (66.7%)	11 (68.8%)	10 (62.5%)	11 (68.8%)	58 (65.2%)
WTO Developed (%)	3 (37.5%)	3 (37.5)	2 (20.0%)	3 (20.0%)	3 (18.8%)	3 (18.8%)	1 (6.3%)	18 (20.2%)
Other [#] (%)	1 (12.5%)	0	1 (10.0%)	2 (13.3%)	2 (12.5%)	3 (18.8%)	4 (25.0%)	13 (14.6%)
Watch List	24	25	36	32	37	39	32	225
WTO Developing (%)	17 (70.8%)	17 (68.0%)	20 (55.6%)	18 (56.3%)	18 (48.6%)	17 (43.6%)	14 (43.8%)	121 (53.8%)
WTO Developed (%)	2 (8.3%)	3 (12.0%)	8 (22.2%)	6 (18.8%)	8 (21.6%)	4 (10.3%)	4 (12.5%)	35 (15.6%)
Other [#] (%)	5 (20.8%)	5 (20.0%)	8 (22.2%)	8 (25.0%)	11 (29.7%)	18 (46.2%)	14 (43.8%)	69 (30.7%)
Total*	37	39	58	65	55	57	51	362
WTO Developing (%)	23 (62.2%)	25 (64.1%)	32 (55.2)	35 (53.8%)	30 (54.5%)	28 (49.1%)	26 (51.0%)	199 (55.0%)
WTO Developed (%)	5 (13.5%)	6 (15.4%)	12 (20.7%)	13 (20.0%)	11 (20.0%)	7 (12.3%)	5 (9.8%)	59 (16.3%)
Other [#] (%)	9 (24.3%)	8 (20.5%)	14 (24.1%)	17 (26.2%)	14 (25.5%)	22 (38.6%)	20 (39.2%)	104 (28.7%)

Notes

[#]Other refers to WTO Members classified as transition countries and countries that were not WTO Members in the relevant year.

*Note that Total is not simply the sum of the Priority Watch List and Watch List. Total also includes Priority Foreign Countries, countries being monitored under Section 306, and countries noted as being of “concern” in the “Other Observations” sections. The “Other Observations” section was eliminated in the 1999, 2000, and 2001 reports.

Source

USTR (1995; 1996; 1997; 1998; 1999; 2000; 2001).

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