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# Trade-Related Aspects of Intellectual Property Rights

## Making Trade Policy

The inclusion of intellectual property rules in the international trading system was a watershed event. Negotiated during the Uruguay Round, the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) significantly broadened the reach of the trading regime. Prior to TRIPS, trade rules generally focused on “don’ts”—telling countries which practices to avoid or scale back. For example, General Agreement on Tariffs and Trade (GATT) members were told to eliminate quotas, to reduce tariffs, to avoid discriminating among GATT members (by mandating most favored nation, or MFN, status) and against foreign goods (by mandating national treatment), and, finally, to avoid standards and technical requirements that unnecessarily restricted trade. Provided that countries respected these don’ts, they remained free to adopt or reject any domestic policies they wished. For example, many countries chose not to enforce intellectual property rights—a perfectly acceptable policy under the GATT system.

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*International Trade Meets Intellectual Property: The Making of the TRIPS Agreement and International Trade Meets Public Health—Patent Rules and Access to Medicines* are edited and revised versions of the cases with the same names originally written for the Case Program at the Kennedy School of Government. For copies or permission to reproduce the unabridged cases please refer to [www.ksgcase.harvard.edu](http://www.ksgcase.harvard.edu) or send a written request to Case Program, John F. Kennedy School of Government, Harvard University, 79 John F. Kennedy Street, Cambridge, MA 02138.

## Depth

By contrast, the TRIPS agreement requires countries to “do” something. World Trade Organization (WTO) members are obliged to adopt policies that protect intellectual property in areas such as patents, trademarks, and copyrights. Though countries remain free to provide even more protection than TRIPS requires, the agreement sets minimum standards. These minimum standards represent a significant reduction in signatories’ autonomy of national policy. Such policy constraints are binding because the Uruguay Round Final Act established a strong mechanism for dispute settlement that applies equally to TRIPS and the other rules governing trade in goods and services. In short, all WTO members are required to adhere to TRIPS, and those who fail to do so will suffer consequences.

The advocates of TRIPS rules achieved remarkable success: a far-reaching agreement in a forum that would work to ensure compliance. But the success of the TRIPS campaign has given rise to controversy. Some critics argue that intellectual property rules have no place in a trade agreement. Others worry about the implications of TRIPS for public health in developing countries. Issues relating to indigenous knowledge have also been controversial. Many observers also point out that TRIPS set a precedent by expanding the scope of issues covered in the WTO, opening the door to the inclusion of even more issues, such as labor and environmental standards.

## Coverage

The corporations supporting TRIPS made their case for trade policies enforcing intellectual property rights (IPRs) in moral terms. A failure to respect intellectual property (IP) rights, they argued, is tantamount to theft. But the analogy between IP and other kinds of property is not precise. For example, property rights are generally permanent, while patents and copyrights generally expire after a specific period. In addition, the time granted for exercising a patent differs from that granted for a copyright. Therefore, probably the most important policy question regarding such rights is not moral (whether they should exist) but practical—their optimal duration.

The economic case for protecting intellectual property rests on the tension between encouraging the efficient use of knowledge, on the one hand, and providing the appropriate incentive for its creation on the other. Knowledge is a classic public good. Its benefits are “nonrivalrous”—that is, the use of knowledge by one person does not detract from the ability of others to use it. Thus, the additional cost to society of using knowledge is zero. If there were nothing more to learn, the most efficient action would

be to eliminate IPRs and make all knowledge available without charge. But our knowledge is not complete, and setting its price at zero would eliminate any financial incentive to seek more. One way to deal with this problem is to subsidize knowledge creation, and indeed most basic research is funded by national governments. But other mechanisms may also be required. Through intellectual property rights such as patents, an inventor is rewarded for his or her discovery for a certain length of time, after which the knowledge can be used without charge.<sup>1</sup>

Countries obviously differ in their ability to contribute knowledge. At one extreme, developing countries may have a strong interest in encouraging the diffusion of existing knowledge but little concern about stimulating the creation of new knowledge—and thus little interest in protecting intellectual property. In more technologically advanced countries, however, the need for new knowledge is generally much greater. Such national diversity may well warrant different national patent policies.

But because knowledge spills over national borders, a case can also be made for allowing inventors to capture some of the international benefits of their discoveries. Otherwise, countries would have an incentive to free ride on the discoveries of others and the world would spend too little on knowledge creation. On this argument, the provision of international IPRs would add to international innovation. Yet making knowledge expensive might limit its diffusion, even as the ability of innovators to operate abroad without fear they will be copied might encourage diffusion. Therefore, the overall net impact of international IPRs on global welfare is theoretically ambiguous.

But even if international IPRs are desirable, they may not belong in trade agreements. To be sure, the existence of such rules will affect what is traded. Producers of software, for example, will not be able to export their products and earn profits if foreign countries do not enforce IPRs and prevent other companies from copying the software without paying royalties. In this sense the failure to enforce IPRs, like a ban on imports, acts to inhibit trade and is therefore viewed as a trade barrier. However, a country that does not recognize such property rights will not grant the producers of such software the right to any returns. Moreover, as written in the WTO rules, TRIPS actually affects more than trade. Although the agreement's name is "Trade-Related Aspects of Intellectual Property Rights," countries are expected to enforce such rights throughout their own domestic economies. IPRs could therefore alter the returns earned by domestic producers in purely domestic transactions.

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1. A second question in economics is relevant here: the relationship between monopoly and innovation. The prospect of having a monopoly might induce more innovation, but holding a monopoly could reduce the incentive to innovate. Providing a *temporary* monopoly reduces the dangers that a firm will rest on its laurels.

## Winners and Losers

Granting IPRs internationally has distributive implications, transferring income from knowledge users to knowledge producers. Indeed, its welfare consequences differ dramatically from those of trade. Under competitive conditions, both exporting and importing nations benefit from trade liberalization. IPRs, however, tend to create net winners and losers. Its differential impact makes IP a particularly controversial issue, especially in the area of pharmaceuticals.

Given this alignment of winners and losers, the introduction of TRIPS rules that heavily benefit high-technology corporations led to concerns about how power is distributed in the WTO. Though some developing countries saw IPRs as a mechanism for encouraging foreign investors to bring the latest technologies to their markets, most viewed the rules as reflecting the continuing dominance of firms based in developed countries.

## Enforcement

The motives of those seeking to introduce IP into the WTO were clear. If the Uruguay Round had focused only on IPRs, with the attendant creation of winning and losing countries, obtaining a binding multilateral agreement would have been difficult. But because the Uruguay Round dealt with a number of trade issues, the losers could be compensated with concessions in other sectors (such as the elimination of the Multi-Fiber Arrangement [MFA]). In addition, its dispute settlement mechanism made the WTO an attractive forum for IPR supporters. Countries found violating TRIPS could face the loss of benefits in other areas.

But inclusion in the WTO could boost the adoption and enforcement of many other systems of rules—as proponents of competition policy initiatives and of labor and environmental standards recognize. Indeed, a popular argument has been that if the trade rules provide intellectual property protection for companies, then they should also protect workers and the environment. For this reason, some see the inclusion of TRIPS as a dangerous precedent, fearing that the trade regime may become too overloaded to function effectively.

Other observers see TRIPS as quite different from labor and environment standards, arguing that the failure to provide IP protection constitutes a genuine trade barrier by depriving innovators of the ability to reap gains from trade. Producers of easily “pirated” commodities such as software, motion pictures, videocassettes, records, books, and pharmaceuticals are particularly vulnerable. But this argument assumes the existence of precisely those intellectual property rights not recognized by countries that refuse to enforce them.

## Participation

Before the Uruguay Round, the United States had sought—using its Special 301 legislation—to unilaterally introduce intellectual property protection in trade. The United States had also advanced IPRs in regional trade agreements, notably the North American Free Trade Agreement (NAFTA). But the idea of making IPRs part of the WTO was particularly attractive, because the organization has such broad membership and because it makes cross-retaliation possible.

## Developing Countries

The principle of special and differential treatment for developing countries is a pillar of the trading system. Its execution is fairly straightforward when border barriers are concerned: tariffs and quotas can be different for different countries. But applying such treatment to rules—which are either enforced or not—is not so easy. Thus, the preferential treatment of developing countries has been limited to the longer time periods they have been given to come into compliance with the agreement. But many developing countries lack an extensive IP regime, and their need to establish one consumes scarce administrative and legal resources.

As the second case study in this chapter elaborates, TRIPS has been especially controversial in its application to pharmaceuticals. Countries were particularly fearful that the agreement could be used to block their access to the medicines they required to deal with public health crises such as AIDS. TRIPS did provide for noncommercial use and compulsory licensing should such crises occur. It also made clear that nothing in the agreement barred the parallel importation of products legally sold in other countries. Nonetheless, developing countries (and others) felt it was necessary to clarify their rights under the agreement.

## Governance

Many WTO members did not enforce IPRs prior to the TRIPS agreement. Some members had partial enforcement; others had different systems from that outlined in TRIPS. For example, in some countries the entity that was first to invent a product was granted the patent; in others, it went to the first to file. In addition, they differed in what kind of knowledge could be patented and for how long. By setting minimum standards for all members, the WTO rules required many countries to change how their domestic IP regimes functioned. National governments could no longer implement new regimes that were less stringent than TRIPS, even when they believed it was in their interest to do so.

For many countries, the inclusion of intellectual property rules in the Uruguay Round Final Act effectively altered the internal political balance between supporters and opponents of intellectual property protection. By packaging IP rules with trade, IP supporters won gains they otherwise would not have been able to achieve. But these changes came at a price: the tactic antagonized and mobilized groups, both national and international, concerned about the impact of TRIPS. Most notably, many such groups organized to protest what they foresaw as one result of the agreement: the reduced availability of pharmaceuticals in developing countries. Eventually these groups formed coalitions that were able to bring their concerns to the Doha ministerial.

## **CASE STUDY: International Trade Meets Intellectual Property—The Making of the TRIPS Agreement (TRIPS, Case 1)**

As usual, it all comes down to sex, drugs, and rock 'n' roll.

The 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, established the most comprehensive set of global trade rules for intellectual property—protecting everything from *Basic Instinct* to Prozac to Nirvana's *In Utero* (along with Roundup weed killer and Microsoft Windows). After seven years of negotiating, industries that rely on copyrights, patents, and trademarks received more protection than anyone had believed possible at the outset of the talks.

TRIPS was concluded in the context of the Uruguay Round of the General Agreement on Tariffs and Trade talks. GATT talks had usually been concerned with more conventional trade issues such as tariffs, and many countries initially had no interest in adding intellectual property protection to the Uruguay Round agenda; some were opposed to merely discussing IP under the auspices of the GATT. Moreover, even supporters—namely, the United States, Europe, and Japan—had serious disagreements about what constituted appropriate protection. Right up to the 1986 ministerial meeting that launched the negotiations, the interested parties had no idea whether intellectual property would be part of the round.

Although intellectual property protection was ultimately included in the ministerial declaration (i.e., the agenda for the round), the first two years of TRIPS talks showed little movement. As one US negotiator remembers, “There was no real discussion at all.” Major rifts existed between developed and developing countries, and many of the negotiators had no previous experience with intellectual property. At the Uruguay Round midterm review in 1988, TRIPS was considered to be one of the “problem groups,” lacking even a consensus on a framework for the negotiations.

The deadlock over TRIPS was broken in 1989, and negotiators began to discuss ways to protect, enforce, and settle disputes over intellectual

property. However, because of the different legal traditions of protection in the United States, Europe, and Japan, the supporters' persistent disagreements soon intensified. If there were to be global standards, whose would they be? In the midst of this discussion, an impasse that developed in 1990 over agricultural subsidies brought the *entire* Uruguay Round to a halt.

Three years later, in December 1993, the Uruguay Round ended at last, after several sleepless nights of high-stakes negotiating. Officials emerged with more than 400 pages of detailed trade agreements and 22,000 pages of supplementary information and commitments. Among these documents was the final TRIPS agreement.

Many characterized the TRIPS talks as having been initiated and driven by US knowledge-based industries, particularly pharmaceuticals, entertainment, agrochemicals, and computer software. As one participant puts it, "It was a partnership between industry and government that had never existed before in an international trade negotiation." Some say this partnership led to "potentially the most important legal advance for the world trading system since the establishment of the GATT in 1947" (Ryan 1998, 1).

## What Is Intellectual Property?

Intellectual property can be defined as information with a commercial value. Intellectual property rights are a composite of "ideas, inventions, and creative expressions" and "the public willingness to bestow the status of property on them" (Sherwood 1990, 11; quoted in Braga 1995, 382). In the United States, the right to protect IP is recognized in the Constitution (Article I, Section 8).<sup>2</sup>

Economists generally believe in the need to protect intellectual property, arguing that free market forces alone do not provide sufficient incentive to create knowledge. An innovator cannot appropriate the full benefit of his or her innovation. Therefore, many economists maintain that the creation of knowledge must either be subsidized by the government or be protected through the creation of temporary monopolies, which can pay for the innovative activity. Policymakers must determine how much protection is needed to allow an adequate rate of return to stimulate innovation.

Policies to protect intellectual property include the granting of patents, trademarks, and copyrights. Patents protect inventions that are novel, not obvious to those in the field, and useful. A patentee has the right to exclude others from using, making, or selling the patented invention for

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2. "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Harvard Law School professor William Alford notes in remarks to the author that Article I, Section 8, does not apply to trademarks.

a specified period of time. Trademarks are commercial symbols used to identify goods and services or their producers (e.g., Coca-Cola, Gucci). Copyrights protect works of authorship, such as books, from the time of their creation. Intellectual property protection is also often extended to trade secrets, industrial designs, layout designs of integrated circuits, and geographical indications that identify a product, such as wine, with a particular region (e.g., Chablis, Champagne).

The stakes in protecting intellectual property were high for many US companies. Not only is the cost of product development in the knowledge-based and artistic industries significant, but success is rarely guaranteed. The cost of imitating these products, however, is often relatively low. Before TRIPS was completed, the US International Trade Commission (ITC) estimated that American companies lost between \$43 and \$60 billion annually due to inadequate intellectual property protection abroad.<sup>3</sup> Pharmaceuticals, chemical products, films, software, publications, and sound recordings were among the products affected.<sup>4</sup>

International markets were of growing significance to the US film and television business. Hollywood was also important to the US economy; by 1991, the film and television industry generated an annual trade surplus of more than \$4.5 billion, second only to the aerospace business.<sup>5</sup> But there were risks involved in making movies—two-thirds of all films did not recoup their production costs. As videocassette recorders became more readily available, allowing anyone to copy videotapes, the industry's problems with piracy abroad increased. The Motion Picture Association of America (MPAA) reported in 1989 that piracy accounted for some \$1.2 billion in lost revenues. In 1990, the MPAA spent \$20 million fighting film, videocassette, and cable TV "bandits."<sup>6</sup> "Keep in mind," remarked Jack Valenti, then president of the MPAA, "that the US film industry does about \$24 billion a year. Forty-one percent of that comes from international markets, so it is increasingly crucial and important that those markets remain open and that our IP is protected from thievery. We are constantly vigilant because, like virtue, we are every day besieged."<sup>7</sup>

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3. "Montreal Trade Talks; Intellectual Property Talks Stalled," *The Financial Times*, December 1, 1988, section I, 4. Debate continues over the actual value of foreign infringement of US intellectual property; critics note that USITC figures are based on data supplied by domestic industries.

4. In 1989, US IPR-related industries exported \$58.8 billion in goods covered by patents, trademarks, and copyrights—about 16 percent of US merchandise exports (Maskus 1993, 15).

5. Bruce Stokes, "Tinseltown Trade Wars," *The National Journal*, February 23, 1991.

6. Faye Rice, "How Copycats Steal Billions," *Fortune Magazine*, April 22, 1991, 157.

7. Unless otherwise noted, all quotes from Jack Valenti are from an August 1997 interview with Charan Devereaux. According to industry sources, exports accounted for 22 percent of revenues in 1985, growing to 35 percent by 1989. See Bruce Stokes, "Tinseltown Trade Wars," *The National Journal*, February 23, 1991.



With respect to the pharmaceutical industry, experts note that only one commercially viable drug emerges from every 4,000 to 10,000 compounds screened in a process that often involves 10 years of testing and clinical trials (Ryan 1998, 5). In addition, to discover and develop a new medicine and bring it to market in the United States costs on average \$500 million.<sup>8</sup> Given these tremendous costs, many US and European pharmaceutical companies argued that the copying and sale of patented drugs around the world diminished the amount of money available for further research. The drug company Merck & Co. found that global patent piracy cost the US pharmaceutical business about \$6 billion in 1986, possibly reducing the industry's R&D investment by between \$720 million and \$900 million (USITC 1993, 9-3). In addition, Pfizer's chairman Edmund Pratt estimated that battles to defend his company's patents had cost over \$100 million between 1981 and 1991.<sup>9</sup> US pharmaceutical companies were not getting "a fair shake," one Pfizer executive noted. For example, in six Latin American countries, Pfizer's sales of 12 patented drugs amounted to \$24.6 million in 1984. Companies that copied these drugs, however, brought in \$30.2 million in sales.<sup>10</sup>

The position of IP-based industries was not universally accepted, however. Many developing nations opposed the idea of strengthening international intellectual property rights. "And with good reason," says F. M. Scherer, professor of public policy and management at Harvard's John F. Kennedy School of Government. "In the US, we are lovely hypocrites. When we were a developing nation we systematically appropriated other people's technology. So that was the way we developed, but we don't want other people to appropriate our technology in order to develop. But of course we have no historical memory, so we don't even know we're being hypocritical."<sup>11</sup>

Nor were developing nations alone in their reservations. Some industrialized nations traditionally did not allow patents on foodstuffs and medicines, holding that monopolies should not be permitted on products so important to consumer welfare. Even Switzerland, home at one time to three leading pharmaceutical companies, offered no patent protection on drug products until 1977 (Scherer 1998, 6). As a result, some experts decried the characterization of copying products as "piracy," since such copying was often lawful under a country's legal system and existing in-

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8. Ambassador Clayton Yeutter (United States Trade Representative, 1985-88) in the foreword of Gorlin (1999, ii). In addition, a number of PhRMA publications cite the \$500 million figure (attributing it to a Boston Consulting Group study of January 1996).

9. Faye Rice, "How Copycats Steal Billions," 157.

10. Michael J. Zamba, "Going after Patent Pirates at Punta del Este," *Christian Science Monitor*, September 18, 1986, 22.

11. Unless otherwise noted, all quotes from F. M. Scherer are from a December 1998 interview with Charan Devereaux.

ternational agreements. According to Scherer (1998), use of the term was “a big public relations scam”:

There is a law of the seas that says “thou shall not steal merchandise from other people’s ships.” Doing so by force—taking another’s ship and its property—is piracy and was mutually condemned by all nations. Some companies branded the activity of knocking off a drug that was patented in the United States, but not in India, or knocking off a piece of software that was copyrighted in the United States, but not in China, they branded that piracy. But the production of these products was perfectly consistent with the laws of the country in which the knocking-off firm was located. It was not violating any international law. Where was the law violation? So it’s not piracy. But piracy has a terribly emotional impact and I’m sure the word was chosen deliberately in order to get the most public relations impact possible.

Other observers note that many developing countries had laws against copying certain products such as clothing and music, but often these laws were not enforced. In such cases, the charge of piracy made some sense, they said.

## International Intellectual Property Protection

The multilateral treaties on intellectual property that existed before the Uruguay Round—the most important being the Paris Convention for the Protection of Industrial Property (1883), relating to patents, trademarks, and industrial designs, and the Berne Convention for the Protection of Literary and Artistic Work (1886), an international agreement on copyrights—were administered by the World Intellectual Property Organization (WIPO). Established in 1967, WIPO joined the United Nations system in 1974, becoming one of 15 specialized UN agencies. WIPO was responsible for promoting the protection of intellectual property throughout the world, and its activities were largely devoted to helping less-developed nations draft and administer national IP laws (see [www.wipo.int](http://www.wipo.int)).

Many IP-related interests in the United States, Canada, and western Europe considered WIPO to be toothless. Membership in the existing conventions was not universal and no enforcement or dispute resolution mechanisms existed. According to one observer, this system was “largely incapable of disciplining even the most egregious forms of trademark and copyright infringement” (Maskus 1990, 168). For patents, the central tenet of the Paris Convention was *national treatment*: in its patent protection, a country had to treat foreign and domestic producers the same. This system “gave countries around the world a lot of discretion in designing their patent laws,” says Arvind Subramanian, a former member of the GATT Secretariat’s TRIPS group. “That’s why you found in virtually all developing countries no protection for pharmaceutical or chemical prod-

ucts. This was legitimate under the Paris Convention.<sup>12</sup> For example, according to WIPO, of the 98 member nations of the Paris Convention, 49 excluded pharmaceutical products from protection and 22 excluded chemical products.<sup>13</sup>

With the support of US companies that relied on patents, especially Pfizer, the United States hoped to strengthen patent protection under WIPO by revising the Paris Convention. But the four conferences held between 1980 and 1984 failed, largely because the debates between the developed and developing countries could not be resolved. The United States and other industrialized countries argued that without patent protection, companies had no incentive to invest to create new and better drugs. Developing countries countered that they represented a very small slice of global market share. In addition, they said, most new drug innovations targeted the health problems of the *industrial* world—conditions such as ulcers and heart disease. In economic terms, increasing IP protection would bring the developing countries no significant dynamic gains but would inflict considerable static costs: increased prices, more royalties to foreigners, and harm to consumer welfare. Finally, the thriving generic drug industries in countries such as India, Brazil, and Mexico could be affected by increased patent protection. “The efforts in WIPO were unsuccessful because there was no scope for making trade-offs,” Subramanian remembers. “Developing countries would say, ‘If we were to do this, what would we get in return?’ Apart from the fact that they were violently opposed to it at that stage, even if they were to concede the question was, What was the payoff for them?”

The inability to exercise leadership at WIPO frustrated some US government officials. “The fact that we were the number one market in the world and probably the best on intellectual property protection was often lost on everybody,” recalls Gerald Mossinghoff, US ambassador to two of the sessions on revising the Paris Convention and later president of the Pharmaceutical Research and Manufacturers of America (PhRMA). “We were one vote among 150. I thought, ‘This is crazy. What happened to the leadership role of the United States?’”<sup>14</sup>

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12. Unless otherwise noted, all quotes from Arvind Subramanian are from a January 2000 interview with Charan Devereaux.

13. In addition, 45 members excluded animal varieties; 44, methods of treatment of the human or animal body; 44, plant varieties; 42, biological processes for producing animal or plant varieties; 32, computer programs; and 35, food products (WIPO 1988, annexes I, II, as cited in Drahos with Braithwaite 2002, 124).

14. Unless otherwise noted, all quotes from Gerald Mossinghoff are from an August 1997 interview with Charan Devereaux. After serving as chairman of the General Assembly of WIPO, Mossinghoff chaired the Subcommittee on Intellectual Property of President Reagan’s Cabinet Council on Commerce and Trade. He was also Assistant Secretary of Commerce and Commissioner of the US Patents and Trademarks Office before becoming president of PhRMA.

## US Industry Frustrations

Industry groups had begun to approach the US government about what they viewed as piracy of their intellectual property in the mid-1970s. In particular, the agrochemical sector was frustrated by the copying of its products in Hungary.<sup>15</sup> Pesticides and other chemicals were extremely expensive to develop, test, and study—between \$13 and \$20 million per product, industry representatives said.<sup>16</sup> They argued that the chemicals manufactured in Hungary were sold in both domestic and international markets, including Brazil, India, and Taiwan, without the permission of the companies that developed them. The US National Agricultural Chemicals Association estimated that the United States stood to lose \$150 million in exports in 1979 alone as a result of Hungary's efforts.<sup>17</sup> Jim Enyart, a Washington, DC representative of Monsanto, decided to do something about it. Together with representatives of two other agrochemical producers, FMC and Stauffer Chemical, Enyart approached officials in Congress, the Commerce Department, the US Trade Representative (USTR), and the US Patent and Trademark Office (USPTO) in an effort to gain some leverage in dealing with the Hungarians.

The agrochemical companies made the case that intellectual property should be treated as a trade issue and that its systematic theft therefore constituted an unfair trade practice. Enyart remembers the government's initial response. "At the time everyone said: 'Oh gee, patents are highly technical, very esoteric things. What do they have to do with trade?' And we pressed them and said: 'Look, intellectual property is property. It costs money and time to create; it has commercial value, and if people steal it, it's like stealing any other kind of property.'" This argument was a hard sell, according to Enyart, because "the minute you would say 'patent' everybody's eyes would glaze over."<sup>18</sup>

But in the end, the coalition found allies. In June 1979, the Commerce Department led a delegation to Hungary and leaned on local government officials to do something about the agrochemicals issue. Senator John Danforth (R-MO) of the Senate Subcommittee on International Trade was

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15. These chemicals included Roundup weed killer (Monsanto), Furandane (FMC), and Eradicane (Stauffer Chemical).

