

THE WTO MEDICINES DECISION: WORLD PHARMACEUTICAL TRADE AND THE PROTECTION OF PUBLIC HEALTH

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On November 14, 2001, the Ministerial Conference of the World Trade Organization, meeting in Doha, Qatar, adopted the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).¹ The declaration affirms that the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights “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,” and it reaffirms that the Agreement “provide[s] flexibility for this purpose.”² The Doha Declaration mandated further negotiations on one important subject, providing in its paragraph 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”

Nearly two years later, on August 30, 2003, the WTO General Council adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Decision).³ The leadership of the WTO hailed the Decision as evidence that the organization could deal effectively with important issues of social concern.⁴ However, the reaction among a broad cross-section of stakeholders was more tempered.⁵ Nongovernmental organizations (NGOs) concerned about access to medicines were disappointed by the complexity of the arrangement, arguing that it would be unworkable in practice.⁶ Similar misgivings were expressed

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¹ Declaration on the TRIPS Agreement and Public Health (Nov. 14, 2001), Doc. WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration]. The Doha Declaration and many other WTO documents referred to in this article are available at the WTO Web site, < <http://www.wto.org> >.

² Doha Declaration, *supra* note 1, para. 4 (referring to Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994, *in* WORLD TRADE ORGANIZATION, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 321 (1999) [hereinafter TRIPS Agreement]). The TRIPS Agreement is applicable to all members of the WTO.

³ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), Doc. WT/L/540 (Sept. 1, 2003) [hereinafter Decision].

⁴ *E.g.*, Intellectual Property: Decision Removes Final Patent Obstacle to Cheap Drug Imports, WTO Press Release, Press/350 (Aug. 30, 2003) (quoting Director-General Supachai Panitchpakdi).

⁵ Officially, the World Health Organization (WHO) applauded the Decision, noting that the key to success lay in its implementation. Statement of the World Health Organization on WTO Access to Medicines Decision (Sept. 1, 2003), *available at* < <http://www.who.int> >. Privately, some individuals in the Essential Drugs and Medicines Policy (EDM) Division worried about the bureaucratic complications involved in using it. Author’s discussions with Jonathan Quick, director, EDM, and Germán Velásquez, coordinator, Drug Action Programme, EDM, at WTO Ministerial Conference, Cancún (Sept. 2003).

⁶ Elizabeth Becker, *Cheaper Medicines for the World’s Poor; Trade Rules Altered on Patented Drugs*, N.Y. TIMES, Sept. 2, 2003, at A1 (quoting representative of Médecins sans Frontières); *Developing Nations Prepare to Use WTO Pact on Cheap Drugs; Industry Sees Little Impact*, 20 Int’l Trade Rep. (BNA) 1434 (Sept. 4, 2002) (quoting Oxfam) [hereinafter BNA].

by developing country producers of generic pharmaceuticals.⁷ Spokespersons for the group of pharmaceutical companies that engage in substantial research and development (commonly known as Pharma) said they welcomed the Decision as finally resolving an open issue, but these companies later lobbied actively in Canada to restrict implementing legislation.⁸ The developing countries that had led the negotiations expressed satisfaction with the result,⁹ but others harbored doubts.¹⁰ The United States accepted the Decision as a problematic compromise, but has since sought to limit its scope of application.¹¹

What is it about the Decision that provoked such a broad range of reactions? Specifically, what were the policies of the interested parties that succeeded in giving the Decision its final shape and what is the meaning of the interplay between them? In exploring these questions, this article pursues two principal lines of inquiry. First, it analyzes developing country negotiating strategy regarding the Decision in light of the result achieved and draws lessons from that experience. Second, it places the Decision in the context of the trend in U.S. trade policy toward the use of bilateral and regional arrangements to correct what the United States perceives as specific deficiencies in WTO rules, with particular reference to the TRIPS Agreement. The article considers this trend from the standpoint of developing countries, which have substantially increased their negotiating effectiveness in Geneva but have yet to come to grips with the U.S. forum-shifting strategy. The success of this strategy to date suggests that economic and political power remains a key factor in determining the outcome of trade negotiations—a fact that should not come as a great surprise—and that the United States may be more effective in exerting its power in bilateral or limited multilateral settings than at the global multilateral level. Drawing in substantial part on an analysis of negotiating strategies at the WTO, the article considers ways that developing countries might address U.S. efforts to restrict flexibilities regarding TRIPS and public health in bilateral and regional settings.