16. Jack Early, President, National Agricultural Chemicals Association, testimony for a hearing before the subcommittee on International Trade of the Senate Committee on Finance, "Continuing the President's Authority to Waive the Trade Act Freedom of Emigration Provisions," 96th Congress, July 16, 1979, 77.

17. Bradley Graham, "Hungarians Respond to Senate Threat: Hungarian Trade Status in Doubt in Senate Panel," *The Washington Post*, August 4, 1979, D7.

18. Unless otherwise noted, all quotes from Jim Enyart are from a 1997 interview with Charan Devereaux.

also sympathetic. In hearings on Capitol Hill concerning renewal of most favored nation trading status for Hungary, Danforth questioned whether trade rights should be granted to a country that copied IP from US industries.<sup>19</sup> After hearing testimony from the chemical companies, committee chairman Senator Abraham Ribicoff (D-CT) declared that Hungary's MFN status was "in serious jeopardy."<sup>20</sup> This "kind of got the Hungarians' attention," says Enyart. Negotiations ensued between Hungarian officials, the chemical companies, the US Commerce Department, the USTR, and the USPTO. Days after the Senate hearing, Monsanto signed an agreement with the Hungarian agrochemical export trade organization that, according to a company official, would end Hungary's pirating of Monsanto's patented process.<sup>21</sup> Recalls Enyart: "We were slowly breaking down this idea that the whole range of intellectual property issues was just too complicated to deal with."

### ***Intellectual Property and the GATT***

Having achieved some success in Hungary, the agrochemical companies wanted to join forces with other industries to further the cause of IP protection. Enyart hoped to work with companies that were looking to protect not only patents, as was his industry, but also copyrights and trademarks. The idea, says Enyart, was that "if we worked together to influence the government we could get a hell of a lot farther." Ultimately, Monsanto joined the Anti-Counterfeiting Coalition, a group led by Levi-Strauss that included other trademark-based companies such as Samsonite, Izod, Chanel, and Gucci.<sup>22</sup> One of the coalition's recent efforts had been an unsuccessful attempt to achieve trademark protection in the 1973–79 Tokyo Round of the GATT multilateral trade talks.

Intellectual property was not a major topic of negotiation during the first six rounds of GATT, for the original 1947 agreement did not require that

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19. Those testifying at the July 19, 1979, hearing before the Senate Subcommittee on International Trade of the Committee on Finance, 96th Congress, 1st Session, "Continuing the President's Authority to Waive the Trade Act Freedom of Emigration Provisions," included Jack Early, president, National Agricultural Chemicals Association; Robert McLellan, vice president of international and government affairs, FMC Corp.; and Nicholas Reding, managing director, Monsanto Agricultural Products Co.

20. Quoted in Graham, "Hungarians Respond to Senate Threat," D7.

21. "Monsanto, Hungary in Agreement on Herbicide Marketing," Dow Jones News Service, July 25, 1979.

22. Founded in 1978, the International Anti-Counterfeiting Coalition had by 1997 grown to 180 members; among them were trademark-based companies, law firms, trade associations, and investment firms.

member countries adopt minimum standards of IP protection.<sup>23</sup> However, in the seventh round of talks, held in Tokyo, the Anti-Counterfeiting Coalition worked with representatives from the United States and the European Community to propose an anticounterfeiting code.<sup>24</sup> The code called for GATT signatories to intercept and dispose of counterfeit goods at international borders. “That effort started very late in the Tokyo Round,” recalls TRIPS negotiator Mike Hathaway, who also worked on the 1979 code. “Even though we got a draft agreement, we didn’t really achieve anything other than having a text out there for multilateral consideration. But it did serve to put IP on the GATT agenda.”<sup>25</sup> A revised draft, supported by Canada and Japan, was submitted in 1982; though some responded positively to the anticounterfeiting code, it still was not put into effect.

### ***US Legislation: Section 301***

Trademark industries and agrochemical companies were not the only IP-based industries distressed about intellectual property rights protection. Emery Simon, who was a US negotiator for the TRIPS agreement from 1986 until 1993 and was subsequently executive director of the Business Software Alliance, observes:

In the immediate aftermath of the Tokyo Round we had a series of technological developments. One was the advent of videocassette recorders. That precipitated a specific video piracy problem. The second development was the increasing use of audiocassettes. We switched from 8-track to regular cassette tapes and there was widespread use of Walkmen. Those kinds of technologies led to music piracy. The third development was software. The PC became kind of a staple in the mid-1980s after IBM introduced its PC in 1982. So then we had a software piracy problem. Simultaneously, we have had a long-standing patent problem in that there were deficiencies in the Paris Convention which permitted a number of countries that were not party to it or which interpreted the convention very loosely to exclude

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23. In the original GATT agreement, intellectual property is mentioned in Article XX, “General Exceptions”:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: . . . (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices[.]

24. In each round of talks following its inception, GATT produced new accords. World trade expanded dramatically during this period, from \$60 billion in 1950 to approximately \$4 trillion in 1991.

25. Unless otherwise noted, all quotes from Mike Hathaway are from a September 1997 interview with Charan Devereaux.

patentability of chemicals, including agricultural chemicals and pharmaceuticals. So markets developed for those [pirated goods] as well.<sup>26</sup>

Frustrated with *multilateral* approaches to IP protection (such as the Tokyo Round and WIPO), some US industries began to seek other means to address their IP concerns. One strategy was to increase *bilateral* pressure on countries that did not respect US companies' intellectual property rights. In 1982 the USTR conducted consultations with Korea, Mexico, Singapore, and Taiwan in an effort to strengthen patent, trademark, and copyright protection. In addition, Monsanto led an effort to make international violations of US IPRs subject to retaliation under US trade laws. US companies hoped that if trade actions were linked to a country's enforcement of intellectual property rights, protection for their products would increase.

Success was achieved when the Trade Act of 1984 made intellectual property rights actionable under section 301 of the 1974 Trade Act. Section 301 permits the US government to unilaterally raise tariffs against trading partners that maintain "unjustifiable or unreasonable" restrictions against US trade. Thus, for the first time, the US government was authorized to take retaliatory action against countries that failed to offer "fair and equitable provision of adequate and effective protection of intellectual property rights." Under section 301, companies and trade associations could petition the USTR to investigate countries for IPR violations. Congress also moved to make protection for US intellectual property a condition for continued eligibility under the Generalized System of Preferences (GSP), which granted concessional tariffs to imports from less-developed countries.<sup>27</sup> IPRs were clearly positioned on the US trade agenda.

Some observers credited the efforts of the US intellectual property industries with a pivotal role in developing this new powerful bilateral tool. "The IP industry in the US was extremely savvy and clever because they made intellectual property a moral issue," one explains:

What happened in the US in the 1980s was that you had this growing momentum against those "pirates" and "robbers" out there, articulated by industry in a very moral tone. What developing countries were doing was seen as ethically objectionable. That's why the IP movement is a fascinating political economy story, because industry articulated this very, very cleverly. Their success was reflected in the fact that 301 got enacted in the United States. The rhetoric was translated into legislation.

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26. Unless otherwise noted, all quotes from Emery Simon are from an October 1997 interview with Charan Devereaux.

27. The GSP provides preferential duty-free entry to more than 4,000 products (which otherwise be subject to customs duty) from about 140 designated beneficiary countries and territories. The program was instituted on January 1, 1976, under the Trade Act of 1974. See [www.customs.ustreas.gov](http://www.customs.ustreas.gov).

With the new legislation in place, the International Intellectual Property Alliance (IIPA) sought to inform the USTR about trade in intellectual property and the problems faced by the film, publishing, and recording industries.<sup>28</sup> In 1985, the IIPA wrote a report titled *Piracy of US Copyrighted Works in Ten Selected Countries*, which estimated US losses in those countries, including the Republic of Korea, at \$1.3 billion annually (IIPA 1985, i).<sup>29</sup> Partly in response to this report and complaints from pharmaceutical makers, chemical companies, and the MPAA, the US government launched a section 301 case against the Republic of Korea in September 1985. After bilateral negotiations, the two countries reached an agreement in July 1986. Korea agreed to strengthen its copyright law and enforcement as well as to protect software and introduce product patents for pharmaceuticals and chemicals.<sup>30</sup> It also agreed to protect the trademarks of foreign firms and to give extensions to agricultural chemical patents. Jayashree Watal, a TRIPS negotiator for India, notes, “US trade negotiators, thus, achieved their first major victory on strengthening the protection of IPRs in a developing country using the threat of sanctions” (Watal 2001, 19). One negotiator calls the bilateral IP agreement between the US and Korea a model for TRIPS.

## Getting IP on the Uruguay Round Agenda

The Uruguay Round of GATT talks began under economic conditions substantially different from those when the Tokyo Round was completed. One obvious change was the large US merchandise trade deficit, which had grown dramatically since the late 1970s. In the face of West German and Japanese trade surpluses, many US government officials began to agitate for a new round of GATT talks to level the playing field. The notion of making a major push to include IP in the round was evolving at the same time.

Pfizer chairman Edmund Pratt and IBM chairman John Opel were instrumental in arguing that intellectual property should be included on the Uruguay Round agenda. Both executives served on the President’s Advisory Committee on Trade Negotiations (ACTN) during the Carter and

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28. Founded in 1984, the IIPA originally comprised five trade associations: the Motion Picture Association of America, the Recording Industry Association of America, the National Music Publishers’ Association, the American Film Marketing Association, and the American Association of Publishers.

29. The other nine countries included in the study were Singapore, Taiwan, Indonesia, Philippines, Malaysia, Thailand, Brazil, Egypt, and Nigeria.

30. Some countries issued patents for the *process* of making a drug, and not for the *product*—the drug itself. Critics said that if only process patents were issued, companies could legally copy drugs by arguing they were using a different manufacturing process.



Reagan administrations, Pratt as the committee's chair and Opel as head of the IP task force.<sup>31</sup> "Both of them," according to one US TRIPS negotiator, "had problems with piracy and theft of their IP and they decided to get intellectual property into the trade venue where you had some teeth in the enforcement mechanism." Pratt and Opel displayed enthusiasm for the political process as well as the issues. As one of Pratt's colleagues recalls, "He liked Washington and he liked politics, as opposed to some chief executives who will do it, but only reluctantly. He loved the Washington world." "Pratt and Opel," remarks a US negotiator, "basically engineered, pushed, and cajoled the government into including IP as one of the topics for the negotiation."

In 1985, USTR Clayton Yeutter created the position of assistant USTR for international investment and intellectual property, a job filled by Harvey Bale. Working with Bale and Yeutter, Pfizer and IBM employees developed a position paper directed at White House staff; it prompted a presidential statement on the importance of intellectual property to the United States (Santoro 1992, 9).

As the former CEO of the maker of Yale locks, Commerce Secretary Malcolm Baldrige also had an interest in intellectual property; patents had been important to his company's business. After meeting with representatives of the motion picture, publishing, software, and recording industries in the summer of 1984, Baldrige committed to improve protection for US IP both at home and abroad. His commitment was translated into a major initiative under which two Commerce Department agencies, the International Trade Administration (ITA) and the USPTO, joined forces to combat the problem (Hill 1985, 4).

In addition, Baldrige established an intellectual property subcommittee of the Cabinet Council on Commerce and Trade and expressed interest in moving IP into a venue where the United States could exercise greater leadership. Gerald Mossinghoff, who became the chair of the IP cabinet council subcommittee, recalls: "There was a consensus that we would move the main push for multilateral intellectual property out of the WIPO, where typical UN procedures apply, into the GATT where we were accustomed to negotiating from a position of strength." Around the same time, Jacques Gorlin, a trade expert and consultant to IBM, wrote a paper described by one observer as "the first intellectual articulation of having broader IP standards plus an enforcement text in the GATT agreement."<sup>32</sup>

But not all US government and business interests wholeheartedly supported the idea of including a broad discussion of IPRs in the GATT. Many of the copyright-based industries were apprehensive. Protection for

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31. The ACTN was created by Congress in 1974; Pratt was appointed by President Carter in 1979.

32. Jacques Gorlin's 1985 paper for IBM was titled "A Trade-Based Approach for the International Copyright Protection for Computer Software."

movies, recordings, and books was already fairly strong in the international arena, thanks to the Berne Convention.<sup>33</sup> Copyright industries were therefore concerned that they might *lose* ground if IP was brought into the GATT. Eric Smith, president of the IIPA, explains:

Early on in 1985, when Jacques Gorlin wrote his paper for IBM, we were very wary of it. In 1985 and 1986, we had just begun the process of using the section 301 action. A 301 action had been brought against Korea and there was a lot of movement by the US government to improve protection on a bilateral basis. We were beginning to have very significant success. At that point, Singapore, Taiwan, Korea, and Indonesia—big pirate countries where we had no protection for copyrights—were beginning to move toward protecting US copyrights. . . . Of course, at this point the international standard in protection was the Berne Convention. The Berne Convention was accepted by everyone, even though the United States was not a member. We got Berne-level protection because the whole principle of the convention was national treatment. The bilateral mechanism was working very well and it looked like it would continue to work as well or even better than we had ever thought. So placing copyright standards into a trade negotiation, which is characterized by splitting the difference at the end of the day, now that made everybody nervous as hell.<sup>34</sup>

Some US government officials believed that the struggle should focus less on bringing IP into the GATT talks and more on getting the United States to agree to the principle of national treatment and sign on to the Berne Convention. Such an act, they maintained, would give the United States a better platform from which to argue that other countries should improve their copyright protection.

### ***The Proponents Organize***

USTR Clayton Yeutter advised IBM's John Opel and Pfizer's Edmund Pratt to seek business allies in other industrialized countries to help overcome resistance to including IP in the GATT (Santoro 1992, 10). "We told them government couldn't do this alone," recalls one former trade official:

We had to get business support in Europe and Japan to make this happen. So we would need them to get their European counterparts to go to their governments and say, "We want this." Japanese and Europeans—the Europeans particularly—are very conservative. . . . The US government over the years has tended to look at these issues in a business way: "We have a problem here, let's solve it." The European approach is more traditional. Their view is, "We have a problem here, but maybe there is no solution. The Indians and the Brazilians and the Argentineans, they're going to oppose all this and they outnumber us. It's only going to create a lot of friction. Besides we have a lot of other unfinished business." While the United States tends to bite off more than it can chew . . . the Europeans hardly want to bite off anything.

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33. Although the United States was not a member of the Berne Convention until 1988, US companies benefited from its concept of national treatment.

34. Unless otherwise noted, all quotes from Eric Smith are from an October 1997 interview with Charan Devereaux.

In March 1986, Pratt and Opel founded the Intellectual Property Committee (IPC), a group of 13 CEOs committed to moving intellectual property onto the GATT agenda.<sup>35</sup> Jacques Gorlin, consultant to IBM and the IP taskforce of the President's Advisory Committee on Trade Negotiations, was hired to lead and staff the organization. "Our first task," Gorlin recalls, "was to go to Europe and Japan and work with the private sector within those countries to get them to put pressure on their trade ministries."<sup>36</sup> From June through August of 1986, IPC representatives traveled to Tokyo, Bonn, London, Paris, Brussels, and Copenhagen to make their case. Ultimately, the IPC formed a tripartite coalition with the European Union of Industrial and Employers' Confederations (UNICE, or Union des Industries de la Communauté européenne) and the Keidanren, a powerful private federation of economic organizations in Japan. These groups worked to convince their governments that intellectual property should be on the agenda for the GATT talks. Pratt noted that the joint action by US, European, and Japanese business groups was a significant breakthrough in the involvement of the international business community in trade negotiations (quoted in Drahos 1995, 13; cited in Sell 2003, 106).

Representatives of the IPC also traveled to Geneva to meet with officials at WIPO. The UN agency was run by Arpad Bogsch, who had been the US representative to the Paris and Berne Conventions in 1962 and had organized the conference that established WIPO in 1967 (he retired from WIPO in 1997). The organization was born and built from his vision.<sup>37</sup> Some intellectual property industries were dissatisfied with WIPO, viewing the protection offered by the regime it administered as insufficient. Enyart characterizes WIPO as "like many other UN agencies, kind of taken over by the developing countries"; it "spent enormous amounts of time talking about how everybody ought to have technology for free and governments were going to give it to everybody. Notwithstanding the fact that governments own no IP to speak of." (Other observers object to this characterization of WIPO, recognizing its value as a technical body.) The IPC nevertheless hoped to gain WIPO's support for including IP in the GATT talks. As Enyart tells it, Bogsch "invited us up to his penthouse overlooking Lake Geneva":

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35. The IPC's 13 member companies were Pfizer, IBM, Merck, General Electric, Dupont, Warner Communications, Hewlett-Packard, Bristol-Myers, FMC, General Motors, Johnson & Johnson, Monsanto, and Rockwell International.

36. Unless otherwise noted, all quotes from Jacques Gorlin are from a September 1997 interview with Charan Devereaux.

37. Ryan notes that WIPO's story of institution-building leadership by one person is matched in the history of international governmental organizations only at the GATT and the International Labor Organization (ILO). Eric Wyndham White at the GATT and David Morse at the ILO each served as director-general for some 20 years beginning in 1948 (Ryan 1998, 127).

He fed us a multicourse lunch from his private dining room. It was concluded with cognac and cigars. . . . Finally, we said to him, "Look, Mr. Bogsch, we have found WIPO to be not constructive in the protection of IP and we are going to do something about it. You are either going to help out or we are going to go right around you." And he said, "Well, you can't do that, we are the only authorized organization." And we said, "Well, we are going to do it. You've got your choice; you either get on board or get left in the dust." . . . It turned out, when the negotiations started in GATT, Mr. Bogsch became very friendly and said that there was a great deal of expertise in WIPO and how there ought to be a huge role for WIPO in the TRIPS agreement. You will notice that the TRIPS agreement has a reasonably weak consultative role for WIPO.

Within the US government, Assistant USTR Bale became the point man for getting IP into the GATT talks. Bale and his colleague Emery Simon established an interagency process to promote a consensus for bringing the issue to the Uruguay Round. According to Simon, "It was not an easy process." The two also worked to convince America's major trading partners to support the inclusion of IP on the agenda. Discussion at that point focused not on details, specific industries, or standards, but just on the idea that the negotiation should take place. Although they worked closely with the IPC, Simon makes clear that "we were really doing two different jobs."

In the spring of 1986, six months before the Uruguay meeting, Bale met in Canada with the Friends of Intellectual Property, a group he organized. He recalls the government representatives from Europe, Japan, Australia, and Canada who gathered to discuss the issues displaying "a lot of curiosity, but not a lot of immediate support."<sup>38</sup> Soon thereafter Bale met with the GATT Secretariat to discuss the possibility of including IP in the Uruguay Round. According to Bale,

The reaction of the GATT Secretariat was, "Well, maybe there's a chance for counterfeiting to be addressed, but not other issues"—not copyright, not patents, not trade secrets. Their perception was that there was too much opposition coming from developing countries. There was too much of a North-South issue.

### ***The North-South Issue***

Some developing countries did not agree that intellectual property should be protected like any other property. Technological innovation was not universally seen as a private capital good; many saw it as a public good that could be used to protect health or promote economic development. Indira Gandhi, for example, told the World Health Assembly in May 1982 that "the idea of a better ordered world is one in which medical discover-

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38. Unless otherwise noted, all quotes from Harvey Bale are from a 1997 interview with Charan Devereaux. Bale worked at USTR from 1975 until 1987, when he became international trade manager at Hewlett-Packard; he became senior vice president international for the US Pharmaceutical Manufacturers Association (PMA, later renamed PhRMA) in 1989. In 1997, Bale became director-general of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

ies will be free of all patents and there will be no profiteering from life and death” (quoted in Siebeck et al. 1990, as cited in Chaudhry and Walsh 1995, 88). Some developing countries viewed patents as a significant obstacle to technology transfer and believed managing and controlling patents to be key to development policy.

Developing countries that resisted the inclusion of IP in trade negotiations also cited the importance of protecting indigenous industries and controlling prices. Stronger IP protection was seen by many of these countries as a vehicle enabling foreign multinationals to exercise monopoly power and excessive control over technology, thereby forcing many domestic companies out of business and inflating prices. Finally, many developing countries argued that the Uruguay Round was not the appropriate venue for agreements on intellectual property. India was a strong proponent of this view, holding that IP was not “trade-related” and, hence, did not belong in the GATT structure. Inasmuch as GATT’s mandate extended only to trade in tangible goods, IPR issues should continue to be addressed in the WIPO.

Nevertheless, some observers suggest that developing countries did not believe intellectual property to be the most threatening issue under consideration for the Uruguay Round. In the lead-up to Punta del Este, three so-called new issues were discussed: services, investment, and intellectual property. “On the developing countries’ side, I think they were more focused on the services onslaught than the TRIPS onslaught,” says former GATT Secretariat staff member Arvind Subramanian. “They were really, really opposed to liberalization of services. Some would say that the developing countries made a strategic mistake: they expended a lot of negotiating coinage trying to resist services and kind of overlooked TRIPS.”

### ***A Decisive Moment***

Right up to the GATT ministerial meeting in Punta del Este, the status of IP remained uncertain. Inclusion of intellectual property rights had been considered from the outset by the Preparatory Committee, established in November 1985 to discuss the next round of GATT negotiations. The committee’s debates intensified through 1986; the United States raised the stakes by proposing that IPRs be covered in general rather than only in relation to trade in counterfeit goods. A group of 10 countries led by Brazil and India took a hard-line stance against the US position.<sup>39</sup> Even within the European Community, some believed that GATT was not an appropriate venue for IP; they feared that the complicated issue would overload the system, jeopardizing the whole negotiation. At the final preparatory meeting, Commerce Secretary Baldrige declared that President Reagan

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39. The other eight countries were Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania, and Yugoslavia.

wanted intellectual property in the talks, and implied that the US would not move forward without it.

Baldrige and Agriculture Secretary Richard Lyng accompanied USTR Clayton Yeutter to the GATT ministerial meeting where Yeutter declared he would walk out of the talks unless four key US priorities were on the agenda for the new round. “We regard the issues of agriculture, services, investment and intellectual property as critical to the future of all GATT members,” Yeutter said. “We cannot envision nor agree to comprehensive new trade negotiations that do not include these four issues on the agenda.”<sup>40</sup> Pfizer’s Edmund Pratt, who also attended the ministerial, noted that if the business community “doesn’t get most of the new issues, our enthusiasm for the new round will go down substantially.”<sup>41</sup> In the end, intellectual property was included in the September 1986 Punta del Este statement that launched the Uruguay Round—but the battle had just begun. “We wanted to get it on the agenda, get a foot in the door, but nobody knew where it was going to go from there,” notes Bale. “Nobody had a clue what this agreement was going to look like.”

## The TRIPS Negotiations

### *The First Two Years*

The TRIPS group, chaired by Lars Anell from Sweden, was one of 15 negotiating groups in the Uruguay Round of GATT. However, the presence of IPRs in the Uruguay Round process did not imply that there was any sort of international consensus on the issue, or even a mandate for broad discussion. The language of the ministerial declaration establishing the negotiation objective for IP, written by the Swiss and Colombian ambassadors, was somewhat ambiguous and general:

In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiation shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines. Negotiations shall aim to develop a multilateral framework of principles, rules, and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT.

These negotiations shall be without prejudice to other complementary initiatives that may be taken in the WIPO and elsewhere to deal with these matters.<sup>42</sup>

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40. Yeutter quoted in Mary Beth Franklin, “Protectionism Would Result in ‘Suicidal’ Trade War,” United Press International, September 15, 1986.

41. Pratt quoted in Clyde H. Farnsworth, “US Rejects a European Trade Move,” *The New York Times*, September 15, 1986, D10.

42. “Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods,” in *WTO/GATT Ministerial Declaration on the Uruguay Round (Declaration of 20 September 1986)*, [www.jus.uio.no](http://www.jus.uio.no).

Many developing countries understood the Punta del Este statement as limiting treatment of IP to the problem of trade in counterfeit goods, not as opening the negotiations to set global standards of protection for IPRs, raise the levels of such protection, or strengthen enforcement procedures. India and Brazil were among those resisting the notion that the statement should lead to a discussion of whether their own national legal systems offered foreign suppliers adequate IP protection.

Progress in the intellectual property group was consequently slow. With the United States emphasizing the need to set standards of protection and developing countries focused on having access to new technologies and balancing the interests of IPR owners and users, few points of agreement emerged. “The first two years was a depressingly familiar assertion and reassertion of everyone’s positions,” recalls Subramanian. US negotiator Mike Kirk concurs:

The first two years were almost exclusively, to use the phrase of one of the guys involved, a Kabuki dance where we just talked in generalities. We would lob principles at the South and they would either sit there and ignore them or occasionally lob an idea back at us. But there was no real discussion. And since you’re talking in the context of a trade negotiation, you’ve got primarily trade negotiators present, many of whom didn’t have the foggiest idea of what the intellectual property issues were all about. . . . So you had this general discussion that went on for a couple of years as people became educated on what IP was.<sup>43</sup>

Many echoed Kirk’s conclusion that participants’ general lack of experience in IP slowed the negotiation process. The US team, in contrast, drew on a variety of federal agencies and included intellectual property experts as well as trade negotiators. Gorlin, the head of the IPC, emphasizes that difference:

One of the things that the United States was very good about, which other countries were not, was the relationship between the Patent Office, the Copyright Office, and the USTR. USTR was the leader in the round because it was a GATT case. But the relationship between Mike Kirk at the Patent and Trade Office and Emery Simon and others who did IP at USTR was tremendous, a model relationship. It was especially good when Mike Kirk was there the last couple years. In some countries, the patent people weren’t brought in by the trade people. But in the United States, it worked beautifully.

The US negotiating team attempted to make some progress. “We set up a negotiating group, including mostly the OECD [Organization for Economic Cooperation and Development] countries, and went through a substantive review of standards,” recalls Mike Hathaway, the lead US negotiator until 1989. But despite these efforts, the first couple of years of the TRIPS talks were dominated by the North-South debate. Hathaway adds,

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43. Unless otherwise noted, all quotes from Mike Kirk are from a September 1997 interview with Charan Devereaux.

We certainly had fun for two years, beating down arguments made by India. For example, patented products made up only 3 percent of all medicinals. The difference between the price a pharmaceutical pirate would charge and a legitimate producer would charge was at most around 15 percent. The pirates pretty much charged the same amount as the legitimate products; it was really the market, the ability to pay, that set the price. The difference to the consumer in terms of cost was almost nil, and think of the difference in what you get from a legitimate producer in terms of education, care, and reliability of product. No one could defend the existence of counterfeit birth control pills that were on the market. The advantages to the consumer of protecting legitimate products were really quite good even if you didn't count the biggest advantage, the market incentive to produce cures for illnesses.

The IPC founded by IBM and Pfizer was active during this period. According to Gorlin, preoccupation with the North-South debate blocked any “substantive negotiation . . . , so we took advantage of those two years.” In November 1986, IPC IP specialists met with their counterparts at the Keidanren in Japan and UNICE in Brussels to begin drafting a framework for the round. Gorlin explains, “We basically wanted to come up with a book that said, ‘This is what we want.’”

From the IPC's perspective, it was important that industry articulate the minimum acceptable standards for intellectual property protection. IPC representatives believed that the most relevant expertise on intellectual property was found in industry, where experts understood how any proposed standards would actually function. “You can be the top patent attorney with a tremendous amount of international experience in the Patent and Trademark Office,” Gorlin maintains, “but if that is the only experience you've had, you will really not know the effect different laws and language will have on your ability to enforce a patent. So we basically said, ‘Look, it is only the private-sector IP specialists who really know what types of minimum standards will help us.’”

Owing to their different IP systems, the Americans, Japanese, and Europeans did not always agree on what the minimum standards were. Instead of attempting to negotiate treaty language, industry officials tried to identify what baseline characteristics their patent, copyright, and trademark regimes shared. “For example,” explains Gorlin, “we didn't say, in terms of patents, that it had to be a first-to-file system as opposed to a first-to-invent system. We just said that every country has to have a system for giving a patent.” Such compromises were not always straightforward, however. He elaborates:

The negotiation of that basic framework was tough. We spent long hours. But we shared the same objective of trying to come up with an agreed text. In some areas, the biggest problems the Europeans and the Japanese had were not necessarily with the developing countries, but with the United States because we were their largest market. For example, the Japanese were very concerned about changing the US market because of all the Japanese electronic industries that were basically only exporting to the United States. So there were tensions. There were certain



things we had to change and that we recommended. I mean, we were not government; we were industry. But our thrust was to create a set of minimum standards that would reflect the level of IP protection in those countries that had good IP protection.

The IPC also sought support from and consensus with US trade groups. While UNICE and the Keidanren represented all the employer industries in Europe and Japan respectively, the IPC represented only 13 companies. It therefore arranged meetings every six to nine months with industry associations; 30 to 40 would review drafts of recent work. Eric Smith, who represented the copyright industries through the IIPA, was invited to help develop the basic framework. He recalls that “the IPC people were pretty great. They welcomed us and they knew that we had the constituency that could help sell TRIPS in the United States and they didn’t. So they invited us.”

Completed in June 1988, the 100-page IPC report detailed minimum standards for an acceptable TRIPS agreement. It was viewed as the product of a unique collaboration among the US, European, and Japanese business communities. Hewlett-Packard president and CEO John A. Young characterized the undertaking as “unprecedented[,] . . . the first time that the international business community has jointly developed a document of this magnitude and such substantive detail for presentation to our government negotiators.”<sup>44</sup> Delivered to the US negotiators, the document contributed significantly to the final agreement. According to one negotiator, “There were really two prototypes for what eventually became the TRIPS agreement. One was the IPC’s basic framework and the other was a bilateral agreement the United States negotiated with Korea in the summer of 1986.”

While the US government was interested in the coalition’s position, other countries were not so receptive. Pfizer general counsel Lou Clemente remarked, “The European governments were less willing to adopt these views. Instead, they chose to emphasize the differences between the United States and Europe. The Japanese government was even less responsive to the document. In the Japanese culture there is a much different relationship between government and business. In Japan, it is the government which decides what is best for Japan and for Japanese business” (quoted in Santoro 1992, 12).

As the TRIPS effort continued, new trade legislation was passed by Congress that further strengthened the United States’ ability to apply pressure on countries that denied IP protection to US firms. The 1988 Omnibus Trade and Competitiveness Act included a provision known as “Special 301,” which required the USTR to submit an annual report to Congress identifying nations that denied adequate protection for IPR or that denied fair and equitable market access to US IPR holders—and to re-

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44. IPC press release, June 14, 1988; quoted in Santoro (1992, 12).

tialiate more quickly. The most serious violators were designated “Priority Foreign Countries”; other countries, placed on a “Priority Watch List,” were subject to bilateral negotiations, while nations that merely required monitoring were put on a “Watch List.”

The brainchild of TRIPS negotiator Mike Hathaway, Special 301 provoked great resentment among US trading partners and was denounced internationally. Yet from the perspective of US industry and many in Congress, threats of action under Special 301 succeeded in encouraging many countries to begin strengthening their intellectual property laws. In 1989, 25 countries were cited under Special 301, with Brazil, India, South Korea, Mexico, China, Saudi Arabia, Taiwan, and Thailand placed on the Priority Watch List. Brazil and India warned that US actions under 301 threatened the Uruguay Round and violated the GATT.

Under the 301 initiatives, USTR investigated Brazil’s computer software protection and pharmaceutical patents. In response, Brazil created software copyright protection in its Software Law of 1987. But when the Brazilian government showed no commitment to increase process and patent protection for drugs, the United States increased tariffs to 100 percent on Brazilian exports of certain paper products, consumer electronics, and pharmaceutical products, affecting trade worth about \$39 million. The tariff increases, which took effect October 1988, virtually prohibited Brazil from exporting these products to the US market during 1989 and the first half of 1990.<sup>45</sup> In its written submission to the TRIPS negotiating group in October 1988, Brazil argued that the group had a mandate to discuss “rigid and excessive protection of IPRs” (Watal 2001, 25).

In the end, the United States backed down from its section 301 retaliation when Brazil filed a complaint under the GATT. Following assurances by Brazil’s president that patent protection would be extended to pharmaceutical products, USTR Carla Hills rescinded the tariffs (Brazil’s legislation was not enacted until 1996). According to a former USTR official, Hills “didn’t want to be found in violation of the GATT. When she rescinded the tariffs the Brazilians withdrew their complaint.”

### ***The Mid-Term Review and Beyond***

At the December 1988 Uruguay Round midterm review in Montreal, TRIPS remained among the problem groups, unable to arrive at a consensus for the framework of the talks. Mike Kirk recalls, “We were not ready for the midterm review, but it was a nice wake-up call. It told everybody, ‘Okay, if we’re going to achieve anything we’ve got to get a little bit more focused; we’ve got to come to grips with the issues a little bit better.’ ” Developing countries continued to block any discussion of substantive standards. In addition, Europe’s official position was “far, far behind that of the United States,” according to one US observer, who suggested that the

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45. USTR, “Report to Congress on Section 301 Developments, January 1995–June 1996.”

Europeans “were much more willing to provide exemptions that would have allowed India and Brazil to, in effect, gut any IPR obligations.”<sup>46</sup>

The deadlock over TRIPS was finally broken in April 1989 at the Trade Negotiations Committee meeting in Geneva. “After April,” according to Kirk, “we really got it together and started moving forward.” Several US observers gave credit to the Association of Southeast Asian Nations for moving the talks along (at that time, ASEAN comprised Brunei Darussalam, Indonesia, Malaysia, the Philippines, Singapore, and Thailand). Former assistant USTR Bale explains, “The ASEAN countries were kind of middle-ground mediators. . . . India and Brazil were the most strenuous in their opposition to TRIPS, followed by Egypt and Pakistan. I’d say those were the four major opponents to the issue. But other countries that were far more interested in trade organization, like the ASEAN countries, felt it was essential that the United States have its way on TRIPS.” Developing countries agreed to lift their block; India and Brazil were the last holdouts.<sup>47</sup> The negotiation objectives were clarified and the issues of adequate IPR standards and their enforcement were specifically identified as part of the talks. It was also agreed that the negotiations would take the developmental and technological concerns of developing countries into account. At last, US negotiators sighed, there was a framework for the TRIPS negotiations.

Why did developing countries agree to broaden the discussion? A number of observers believe that some nations were willing to trade support of TRIPS for improved access to industrial markets in agriculture, textiles, and light manufacturing products. “A negotiator from Argentina said that they didn’t give a damn what was in the IP code as long as they got what they wanted in agriculture,” notes Enyart. “Which shows you that these nontraditional GATT agreements [like TRIPS] would probably never make it if they weren’t carried in a wider negotiation.” As Simon puts it:

One of the reasons why people try to get these issues onto the trade agenda is because there are cross-sectoral trade-offs. If you are negotiating on IP with Brazil and you say to the Brazilian, “If you don’t protect US software, we won’t protect Brazilian software in the United States,” that is a meaningless threat. However, if you say to the Brazilians, “If you don’t protect US software then we won’t let you export coffee to the United States,” then that is a meaningful threat. The big break after the midterm review was a much clearer engagement on agricultural issues. Developing countries in general wanted substantial liberalization on agricultural exports. So, suddenly, they had more of a stake in these negotiations. For us, the IP agenda was one of our big stakes. So, in return for being more forthcoming on agriculture, which really took another four and a half years, we got some greater forthcomingness on IP.

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46. For example, European proposals excluded patents on plant and animal varieties and on biological processes for producing plants and animals.

47. India resisted until September 12, 1989, “when it announced it had accepted in principle the international enforcement of trade-related IP rights within the Uruguay Round context” (Sell 2003, 109).

The Uruguay Round agreement reduced agricultural tariffs and agricultural subsidies.<sup>48</sup> In addition, the Uruguay Round agreement phased out the MFA. Since 1974, the MFA had permitted discriminatory use of textile quotas, mostly applied by developed countries to products from developing countries (India also maintained high barriers under the MFA). Those expected to gain most from the MFA phaseout were low-income countries in South Asia as well as Hong Kong, South Korea, Taiwan, Singapore, and China (at the time, not a GATT member). Observers note that one of the key underlying bargains of the Uruguay Round was the acceptance of TRIPS by some developing countries in exchange for the end of such quotas. It was “a TRIPS-for-MFA deal,” says one source.<sup>49</sup>

In addition to being attracted by the carrot of lower tariffs in textiles and agriculture, some developing countries threatened by the stick of section 301 saw TRIPS as the lesser of two evils. Under TRIPS, intellectual property conflicts would be subject to the WTO dispute settlement machinery. Though they strongly disliked “cross-sanctions”—reprisals on goods trade for breaches of TRIPS—developing countries found the prospect of answering exclusively to the United States even less appealing. In addition, many Latin American countries, including Chile and Mexico, were already strengthening their IP protections. Though these nations continued to hold their earlier positions on TRIPS, they were described as displaying a “marked lack of fervor” in pursuing those objectives (Watal 2001, 31). “Section 301 is really the ghost of this whole Hamlet story,” according to Subramanian, “because it turned out to be key in shaping the eventual outcome. It had a huge influence in terms of changing developing countries’ position on intellectual property.”

Some developing countries also recognized that certain multinational companies increasingly viewed IP protection as decisive in attracting foreign investment. Providing IPRs had become one more way to vie for foreign capital in a competitive world. More generally, many developing countries, believing the GATT to be their best defense against stronger nations, viewed IP protection as the price they had to pay for the success of

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48. Some argued that these changes would improve market access for developing countries, though others maintained that such benefits were overstated. Agricultural tariffs were reduced by an average of 36 percent in developed countries and 24 percent in developing countries. Because agricultural tariffs were to be reduced by 36 percent *overall*, developed countries could reduce tariffs in some areas while maintaining significant protections in other sectors.

49. Later, however, developing countries would be frustrated by the implementation process of the textiles deal. The MFA phaseout was “backloaded,” meaning almost half of the textile products in question would not be liberalized until the very end of the 10-year implementation period. Many countries also worried that when textile quotas were eliminated, they would be replaced with other barriers.

the Uruguay Round. “There was a systemic issue at stake,” Subramanian explains, “a real fear that if they didn’t agree to intellectual property, the US would turn away from the Uruguay Round and that was not in the interest of developing countries.”

## A Landmark

The break in the deadlock led to a flood of substantive proposals.<sup>50</sup> In general, submissions from developing countries favored looser standards and enforcement. The question of where to lodge the TRIPS agreement—in the GATT or in WIPO, as developing countries favored—also remained open. Jayashree Watal, then a negotiator for India, notes, “In retrospect, it appears that some developing countries paid more attention to this aspect than to taking coordinated positions on substantive norms and standards of IPRs” (Watal 2001, 28).<sup>51</sup>

Perhaps the most important proposal came from the Europeans, whose draft TRIPS agreement was forwarded in 1990. Subramanian calls it “a landmark in the process. . . . For some time, TRIPS had been seen as an exclusively US-led initiative. . . . But when the EC tabled [i.e., submitted] its proposal, that signaled a change in the European position from one of being mildly in favor of an IP agreement to one that was almost as strong as that of the US. It changed the balance of power.”

The Europeans had strategic as well as commercial reasons for becoming more assertive about pursuing TRIPS. Looking ahead to the final Uruguay Round agreement, the negotiators knew that changes in European agricultural policy were inevitable. In all likelihood, these changes would be most unappealing to France. The Europeans pushed for intellectual property rules related to geographical indications on wine as one method of satisfying the French, and thereby helping to sell the agreement as a whole.

As the negotiations moved through 1990, their focus shifted to disagreements between the countries that largely controlled IP. One negotiator recalls, “Increasingly it became a North-North debate, and everybody else was going along for the ride.”

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50. Legal drafts were submitted by the European Community, Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Japan, Nigeria, Pakistan, Peru, Switzerland, Tanzania, the United States, Uruguay, and Zimbabwe.

51. Watal notes that the written submissions of Korea, Peru, and Brazil argued for a balance between the rights and obligations of IPR owners. In addition, Korea made a case for liberal compulsory licensing of patents. India argued that patents were linked to critical developmental priorities such as “food production, poverty alleviation, nutrition, health care, and disease prevention” (Watal 2001, 29).

## ***Negotiating Standards***

Once a framework had been established for the negotiations, a variety of contentious issues needed to be resolved. Six of the differences between the United States, the European Community, and Japan were paramount.

**Geographical Indications.** The European Community and Switzerland wanted strong protection for geographical indications that “identify a good as originating in the territory of a Member, or a region or a locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin” (GATT, Article XXII). For example, such protection would apply to wines associated with specific regions, preventing US wineries from naming their products *champagne*, *bordeaux*, *chablis*, and so forth.

**Patents.** Disagreements continued about exceptions to patentable subject matter. For example, should plant and animal varieties be patented? Another area of dispute was the basis on which patents were awarded. While other countries used a first-to-file system, the United States granted patents to the first to invent a product—but insisted that foreign inventors seeking patents in the United States be the first to file. Therefore, it was possible for a US patent to be awarded to a US applicant rather than a foreign applicant who actually made the invention first.

**Pharmaceuticals.** In addition to ensuring protection for pharmaceutical patents more generally, the US pharmaceutical industry was especially interested in limiting compulsory licensing that could force patent owners to license their technologies to local domestic producers. The industry also wanted “pipeline” protection—that is, patent protection for pharmaceuticals that were in the research pipeline but not yet on the market.

**Software.** The United States wanted to accord software the same copyright protection as literary works, but the Japanese resisted.

**Moral Rights.** Europeans supported the inclusion of *moral rights*, which would protect an author’s work by preventing others from claiming authorship of it or making deforming changes to it. US copyright law did not recognize moral rights.

**Rental Rights.** The US recording industry wanted to prohibit commercial rental of recorded works. In 1989, IIPA president Eric Smith drafted a preliminary 301 petition against Japan regarding the approximately 7,000 Japanese rental shops from which consumers could rent and then copy CDs.

One challenge in negotiating such issues was what one participant describes as “the all-or-nothing” nature of IP. “You can’t split the difference,”

he explains. “It’s not like you can have *half* of an exclusive right. You either have an exclusive right, or you don’t.” Most trade negotiators were accustomed to a more traditional system in which a middle ground could be negotiated and deals could be cut relatively quickly. “You go into a smoke-filled room with about 25 other countries and hammer out the deal, then you walk out, the white smoke lifts, and that’s it. But you can’t do that in IP. . . . TRIPS just did not fit the old paradigm.”

Another problem with the negotiations, from the US perspective, was the perceived unwillingness of the Europeans to spend any political capital. During the TRIPS negotiations, one American recalls, “the Europeans traditionally would cater to and appear to side with the developing countries on certain issues, knowing the US had a common interest on the protection of IP and that the US was not going to cave in.” Some observers go so far as to accuse the Europeans of getting a free ride through TRIPS on the back of US efforts. Others characterize it differently. According to one, “the EU negotiators were smarter than the US negotiators. The US goes for a sledgehammer approach to everything, which has its strengths and drawbacks. But the Europeans were much more subtle. If you work in the [European] Commission, which is a hotbed of intrigue, then it is a piece of cake handling the Americans. If you can manage a Commission process involving the Italians, the French, the Germans, and the Brits, then you can manage any negotiation. No problem.”

More than politics and tactics separated the US and European teams. One difference was the consistency of the players. “This is one of the things that I think the EC has an advantage in,” according to Kirk.

In the trade directorate there, the folks that were involved in the TRIPS negotiation had been involved in this area for many years, and in the trade talks—the Tokyo Round, etc. They are still there, the same people. And in the US, there has almost been a complete turnover in the IP negotiating group. They started out with Harvey Bale who went to PhRMA, then Mike Hathaway who went into private practice, Bruce Wilson who went to the Hill, and then myself who left and came here [to the American Intellectual Property Law Association]. My concern about the future, and it’s a serious concern, is that if we ever get into one of these things again who are you going to turn to? Who was there that really knew? We don’t structure ourselves very well for this in the United States.

The US and European negotiating teams also approached their interactions with representatives of domestic industry very differently. “In terms of bringing industry input,” recalls one observer, “the European Commission people were removed from the pressures of lobbying.” EC officials communicated with representatives of the member states, but paid little attention to industry. In fact, European industry representatives often approached the US team in hopes of gaining more influence in the talks. In contrast, US negotiators met directly with industry representatives. Although these consultations slowed the US team in establishing an

initial position, says one observer of the process, it enjoyed much better real-time information from the private sector.

### ***The Talloires Text and the Draft Composite Text***

In order to counter the TRIPS proposals put forward by the US, Europe, and Japan, 14 developing nations created a common text with help from the UNCTAD Secretariat. The document became known as the Talloires text, after the picturesque French town where the delegations worked. Jayashree Watal notes that the Talloires process could have been a chance for interested developing countries to coordinate positions on each substantive issue, but because of their lack of technical expertise, time, and coordination, they “lost a crucial opportunity to put forward a more detailed text.” However, the document did become the basis for negotiating a number of articles in the final TRIPS agreement (Watal 2001, 31–32).

Continued lack of overall consensus in the TRIPS group led Swedish ambassador Lars Anell, the group’s chairman, to prepare a draft TRIPS text with his staff in June 1990. The document was essentially a summary of the issues and positions under debate. Anell combined the various legal proposals submitted by the negotiators, including alternate options in brackets in areas of disagreement.

Using the draft text as a baseline, the TRIPS negotiators followed the “Green Room” pattern of GATT talks. In the Green Room process, delegates from all the engaged countries face each other across a table to discuss and exchange texts. For six months, participants whittled away at the issues, trying to remove as many of the brackets as possible. “That period was the heart of the negotiating process,” Subramanian remembers. “It was very technical, but the text was considerably streamlined.” For example, many developing countries argued in favor of a rule permitting parallel imports—bringing goods into a country without the consent of the rights holder after those goods were placed on the market; the United States and Europe argued against it. (In the end, negotiators agreed that the exhaustion of intellectual property rights, the basis for parallel imports, could not be made an issue in any WTO dispute settlement.) The result of the overall negotiation process was the December 1990 “Draft Composite Text” presented at the Brussels ministerial meeting.

### **The Uruguay Round Breaks Down**

In December 1990, an impasse between the United States and the European Community over agricultural subsidies brought the entire Uruguay Round to a halt. At the time of the breakdown, tremendous progress was being made in TRIPS. “We were sitting there thinking we were doing some serious negotiating,” recalls Kirk, “and the Argentine ambassador walked in and whispered in the ear of his negotiator at the table and the guy just



stood up and said, 'We are walking out. This whole meeting is over.' And sure enough, everybody got up and walked out and it was over because agriculture fell apart."

In February, Bush administration officials, working through GATT staff, endeavored to resurrect the failed round. The Americans offered the Europeans an olive branch by abandoning their most prominent demand in farm trade policy—that the European Community commit to reduce its subsidized grain exports by 24 percent over six years.

### ***The Dunkel Draft***

When the talks were restarted in early 1991, the TRIPS negotiation process continued, but little progress was made. Many issues from the year before remained unresolved, including moral rights, patents, the scope of protection for computer programs, the length of protection for sound recordings, trade secrets, dispute settlement, and transition periods for complying with the agreement. As GATT Director-General Arthur Dunkel explained at the time, "the reason why the list is essentially unchanged is that there has been a general reluctance to settle these issues until there is a perception that the Uruguay Round negotiations as a whole are in their final lap."<sup>52</sup> Jacques Gorlin remembers, "Since the remaining TRIPS issues were mostly political and related not only to each other, but also to concessions being made and received in other negotiating groups, the TRIPS negotiations proceeded at a snail's pace throughout most of [the] year" (Gorlin 1999, 5). Instead of leaving negotiators to work out language in face-to-face negotiations, Anell began to propose suggested text to the delegates.

The GATT Secretariat tried to break the continuing deadlocks in the overall Uruguay Round by presenting a comprehensive "Draft Final Act" for the entire negotiation in December 1991. The Dunkel Draft, which took its name from the GATT's director-general, paved the way for the completion of the talks. Instead of bracketing areas of disagreement, the Secretariat staff proposed its own text in consultation with the interested parties. According to longtime observers, this approach was unique in the history of the GATT, which traditionally had functioned as a kind of legal advising body to the member states. But the pending issues of agricultural and aircraft subsidies and of TRIPS, recalls one observer, drove the Secretariat to "put out a text on its own, which it never really had done before to such an extent with such controversial areas. It brokered the differences."

By some accounts, Dunkel had initially expressed doubts about including intellectual property on the Uruguay Round agenda, in large part because he was concerned about its implications for pharmaceuticals in developing countries. He had spoken publicly about the importance of

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52. GATT document MTN.TNC/w/89/Add.1, 8 (dated November 7, 1991); quoted in Gorlin (1999, 2).

access to health care and the right of nations to regulate drug prices. From the point of view of some in the United States, such positions made him a tainted interlocutor.

The Dunkel Draft was nevertheless largely supportive of the US IP interests. Some observers believe that Dunkel recognized the GATT could not afford to lose the backing of companies such as Pfizer and IBM. In the United States, traditionally trade-bolstering industries such as steel and automobile manufacture were displaying less enthusiasm for free trade; the most aggressive support came instead from industries heavily dependent on intellectual property and high technology. Those industries were also seen as crucial for getting the GATT through Congress.

Others add that Dunkel himself had little to do with the TRIPS agreement draft. On this account, the TRIPS agreement was essentially a version of the December 1990 TRIPS Draft Composite Text, revised by Anell in consultation with interested delegations. “It was Lars Anell and his assistant Adrian Otten who sat through all of the negotiations,” one observer points out. “It was the two of them who created that text. Ultimately they were working within fairly circumscribed parameters principally to do with what the negotiations had been all about.” Participants in the TRIPS negotiations acknowledge that without the Draft Composite Text, there would have been no substantive TRIPS agreement: “we would have gotten little or nothing—just as it happened in investment and services,” in the words of one. For that reason, several negotiators refer to Lars Anell as hero of the story, and of the GATT Secretariat (Ryan 1998, 112).