Clearly, the Decision adopted by the WTO is not a solution to the HIV/AIDS pandemic or the myriad other public health problems confronting developing (and developed) countries.¹² The global response to HIV/AIDS remains a continuing catastrophe and, more generally, billions continue to live with inadequate health care. Nonetheless, the Decision constitutes one helpful piece of a much larger public health puzzle.

I. THE PROBLEM ADDRESSED BY THE DECISION

To understand how the Decision was supposed to achieve the objective of paragraph 6 of the Doha Declaration—to enable countries lacking manufacturing capacity in pharmaceuticals to make effective use of compulsory licensing—one must first examine the nature of the problem.

⁷ Author's discussions with D. G. Shah, secretary-general, Indian Pharmaceutical Alliance, at WTO Ministerial Conference, Cancún (Sept. 2003).

⁸ The Pharma companies are typically the first to obtain marketing approval and are considered the "originators" of new drugs. The U.S. Pharma lobbying group (the Pharmaceutical Research and Manufacturers of America) uses the acronym "PhRMA." The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is a lobbying group for "international" Pharma. For initial favorable responses from IFPMA and PhRMA representatives, see BNA, *supra* note 6. For the companies' lobbying activity, see text at note 272 *infra* and paper of Rx&D *infra* note 106.

⁹ Becker, *supra* note 6 (quoting head of South African delegation to the WTO, Faizel Ismail); BNA, *supra* note 6 (quoting Kenyan ambassador to the WTO, Amina Chawahir Mohamed).

¹⁰ See WTO General Council, Minutes of Meeting on 25, 26 and 30 Aug. 2003, Doc. WT/GC/M/82 (Nov. 17, 2003) [hereinafter General Council Minutes].

¹¹ Compare Office of United States Trade Representative [USTR], Statement of Ambassador Linnet F. Deily, Permanent Representative to the World Trade Organization and Deputy U.S. Trade Representative, Following Agreement in WTO on Access to Medicines (Aug. 30, 2003), *with* text at note 248 *infra*.

¹² The complex medicines situation, including the ongoing failure in HIV/AIDS treatment, is considered in Frederick M. Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines*, in INTERNATIONAL PUBLIC GOODS, THE PUBLIC DOMAIN, AND THE TRANSFER OF TECHNOLOGY AFTER TRIPS (Keith Maskus & Jerome H. Reichman eds., forthcoming 2005).

The TRIPS Agreement Text

Article 31 of the TRIPS Agreement permits all WTO members to grant compulsory patent licenses, that is, licenses to another producer to make the patented product without the patent holder's consent.¹³ The article does not limit the grounds on which such licenses may be issued,¹⁴ but it does impose certain obligations of a substantive and procedural nature. On the substantive side, Article 31 requires that the patent holder be paid adequate remuneration in the circumstances of the case and that licenses be "non-exclusive." License applications are to be considered on their individual merits.¹⁵ On the procedural side, an ordinary commercial track requires that the applicant first seek a voluntary license from the patent holder on reasonable terms and conditions.¹⁶ Under a separate "fast track," the precondition of prior negotiations may be waived (for national emergency, other circumstances of extreme urgency, or public noncommercial use).¹⁷ Licenses are subject to termination when the conditions giving rise to the grant are no longer present.¹⁸

Article 31(f) provides that licenses should be issued "predominantly for the supply of the domestic market" of the member granting them.¹⁹ Thus, a country with manufacturing capacity for a pharmaceutical product can issue a license for its local manufacture and supply all of the country's internal needs, and it can also authorize export of a "non-predominant" part of the production. A member may also issue a license for the importation of a product to meet all of its domestic needs.²⁰ The Article 31(f) restriction on exports does not apply when a compulsory license is issued to remedy an anticompetitive practice.²¹