Ultimately, the Dunkel Draft’s TRIPS agreement provided strong IP protection, but delayed its implementation for developing countries for five to ten years. US pharmaceutical companies were especially critical of these transition periods and also criticized the draft because it lacked pipeline protection for drugs under development. The entertainment industry complained that discriminatory practices in the copyright area were not explicitly addressed. But observers say these concerns must be put into perspective. For example, even longer implementation periods were under consideration—including a 15-year transition period for pharmaceuticals, proposed by the European Community and India. US negotiators were able to reduce that time frame.

## The End Game

By December 14, 1993, every item in the Uruguay Round had been decided except for elements of the entertainment industry’s “audiovisual” issue (i.e., movies, television, and recordings). Stories in the *New York Times*, *Los Angeles Times*, and *Washington Post* chronicled the “culture war” being waged between Europe (primarily France) and the United States.

Differences between French and US filmmakers dated back to the industry's very beginnings, when the French credited the discovery of the cinema to the Lumière brothers of Lyons and the Americans to Thomas Edison.<sup>53</sup> In this case, Hollywood blasted the French as blatant protectionists, citing national policies that favored European films and television. The French accused the United States of cultural imperialism, with President Mitterand charging that Americans were trying to impose their "totalitarian" dominion over the minds of the world.<sup>54</sup> According to Pascal Rogard, the chief French film industry lobbyist, "French films are the cinema of creation. American films are products of marketing."<sup>55</sup>

The principal areas of disagreement fell under the purview of TRIPS and the agreement on trade in services. The French government taxed blank videocassettes and recorders, giving the proceeds to French filmmakers to compensate them for the illegal copying of their works that inevitably occurred. The Motion Picture Association of America argued that under the TRIPS principle of national treatment, US filmmakers should share in these levies. In the trade in services negotiations, the United States also pressed for changes in European laws that reserved 51 percent of local television programming for European productions. For their part, the French sought to make an explicit "cultural exception" part of the deal.

The US entertainment industry had commitments of support from both the Bush and Clinton administrations. President George H. W. Bush had said he would not sign a GATT that exempted audiovisual services from international trade rules. President Bill Clinton had told 16 top entertainment executives in October 1993 that he would not sign any agreement in which film, television, and video were "singled out for unacceptable restrictions."<sup>56</sup> The MPAA's Jack Valenti threatened to try and block congressional approval of the Uruguay Round if audiovisual services were exempted from the agreement. "I don't want there to be any ambiguity," he said. "If these quotas exist, this is Armageddon time. I'm on the Hill in a New York minute bringing out every Patriot missile, every F-16 in our armory, leading whatever legions we can find to oppose this agreement."<sup>57</sup>

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53. Roger Cohen, "Aux Armes! France Rallies to Battle Sly and T. Rex," *The New York Times*, January 2, 1994, Section 2, 1.

54. Mitterand quoted in Charles Bremner, "Where Did French Films Go Wrong?" *The Times* (London), December 10, 1993, 18.

55. Rogard quoted in Charles Goldsmith and Charles Fleming, "The GATT Challenge—Big Picture," *The Wall Street Journal Europe*, November 23, 1993, 1.

56. Clinton, quoted in Karen Tumulty, "Europe's US Film Curbs Could Scuttle Trade Talks," *The Los Angeles Times*, December 4, 1993, A1.

57. Bruce Stokes, "Tinseltown Trade Wars," *The National Journal*, February 23, 1991.

Some felt that the US industry's rhetoric and posturing on these issues "certainly got the French riled up." One US official remembers:

The French went to the European Commission and said very strongly, "Over our dead bodies will you make any concessions in these areas." I think we would have been better off if [US entertainment industry representatives] would have just shut up and sent some of their people to France to see what might be possible. How do you negotiate with somebody if you've got one of your team sitting over there across the ocean calling them a bunch of scumbags? It doesn't lead to progress, I think.

However, other observers note that the Uruguay Round package was already a big win for the MPAA, suggesting that Valenti and others decided to underplay the existing gains in order to bolster their position to demand those concessions they had yet to win.

The Uruguay Round negotiations were coming to a close. Initially, most countries considered June 1993—the expiration date for the US Congress's fast-track authorization—to be the final deadline for the completion of the GATT talks. A delay in the agreement would subject the Uruguay Round text to line-by-line scrutiny by US legislators rather than an up-or-down vote on the trade agreement's implementing legislation. It was widely held that such an outcome would doom the compromises reached over six years of negotiating to a death by a thousand cuts.

But Congress extended fast track, and the new deadline for completion of the Uruguay Round became midnight on December 15, 1993. USTR Mickey Kantor and EU negotiator Sir Leon Brittan sat down in Geneva one last time to hammer out a final agreement. The bottom-line US proposal, issued at 3 A.M., included further intellectual property protection for the record and movie industries. One by one, aides on both sides dropped away from the talks, exhausted. Jack Valenti, who also participated in the negotiations, claims to have gone three days without sleep and one without food. Finally, just before dawn in Geneva (and before midnight in Washington, DC), Kantor called President Clinton for approval to abandon the audiovisual issue in exchange for completing the rest of the global trade pact. Clinton agreed.

In the end, despite criticisms, the TRIPS Dunkel Draft became part of the Uruguay Round Final Act with only minor modifications (for example, developed countries managed to insert a clause tightening restrictions on compulsory licensing for semiconductors as well as protections for confidential test data). Negotiations closed and the Uruguay Round Final Act was adopted by the 117 members of GATT in Marrakesh, Morocco, in April 1994.

The Uruguay Round Final Act delineated the most sweeping changes to the world trading system since the original 1947 GATT agreement. Worldwide tariffs were slashed by more than a third and many nontariff barriers, such as quotas, were reduced as well. The agreement also set up

a new body called the World Trade Organization to replace the GATT dispute resolution system. Many changes were required to bring US law into agreement with the terms of the act—changes that had to be approved by Congress.

## Getting the Uruguay Round Agreement (and TRIPS) Through Congress

After the heated battle in Congress over the North American Free Trade Agreement (NAFTA), some worried about the prospects for the Uruguay Round implementing legislation. The erstwhile NAFTA opponents rallying against the Uruguay Round agreements included former presidential candidates Ross Perot and Patrick J. Buchanan, Senator Jesse Helms (R-NC), consumer advocate Ralph Nader, and many environmentalists. Some believed that the proposed World Trade Organization would threaten US sovereignty, others emphasized the agreement's potential to harm American workers and the environment, and some decried the so-called favoritism being shown to big business.

US industry largely favored the Uruguay Round Agreements Act and worked to support its passage. Gerald Mossinghoff, then the president of PhRMA, recalls meeting “every morning when it was pending to decide who’s doing what, who’s seeing what congressman, who’s weak, who’s strong, where do we put an ad, and where do we find grass-roots support. It was a full-court press.” PhRMA formed a coalition with other high-tech trade associations to work toward passage of the agreement. Ads were published in the *Washington Post*, the *New York Times*, the *Wall Street Journal*, and other newspapers, proclaiming “America’s High-Technology Industries Need GATT.”

Among those opposing the Uruguay Round Agreements Act were a group of Democrats led by Senate Commerce Committee Chairman Ernest Hollings (SC). Hollings delayed the bill by holding a series of hearings in which he criticized US trade policy. However, key members of the Democratic leadership—among them, Majority Leader Richard Gephardt (MO), House Speaker Thomas Foley (WA), and Senate Majority Leader George Mitchell (ME)—supported the Uruguay Round. In addition, in a pre-Thanksgiving agreement, Clinton guaranteed that Congress could back out of the new WTO if it arbitrarily began ruling against American interests. This assurance satisfied the great majority of Democrats and Republicans.

Meeting in a lame-duck session after the 1994 elections, just before Republicans assumed control of both houses, Congress passed the Uruguay Round Agreements Act—288 to 146 in the House and 76 to 24 in the Senate. Passage also required an additional vote to waive congressional rules against any bill that added to the federal deficit. Following this last action of the 103rd Congress, President Clinton signed the text into law on De-

ember 8, 1994. The enactment of the Uruguay Round and the passage of NAFTA the year before made trade a signal success of Clinton's first two years as president.

## US Industry Reaction to the Final Agreement

The principal provisions of the TRIPS agreement included

- protection of patents for 20 years after the date of filing, regardless of place of invention or manufacture;
- patent protection for pharmaceutical products;
- patent protection for life forms (with certain exclusions for plants and animals);
- protection of copyrights for at least 50 years, with extension of copyrights to software;
- exclusive rental rights to authors of computer programs and films as well as to performers and producers of sound recordings and broadcasts;
- recognition of "well-known" trademarks;
- protection of confidential test data;
- protection of semiconductor layout designs for 10 years;
- the scope of the enforcement obligation;
- supervision of the agreement under the WTO by a council on TRIPS; and
- submission of conflicts arising under TRIPS to the WTO's dispute settlement mechanism.

The US software industry was pleased that TRIPS accorded its products the same 50-year protection as literary works (the Japanese had rescinded their initial opposition to this provision). US pharmaceutical companies were satisfied that nations could no longer discriminate against them "by field of technology": that is, countries could not maintain laws that denied patents only to medicines. In Kirk's judgment, "The issues that were on the table in 1986 and 1987 when this thing got kicked off all got addressed fairly well. It was almost preordained that software would be protected as a literary work and pharmaceutical products would be patentable. . . . The pharmaceutical guys and the software guys started the round. They're the guys that drove the process. They had their oars in right up front."

The US record industry also made gains under the TRIPS agreement. Though many countries had no tradition of protecting sound recordings,

they were now obligated to implement such protection. Moreover, its term was increased from 20 years (established under the Rome Convention) to 50 years. In addition, record companies were given the right to prohibit rental, subject to a grandfather clause that benefited Japan. Though the movie industry did not get everything it wanted, films and related products received improved IP protection under TRIPS. Because the Berne Convention was incorporated into the TRIPS agreement (see TRIPS Article 9), copyrights for films were enforceable through the WTO Dispute Settlement Understanding (DSU). Films also received protection under TRIPS Article 11 on rental rights.

Not all of the industry gains in the TRIPS agreement were concrete. When asked what had been achieved for the recording industry, Neil Turkewitz, senior vice president of the Recording Industry Association of America, replied: "Number one is not about the details, number one is the fact that the environment of the whole negotiating round, as well as the results, was a sign that intellectual property had risen to the forefront of consciousness of trade negotiators because of its prominence in global commerce. So I would start off with the recognition of the role of IP in the economic environment leading into the 21st century."<sup>58</sup>

To be sure, not all US companies were entirely satisfied with the agreement. Pharmaceutical companies' disappointment with the transition period for developing countries and lack of pipeline protection for their products had been softened by the inclusion of a "mailbox" provision that essentially allowed companies to file a patent in a country before it fully established a patent system (thereby giving some protection during the transition period). Agrochemical companies believed that their bioengineered plants were inadequately covered. Finally, US negotiators, who had hoped to end European demands that US winemakers cease using the names of French regions such as Chablis and Champagne to describe their products, expressed frustration that the issue had been put off for future discussion. Yet most industry representatives celebrated the agreement. Valenti reflects, "I think that TRIPS was one of the most important things that this trade association [the MPAA] and other IP trade associations have accomplished, certainly in the last decade or so."

Some observers add that while industry players complained loudly about a few issues, they were well aware that they had largely gotten their way. The protests of the pharmaceutical industry, for example, were "deliberately disingenuous," according to one analyst, who explains that "it's kind of a standard bargaining technique to say you are unhappy with the text. If you said you were happy, then the other side would say, 'Well, we've given him too much.'"

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58. Unless otherwise noted, all quotes from Neil Turkewitz are from an October 1997 interview with Charan Devereaux.

## Conclusion

Intellectual property moved onto the GATT agenda largely through the efforts of American business interests. “As opposed to pretty much every other issue that was on the Uruguay Round,” one business source observes, “IP was probably the one issue that was totally pushed by industry, first in the United States and then overseas.”

Because the commercial stakes were so high, TRIPS became vital to the success of the round (for a TRIPS timeline, see appendix 3A). “There could not have been an Uruguay Round without intellectual property,” says Subramanian. “The United States could not have come back with an agreement [that lacked] serious obligations on IP. Developing countries absolutely misread the evolution of TRIPS. They think they made a mistake by leaving the door slightly ajar. That’s completely academic. The TRIPS juggernaut was really unstoppable.”

Nevertheless, such important changes in international intellectual property protection would have been unlikely in the absence of a multilateral trade process such as the GATT. “In WIPO,” Kirk emphasizes, “it is one-dimensional; it is all IP; there is nothing on the other side of the equation. . . . But for the fact that [TRIPS] was part of this big negotiation it never would have happened. It just flat-out would not have happened.”

Although TRIPS’ future impact was unclear at the time, one thing was certain: intellectual property would continue to grow in importance and complexity as information-based products and new forms of technology entered international commerce (Maskus 1990). By the mid-1990s, high-technology goods accounted for about one-quarter of all US goods and services sold in foreign markets (Good 1996, 853). If the TRIPS negotiations had succeeded in setting only minimum standards, then what would come next? Bonnie Richardson of the MPAA observes:

Technology is changing so fast. And that’s the trouble with the multilateral trading system: It takes 10 years to get an agreement like the Uruguay Round put together, maybe longer if you look at all the preliminary negotiations. And in 10 years the world changes completely in a high-tech industry like ours. So you are always playing catch-up; you are always writing the rules for what happened in the last 10 years. But if you write them right, at least it provides you guidance for the direction you are heading.<sup>59</sup>

## CASE STUDY: International Trade Meets Public Health— Patent Rules and Access to Medicines (TRIPS, Case 2)

The TRIPS agreement was the most comprehensive and far-reaching international agreement on intellectual property rights ever made. By rais-

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59. Unless otherwise noted, all quotes from Bonnie Richardson are from an August 1997 interview with Charan Devereaux.



ing the recognition and enforcement of patents, copyrights, and trademarks from an area of national discretion to an international commitment, TRIPS represented the WTO's most radical departure from its predecessor, the GATT. Of course, negotiating the agreement was just the beginning of the TRIPS story—implementation came next.<sup>60</sup>

## Pharmaceuticals Take Center Stage

Perhaps the most widely discussed TRIPS-related issue was the debate over the impact of the agreement on efforts to improve public health in the developing world. When the Uruguay Round was launched in 1986, more than 50 countries did not confer patent protection on pharmaceuticals (UNCTAD 1996; cited in Correa 2000, 12). The TRIPS agreement obliged every WTO member to recognize patents in all fields of technology—including drugs. But some believed that by establishing or strengthening patent regimes in developing countries, TRIPS would increase the price and decrease the number of sources for pharmaceuticals, thereby restricting the access of the poor to affordable medicines. Concerns about TRIPS and health care intensified as the incidence of HIV/AIDS—which would become the leading cause of mortality worldwide for adults age 15–59—rose dramatically.<sup>61</sup> Though 95 percent of those infected with HIV lived in developing countries, fewer than 5 percent received the anti-retroviral treatment.<sup>62</sup>

In nongovernmental organizations (NGOs), most worries about international IP obligations and affordable medicines began after the TRIPS agreement was negotiated. As James Love, who directs the Consumer Project on Technology,<sup>63</sup> remembers, in 1994 “there was virtually no awareness in the United States or European [NGO community] of the scope and importance of the trade effort to raise levels of patent protection on medicines” (Love 2002). Some countries, however, were already concerned about TRIPS. In Brazil, for example, a labor federation held an international meeting in São Paulo in 1994 to discuss the pressures to modify

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60. Developed countries were directed to comply with TRIPS by 1996 and developing countries were to implement the agreement by January 1, 2000. Least-developed countries were given until 2005 to comply.

61. World Health Organization, *Facts and Figures: The World Health Report 2003*, 2.

62. WHO (2002, 1); WHO Press Release WHO/58, July 9, 2002.

63. The Consumer Project on Technology, a nonprofit organization started by Ralph Nader in 1995, focuses on intellectual property rights and health care, electronic commerce, and competition policy (see [www.cptech.org](http://www.cptech.org)).

Brazilian pharmaceutical patent laws. Similarly, debate was growing in the Argentinean National Congress over patents and health care.

The first major international NGO meeting on health care and TRIPS was held in Bielefeld, Germany, in 1996. Organized by Health Action International (HAI),<sup>64</sup> a nonprofit network of organizations from 70 countries, the meeting brought together a group of public health activists who would ultimately form the core of an NGO campaign to increase access to medicines in developing countries (Love 2002). That same year, the Indian National Working Group on Patents hosted government representatives and generic drug producers in New Delhi as they discussed TRIPS and health (Love 2003).

During the mid-1990s, HIV infection continued to rise—especially in southern African countries. In Zimbabwe, for example, less than 10 percent of the adult population was infected with HIV in 1985; in 1997, between a fifth and a quarter were believed to be HIV-positive. By the end of 1997, more than two-thirds of the world's 21 million people infected with HIV lived in Africa south of the Sahara Desert. This region also accounted for 83 percent of the world's AIDS deaths (UNAIDS/WHO 1998).

As HIV infections continued to rise in Africa, numbers of AIDS cases in many industrialized countries began to fall. By 1996, effective antiretroviral therapy—combinations of drugs that postpone the development of AIDS and prolong the lives of the HIV-positive—was widely available in nations that could afford the treatment (around \$10,000 annually). In western Europe, new AIDS cases dropped by 38 percent between 1995 and 1997, a downturn that one report from the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) attributed primarily to the new antiretroviral drugs. Similarly, the United States saw its first-ever decrease in annual new AIDS cases in 1996 (UNAIDS/WHO 1998).

## Close-Up: South Africa

The debate over patents and access to medicines came into focus when a dispute over intellectual property rights and pharmaceuticals arose in the Republic of South Africa. With 1 in 10 South African citizens infected with HIV, and facing some of the highest drug prices in the world, the minister of health introduced an amendment to the South African Medicines and Related Substances Control Act of 1965. Dr. Nkosazama Zuma,

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64. According to HAI Europe's Web site ([www.haiweb.org](http://www.haiweb.org)), HAI "is a non-profit, global network of health, development, consumer and other public interest groups in more than 70 countries working for a more rational use of medicinal drugs. HAI represents the interests of consumers in drug policy and believes that all drugs marketed should be acceptably safe, effective, affordable and meet real medical needs" (accessed 2002).

variously described as “outspoken,” “a lightning rod,” “passionate,” and “quirky,” was not afraid of controversial positions and had the support of President Nelson Mandela, South Africa’s first postapartheid president. Section 15(c) of the amended act began, “The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public”—conditions that applied to medicines under patent (see appendix 3B).

In addition to establishing a transparent pricing mechanism for AIDS drugs, Zuma’s new provisions permitted parallel importing of medicines, compulsory licensing, and generic drug substitution. *Parallel importing* would enable South Africa to obtain patented drugs more cheaply by buying them from a foreign supplier rather than the manufacturer’s local subsidiary. *Compulsory licensing* would permit the production of drugs without the patent holder’s authorization in return for some compensation to the patent holder. Under *generic drug substitution* provisions, pharmacists were obliged to tell customers when a cheaper generic existed and to sell that medicine unless the doctor or the patient forbade it. Passed by the South African parliament, the South African Medicines and Related Substances Control Amendment Act of 1997 was signed into law by President Mandela.

In the United States, reaction from the pharmaceutical industry came swiftly. In May 1997, Aldridge Cooper of Johnson & Johnson and Harvey Bale of PhRMA wrote USTR officials and Commerce Secretary William Daley about their concerns.<sup>65</sup> Many other drug company representatives criticized the South African legislation, and 47 members of Congress signed a letter to USTR Charlene Barshefsky asking her to “pursue all appropriate action” against the law, which “effectively abrogates the intellectual property rights of foreign pharmaceutical companies.”<sup>66</sup>

According to industry analysts, pharmaceutical companies were most worried that the Medicines Act could set a precedent of overriding pharmaceutical patents. PhRMA estimated that developing a new drug took on average 14 years and \$500 to \$800 million. In addition, the association argued that average returns from marketing new drugs had dropped by

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65. Barton Gellman, “Gore in Conflict of Health and Profit,” *The Washington Post*, May 21, 2000, A1.

66. The February 2, 1998, letter, whose signatories included the Republican chairman and ranking Democrat of the House Subcommittee on Africa, pointed to “at least two egregious provisions” in the new law: “First, it permits the parallel importation of patented products and second, it allows for the administrative expropriation of patented technology. Both provisions are violations of the TRIPS Agreement. Article 28 of the Agreement obligates member countries to prohibit parallel imports of patented products and Article 27 prohibits discrimination on the enjoyment of patent rights based on the field of technology” (see [www.cptech.org](http://www.cptech.org)).

approximately 12 percent since 1984.<sup>67</sup> According to industry leaders, strong intellectual property protection was crucial to maintaining vital and innovative research-based pharmaceutical companies. Should South Africa's Medicines Act be allowed to stand, other countries might follow, diluting patent protection and thereby reducing returns on the industry's investments. To be sure, the WHO's Michael Scholtz pointed out, lost profits from price cuts in Africa would amount to no more than "three days' fluctuation of exchange rates." But "If cheaper drugs in Africa put downward pressure on the global price, then the core markets of the pharmaceutical industry are at risk."<sup>68</sup>

In South Africa, the dispute between government and industry was characterized by mistrust on both sides. As the *New York Times* reported, "The dispute is bitter, and driven by deep suspicions. Virtually everyone interviewed quietly suggests—off the record—that the other side is hatching a plot." The South African Pharmaceutical Manufacturers Association (PMA) sponsored newspaper ads condemning the Medicines Act: they showed a crying baby under the headline "Health Warning! Remain Silent and the Unsafe Control of Medicine Could Cost You Forever." The ad contended the legislation would "ease the entry into established markets of counterfeit, fake, expired and harmful medicines." Members of both government and industry traded threats. The executive director of the PMA noted, "Health is a very emotive topic. When one party is totally unreasonable, the other becomes totally unreasonable. It becomes tit-for-tat. It's playground tactics, I'm afraid."<sup>69</sup>

In February 1998, a coalition of 39 Western pharmaceutical companies, represented by South Africa's PMA, filed a suit in Pretoria arguing that the Medicines Act was unconstitutional because it gave the health minister excessive power, that it violated TRIPS, and that it discriminated against the industry. Merck, the US-based drug company, backed away from a planned \$10 million investment in South Africa, blaming the new law.<sup>70</sup>

The Republic of South Africa's Medicines Act was domestic legislation. However, officials and activists in other countries in the region also took the issue of access to medicines and TRIPS to the World Health Organi-

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67. A number of PhRMA publications cite the \$500 million figure (attributing it to a Boston Consulting Group study of January 1996); \$800 million and the drop in return appear in PhRMA's submission to the US Federal Trade Division and the Department of Justice, Antitrust Division, of April 22, 2002, "Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights," page i.

68. Scholtz, quoted in Barton Gellman, "An Unequal Calculus of Life and Death," *The Washington Post*, December 27, 2000, A1.

69. Donald G. McNeil Jr., "South Africa's Bitter Pill for World's Drug Makers," *The New York Times*, March 29, 1998, section 3, 1.

70. Donald G. McNeil Jr., "South Africa's Bitter Pill for World's Drug Makers," section 3, 1.

zation, the United Nations health agency. In January 1998, Dr. Timothy Stamps, Zimbabwe's minister of health, introduced a draft resolution for a new WHO Revised Drug Strategy to ensure that "public health rather than commercial interests have primacy in pharmaceutical and health policies." Staff from HAI assisted in drafting the language of the resolution, which expressed concern about "the situation in which one third of the world's population has no guaranteed access to essential drugs, in which new world trade agreements may have a negative impact on local manufacturing capacity and the access to and prices of pharmaceuticals in developing countries." It also asked WHO members to review their options under TRIPS to safeguard access to essential drugs. The WHO Executive Board recommended the adoption of Stamps's proposal.

The ensuing meeting at the 51st World Health Assembly in May 1998 was contentious, with European and US delegations opposing the resolution. US delegates were concerned about the implications of the WHO involving itself in trade matters. With delegates unable to agree on language, WHO Director-General Gro Harlem Brundtland referred the matter back to the WHO's Executive Board. "The revised drug strategy resolution addressed many issues," she said, "such as national drug policies, drug regulation, quality assurance, drug prices, ethical drug promotion, and patient information. But it was the question of new trade agreements and pharmaceuticals which attracted the most attention."<sup>71</sup> Brundtland and WTO Director-General Ruggiero agreed to meet twice a year to discuss matters "related to world trade and health."

NGOs saw the World Health Assembly meeting as a turning point on the issue of TRIPS and access to drugs—"hugely important," according to James Love. "This whole debate in 1998 woke people up. It really got the attention of the public health community, which really started to get engaged at this point. It was what paved the way for the Doha Declaration—it was the Doha before Doha."<sup>72</sup> NGOs continued to organize around the issue of access to medicines. In September 1998, Thai NGOs staged a small demonstration outside the US Embassy in Bangkok to demand that the US administration stop pressuring Thailand to amend its pharmaceutical patent laws.<sup>73</sup> Also in 1998 a South African nonprofit called Treatment Access Campaign (TAC) was launched to mobilize national support for access to treatment by people living with HIV/AIDS; five years later,

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71. Speech of WHO Director-General Gro Harlem Brundtland at the WHO Executive Board ad hoc working group on Revised Drug Strategy, Geneva (October 13, 1998); reprinted in WHO (1999, 69).

72. Unless otherwise noted, all quotes from James Love are from a 2002 interview with Charan Devereaux.

73. Anjira Assavanonda, "Health—NGOs Rally Against Patent Law Changes," *Bangkok Post*, September 5, 1998, 2.

the *Wall Street Journal* called it “one of the most effective activist organizations to arise in democratic South Africa.”<sup>74</sup>

Activists also attributed the rapid escalation in concern about TRIPS to the tactic of using the Internet to organize. As early as 1995, James Love and other health activists began posting on the Web their worries about the agreement. Through these efforts an Internet newsletter known as *IP-Health* sprang up, covering intellectual property and health. “Even though the Web had been around for a little while, most people didn’t really get Webbed up until 1996/1997,” Love asserts. “Technically, we were using the Internet extremely early compared to most groups.”

## The US Government Response

In the United States, the South African Medicines Act and the WHO debate over TRIPS were generally treated as trade issues. The office of the US Trade Representative and the Commerce Department pressed South Africa to change its law, which had yet to go into effect. In April 1998, USTR placed South Africa on the Special 301 Watch List, noting that South Africa’s new law “appears to empower the Minister of Health to abrogate patent rights for pharmaceuticals. It also would permit parallel imports.”<sup>75</sup> A State Department report later noted that South Africa was placed on the Watch List “based largely on the potential impact of Article 15(c), not only in the South African market but also due to its global precedent and the undermining of WTO principles.”<sup>76</sup>

But not all agreed that the Medicines Act violated TRIPS. While some argued that Article 27.1 of TRIPS required that patent rights should be enjoyed without discrimination as to the field of technology (and thus special rules on compulsory licensing for pharmaceuticals would be discrim-

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74. Mark Schoofs, “AIDS Activists Get Aggressive—South Africa’s TAC Plans Civil Disobedience to Focus on Drugs,” *The Wall Street Journal*, March 20, 2003, A16.

75. USTR press release, “USTR Announces Results of Special 301 Annual Review,” May 1, 1998.

76. US Department of State, “US Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(c) of the South African Medicines and Related Substances Control Act of 1965,” February 5, 1999. The document adds: “The Administration understands the South African Government’s wish to fulfill its commitment to make medicines more affordable for its people. Although Article 15(c), as it now stands, would authorize abrogation of pharmaceutical patents and would permit parallel imports, both WTO-inconsistent actions, the South African Government to date has not allowed parallel importation of a US patented pharmaceutical nor has it suspended any patents or other intellectual property rights held by US pharmaceutical producers. The US Government has nonetheless made clear that it will defend the legitimate interests and rights of US pharmaceutical firms. In our multilevel, broad-based discussions with the SAG, USG officials have explained that abrogating intellectual property rights of pharmaceutical firms is not a viable means of accomplishing SAG objectives to make medicines more affordable for South Africans.”

inatory), others pointed out that flexibility had been built into the system. Article 31 permitted compulsory licensing of patents with some conditions (for example, the license should be “predominantly for the supply of the domestic market” with “adequate remuneration” for the patent holder). Some opponents of parallel importing maintained that Article 28 prevented third parties from importing patented products. But others countered that Article 6 clearly stated that the WTO would not resolve disputes over “exhaustion of intellectual property rights,” the basis for allowing or preventing parallel importing. NGOs cited Article 6 in accusing some government officials and the pharmaceutical industry of mischaracterizing parallel importing as inconsistent with the TRIPS agreement (see appendix 3C). On the other side, PhRMA also argued that under TRIPS Article 39.3, pharmaceutical R&D data should be protected against disclosure, and under Article 41, WTO member countries are obligated to provide effective remedies to prevent the infringement of intellectual property rights.

The pharmaceutical industry and some members of Congress pushed the Clinton administration to increase pressure on South Africa. One US trade official recalls that when he asked PhRMA representatives what conditions would allow them to accept parallel importing, “They said no, we really just want you to hold the line and continue to pressure South Africa to terminate this law altogether.”<sup>77</sup> Representative Rodney Frelinghuysen (R-NJ) inserted a provision into a congressional appropriations bill that cut aid to the government of South Africa until the State Department reported on its efforts to “negotiate the repeal, suspension, or termination” of the South African law.<sup>78</sup> The administration also decided to withhold preferential tariff treatment from certain South African exports under the Generalized System of Preferences until progress on IPR protection had been demonstrated. Despite such pressures, when South Africa passed a new medicines bill in November 1998, it included language identical to Article 15(c) of 1997, which had provoked so much debate.

In a February 1999 Binational Commission meeting, Vice President Gore reportedly told Deputy President Thabo Mbeki of South Africa, “I want to make you aware of the strong and growing domestic pressure being brought to bear in Washington. I’m concerned that, without significant progress toward a resolution, a single trade issue could overshadow our bilateral relationship.”<sup>79</sup> For more than four years, Gore and Mbeki had cochaired the US–South Africa Binational Commission (established in March 1995 to facilitate bilateral cooperation between the United States and postapartheid South Africa), a forum for wide-ranging discussions on

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77. Quoted in Barton Gellman, “Gore in Conflict of Health and Profit: Gore at Center of Trade Policy Reversal on AIDS Drugs to South Africa,” *The Washington Post*, May 21, 2000, A1.

78. PL 105-277, Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (approved October 21, 1998).

79. Gore, quoted in Gellman, “Gore in Conflict of Health and Profit,” A1.

such issues as expanding South Africa's rural electrification and privatizing telecommunications services. Observers say that Vice President Gore tried to ease the confrontation over drugs. Gore and Mbeki referred the dispute to a new trade council created by their Binational Commission, and in the spring of 1999 Gore dispatched a staff member to negotiate a solution with South African officials. In February, however, PhRMA recommended that USTR move South Africa to its Priority Watch List, a step closer to formal sanctions.<sup>80</sup> Gore's office pressured USTR not to do so.<sup>81</sup>

In April 1999, during its annual review of IPR violators, USTR once again placed South Africa on the 301 Watch List and scheduled a September out-of-cycle review of its progress. "The US is trying to get more than it got in [international] agreements," said Gary Hufbauer of the Institute for International Economics in Washington. "It's a little bit of bluff."<sup>82</sup> In addition to citing concerns about compulsory licenses and parallel imports, the USTR report noted that "South African representatives have led a faction of nations in the World Health Organization (WHO) in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS."<sup>83</sup> USTR also noted that copyright piracy and trademark counterfeiting was widespread.

One month later, the World Health Assembly unanimously adopted a Revised Drug Strategy Resolution (WHA52/19, May 1999) that gave the WHO a mandate to monitor the effects of trade agreements on public health. "When trade agreements affect health, WHO must be involved from the beginning," Brundtland told the 52nd World Health Assembly.<sup>84</sup>

## NGOs Organize

As these discussions were taking place, nongovernmental groups continued to organize to increase access to AIDS drugs. Until the end of 1998, concerns about the effects of IPRs on the availability of medicines in developing countries were raised mainly by a group of public health officials in southern Africa and by a few NGOs. While participating NGOs

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80. Submission of the Pharmaceutical Research and Manufacturers of America (PhRMA) for the Special 301 Report on Intellectual Property Barriers, February 16, 1999.

81. Jonathan Weisman, "AIDS Protesters Track Gore on Campaign Trail: Activists Want Change in S. Africa Policy," *The Baltimore Sun*, June 23, 1999, 1.

82. Hufbauer, quoted in Bob Davis, "Gore Hopes New AIDS Pact Will Help Shake Protesters," *The Wall Street Journal*, August 12, 1999, A24.

83. USTR press release, "USTR Announces Results of Special 301 Annual Review," April 30, 1999. USTR cited industry estimates that between 1997 and 1998, US trade losses related to copyright piracy in South Africa had increased more than 35 percent.

84. World Health Organization, "WHO to Address Trade and Pharmaceuticals," Press Release WHA/13, May 22, 1999.



like Health Action International were well known in the public health community, their focus was on organizing health groups, not running wider media campaigns. But in 1999, Médecins Sans Frontières (MSF)—also known as Doctors Without Borders—launched an international campaign to improve the availability of “essential medicines,” arguing that one-third of the world’s population lacked access to much-needed drugs.

MSF kicked off its international Access to Essential Medicines Campaign with the release of a report on the lack of research and development of drugs for diseases that primarily affect the poor. To demonstrate the legitimacy of its campaign, MSF worked to publish articles in prestigious medical journals such as *JAMA: The Journal of the American Medical Association* and *Lancet*. As MSF’s former worldwide director of press and campaigns Samantha Bolton puts it, “The first thing was to look at the real problems in the field and then try to get medical evidence so that we’d have credibility—not just be stating an opinion.”<sup>85</sup> MSF also partnered with other NGOs, including HAI, the Consumer Project on Technology, and Oxfam International (Oxfam focuses on poverty by using research, lobbying, and media campaigns to influence policy). Finally, it used hooks to create greater public awareness about the problem of access to drugs. For example, in 1999 the staff organized events on World Tuberculosis Day at the European Commission and the European Parliament in Brussels.

In addition to lobbying for increased research and development into diseases affecting the poor, MSF paid close attention to intellectual property rights. While some antiglobalization protesters openly opposed the WTO altogether, MSF took a different public stance. The organization made statements supporting TRIPS, but expressing concern about the agreement’s implications for health care. Intellectual property protection, the campaign organizers argued, should be balanced against health concerns. “MSF is not against patents and not against patent legislation,” said the campaign’s leader, Ellen ‘t Hoen. “True innovation deserves to be protected and to be awarded. We advocate a balanced IP regulation that takes into account the specific needs and priorities of developing countries and that follows the principles that are outlined in the TRIPS: patents should benefit the innovator and those who need access to the innovation.”<sup>86</sup> In some ways, organizers point out, antiglobalization protesters who lobbied for the end of the WTO helped the Access to Essential Medicines cause. “Because they were so extreme, we seemed moderate in comparison,” one NGO leader noted. However, some observers believe that the NGOs were much more anti-TRIPS than their public statements indicated. In March 1999, MSF cosponsored a conference in Geneva with HAI

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85. Unless otherwise noted, all quotes from Samantha Bolton are from a 2002 interview with Charan Devereaux.

86. Statement by Médecins Sans Frontières (MSF) on TRIPS and affordable medicines, Geneva press briefing, June 19, 2001, [www.accessmed-msf.org](http://www.accessmed-msf.org).

and the Consumer Project on Technology to examine compulsory licensing as a potential strategy to increase access to medicines. Campaign organizers also discussed TRIPS and public health with WHO representatives and with government officials—including ministers of health of many African nations.

The MSF Access to Essential Medicines Campaign grew out of not the AIDS issue specifically but tropical and infectious diseases more generally. For example, among infectious diseases, tuberculosis was the second leading killer in the world (after lower respiratory infections), responsible for two million deaths annually. The resurgence of sleeping sickness in sub-Saharan Africa and the problem of malaria in the developing world were also major challenges. In fact, organizers at MSF initially wondered if AIDS drugs belonged in their campaign at all. Bolton recalls,

At one point we were deciding should we or shouldn't we include AIDS in the campaign because there are so many other organizations working on it—what could we add? But many of the other diseases we deal with, they're not sexy enough, they're not going to catch people's imagination because no one's ever heard of them. And AIDS was one of the biggest problems we were facing in the field. So we actually made a strategic decision to include it and figured the more voices that could join, the better.

According to observers, US and European AIDS activists had shown little engagement with the issue of access to medicines in developing countries up to this point. Instead, they focused their energies on AIDS treatment at home. The 1993 comment of David Barr of Gay Men's Health Crisis was typical: "I can't get AIDS medicine in the Bronx! Don't tell me about people in Africa."<sup>87</sup> However, harnessing the political power of the Gay Men's Health Crisis, ACT UP (the AIDS Coalition to Unleash Power), and similar groups was recognized as a key element in advancing the Access campaign. "The only way you'll change US policy," Love remembers being told by a US government official, "is by talking to the AIDS activists. They can do anything. You have no idea how powerful they are." Love and other Access to Essential Medicines Campaign organizers approached key AIDS groups (ACT UP among them) to discuss pharmaceutical patents, TRIPS, and the details of the South Africa case. With AIDS on the decline in the United States, activists turned some of their attention to South Africa.

In June 1999, Vice President Gore announced his intention to run for president over calls from AIDS protesters charging that "Gore's greed kills."<sup>88</sup> ACT UP dogged Gore's campaign trail, accusing him of "medical

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87. Barr, quoted in Barton Gellman, "An Unequal Calculus of Life and Death: As Millions Perished in Pandemic, Firms Debated Access to Drugs," *The Washington Post*, December 27, 2000, A1.

88. Anne E. Kornblut, "Citing Family Values, Gore Announces Candidacy; Speech Distances Him from Clinton," *The Boston Globe*, June 17, 1999.

apartheid" in South Africa.<sup>89</sup> Though Gore worked to resolve the dispute, many believe that the protests added urgency to these negotiations. Other US government officials also responded to the demonstrations. In July 1999, the House Subcommittee on Criminal Justice, Human Resources, and Drug Policy of the Committee on Government Reform held a hearing on the role of the United States in combating the global HIV/AIDS epidemic, focusing on trade policy toward South Africa. Observers say the relationship between trade officials and drug industry representatives was also changing. For example, USTR Barshefsky was reportedly taken aback when several pharmaceutical executives argued that the problems with treating AIDS in Africa were not related to high pharmaceutical prices but the lack of health care infrastructure components such as computers. "I don't think you're suggesting a lack of computers is what's causing this pandemic?" she asked, according to people at the meeting.<sup>90</sup>

In September 1999, US trade negotiators eased their demands on South Africa. Instead of seeking the repeal of the Medicines Act, they asked South Africa to sign a statement pledging that the law would not violate TRIPS. A USTR press release declared, "The two governments have identified common ground with respect to South Africa's implementation of its so-called Medicines Act. The United States very much appreciates South Africa's assurance that, as it moves forward to bring improved health care to its citizens, it will do so in a manner consistent with its international commitments and that fully protects intellectual property rights." The South African Ministry of Trade and Industry sounded a concurring note, though with a different emphasis: "It is the express position of the South African Government that, in the implementation of provisions of the Medicines Act—which permits parallel importation and compulsory licensing of patents for pharmaceuticals—it will honour its obligations under the TRIPS Agreement."<sup>91</sup>

USTR removed South Africa from the Special 301 Watch List and also committed to implement GSP benefits that had earlier been withheld.<sup>92</sup> "We don't think very highly of either compulsory licensing or parallel imports," said one US trade official, "but in recognition of the fact they have

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89. Lakshmi Chaudry, "US to South Africa: Just Say No," *Wired*, April 25, 2000.

90. Helene Cooper, Rachel Zimmerman, and Laurie McGinley, "Patents Pending: AIDS Epidemic Traps Drug Firms in a Vise: Treatment vs. Profits—Suit in South Africa Seeks to Block Generic Copies; US Reverses Its Policy—Activists Warn Mr. Papovich," *The Wall Street Journal*, March 2, 2001, A1.

91. USTR press release 99-76, "US-South Africa Understanding on Intellectual Property," September 17, 1999; Republic of South Africa, Department of Trade and Industry, "Joint Understanding Between the Governments of South Africa and the United States of America," September 17, 1999.

92. See USTR press release, "The Protection of Intellectual Property and Health Policy," December 1, 1999.

a major health care crisis there . . . we are also showing movement on this.”<sup>93</sup> Drug makers showed some enthusiasm about the US–South Africa statement. PhRMA spokesman Jeff Trehwitt said South Africa’s health minister appeared “very flexible” in working with the industry.<sup>94</sup> However, before the statement was released, US pharmaceutical industry officials noted that South Africa “would need to modify the law.” Shannon Herzfeld, senior vice president for international affairs at PhRMA, said a statement “is not an acceptable outcome.”<sup>95</sup>

Demonstrations by NGOs continued. In October 1999, two hundred protesters blocked traffic in front of USTR’s offices in Washington, saying developing countries needed generic AIDS drugs. A few weeks later, a dozen protesters were arrested after occupying USTR offices where they chained themselves together at the wrists.<sup>96</sup>

In November, the Access to Essential Medicines Campaign took its TRIPS concerns to the 1999 WTO ministerial conference in Seattle, Washington. The WTO ministerial was intended to launch a new round of multilateral trade talks. At the conference the campaign’s director, Dr. Bernard Pécoul of MSF, called for the formation of a WTO Working Group on Access to Medicines. That month, MSF was awarded the Nobel Peace Prize for its humanitarian work and donated the \$1 million prize to support the Access Campaign. In addition to providing money, observers say, the Nobel Prize also helped legitimate the organization’s efforts on this issue.

At the Seattle ministerial, President Bill Clinton announced, “Intellectual property protections are very important to a modern economy, but when HIV and AIDS epidemics are involved, and like serious health-care crises, the United States will henceforward implement its health care and trade policies in a manner that ensures that people in the poorest countries won’t have to go without medicine they so desperately need.”<sup>97</sup> Speaking on Global HIV/AIDS Awareness Day, Clinton promised that USTR and the US Department of Health and Human Services would work together to ensure that US trade policy was flexible enough to respond to critical public health crises.

The Seattle WTO conference collapsed amid controversy. Many attributed its failure to the lack of a clear agenda going into the talks. Some also

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93. Quoted in “US, South Africa Strike Deal in TRIPS Fight over Drug Protection,” *Inside US Trade*, September 24, 1999.

94. Ceci Connolly, “Deal Made on AIDS Drug Sales; US, South Africa Reach Agreement,” *The Washington Post*, September 18, 1999, A11.

95. Herzfeld, quoted in Bob Davis, “Gore Hopes New AIDS Pact Will Help Shake Protesters,” *The Wall Street Journal*, August 12, 1999, A24.

96. “Activists Protest Federal Policy on AIDS Drugs,” *The Los Angeles Times*, October 7, 1999, 19A. Derrill Holly, “Protesters Arrested after Demonstration Against Patent Restrictions,” Associated Press, November 19, 1999.

97. President Bill Clinton, address to the WTO in Seattle, December 1, 1999.

criticized President Clinton's commitment to include labor standards in trade agreements and his endorsement of sanctions to enforce such standards. This position, advocated by organized labor in the United States, was opposed by many developing countries; they argued that such provisions would function only to restrict their exports.

The WTO ministerial conference was also the target of large protests by environmental, consumer, and labor groups. Though many demonstrated peacefully, a minority of protesters vandalized property, leading to chaos in the streets. At the time, some analysts believed that the protests played a large role in the conference's collapse, but others held that the demonstrations merely drew attention to the ministers' failure to reach an agreement. Clinton and other officials were criticized for failing to more vigorously rebut the assertions made by anti-WTO protesters. For example, while many protesters claimed to defend the interests of developing countries, WTO supporters noted that with the collapse of the ministerial, poorer nations lost the chance to negotiate reductions in US, European, and Japanese agricultural subsidies and thereby to increase their agricultural exports. A *Wall Street Journal* editorial presented Seattle as an example of what happens when "business and politicians allow trade to become hostage to special interests."<sup>98</sup>

## South Africa Revisited

Despite the September 1999 US–South Africa joint statement on the Medicines Act, the issue continued to provoke political debate in the United States. In May 2000, Senator Dianne Feinstein (D-CA) threatened to filibuster a bill liberalizing trade with African and Caribbean countries because an amendment she had cosponsored with Senator Russ Feingold (D-WI) had been stripped out. The amendment, originally drafted with the assistance of Rob Weissman from the Consumer Project on Technology, would have prevented the United States from challenging laws or policies of sub-Saharan African countries that promoted access to AIDS drugs, as long as those laws or policies were consistent with the TRIPS agreement. A *Washington Post* editorial was sympathetic to her position, arguing that "pharmaceutical firms ought to concede that AIDS is an exceptional disease and that this justifies a limited weakening of intellectual property rules."<sup>99</sup> Feinstein insisted that affordable medications had to be made more available.

Heading off the potential filibuster, the Clinton administration issued an executive order on pharmaceuticals and AIDS similar to the amendment's

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98. "While the WTO Burns" (editorial), *The Wall Street Journal*, December 2, 1999, A22.

99. "Good Deals for Africa" (editorial), *The Washington Post*, May 6, 2000, A18.

language.<sup>100</sup> The United States would keep its right to seek enforcement of the WTO's TRIPS agreement but forgo the pursuit of IPR commitments beyond TRIPS in this severe health crisis. According to USTR Barshefsky, Clinton's order gave the same treatment to sub-Saharan African countries that the United States had given South Africa, "striking] a proper balance between the needs of African countries . . . and the need to ensure that basic intellectual property rights are protected."<sup>101</sup> But pharmaceutical industry representatives took strong exception to Clinton's action. "We recognize that AIDS is a major problem, but weakening intellectual property rights is not the solution," said Alan Holmer, president of PhRMA.<sup>102</sup>

At the same time, the pharmaceutical industry made a public commitment to supply lower-priced AIDS drugs to developing nations—especially in Africa. In a May 2000 event, five drug companies (Merck, Hoffmann-La Roche, Bristol-Myers Squibb, Glaxo Wellcome, and Boehringer Ingelheim) announced they would make AIDS medicines available to the poorest nations at deep discounts through the Accelerating Access Initiative, a public-private partnership with five UN organizations—the WHO (which took over leadership of the initiative in November 2001), UNAIDS, UNICEF, the World Bank, and the UN Development Program. Such a joint agreement by pharmaceutical companies was unprecedented. Peter Piot, director of UNAIDS, praised the effort: "It's the first time the companies are collectively willing to discuss a truly significant decline in prices." While some companies spoke of possible costs as much as 85 percent or 90 percent below those in the United States, or about one-fifth of the prices in some African nations, initially there were no announcements of actual reductions.<sup>103</sup> Instead, companies would negotiate prices with interested

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100. Executive Order 13155, Access to HIV/AIDS Pharmaceuticals and Medical Technologies, May 10, 2000.

101. Barshefsky, quoted in Lisa Richwine, "US Pledges AIDS Drug Help for sub-Saharan Africa," Reuters News, May 10, 2000.

102. Holmer, quoted in Jim Abrams, "Senate Passes Africa Trade Bill after Decision on AIDS," Associated Press Newswires, May 11, 2000.

103. Information about Accelerating Access and Piot quoted in Michael Waldholz, "Into Africa: Makers of AIDS Drugs Agree to Slash Prices for Developing World—Five Firms' Pact with UN Will Still Leave Medicine Unaffordable for Millions—Black Markets and Generics," *The Wall Street Journal*, May 11, 2000, A1. The pharmaceutical industry also highlighted its efforts to assist those in need of medicines for other conditions. For example, since 1987, Merck has worked with aid groups to give away more than 600 million tablets of Mectizan to cure river blindness, a condition that affects millions of people in West Africa. Its pledge has led the United Nations to conclude that river blindness could be eradicated by 2007. Glaxo-SmithKline, in what the company called "the largest drug donation program in history," agreed to donate its Zentel (albendazole) until the tropical disease lymphatic filariasis (more commonly known as elephantiasis) was eliminated—a 20-year commitment estimated at 5–6 billion tablets worth \$1 billion. According to GlaxoSmithKline, by 2001, 26 million people had been treated in 22 countries (Karen Lowry Miller, "The Pill Machine; How Much

countries on a case-by-case basis, requiring assurances that the drugs would not be reexported elsewhere and demonstration of an adequate health care infrastructure.

The Accelerating Access Initiative held risks for the industry. The negotiations could reveal information about profit margins, which might lead to demands in the United States and Europe for domestic price reductions. Some feared that low prices could fuel a black market in AIDS drugs in wealthier countries. In addition, calls for lower-priced drugs and reduced patent protection might expand to include diseases other than AIDS. At the same time, companies worried that without price cuts, nations seeking cheap pharmaceuticals would turn to generic producers in countries such as India, Thailand, and Brazil—or engage in compulsory licensing. “If we don’t solve the drug access problem, then our intellectual property is at risk,” warned Raymond Gilmartin, Merck’s chairman and CEO. Companies “need to demonstrate that intellectual property is not an obstacle” to access in developing countries.<sup>104</sup>

Some critics argued that the Accelerating Access Initiative was simply part of a larger strategy to make drugs available without threatening pharmaceutical patents. “Most of all, the drug companies wanted to squelch an increasingly damaging debate on prices and patents that the UN agencies had helped touch off,” Barton Gellman concluded in a front-page *Washington Post* investigation of the program.<sup>105</sup> The activist Ralph Nader, founder of the Consumer Project on Technology, wrote to WHO Director-General Brundtland calling Accelerating Access “an ill-advised public relations effort” saying it would undermine compulsory licensing campaigns, pressure poor countries to adopt overly restrictive IP policies, and “undermine the success of Southern generics producers who have been the most effective agents in bringing down the prices of HIV drugs.”<sup>106</sup>

Critics also noted that Accelerating Access was able to do no more than scratch the surface of the HIV/AIDS problem. A year after its launch, only 2,000 Africans had received cut-price drugs under the program. In comparison, they observed, in Brazil 115,000 patients received antiretroviral

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Money Should Big Drug Firms Have to Lose to Treat the World’s Poorest Patients?” *Newsweek International*, November 19, 2001, 46; see also GlaxoSmithKline press release, “10 Million People to Receive Free Medicines on One Day,” July 25, 2003).

104. Gilmartin, quoted in Mark Schoofs and Michael Waldholz, “New Regimen: AIDS-Drug Price War Breaks Out in Africa, Goaded by Generics—Merck, Others Plan to Slash Costs of Key Medicines in Bid for High Ground—Weighing Patents and People,” *The Wall Street Journal*, March 7, 2001, A1.

105. Barton Gellman, “A Turning Point that Left Millions Behind; Drug Discounts Benefit Few While Protecting Pharmaceutical Companies’ Profits,” *The Washington Post*, December 28, 2000, A1.

106. Ralph Nader, letter to Dr. Gro Harlem Brundtland, director-general of the World Health Organization, July 23, 2001, [www.cptech.org](http://www.cptech.org).

drugs in 2001 alone through a government initiative. Raymond Gilmartin, chairman of Merck, defended Accelerating Access: “We were proceeding along the lines that you do in any market—like contracting with a managed-care organization or with Wal-Mart.” Though such negotiations often take many months, the delay “was creating the impression that our offer wasn’t real and that there were too many strings attached.”<sup>107</sup> A year later, in March 2002, a total of more than 35,500 Africans had received reduced-price drugs.<sup>108</sup> Many viewed the negotiation process as too cumbersome and drug prices as still too high.

Some observers believed that regardless of the success of the Accelerating Access Initiative, simply lowering prices on drugs would not stop the AIDS pandemic in Africa. For effective treatment, patients had to be closely monitored by trained medical personnel—requiring a health infrastructure that was not always in place. Without such monitoring, inconsistent self-medication could lead to drug resistance, as had happened with tuberculosis. Governments, multilateral organizations, and major employers in Africa needed to address all the barriers to care. Moreover, critics of South Africa’s ineffectual response to AIDS were growing louder, calling on the government to work harder to get drugs to the people. President Thabo Mbeki stoked the controversy further when he publicly questioned the safety and efficacy of standard HIV/AIDS medications. Mbeki was also skeptical of long-accepted conclusions about the nature of AIDS and refused to support giving antiretroviral drugs for pregnant women, despite research indicating that such medication could greatly reduce the chances of transmission from mother to child.

Pfizer chose not to join Accelerating Access; in December 2000, the company announced its own initiative in South Africa. Rather than simply lowering prices, Pfizer would *donate* \$50 million worth of the drug Diflucan to help fight opportunistic fungal infections in South African HIV/AIDS patients.<sup>109</sup> Months before this announcement, ACT UP activists rallied at Pfizer’s headquarters in New York demanding that the company reduce Diflucan’s price or allow generic versions of the drug to be sold.<sup>110</sup>

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107. Figure of 2,000 and Gilmartin quoted in Gardiner Harris, “Adverse Reaction: AIDS Gaffes in Africa Come Back to Haunt Drug Industry at Home—Price Cuts Abroad Deepen Domestic Trouble as Firms Reveal ‘True’ Cost of Pills—John le Carre’s New Villain,” *The Wall Street Journal*, April 23, 2001, A1.

108. Industry figure quoted in Ben Hirschler, “AIDS Drugmakers Say They’re Boosting African Supply,” Reuters, January 14, 2003.

109. Though Diflucan is not an AIDS drug, it effectively treats two serious opportunistic fungal infections associated with the disease, cryptococcal meningitis and esophageal candidiasis. Diflucan is also used in the treatment of vaginal yeast infections; worldwide, its sales in 1999 exceeded \$1 billion. (See Steven Swindells, “Pfizer in AIDS Drug Deal with South Africa,” Reuters, December 1, 2000.)

110. ACT UP New York press release, September 7, 2000.



In another move by activists, Zackie Achmat of South Africa's Treatment Access Campaign illegally brought a suitcase of a generic version of Diflucan from Thailand—where Pfizer's patent was not recognized—into South Africa; at a packed news conference, he pointed out that Pfizer's drug was 28 times more expensive.<sup>111</sup> South Africa's Medicines Control Council granted a legal exemption to the activists, allowing them to import the generic medicine.

Pfizer began its South African Diflucan donation program in April 2001, giving away the drug in public-sector clinics; the program later expanded to other countries, mainly in sub-Saharan Africa, giving away 4 million doses of the drug by March 2004.<sup>112</sup> But a spokesman for the Treatment Access Campaign warned that Pfizer's approach was not a sustainable solution: indeed, though the donations were "bettering the lives of a number of people," the program was really "a successful attempt to divert attention from patent questions and voluntary licensing."<sup>113</sup>

As such industry initiatives went on, prices for AIDS drugs continued to drop. In February 2001, the Indian generic drug maker Cipla promised to sell a combination of three AIDS drugs to African nations at \$600 per patient per year—and to sell the drugs to MSF for only \$350.<sup>114</sup> Several large pharmaceutical companies, including GlaxoSmithKline and Merck, announced another round of price reductions for AIDS drugs in Africa. Similarly, Bristol-Myers Squibb dramatically lowered the price of the antiretroviral d4T in South Africa—following pressure from a group of Yale law students (Yale University held the patent on d4T and exclusively licensed the drug to the company). John McGoldrick, executive vice president at Bristol-Myers, declared that the price cut was "not about profits and patents. It's about poverty and a devastating disease. We seek no profits on AIDS drugs in Africa, and we will not let our patents be an obstacle."<sup>115</sup> Drug companies urged governments of wealthy countries and private foundations to offer financing to African nations so that they could buy AIDS medicine.

Meanwhile, the pharmaceutical industry continued its effort in South Africa to challenge the Medicines Act. In March 2001, the suit brought by the 39 companies opened in Pretoria to international outrage. Activists

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111. See Andrew Maykuth, "AIDS Drug Patent Issue Draws Drug Companies, South Africa into Conflict," Knight Ridder Tribune Business News, March 4, 2001. The daily cost of Diflucan (retail) in South Africa was between \$13 and \$17.

112. See Pfizer's Web site at [www.pfizer.com](http://www.pfizer.com).

113. Quoted in "S. African AIDS Groups Urge World Protest over Pfizer Drug Patent," Agence France-Presse, July 19, 2001.

114. "Medical Group Will Provide Free AIDS Drugs in 10 Countries," *Chicago Tribune*, February 25, 2001, 6.

115. McGoldrick, quoted in Melody Petersen and Donald G. McNeil Jr., "Maker Yielding Patent in Africa for AIDS Drug," *The New York Times*, March 15, 2001, A1.

framed the court battle as pitting the property rights of rich multinational corporations from the West against the attempts of the entire developing world to curb a major public health crisis. Celebrities such as Whoopi Goldberg, Carlos Santana, and the members of the band REM called for the case to be dropped. NGOs publicly questioned the industry's position that high drug prices supported further pharmaceutical research and development, pointing out to reporters that these R&D budgets were eclipsed by the amount of money spent on marketing. In addition, they emphasized that some of the funding for AIDS drug R&D was public. "The patents for important antiretrovirals such as d4T, ddI, and ddC are held by the US government or academic institutions," noted Achmat.<sup>116</sup>

Stories in the mainstream press were often critical of the pharmaceutical industry's tactics and sympathetic to NGO views (for a selection of press headlines over time, see appendix 3D). For example, a *New York Times* news analysis suggested that "the industry itself fueled the backlash by staunchly defending its intellectual property in the face of [the AIDS] pandemic." The high-profile case "painted the industry as greedy and uncaring," concluded an article in the *Financial Times*. Calling pharmaceutical companies "the pariah du jour," the *Wall Street Journal* pointed to their missteps: "in the last two years, the industry responded to international calls for lower AIDS-drug prices in poor nations with a series of gaffes that have tarnished its reputation, weakened its political positions and emboldened its adversaries in a host of battles in the US and abroad."<sup>117</sup>

By mid-April, the pharmaceutical companies had withdrawn their case against the Medicines Act, and South Africans celebrated in the streets. The industry was deeply frustrated by the press coverage of the suit, decrying its unfair and overly simplistic portrait of drug companies as the sole villain in the AIDS tragedy. Rick Lane, president of the worldwide medicines group of Bristol-Myers, felt that they had "underestimated the capacity to be made villains, as people without answers look for excuses." Jean-Pierre Garner, Glaxo's chairman and CEO, asked, "Do you want us to give these drugs away for free? Then there won't be any more drugs to treat AIDS or anything else. Isn't it ironic that the companies that brought the drugs to market are the ones being criticized for people dying?"<sup>118</sup> Pharmaceutical companies continued to argue that upholding patent protection was vital to maintaining R&D expenditures.

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116. Joint MSF/TAC/Oxfam press release, "Voices Around the World Condemn Drug Industry Hypocrisy," April 17, 2001, [www.accessmed-msf.org](http://www.accessmed-msf.org).

117. Andrew Pollack, "Defensive Drug Industry: Fueling Clash over Patents," *The New York Times*, April 20, 2001, A6; David Firn, "Patent Disputes and Litigation Take the Shine off of 2001," *The Financial Times*, December 17, 2001; Harris, "Adverse Reaction: AIDS Gaffes in Africa," A1.

118. Both Lane and Garner are quoted in Harris, "Adverse Reaction: AIDS Gaffes in Africa," A1.

## WTO Debates over TRIPS

A week before the pharmaceutical industry dropped its case in South Africa, the WTO and WHO held the Workshop on Differential Pricing and Financing of Essential Drugs (the government of Norway was a co-sponsor). On April 8–11, 2001, in Høsbjør, Norway, representatives from national governments, UN agencies, pharmaceutical companies, generic drug companies, and NGOs (including the Consumer Project on Technology, HAI, and MSF) came together to discuss differential pricing—the practice of charging different prices in different markets according to the buyer’s purchasing power. Adrian Otten, director of the Intellectual Property and Investment Division at the WTO Secretariat, observed that while the WTO and WHO had held other joint meetings, this was “the first time that we have done anything together on this scale.”<sup>119</sup>

In June 2001, the WTO TRIPS Council held a special session on intellectual property and access to drugs at the urging of the WTO’s African members, who said that TRIPS faced a “crisis of legitimacy.”<sup>120</sup> However, that view was not universal. Supporters of TRIPS noted that the agreement allowed a great deal of leeway for the use of compulsory licensing—not just in national emergencies but also in cases of public noncommercial use, as well as when patent rights were abused by their holder. In addition, TRIPS members could “adopt measures necessary to protect public health and nutrition . . . provided such measures are consistent with the provisions of this Agreement” (Article 8.1, a provision some NGOs called meaningless). Finally, under TRIPS, the WTO would not resolve disputes over “exhaustion of intellectual property rights,” the basis for allowing or preventing parallel importing (Article 6). In the view of WTO Director-General Mike Moore, TRIPS thereby struck “a carefully-negotiated balance between providing intellectual property protection—which is essential if new medicines and treatments are to be developed—and allowing countries the flexibility to ensure that treatments reach the world’s poorest and most vulnerable people. Countries must feel secure that they can use this flexibility.”<sup>121</sup>

Some officials from the WHO countered, “The flexibility in the TRIPS agreement is not being used.”<sup>122</sup> More than 100 NGOs attended the WTO TRIPS meeting and urged the WTO to address the concerns of developing

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119. Adrian Otten, opening remarks, TRIPS: WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs, April 11, 2001, [www.wto.org](http://www.wto.org).

120. Frances Williams, “Battle over Cost of Pharmaceuticals Moves to WTO,” *The Financial Times*, June 20, 2001, 12.

121. WTO press release, “Moore: Countries Must Feel Secure That They Can Use TRIPS’ Flexibility,” June 20, 2001.

122. Williams, “Battle over Cost of Pharmaceuticals Moves to WTO,” 12.

countries by adopting a seven-point strategy, including an extension of the TRIPS implementation deadline for the least-developed countries. In addition, the NGOs argued, to ensure that health concerns were taken into consideration in TRIPS enforcement, developing countries should receive technical assistance on TRIPS not only from developed-country governments and the WTO TRIPS Council but also from health organizations.

NGOs also asserted that developing countries were being bullied by the pharmaceutical industry and threatened with trade sanctions by governments to discourage them from participating in parallel importing or compulsory licensing.<sup>123</sup> NGOs pointed to the United States as exemplifying the kind of pressure they were protesting. In April 2000, the United States had filed a challenge at the WTO against Article 68(1)(I) of Brazil's 1996 industrial property law, which called for "local working" as a condition of receiving patent protection—companies had the choice of manufacturing their inventions in Brazil within three years of obtaining a patent or being subject to a compulsory license. Though the law took effect in May 1997, it had never been enforced.

Activists and Brazilian officials called on the United States to drop its challenge, which they claimed would impede Brazil's ability to fight AIDS. Since 1997, Brazil had provided free HIV/AIDS drugs for patients who needed them, a policy that many NGOs viewed as a model for the developing world. Brazil's treatment program was controversial, however, since its cornerstone was the local production of generic equivalents of brand-name drugs. According to Brazil's health ministry, the country had brought down the price of AIDS drugs by 79 percent and had cut the number of AIDS-related deaths in half.<sup>124</sup> The country produced 7 of the 14 drugs it distributed, and health officials said that threats of compulsory licensing had enabled them to negotiate lower prices with global pharmaceutical companies for some of the remaining AIDS treatments. MSF warned that the US WTO challenge "might handicap the successful Brazilian AIDS program, which is largely based on Brazil's ability to manufacture affordable treatment. . . . The Brazilian patent policy has been key to the success of the strategies to offer universal access to HIV/AIDS medication in Brazil." Brazil's ambassador to the WTO, Celso Amorim, predicted that the US complaint "may prove politically disastrous."<sup>125</sup>

But US trade officials argued that the patent law cited in the WTO complaint did violate TRIPS and did not affect Brazil's AIDS policy, accusing

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123. For example, in a February 2001 report calling for an overhaul of TRIPS, the UK NGO Oxfam noted, "The deeper problem lies in the unwarranted political influence of pharmaceutical corporations which leads to a subordination of trade policy to corporate goals, notably in the USA" (Oxfam 2001, 5).

124. Tina Rosenberg, "Look at Brazil," *The New York Times Magazine*, January 28, 2001, 26.

125. Quotations from Gary G. Yerkey and Daniel Pruzin, "Pharmaceuticals: United States Drops WTO Case Against Brazil over HIV/AIDS Patent Law," *WTO Reporter*, June 26, 2001.

NGOs of being misinformed about the case.<sup>126</sup> The Brazilian law was clearly proscribed by TRIPS Article 27 (reproduced in appendix 3C), which mandated patent protection without discrimination as to whether products were imported or locally produced. Nevertheless, after the WTO had acceded in February 2001 to its request to establish a panel to rule on its complaint, the United States dropped the matter in June 2001. The move came as the UN General Assembly opened discussions in New York on how to combat AIDS. Instead of pursuing the patent issue at the WTO, the United States sent the dispute to a newly created US-Brazil bilateral consultative mechanism.<sup>127</sup> Sources asserted that this backpedaling from the WTO panel reflected an unwillingness on the part of USTR Robert Zoellick to give opponents of trade liberalization an issue that appeared to give credence to the idea of the WTO interfering with poor countries' health policies.<sup>128</sup>

According to USTR, the new US-Brazil bilateral process would "permit more effective and less confrontational consideration of intellectual property issues and ensure that such discussions do not divert attention away from the shared goal of combating the spread of HIV/AIDS."<sup>129</sup> Under the terms of the agreement, Brazil would provide advance notice to the United States before utilizing the "local manufacturing" provision.<sup>130</sup> Zoellick praised the pact as "provid[ing] an early warning system to protect US interests," adding, "I stand four-square behind strong enforcement of the WTO rules on intellectual property. However, litigating this dispute before a WTO dispute panel has not been the most constructive way to address our differences, especially since Brazil has never actually used the provision at issue."<sup>131</sup>

## Anthrax and Accusations

The TRIPS issue, as well as a litany of other trade questions, would be discussed in the upcoming November 2001 WTO ministerial meeting in

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126. The United States challenged Article 68 of Brazil's patent law but not Article 71, which allowed for compulsory licenses for medical emergencies and for the public interest ("US Rebutts Charges That IPR Panel Attacks Brazil's AIDS Policy," *Inside US Trade*, February 9, 2001).

127. USTR press release, "United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute," June 25, 2001.

128. "US, Brazil End WTO Case on Patents, Split on Bilateral Process," *Inside US Trade*, June 20, 2001.

129. USTR press release, June 25, 2001.

130. Joint Communication, Brazil-United States, June 25, 2001.

131. USTR press release, June 25, 2001.

Doha, Qatar, which trade officials hoped would launch a new multilateral round of trade talks.

But the events of September 11, 2001, changed the context of the Doha ministerial dramatically. In the weeks that followed the terrorist attacks on New York and the Pentagon, fears increased as anthrax spores were sent through the US mail. In October, the Canadian health ministry ignored Bayer's patent rights on Cipro, an antibiotic used to treat anthrax, and commissioned a local manufacturer to produce one million tablets of the drug.<sup>132</sup> Bayer responded by donating Cipro to Canada and committing to deliver more in an emergency. As a result, Canada agreed to acquire Cipro exclusively from Bayer. The United States similarly decided to stockpile Cipro; in October, US Health and Human Services Secretary Tommy Thompson threatened to override Bayer's patent unless the German company lowered the price of the drug. Bayer assented to a price of 95 cents a pill, down from \$1.77, and no action was taken to supersede the patent.<sup>133</sup>

However, activists and some developing-country officials seized on Thompson's threat. By even considering compulsory licensing, the United States was accused of judging pharmaceutical patents by a double standard. Four had died from anthrax; in the AIDS epidemic, millions had perished. "Tommy Thompson may not know it, but he became our ally when he threatened that patent," said Jose Viana, an adviser to Brazil's health minister, adding, "He did what he thought was in the best interest of his country. Why can't others do the same?"<sup>134</sup> James Love of the Consumer Project on Technology agreed: "The Cipro thing was timely. When the US did not like the price of a medicine, we were very fast to say we might override patent rights. When Brazil did the same thing (for AIDS drugs), they were savaged."<sup>135</sup> The incident "seriously weakened the industry's bargaining position" at Doha, concluded the *Financial Times*.<sup>136</sup>

As the Doha WTO ministerial approached, NGOs and developing-country officials led by Brazil and India continued to organize on the TRIPS issue, repeating their message to journalists that public health was under threat. Pharmaceutical industry representatives countered that not everyone involved in this movement was motivated solely by their concern for public health. Countries such as Brazil and India, they argued, hoped that the debate would lead to their own large generic drug in-

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132. Amy Harmon and Robert Pear, "Canada Overrides Patent for Cipro to Treat Anthrax," *The New York Times*, October 19, 2002, A1.

133. Theresa Agovino, "US, Developing Countries Set to Clash over Patents Next Week," Associated Press Newswires, November 2, 2001.

134. Viana, quoted in Agovino, "US, Developing Countries Set to Clash."

135. Love, quoted in Sabin Russell, "US Push for Cheap Cipro Haunts AIDS Drug Dispute," *The San Francisco Chronicle*, November 8, 2001, A13.

136. Firm, "Patent Disputes and Litigation."

dustries producing patented pharmaceuticals with a freer hand. Mark Grayson, a spokesman for PhRMA, was blunt: “They’ve hijacked the AIDS crisis to hone their own industrial development.”<sup>137</sup>

In addition, pharmaceutical industry representatives argued that in developing countries, poverty and weak health infrastructures threw up much more serious barriers to drug access than did patents (see Gillespie-White and Salmon 2000). “It is creating false hope to say if changes are made to TRIPS you’ll get drugs to poor people,” Grayson said.<sup>138</sup> In a controversial study published in the *Journal of the American Medical Association* and circulated by the industry, Harvard researcher Amir Attaran concluded, “It is doubtful that patents are to blame for the lack of access to antiretroviral drug treatment in most African countries” (Attaran and Gillespie-White 2001, 1890). In fact, according to the study, few antiretroviral drugs were patented in African countries at all. The real reason Africans could not buy drugs, Attaran said, was more simple—a lack of money. “Companies can offer a discount, a donation, but let’s face it, it’s not their job to build clinics or train doctors,” he told a reporter. “It is, however, what foreign-aid agencies are supposed to do. And they’re not doing it.”<sup>139</sup>

## The Lead-Up to Doha

The United States went to Doha with limited objectives—its focus was on liberalizing trade in agriculture, industrial goods, and services.<sup>140</sup> European negotiators had broader goals, hoping to include four issues they had originally proposed at the 1996 Singapore ministerial: investment policy, competition policy, transparency in government procurement, and trade facilitation. EU negotiators were also focused on agriculture. The French in particular were strongly opposed to language that referred to phasing out agricultural export subsidies. Developing countries favored such a phaseout, which would make their own agricultural products more competitive in the European market.

Many developing countries wanted to include negotiations on anti-dumping measures in the Doha round. Some WTO members opposed these controversial policies aimed at protecting domestic industries from surges of cheap foreign imports. If imports were being sold at prices below their normal value or their cost of production, a levy could be imposed to bring the price up to that of domestic producers. Many countries were particularly angered by the United States’ use of antidumping pro-

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137. Grayson, quoted in Russell, “US Push for Cheap Cipro,” A13.

138. Grayson, quoted in Agovino, “US, Developing Countries Set to Clash.”

139. Attaran, quoted in Miller, “The Pill Machine,” 46.

140. Guy de Jonquières, “All-night Haggling in Doha Ends in Agreement, WTO Meeting New Mood of Cooperation,” *The Financial Times*, November 15, 2001, 11.

visions, which they viewed as disguised protectionism.<sup>141</sup> India, Pakistan, and other countries also wanted to increase the access for their textiles in such markets as the United States, the European Union, and Canada. India in particular strongly resisted negotiations on the new areas raised in Singapore until the “implementation issues” from the Uruguay Round were resolved.

The preparations for the Doha ministerial reflected some key organizational changes. “Since the Seattle ministerial there has been much greater emphasis on the need for ‘transparency’ and ‘inclusiveness’ in the WTO’s institutional machinery,” noted Stuart Harbinson, chairman of the WTO’s General Council (Harbinson 2002, 3). As developing countries participated more fully in the WTO, more meetings were required to achieve results. In addition, rather than sending the trade ministers a document with various bracketed country proposals, as had been done before the Seattle ministerial, before Doha, Harbinson prepared a draft declaration to serve as the starting point of the negotiations.

Going into the ministerial, drug patents and TRIPS remained among the most difficult issues. “It’s really proven a tough nut to crack,” said one WTO official.<sup>142</sup> At a September 2001 meeting of the TRIPS Council, three draft proposals for a declaration on TRIPS were submitted. In their “Declaration on the TRIPS Agreement and Health,” a group of 60 developing countries proposed that “nothing in the TRIPS Agreement shall prevent members from taking measures to protect public health.” The pharmaceutical industry felt the statement was too broad. “That language is extraordinarily potent,” Mark Grayson warned. “With that language, there might as well not be a TRIPS.”<sup>143</sup> Activists from MSF, Oxfam, and other NGOs encouraged delegates from developing countries to demand that any TRIPS language not be limited to AIDS but instead address public health more broadly.

For its part, the United States appeared ready to make some concessions. In the lead-up to Doha, US officials proposed that the TRIPS implementation deadline for the least-developed countries be extended from 2006 to 2016 and suggested a moratorium on WTO challenges to African countries’ efforts to fight AIDS and other pandemics for at least five years—concessions that would not apply to Brazil, India, and Thailand. The European Union did not support the two US proposals, objecting that neither would lead to a meaningful declaration spelling out the relationship between TRIPS and health.<sup>144</sup> In a press conference, EU Commis-

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141. “Getting Close,” *The Economist*, November 10, 2001.

142. Quoted in Paul Blustein, “Drug Patent Dispute Poses Trade Threat: Generics Fight Could Derail WTO Accord,” *The Washington Post*, October 26, 2001, E1.

143. Grayson, quoted in Russell, “US Push for Cheap Cipro,” A13.

144. “EU Criticizes US Position on TRIPS, Calls for Compromise,” *Inside US Trade*, November 12, 2001.



sioner Pascal Lamy said the European Union would seek to strike a middle road between the contrasting US and developing-country positions. According to some sources, USTR Zoellick was irritated by how the European Union had handled the issue.<sup>145</sup>

## The Doha Ministerial

Participants began the WTO ministerial in Doha not only in the shadow of September 11 but also with clear memories of the failure to start a round of trade talks at the 1999 WTO ministerial in Seattle. Many delegates therefore came to Doha ready to work. WTO officials emphasized the importance of reaching an agreement to launch a new set of talks. WTO Director-General Mike Moore reminded the developing countries—three-quarters of the WTO’s 142-nation membership—that without an effective multilateral body, the world would move toward regional trade agreements sure to favor the stronger economic players. “Everyone wants to do a free trade deal with Japan or with the United States,” Moore said. “For the most marginal of our members, who’s knocking on their door? Only us.”<sup>146</sup>

The negotiations kicked off on November 9, 2001, without the protests of the Seattle ministerial (Qatar tightly limited the number of visitors). Much of the bargaining took place in six groups, focused respectively on agriculture, the environment, antidumping measures, implementation of the previous Uruguay Round agreement, investment and competition, and TRIPS.<sup>147</sup> Despite the importance of other areas, some saw the issue of drug patents as dominating the talks. Representatives from US, Swiss, and European drug companies were out in full force at the ministerial. “But,” noted the *Wall Street Journal*, “unlike in 1993, when intellectual-property protections were first negotiated as part of the initial WTO pact, this time the lobbyists were matched by AIDS activists who proved to be a well-coordinated group of opponents.”<sup>148</sup>

Developing-country negotiators knew that the United States and the European Union wanted a new round of trade talks—and that the Bush administration was anxious to keep the world on its side for the “war on terrorism.” India’s commerce and industry minister, Murasoli Maran, took a particularly hard-line approach. “India’s Mr. Maran became the man to see

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145. “Divisions on TRIPS Remain after Lamy, Zoellick Call on WTO Preparations,” *Inside US Trade*, November 9, 2001.

146. Moore, quoted in “Doha Outcome Provides Crucial Boost to WTO,” *Agence France-Presse*, November 15, 2001.

147. “Getting Close,” *The Economist*, November 10, 2001.

148. Geoff Winestock and Helene Cooper, “How Activists Outmaneuvered Drug Makers in WTO Deal—Poor Nations Can Ignore Patents to Meet Public-Health Needs—‘Our Expectations Were Fully Met,’” *The Wall Street Journal Europe*, November 15, 2001, A2.

at Doha,” according to one report, “frustrating US and European efforts to get an agreement. He spent the first five days refusing to negotiate and the last day threatening to walk out of the talks.” Maran’s stance in part reflected pressure back at home: during the negotiations, 25,000 protesters marched in the streets of New Delhi in opposition to the WTO talks.<sup>149</sup>

The Doha negotiations ran well beyond their scheduled deadline of November 13. Though USTR Robert Zoellick was willing to compromise on TRIPS and talk about the use of antidumping measures, he refused to make concessions on textile imports. On the agriculture issue, EU Trade Commissioner Pascal Lamy agreed to negotiate open agricultural markets “without prejudging the outcome” and to reduce export subsidies “with a view to phasing [them] out,” face-saving language that seemed to satisfy the French.

Even after the midnight deadline, India continued to hold out against negotiations on the Singapore issues, but some developing-country ministers were becoming frustrated with India’s tactics. Only hours before the closing ceremonies were to begin, Kenya’s trade minister attacked Maran for jeopardizing the TRIPS deal.<sup>150</sup> As it stood, the draft ministerial declaration read, “Negotiations [on Singapore issues] will take place after the Fifth Session of the Ministerial Committee on the basis of a decision to be taken, by explicit consensus, at that session on modalities of negotiation.” The meaning of this language was uncertain, however. According to the European Union and the United States, the declaration clearly launched Singapore issue negotiations. Yet in a closed-door session that held up the conclusion of the talks, India obtained the following statement from the conference’s chair, Qatari trade minister Youssef Kamal: “My understanding is that at that [fifth ministerial] session, a decision would indeed need to be taken by explicit consensus before negotiations on [Singapore issues] could proceed.”<sup>151</sup> India interpreted his assertion as denying that negotiations on the Singapore issues would necessarily take place. On this interpretation Maran announced, “India is supporting the text” as other ministers at the closing ceremony cheered.<sup>152</sup> The issue would continue to be debated after the close of the ministerial.

At the end of the talks, USTR Zoellick was widely quoted as saying, “Today the members of the WTO have sent a powerful signal to the world—we have removed the stain of Seattle.” Developing countries were

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149. Helene Cooper and Geoff Winestock, “Poor Nations Win Gains in Global Trade Deal, as US Compromises,” *The Wall Street Journal*, November 15, 2001, 1.

150. Cooper and Winestock, “Poor Nations Win Gains,” 1.

151. “Chairman’s Statement Casts Doubt on Final WTO Declaration,” *Inside US Trade*, November 15, 2001.

152. Helene Cooper and Geoff Winestock, “WTO Reaches Agreement on New Round of Talks—But Years of Tortuous Wrangling Lie Ahead—Indian Filibuster Nearly Capsized Deal,” *The Wall Street Journal Europe*, November 15, 2001, 1.

no longer complaining about being left out of crucial discussions. “Unlike in Seattle, Africa has been satisfied with all the stages of consultations,” Nigerian commerce minister Mustafa Bello said.<sup>153</sup>

## The WTO Declaration on the TRIPS Agreement and Public Health

The Declaration on the TRIPS Agreement and Public Health emerged from the Doha Development Agenda as a separate document. Though not as strong as the developing-country proposal, it went beyond the narrower language initially advocated by pharmaceutical companies: “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” (see appendix 3E). In addition, the TRIPS agreement was to be interpreted and implemented in a manner “supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.” For the least-developed countries, the implementation of TRIPS was extended until 2016.

Some saw the final declaration as a triumph for developing countries. Activists believed the declaration on TRIPS represented a significant turning point at the WTO. The debate was reframed, now that public health was linked to intellectual property and trade. Brazil’s foreign minister, Celso Lafer, described the text as an important step: “The declaration doesn’t change the TRIPS agreement at all, but provides a new view of it which is public health-friendly.”<sup>154</sup> Activists who had worked to achieve the declaration were thrilled. The Consumer Project on Technology’s Love called it “the greatest moment of our entire campaign—we are euphoric. We could have written that declaration ourselves.”<sup>155</sup> The WHO later noted, “The Declaration enshrines the principle WHO has publicly advocated and advanced over the last four years, namely, the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and promote access to medicines.”<sup>156</sup>

Pharmaceutical industry representatives also publicly welcomed the WTO’s statement on TRIPS and public health. Some argued that it would have little impact. “The industry wanted to make sure that the final language of this declaration didn’t expand or diminish the rights and obli-

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153. Bello, quoted in “Doha Outcome Provides Crucial Boost to WTO,” Agence France-Presse, November 15, 2001.

154. Lafer, quoted in “Doha Outcome Provides Crucial Boost to WTO.”

155. Love, quoted in Gardiner Harris and Rachel Zimmerman, “Drug Makers Say WTO Setback Will Not Have Significant Impact,” *The Wall Street Journal*, November 15, 2001, B5.

156. World Health Organization, “Statement by the Representative of the World Health Organization,” WTO TRIPS Council, March 2002.

gations within world trade agreements,” said PhRMA’s president, Alan Holmer. “We are now satisfied that the language does not.”<sup>157</sup> Brian Ager, director-general of the European Federation of Pharmaceutical Industries and Associations, agreed: “It’s still very much a political declaration,” not a legal change to the WTO rules.<sup>158</sup> Henry McKinnell, chief executive and chairman of Pfizer, described the battle in Doha as a public relations campaign by Indian generics manufacturers seeking to continue copying drug makers’ discoveries. The Indian companies “make Napster look good,” said McKinnell. But he insisted that the Doha Declaration would have “zero” effect on Pfizer’s profit.<sup>159</sup>

Some observers pointed out that activists were most effective on issues in which their interests aligned with those of developing nations. “This week’s [TRIPS] declaration showed how potent the alliance between the activists and developing countries can be,” noted the *Washington Post*’s Paul Blustein.

The activists’ clout at the WTO is weakest when their goals aren’t shared by developing country governments, whose citizens the activists purport to champion. That’s often a problem for environmentalists, because trade officials in the Third World are leery of establishing international environmental standards. Such standards, they suspect, will be used as an excuse by protectionist-minded rich countries to restrict imports of goods made in poor countries. The issue of drug patents was one on which activists and developing countries saw nearly eye-to-eye.<sup>160</sup>

Even those in industry commented on the changes faced by business groups. Harvey Bale, the director-general of the International Pharmaceutical Manufacturers Association, acknowledged the striking shift from the 1970s and 1980s, when the GATT was much more dominated by the “Quad” countries: the United States, the European Union, Japan, and Canada. Now, Bale said, developing countries are coming together and showing a greater readiness to use their muscle in the WTO, a change that “gives the activists fertile ground.”<sup>161</sup> One news editorial summed up Doha as “a turning point”: “It was not the radical climax for which some campaigners hoped, but it was a significant shift in the balance of power in global trade negotiations.”<sup>162</sup>

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157. Holmer, quoted in Harris and Zimmerman, “Drug Makers Say,” B5.

158. Ager, quoted in Geoff Winestock and Helene Cooper, “Activists Outmaneuver Drug Makers at WTO— Poor Nations Can Ignore Patents to Meet Public-Health Needs,” *The Wall Street Journal*, November 14, 2001, A2.

159. McKinnell, quoted in Harris and Zimmerman, “Drug Makers Say,” B5.

160. Paul Blustein, “Getting WTO’s Attention; Activists, Developing Nations Make Gains,” *The Washington Post*, November 16, 2001, E1.

161. Bale, quoted in Blustein, “Getting WTO’s Attention,” E1.

162. “Power Shifts in the WTO: Developing Countries Flex Their Muscles” (editorial), *The Guardian* (London), November 15, 2001, 23.

## Continuing Controversy—Paragraph 6 and Beyond

Controversy continued, however, over the meaning and significance of the Doha Declaration on the TRIPS Agreement and Public Health. For example, it had left open one key issue: how poor countries with no pharmaceutical manufacturing capabilities could make effective use of compulsory licensing. Ministers appeared to agree that the poorest countries facing serious health threats should be allowed to buy generic drugs from manufacturers in other countries, but the details remained to be worked out. Paragraph 6 of the declaration read:

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

The negotiations over paragraph 6 were difficult. As one observer puts it, negotiators had to decide “which countries should be allowed to import which products, for what diseases, from which possible exporters, under what safeguards, and through which legal form this additional flexibility should be created” (van Thiel 2003, 13)—and positions on all these issues diverged widely. Predictably, developing nations and activists wanted to allow poorer countries to import a broad range of public health products—not just AIDS drugs, for example, but also diagnostic kits and equipment. One US trade official criticized NGOs for “trying to break patent protections on every conceivable health product, even X-ray machines.”<sup>163</sup> In addition, activists believed it should be up to each WTO member to decide when it faced a public health problem. US delegates, in contrast, pushed to limit the agreement to include only drugs treating AIDS/HIV, malaria, tuberculosis, and infectious epidemics of comparable gravity and scale. “Broadening the solution to cover any public health problem, as some are advocating, would divert attention and resources away from these epidemics, at Africa’s expense,” wrote Assistant USTR for Africa Rosa Whitaker to African trade ministers on October 25, 2002, “and risks trivializing the gravity of these serious epidemics.”<sup>164</sup>

Activists and developing countries viewed the limited disease coverage as too restrictive. Ellen ‘t Hoen of MSF argued that such limitations would mean that countries seeking to treat AIDS sufferers could import cheaper antiretrovirals, but would be barred from importing generic antibiotics to treat pneumonia or medicines to treat other opportunistic infections.<sup>165</sup>

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163. Quoted in Neil King Jr., “Progress in Doubt on Drug Patents at WTO Summit,” *The Wall Street Journal*, November 14, 2002, A11.

164. Letter reprinted in *Inside US Trade*, November 15, 2002.

165. ‘t Hoen, quoted in “Drug Companies Push for Limits on Disease Coverage in Drug Patent Deal,” *Inside US Trade*, November 22, 2002.

Ultimately, TRIPS Council Chairman Eduardo Perez Motta proposed more ambiguous language that referred to “public-health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics.” Some developing nations interpreted this as covering any public health problem.

On November 19, 2002, leading executives of 20 US research-based pharmaceutical companies sent a letter to USTR Robert Zoellick, urging him to ensure that WTO language be limited to medicines for serious epidemics and not to allow patents to be overridden for medicines treating diseases such as cancer, heart disease, or diabetes. “While we have been supportive of the Administration since Doha,” the letter read, “it has become increasingly evident that some WTO countries with industries based upon copying medicines are pushing to expand the Doha frame of reference far beyond its original letter and spirit.”<sup>166</sup> In addition, the writers emphasized that a solution should focus on the needs of patients in the “poorest countries” that “truly lack manufacturing capacity.” PhRMA senior vice president for international affairs Shannon Herzfeld said that any agreement should require all but the least-developed countries to prove with “objective verifiable data” that they could not manufacture the drugs domestically, and must therefore issue a compulsory license for manufacture abroad.<sup>167</sup>

The negotiations on compulsory licensing ground to a halt in December 2002 when US officials rejected a draft text by Motta (see van Thiel 2003, 22). The United States was alone in rejecting the text; EU Trade Commissioner Pascal Lamy called US industry objections to the proposed WTO agreement “very stupid.” Lamy also criticized NGO activists for trying to block a deal.<sup>168</sup> In the last-minute negotiations, in which WTO Director-General Supachai Panitchpakdi was directly involved, the United States insisted that any agreement must specify what diseases would be covered, but attempted to keep the negotiations alive by offering to expand that coverage to include 23 diseases.<sup>169</sup> This list, according to a USTR spokesman, was developed by the Department of Health and Human Services and the WHO to identify the “infectious epidemics of most concern to health pro-

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166. Quoted in “Drug Companies Push for Limits on Disease Coverage.” Signing the industry letter were CEOs and senior executives of Hoffmann-La Roche, Novartis Pharmaceuticals, Wyeth, AstraZeneca, Bristol-Myers Squibb, Bayer, Pharmacia, GlaxoSmithKline, Berlex Laboratories, Pfizer, Amgen, Genzyme, Johnson & Johnson, PhRMA, Schering-Plough, Aventis, Allergan, Eli Lilly, Schwarz Pharma, and Abbott Laboratories.

167. Herzfeld, quoted in “Drug Companies Push for Limits on Disease Coverage.”

168. Lamy, quoted in Guy de Jonquières, “EU Condemns Stance of US Drug Groups: Cheaper Drugs for Poorer Nations,” *The Financial Times*, January 21, 2003, 11.

169. “Consensus on TRIPS Unravels as US Blocks Deal on Scope of Diseases,” *Inside US Trade*, January 3, 2003.

fessionals in the developing world.”<sup>170</sup> But developing countries rejected the idea, favoring instead the more general deal proposed by Motta.

After talks broke down, the United States announced a unilateral moratorium on bringing WTO cases against countries that exported drugs to low-income nations under compulsory licenses, provided that those drugs were used to treat a limited set of infectious epidemics.<sup>171</sup> Despite US efforts to persuade other countries that such a moratorium would suffice, developing countries held out for a formal amendment to the TRIPS agreement as a permanent solution.

Soon after, in his State of the Union address, President George W. Bush noted that the price of antiretroviral drugs had fallen from \$12,000 to \$300 annually and asked Congress to commit \$15 billion over five years toward AIDS in Africa. “More than 4 million require immediate drug treatment,” Bush said. “Yet across that [African] continent, only 50,000 AIDS victims—only 50,000—are receiving the medicine they need. . . . A doctor in rural South Africa describes his frustration. He says, ‘We have no medicines. Many hospitals tell people, you’ve got AIDS, we can’t help you. Go home and die.’ In an age of miraculous medicines, no person should have to hear those words.”<sup>172</sup>

The failure to reach a TRIPS and health deal by the December 31, 2002, deadline marked another setback for the Doha Round, which faced other deadlines on agriculture, industrial market access, and services. WTO Director-General Supachai warned countries about the lagging pace of the overall negotiations, which he feared faced “imminent gridlock.”<sup>173</sup> Trade negotiators were eager to reach agreement on the TRIPS issue before the September 2003 WTO ministerial in Cancún, Mexico, meant to serve as a midterm review of the Doha Round. Some officials worried that if the dispute remained unresolved before the meeting in Cancún, the medicines issue would cloud the overall negotiations.

In August 2003, just two weeks before the Cancún ministerial, the deadlock over paragraph 6 was broken. US negotiators ended their obstruction

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170. One version of the footnote, obtained by *Inside US Trade*, reads: “This decision applies to public health problems arising from yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, HIV/AIDS, leishmaniasis, TB, malaria, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, hemorrhagic fevers, and arboviruses and other epidemics of comparable gravity and scale including those that might arise in the future due to natural occurrence, accidental release or deliberate use.” See “Consensus on TRIPS Unravels as US Blocks Deal on Scope of Diseases,” *Inside US Trade*, January 21, 2003.

171. “Consensus on TRIPS Unravels,” *Inside US Trade*, January 21, 2003.”

172. President George W. Bush, State of the Union Address, January 28, 2003, [www.whitehouse.gov](http://www.whitehouse.gov).

173. Supachai Panitchpakdi, quoted in “TNC Fails to Advance Developing Country Implementation Demands,” *Inside US Trade*, March 7, 2003.

when the chairman of the General Council added additional safeguards. In a statement accompanying the agreement that emerged, "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003" (see appendix 3F), the chairman stressed that the 2002 TRIPS and health declaration should be implemented "in good faith to protect public health" and not to further "industrial or commercial policy objectives."<sup>174</sup> Measures to prevent the diversion of cheap drugs to Western markets, including special packaging or different-colored tablets, were also stipulated. In addition, most OECD members agreed to opt out of the system. The deal created a temporary waiver from specific TRIPS rules for pharmaceutical products until WTO members could create a formal amendment to the agreement. "This is a historic agreement for the WTO," Supachai said. "The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual-property rules in order to deal with the diseases that ravage their people."<sup>175</sup>

The activists were not so sanguine; some argued that the agreement on paragraph 6 was too complicated. A joint NGO statement labeled it "a gift bound in red tape" and urged that the waiver not be celebrated until it was seen to actually work.<sup>176</sup> A *Washington Post* editorial similarly cautioned, "While this agreement is fine in principle, many are still doubtful about how well it will work in practice. . . . Drug agreements may be hailed in Cancún, but what matters is whether they improve access to drugs in the poorest countries."<sup>177</sup>

Despite agreement on TRIPS, the talks in Cancún collapsed in September over disputes between developed and developing nations. A group of 22 developing countries, led by Brazil, China, and India, balked at a US-EU proposal on agriculture. In addition, developing countries refused to launch negotiations on the so-called Singapore issues (investment, competition policy, trade facilitation, and transparency in government procurement). "Compared with the past, the role of the developing countries has changed," said Hajime Ito, a senior director in Japan's trade ministry. "They have been able to achieve a homogeneous position that they could

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174. The WTO, "The General Council Chairperson's Statement," August 30, 2003, [www.wto.org](http://www.wto.org).

175. Supachai Panitchpakdi, quoted in "WTO Votes to Bypass Patents on Medicines: Cheap Generics Go to Poor Nations," *The Washington Post*, August 31, 2003, A16.

176. MSF press release, "Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines: A 'Gift' Bound in Red Tape," September 10, 2003 (available at, e.g., [www.epha.org](http://www.epha.org)); it was signed by ACT UP Paris, the Consumer Project on Technology, Consumers International, Essential Action, European AIDS Treatment Group, Health Action International, Health GAP, International People's Health Council, Médecins sans Frontières, OXFAM International, People's Health Movement, SEATINI, Third World Network, and Women in Development.

177. "The Task in Cancún" (editorial), *The Washington Post*, September 10, 2003, A18.



not in the past.”<sup>178</sup> USTR Zoellick wrote in the *Financial Times* that the WTO had become “a forum for the politics of protest” and warned, “the US will not wait: we will move towards free trade with can-do countries.”<sup>179</sup>

Though the Doha Round would eventually continue, some analysts worried that such ongoing disputes would spur the United States and the European Union to further accelerate bilateral and regional trade agreements rather than devoting effort to multilateral talks. They noted that the United States and EU were already working through bilateral and regional avenues to tighten intellectual property protections beyond TRIPS in developing countries. Such “TRIPS-plus” standards for IPRs included limiting compulsory licensing, requiring countries to join the International Union for the Protection of New Varieties of Plants,<sup>180</sup> extending patent terms, and implementing TRIPS early.

The continuing tensions over TRIPS were seen in provisions of the US Bipartisan Trade Promotion Authority (TPA) Act. In July 2002, Congress narrowly passed this legislation, which set priorities for US trade negotiators and ensured a quick vote on implementing legislation for trade deals. While TPA directed negotiators “to respect the Declaration on the TRIPS Agreement and Public Health” made at Doha, it also directed the USTR to ensure “accelerated” implementation of the TRIPS agreement and mandated that the IPR provisions of any multilateral or bilateral trade agreement entered into by the United States “reflect a standard of protection similar to that found in United States law.”

MSF called on all WTO members to “reject any IP provisions more stringent than TRIPS requires (TRIPS-Plus), and to set the Doha Declaration as the ceiling on intellectual property protection for all bilateral and regional trade agreements.”<sup>181</sup> Activists also wrote to members of Congress, criticizing the US-Singapore Free Trade Agreement, the US-Chile Free Trade Agreement, and the Central American Free Trade Agreement (CAFTA) for including “TRIPS-plus” patent protections and for delaying the introduction of generic drug competition. They had similar concerns about the Free Trade Area of the Americas (FTAA) negotiations.

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178. Ito, quoted in Neil King Jr. and Scott Miller, “Trade Talks Fail amid Big Divide over Farm Issues—Developing Countries Object to US, EU Goals; Cotton as a Rallying Cry,” *The Wall Street Journal*, September 15, 2003, A1.

179. Robert B. Zoellick, “America Will Not Wait for the Won’t-Do Countries,” *The Financial Times*, September 22, 2003, 23.

180. The International Union for the Protection of New Varieties of Plants (l’Union internationale pour la protection des obtentions végétales, or UPOV), an intergovernmental organization with headquarters in Geneva, is not mentioned in the TRIPS agreement. It was established by the UPOV Convention, adopted in Paris in 1961 (revised in 1972, 1978, and 1991) to bring new varieties of plants under the protection of IPRs. See [www.upov.org](http://www.upov.org).

181. MSF press release, “Doha Derailed: MSF Supports Developing Countries’ Efforts to Implement the Doha Declaration,” September 10, 2003.

## Return to South Africa

Meanwhile, South Africa announced a major shift in its AIDS policy, committing to undertake the world's largest AIDS treatment program by providing free antiretroviral drugs to its HIV-positive citizens. The plan took advantage of an October 2003 deal that the William Jefferson Clinton Foundation had brokered with Indian and South African generic producers. It lowered AIDS drug prices for a group of 15 African and Caribbean nations to \$0.38 a day—a reduction of more than a third from already discounted prices.<sup>182</sup> South Africa's Department of Health estimated that in the first year of the program more than 50,000 people would receive drugs, a figure that would rise to more than one million by 2007.<sup>183</sup>

South African manufacturers of generics worked to get voluntary licenses for the antiretroviral drugs before going into production. In an out-of-court settlement, GlaxoSmithKline and Boehringer Ingelheim agreed to expand voluntary licensing of their patented AIDS medicines to the South African companies; the deal permitted the drugs to be sold in all 47 sub-Saharan African countries. In return, the South African Competition Commission, a government body, dropped a yearlong investigation into whether the companies had overcharged for their AIDS drugs.<sup>184</sup> In October 2003, the commission had ruled that the two companies had violated South Africa's Competition Act by "abus[ing] their dominant positions in their respective anti-retroviral (ARV) markets" through excessive pricing and "refus[ing] to license their patents to generic manufacturers in return for a reasonable royalty."<sup>185</sup> Though the drug makers held the complaint to be unfounded, GlaxoSmithKline senior vice president Peter Bains said the company was "pleased" to have escaped the months of negative publicity that might have accompanied hearings of the Competition Tribunal. Activists celebrated the agreement. "For us, this is an historic occasion," said Zackie Achmat, chairman of South Africa's Treatment Action Campaign. "It's come late, it's come at a cost of many thou-

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182. The Clinton Foundation also struck a deal with five of the world's leading medical companies to deliver low-priced HIV diagnostic tests for sub-Saharan Africa, cutting costs by as much as 80 percent.

183. Nicol Degli Innocenti and John Reed, "Facing Up to AIDS: South Africa Plans to Treat 1M Patients, But Is It as Short of Political Will as It Is of Doctors?" *The Financial Times*, January 21, 2004, 17.

184. See Julia Flynn and Mark Schoofs, "Glaxo, Boehringer to Let Africa Make More Generics for AIDS," *The Wall Street Journal*, December 11, 2003, D4; "Glaxo, Boehringer Cut a Deal on AIDS Drugs," Reuters and Bloomberg, December 11, 2003.

185. South African Competition Commission Media Release no. 29, "Competition Commission finds pharmaceutical firms in contravention of the Competition Act," October 16, 2003.

sands of lives, but we now want to say to the drug companies, 'Let's put this behind us, and move on.'"<sup>186</sup>

But pharmaceutical companies, aware that large quantities of many types of drugs were stolen every year from South African state hospitals, worried that AIDS drugs would be smuggled to Western markets. "We are very concerned about unscrupulous importers," said Bains. "A clear condition of the voluntary licensing agreement is the inclusion of anti-diversion measures. The drugs must be distributed in sub-Saharan Africa only."<sup>187</sup>

## Negotiation Analysis of the Cases

The success of US intellectual property industries in getting TRIPS onto the Uruguay Round agenda and gaining a favorable agreement is a testament to their skill in negotiating. NGOs and developing-country delegations demonstrated similar skill in winning public health-related concessions on TRIPS at the Doha ministerial in late 2001. The TRIPS cases therefore offer an opportunity to see how actors with vastly different goals employ the same influence toolbox.

### Element #1: Organizing to Influence

The campaign to get TRIPS on the Uruguay Round agenda originated in the vision and commitment of just two people, both CEOs of major US corporations: Edmund Pratt of Pfizer and John Opel of IBM. Pratt and Opel, who represented companies with strong interests in strengthening international protections for intellectual property, educated and involved themselves in the issues, and then developed potent networks of connections with senior US government officials. They established the tone and secured the resources for an intense effort to influence key governments and the negotiation process itself.

By founding the Intellectual Property Committee, Pratt and Opel dramatically increased their leverage in two ways. First, they gained the support of like-minded CEOs in affected US companies. Second, and equally important, they staffed their new organization with highly committed and knowledgeable people, such as Jacques Gorlin, who had as much expertise on the issues as anyone in the US government. The resulting focus

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186. Bains and Achmat are quoted in John Donnelly, "Deal Paves Way for Generic HIV Drugs: Drug Companies to Allow Sales in sub-Saharan Africa," *The Boston Globe*, December 11, 2003, A8.

187. Bains, quoted in Innocenti and Reed, "Facing Up to AIDS," 17.

and knowledge enabled the IPC to exert significant control over how the issues were framed and the agreements drafted. The IPC's 1988 position paper, for example, established minimum standards for IPR protection that were largely adopted in the TRIPS agreement.

The campaign to secure public health exemptions to TRIPS at the Doha ministerial likewise originated in the work of a small group of committed people. Health Action International, the nonprofit network of public health organizations, organized a key 1996 meeting in Germany that cemented the core coalition of activists who would help to lead the campaign. As the AIDS crisis escalated, South Africa became a focal point for organization, with activists working to get the issue on the World Health Organization and the World Trade Organization agendas.

## **Element #2: Selecting the Forum**

In both the TRIPS cases, efforts to select the negotiating forum proved decisive in shaping the outcome. The IPC decided to concentrate on getting intellectual property onto the Uruguay Round agenda, bypassing the World Intellectual Property Organization, which had several disadvantages from its point of view. First, WIPO was seen by industry as powerless to enforce agreements and punish violations. The GATT dispute resolution mechanisms would be further strengthened by the creation of the WTO, allowing for retaliation when trade rules were violated. Second, WIPO was a single-issue forum focused only on intellectual property, limiting the flexibility the United States in using threats, trade-offs, and other inducements to strengthen international IP protection. At the WTO, negotiations on IPRs would be part of a larger undertaking that included talks on many other sectors.

By getting TRIPS onto the agenda of the Uruguay Round negotiations, proponents of stronger international protection for IP opened up important opportunities for cross-sector and cross-issue trades. Key linkages were created among the issues of IP, textiles, agriculture, and light manufacturing products. The quid pro quo for the TRIPS agreement ultimately included concessions on textiles (phasing out the MFA) and agriculture. The linkage to the MFA was particularly important in winning the support of the ASEAN countries and in breaking the developing-country coalition opposing TRIPS.

The activists seeking to win exemptions from TRIPS for public health likewise concluded that their leverage would be greater if they negotiated in trade forums, specifically in the ministerial meetings that set the agenda for new rounds of WTO talks and in meetings scheduled to specifically focus on the medicines issue. However, activists and developing-country officials also brought their case to the World Health Organization, which was initially resistant to addressing the question of drug

patents. But in an unprecedented event, the WTO and WHO cosponsored a workshop to explore the problem of access to medicines. The WHO's involvement increased pressure on the WTO to address the question of access to drugs.

### **Element #3: Shaping the Agenda**

Both the intellectual property industry coalition and the essential medicines coalition advanced their positions by threatening to block the start of new rounds of multilateral trade negotiations. The IPC was successful in persuading the US government, notably Commerce Secretary Malcolm Baldrige and USTR Clayton Yeutter, to make inclusion of IPRs on the agenda a precondition for launching the Uruguay Round.

Stealing a page from the IPC's playbook, the essential medicines coalition made public health-related concessions on TRIPS a precondition for launching the Doha Round of multilateral trade negotiations. Activists and developing-country negotiators knew that the United States and the European Union strongly desired a new round of trade talks. They also knew that the Bush administration was anxious to keep the world on its side for its war on terrorism. The failure of the Seattle ministerial had made Doha a make-or-break meeting, a circumstance that increased developing-country leverage. Rather than wait for the negotiations proper, they forced action at the Doha ministerial. Led by Brazil, developing countries succeeded in winning concessions on TRIPS.

### **Element #4: Building Coalitions**

In both TRIPS cases, effective multilevel coalition building proved to be pivotal. In the first TRIPS case, IPC leaders worked to build a network of relationships with senior US government officials and to convince them of the need to take stronger action on IPRs. Once key members of Congress and administration officials were on board, larger organizations were spurred to focus on the problem. Staff members of the IPC also advised the US delegation to the TRIPS talks throughout the process and even helped to draft some of the agreement's language.

Early on, the IPC also recognized the need to influence government officials in Europe and Japan to support the effort to get IP on the Uruguay Round agenda. However, the group lacked the requisite influence to successfully lobby these officials; nor could US government influence carry the day.

To overcome this barrier, the IPC launched a multilevel coalition building campaign. Because Japanese and European officials would be most likely defer to domestic business interests on IP issues, the IPC worked to build

coalitions with influential organizations—UNICE and the Keidanren—representing European and Japanese businesses. At the same time, the US government engaged in talks with Japan and Europe. The result was a coordinated approach to influencing the “northern” governments to support common positions.

In order to maintain this coalition, the IPC focused on larger principles of protecting IP and establishing a framework for what would be acceptable, rather than focusing on details that could divide the group. By elevating principles and frameworks and suppressing details, the northern coalition could stay united until the battle was won, and only then focus on dividing the spoils.

Coalition building proceeded along similar lines in the second TRIPS case. The group of activists who had coalesced at a meeting organized by HAI made common cause with sympathetic officials in sub-Saharan Africa. Like the IPC in the first TRIPS case, this core coalition sought to broaden its support and weaken potential opposing coalitions. By taking the issue to the May 1998 meeting of the WHO and seeking a resolution on access to essential medicines, they succeeded in raising awareness of the TRIPS agreement in the international public health community.

The subsequent involvement of organizations such as Médecins Sans Frontières, Oxfam, and the Consumer Project on Technology situated concerns about TRIPS patent rules in the broader context of access to potentially lifesaving drugs in poor nations, and so further expanded the coalition beyond a limited group of health policy activists in NGOs. Like the IPC in the first TRIPS case, they engaged in multilevel coalition building. To build support in the professional medical community, NGOs both published articles in respected medical journals and launched a public influence campaign aimed at a more popular audience. MSF’s 1999 Nobel Prize also enhanced its reputation, thereby strengthening its access to medicines effort.

The United States generally treated TRIPS-related issues, including language about pharmaceutical patents in the South African Medicines Act, as trade-related, with USTR taking the lead. Though Vice President Gore took the initiative to address questions about the Medicines Act in the US–South Africa Binational Commission, the US government continued to threaten action against South Africa, placing it on the Special 301 Watch List. But just as the IPC influenced European and Japanese governments by reaching “inside” and forming alliances with domestic business groups, so too did the essential medicines activists seek allies to increase their influence. By partnering with domestic AIDS groups such as ACT UP, which used their political power to organize protests at Gore’s presidential campaign appearances, activists succeeded in pressuring the US government. This pressure worked to counteract the influence of the pharmaceutical industry, which was concerned that precedents set by the South African Medicines Act could weaken international IPR protection.

Outreach to government officials, industry executives, and WHO representatives in the lead-up to the 1999 Seattle ministerial broadened support still further. Momentum continued to build in the first WTO debate on TRIPS and affordable medicines in 2001, leading to the drafting of the Declaration on the TRIPS Agreement and Public Health at the Doha Ministerial.

## **Element #5: Leveraging Linkages**

Linkages between bilateral negotiations and multilateral negotiations were an important source of influence for the IPC in the first TRIPS case. Throughout the 1980s, US intellectual property industries sought to focus the administration's attention on international IPR protection and to provide officials with tools that would make possible greater bilateral influence over trading partners. The Trade Act of 1984 made intellectual property rights actionable under section 301 of the 1974 Trade Act. In addition, Congress made "adequate and effective" IP protection a condition for eligibility under the Generalized System of Preferences. In 1985, USTR created the position of assistant USTR for international investment and intellectual property, and the "Super 301" provision of the 1988 Omnibus Trade and Competitive Act further strengthened reporting requirements for intellectual property. India and Brazil, which were leaders of developing-country resistance to IPR protection, were specifically targeted under Super 301.

These efforts at linkage bore fruit in bilateral negotiations with Korea. After launching a section 301 case against Korea in 1985, the United States negotiated an agreement in 1986 that became a model for the eventual multilateral TRIPS agreement. The linkage between section 301 and the Uruguay Round was also important in achieving agreement with developing countries on TRIPS. Some developing countries far preferred TRIPS to Section 301.

In the second TRIPS case, the most powerful linkage was the one made by activists between TRIPS and the AIDS crisis in developing countries. Though hesitant at first to bring in an issue on which so many organizations were working, they decided that the inclusion of one of the biggest problems in contemporary world health made strategic sense. They were right: by linking TRIPS to the AIDS pandemic, activists were able to infuse their concerns about pharmaceutical patents with a certain moral imperative that resonated in the many press reports about the debate. At the same time, activists were careful to focus narrowly on public health issues and not to oppose TRIPS in its entirety. Their deliberate embrace of "reasonability" deprived their opponents in the drug companies of ammunition, for they could not be branded as impractical radicals. Claims (such as the following from MSF) that they were "not against patents and not

against patent legislation,” and that “True innovation deserves to be protected and to be rewarded,” were critically important in preventing opposition from coalescing.

## **Element #6: Playing the Frame Game**

In the first TRIPS case, the IPC was successful in defining the debate in terms of “intellectual piracy” for the crucial domestic US audience, especially Congress. This description was potent because it evoked images of the worst forms of plunder and illegitimacy. The groundwork for this framing was actually laid earlier, notably in the 1985 IIPA report, *Piracy of US Copyrighted Works in Ten Selected Countries*. Its result was an increased willingness on the part of Congress to enact laws strengthening the administration’s hand in international negotiations over IPRs.

But though copying of products was not in the interest of US IP companies, this act was not illegal if the country in question had no domestic IP protections—no laws were being violated. IPRs could have been framed differently, in accordance with the competing view that TRIPS would hinder development and allow IP industries to monopolize and withhold knowledge from those unable to pay for their products. For example, poorer countries might have labeled the situation “intellectual imperialism,” a charge that would have resonated in the developing world. But the notion of intellectual piracy dominated the debate, and the IPC won the frame game.

The activists seeking to win concessions on TRIPS at Doha likewise proved highly skilled in playing the frame game. In the United States, ACT UP accused government officials of engaging in “medical apartheid” during their demonstrations. Most important, MSF and other NGOs framed their efforts as a campaign to make “essential medicines” more available to dying people in the developing world. The press often picked up this language, describing the debate as pitting dying people against corporate profits. In response, the pharmaceutical industry argued that patent protection was necessary to fund research and development for new cures. The industry also noted that access to AIDS treatment was blocked not by the high price of drugs but by lack of health care infrastructure and political will. However, these arguments did not prove as compelling as the NGOs’ framing.

## **Element #7: Creating Momentum**

In the first TRIPS case, the IPC employed a potent sequencing strategy to excellent effect. Its approach can be summed up as follows: first unify the United States, then unify the North, next co-opt the middle, and finally isolate the implacable opponents.



The starting point for industry leaders was to build the coalition of IP businesses in the United States. The next step was to get IPRs on the US government's agenda, secure support, and set up coordinative mechanisms. With US support solidified, the IPC then turned to gaining support from the European and Japanese governments, first building coalitions with like-minded business groups and then encouraging them to influence their respective governments.

The IPC helped to craft a set "basic principles" to which all the northern countries could subscribe, and it explicitly pressed to defer "internal" negotiations over potentially divisive details. In this way, the northern countries succeeded in jointly creating value and claiming it as a group; they put off for later the question of how they should divide up the pie.

The next step was to expand the coalition, using linkages to market access for textiles, agriculture, and manufacturing products to win the support of ASEAN countries and to prevent the formation of a blocking coalition. This approach—combined with success in arguing that IP protection would be rewarded with increased foreign investment, that developing countries would have longer TRIPS phase-in periods, and that the United States would subject itself to the WTO dispute resolution mechanism—was sufficient to overcome the remaining opposition.

Efforts to build momentum had a decisive impact in the second TRIPS case as well. In part, activists similarly gained momentum by sequentially building their coalition. But they also made skilled use of action-forcing events. In the United States, for example, ACT UP used the upcoming presidential elections as an action-forcing event to push Vice President Gore to reduce US pressure on South Africa to overturn portions of its Medicines Act. As described above, the Doha ministerial also served as an action-forcing event. By in effect holding a new round of trade talks hostage, activists and developing-country officials sought concessions on TRIPS.

Finally, the pharmaceutical industry provided their opponents with a focal point for organizing by making a classic blunder: the decision by a coalition of Western companies to launch and pursue a lawsuit against South Africa's Medicines Act. Far from causing the South African government and local activists to back down, the court action stiffened resistance. Its opening in March 2001 provoked international outrage and extensive negative press coverage. These events provide a textbook example of *reactive coalition building*—the clumsy actions of a powerful player catalyzing the formation of an opposing coalition.

Rather than enter a losing argument over IP protection (and ultimately over prices and margins), the pharmaceutical industry would have been well advised to find a less damaging resolution. Though the companies did shift tactics—they lowered prices through the Accelerating Access Initiative—that initiative required them to negotiate distribution of the drugs with each interested country individually and to ensure that participating nations had a health care infrastructure able to administer the

drugs. One alternative might have been to drop the South Africa case altogether and donate the drugs to the WHO or to set up a foundation. By doing so, they would have avoided opening up debates about true prices and margins; and because the WHO would have been responsible for distribution, the companies would have escaped criticism during the predictably challenging period of actually getting the drugs to sick people. This approach would have focused attention back on the policies of various African governments and the weakness of their public health infrastructures.

## **Conclusion**

The juxtaposition of the two TRIPS cases illustrates that the negotiation toolbox can be employed by any and all parties seeking to shape trade agreements: companies, NGOs, and governments. The parties that use these tools most effectively win a potentially decisive advantage. The cases also illustrate that the negotiation game never really ends. Gains made by the pharmaceutical industry in the first TRIPS case were partially lost in the second, and the story is ongoing. Both battles occurred in the context of a much longer war.

## Appendix 3A

### TRIPS: Timeline

Date	Event
1883	Paris Convention for the Protection of Industrial Property established.
1886	Berne Convention for the Protection of Literary and Artistic Work established.
1967	World Intellectual Property Organization (WIPO) established.
1974	WIPO joins the United Nations system.
Mid-1970s	Industry groups approach the US government about the “piracy” of their intellectual property.
1978	Trademark industries found the International Anti-Counterfeiting Coalition.
1979	The Anti-Counterfeiting Coalition works with negotiators to develop a proposed anti-counterfeiting code during the Tokyo Round of GATT talks. The code is not put into effect.
1970–89	Pfizer chairman Edmund Pratt and IBM chairman John Opel serve on the President’s Advisory Committee on Trade Negotiations (ACTN) during the Carter and Reagan administrations. Pratt chairs the committee, and Opel is head of the IP task force.
1980s	Software “piracy” begins to be identified as a problem (IBM introduced personal computers around 1982).
1984	The Trade Act of 1984 makes IPR infringement actionable under section 301 of the 1974 Trade Act.
Early 1980s	Jacques Gorlin, a trade expert and consultant to IBM, writes a paper described by one observer as “the first intellectual articulation of having broader IP standards plus an enforcement text in the GATT agreement.”
1985	USTR Clayton Yeutter creates the position of assistant USTR for international investment and intellectual property.
1986	A bilateral IP agreement between the US and Korea (later used as a model for TRIPS) is reached.
March 1986	Pratt and Opel found the Intellectual Property Committee (IPC), a group of 13 CEOs committed to moving intellectual property onto the GATT agenda.
1986	The IPC forms a tripartite coalition with the European Union of Industrial and Employers’ Confederations (UNICE) and the Keidanren, a powerful private federation of economic organizations in Japan.

*(table continues next page)*

## TRIPS: Timeline *(continued)*

<b>Date</b>	<b>Event</b>
September 1986	Intellectual property is included in the Punta del Este statement that launches the Uruguay Round.
September 1986	The Uruguay Round begins.
1986–87	The first two years of TRIPS negotiations are characterized by disagreements between developed and developing countries.
June 1988	The IPC creates a report detailing the minimum standards for an acceptable TRIPS agreement.
1988	The US Omnibus Trade and Competitiveness Act includes a provision known as “Special 301” to bolster IP protection.
December 1988	At the Uruguay Round midterm review, TRIPS negotiators reach no consensus for the framework of the talks.
April 1989	The deadlock over TRIPS is broken.
June 1990	Lars Anell, chairman of the TRIPS Working Group, prepares a draft TRIPS text.
December 1990	The TRIPS Draft Composite Text is presented at the Brussels Ministerial Meeting.
December 1990	The Uruguay Round breaks down.
December 1991	The GATT Secretariat presents a comprehensive draft known as the Dunkel Draft.
December 15, 1993	The Uruguay Round closes; the entertainment industry’s audio-visual issue is left on the table.
1994	In the United States, as the last act of the 103rd Congress, the Uruguay Round Agreements Act passes, 288–146 in the House and 76–24 in the Senate.

## **Appendix 3B**

### **South African Medicines and Related Substances Control Amendment Act of 1997, Section 15C**

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and in particular may:

- (a) notwithstanding anything to the contrary contained in the Patents Act 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

## **Appendix 3C**

### **Excerpts from the TRIPS Agreement (1994)**

#### **Article 6: Exhaustion**

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

#### **Article 8: Principles**

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

#### **Article 27: Patentable Subject Matter**

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

#### **Article 28: Rights Conferred**

1. A patent shall confer on its owner the following exclusive rights:
  - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
  - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

### **Article 31: Other Use Without Authorization of the Right Holder**

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: . . .

(c) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly; . . .

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; . . .

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization[.]

## Appendix 3D

### A Selection of Press Headlines on Intellectual Property Rights and TRIPS: What Can We Learn about How the Press Covers the TRIPS/IPR Issue over Time?

- "Intellectual Piracy Captures the Attention of the President and Congress," by Bruce Stokes, *The National Journal*, February 22, 1986, 443.
- "US Businesses Urge Trade Sanctions to Stop Piracy of Software in China," by Daniel Southerland, *The Washington Post*, April 11, 1989, E7.
- "Waging War on Pirates," by Dave Savona, *International Business*, January 1995, 42.
- "Protecting Intellectual Property: Strategies and Recommendations to Deter Counterfeiting and Brand Piracy in Global Markets," by Clifford Shultz and Bill Saporito, *Columbia Journal of World Business*, March 22, 1996, 18.
- "Retribution for Reproduction," *The Economist*, May 18, 1996, 73.
- "The Pill Machine; How Much Money Should Big Drug Firms Have to Lose to Treat the World's Poorest Patients?" by Karen Lowry Miller, *Newsweek International*, November 19, 2000, 46.
- "Trial Opens in South Africa AIDS Drug Suit: Firms Seek to Block Law Allowing Generic Substitutes for Patented Medicines," by Jon Jeter, *The Washington Post*, March 6, 2001, A1.
- "New Regimen: AIDS-Drug Price War Breaks Out in Africa, Goaded by Generics—Merck, Others Plan to Slash Costs of Key Medicines in Bid for High Ground—Weighing Patents and People," *The Wall Street Journal*, March 7, 2001, A1.
- "Defensive Drug Industry: Fueling Clash Over Patents," by Andrew Pollack, *The New York Times*, April 20, 2001, A6.
- "Lifting the Curtain on the Real Costs of Making AIDS Drugs," by Melody Petersen, *The New York Times*, April 24, 2001, C2.
- "The Right to Good Ideas: Patents and the Poor," *The Economist*, June 23, 2001.
- "A Bitter Pill for the Drug Makers: Instead of an Opportunity, the Anthrax Scare Has Raised Awkward Questions about Patent Protection," by Geoff Dyer and Adrian Michaels, *The Financial Times*, October 23, 2001, 27.
- "Drug Patent Dispute Poses Trade Threat: Generics Fight Could Derail WTO Accord," by Paul Blustein, *The Washington Post*, October 26, 2001, E1.
- "Software Pirates, Beware," by Stryker McGuire; with Richard Ernsberger Jr. and Tony Emerson, *Newsweek*, October 29, 2001, 68.
- "'The Real Question Isn't Moral': Three Industry Analysts Wonder if Microsoft's War Against Software Piracy Is in the Company's Own Best Interests. Is It Fighting the Last War?" *Newsweek*, October 29, 2001, 68.
- "Activists Outmaneuver Drug Makers at WTO—Poor Nations Can Ignore Patents to Meet Public-Health Needs," by Geoff Winestock and Helene Cooper, *The Wall Street Journal*, November 14, 2001, A2.
- "Getting WTO's Attention; Activists, Developing Nations Make Gains," by Paul Blustein, *The Washington Post*, November 19, 2001, E1.
- "US Seeks Tougher Cop on the Copyright Block," by Peter Goldstein, *Kiplinger Business Forecasts*, February 11, 2002.



- "Pirates of the Information Age," *The Weekly Standard*, March 18, 2002, 1.
- "Patently Problematic—Intellectual Property and the Poor," *The Economist*, September 14, 2002.
- "US Flip on Patents Shows Drug Makers' Growing Clout—Political Donors Get Help in Reversing Policy on Poor Nations' Access to Cheaper Medicine," by Tom Hamburger, *The Wall Street Journal*, February 6, 2003, A4.
- "Empty Shelves: As US Balks on Medicine Deal, African Patients Feel the Pain—Big Drug Makers, Protecting Their Patents, Seek Limits to a Global Trade Accord—Searching for Insulin in Chad," by Roger Thurow and Scott Miller, *The Wall Street Journal*, June 2, 2003, A1.
- "Drug Patents Draw Scrutiny as Bush Goes to Africa—Laws to Protect Interests of Pharmaceuticals Companies May Be at Odds with Continent's Public-Health Dilemma," by Michael Schroeder, *The Wall Street Journal*, July 9, 2003, A4.
- "Leading the News: Brazil to Stir Up AIDS-Drug Battle—Nation to Authorize Imports of Generics, Citing the Cost of Big Companies' Products," by Miriam Jordan, *The Wall Street Journal*, September 5, 2003, A3.
- "Patents Out of Control? Growing Lawsuits Shake Up Internet Industry," Paul Davidson, *USA Today*, January 13, 2004, B1.

**Appendix 3E**  
**World Trade Organization**  
**WT/MIN(01)/DEC/2, 20 November 2001 (01-5860)**

**Ministerial Conference, Fourth Session;**  
**Doha, 9–14 November 2001**

**DECLARATION ON THE TRIPS AGREEMENT**  
**AND PUBLIC HEALTH**

*Adopted on 14 November 2001*

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

- (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- (c) 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.
- (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

## **Appendix 3F**

### **World Trade Organization**

#### **IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

#### **Decision of the General Council of 30 August 2003**

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization (“the WTO Agreement”);

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

(a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector

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This Decision was adopted by the General Council in light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;<sup>1</sup>

(b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a notification<sup>2</sup> to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members<sup>3</sup> and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) “exporting Member” means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s)<sup>4</sup> has made a notification<sup>5</sup> to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed;<sup>6</sup>

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1. This subparagraph is without prejudice to subparagraph 1(b).

2. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

3. Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

4. Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

5. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

6. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision;<sup>7</sup>

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website<sup>8</sup> the following information:

—the quantities being supplied to each destination as referred to in indent (i) above; and

—the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify<sup>9</sup> the Council for TRIPS of the grant of the licence, including the conditions attached to it.<sup>10</sup> The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification

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7. This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

8. The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

9. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

10. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory license is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid to that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory license is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be

waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfill the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS



Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

## **Annex**

### **Assessment of Manufacturing Capacities in the Pharmaceutical Sector**

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.