A government may issue a compulsory license on a pharmaceutical patent to remedy a problem associated with pricing or availability.²² It can authorize a domestic producer to make the medicine, assuming that there is a domestic producer with that capacity. Such producers may

¹³ For a detailed negotiating history of and commentary on the TRIPS Agreement, see UNCTAD/ICTSD RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005). Article 31 is described and analyzed in *id.* at 460–95. On the problem posed by Article 31(f) of the TRIPS Agreement, see FREDERICK M. ABBOTT, COMPULSORY LICENSING FOR PUBLIC HEALTH NEEDS: THE TRIPS AGENDA AT THE WTO AFTER THE DOHA DECLARATION ON PUBLIC HEALTH (QUNO Occasional Paper No. 9, Feb. 2002), available at < <http://www.geneva.quno.info/index.php?pageid=ind01> > . See also CARLOS CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, HEALTH ECONOMICS AND DRUGS (WHO EDM Series No. 12, 2002), available at < <http://www.who.int> > .

¹⁴ This is expressly confirmed by the Doha Declaration, *supra* note 1, para. 5(b).

¹⁵ TRIPS Agreement, *supra* note 2, Art. 31(a). This is both a substantive and a procedural rule.

¹⁶ *Id.*, Art. 31(b). This condition is not obligatory when licenses are issued to remedy anticompetitive practices. *Id.*, Art. 31(k).

¹⁷ Paul Vandoren and Jean Charles Van Eeckhaute of the European Commission suggested the term "fast track" to describe the emergency/public noncommercial use option under Article 31(b) of the TRIPS Agreement. Paul Vandoren & Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making It Work*, 6 J. WORLD INTELL. PROP. L. 779, 783 (2003) (noting that under Article 31 "procedures to grant compulsory licences are not necessarily cumbersome and lengthy" but, rather, "minimal and flexible," and that the fast-track procedure "covers, in any event, AIDS, tuberculosis and malaria, but also potentially a range of other situations or diseases").

¹⁸ TRIPS Agreement, *supra* note 2, Art. 31(g).

¹⁹ The term "predominantly" may be interpreted in this context as referring to the majority (i.e., more than 50%) of the production. For the definition of "predominantly," see ABBOTT, *supra* note 13, at 26.

²⁰ Article 31(f) of the TRIPS Agreement, *supra* note 2, also permits at least the reexport of a nonpredominant portion of imports under compulsory licensing.

²¹ *Id.*, Art. 31(k).

²² The Doha Declaration, *supra* note 1, states in paragraph 5(b): "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." WTO members often control the price of medicines at the national and subnational levels, and compulsory licensing is one of a variety of mechanisms that can be used to control pricing. As William Cornish has observed with respect to the UK Crown Use (i.e., government use licensing) statute:

[T]he wider potential of its powers were dramatically demonstrated in 1965: the House of Lords held that the Ministry of Health might authorise an importer to bring in drugs not made by the patentee for use in the NHS hospital service. In the cases to which it is applicable, the Crown's ability to override the patentee's decisions on exploitation may prove a decisive counterweight to full monopoly power.

W. R. CORNISH, INTELLECTUAL PROPERTY 296 (4th ed. 1999) (footnote omitted).

be found in the United States, Germany, India, Brazil, and China, or in other pharmaceutical-producing countries, but not in most countries.²³ Additionally, if “generic” off-patent supplies of the product are available abroad, a country may authorize the importation of the product without the consent of the domestic patent holder. But prospective users of compulsory licensing face problems if (1) there is insufficient or no domestic manufacturing capacity for the product, and (2) the product is on patent in potential exporting countries and exports from these countries under compulsory licenses are limited by Article 31(f).

The Practical Implications

Until January 1, 2005, the restriction imposed by Article 31(f) of the TRIPS Agreement was not likely to present a practical problem because India, a thriving generic drug manufacturer and exporter, would not be providing patent protection for pharmaceutical products before that date.²⁴ India had successfully developed its generic drug industry partly because it had not provided patent protection for the products of the Pharma companies under patent elsewhere.²⁵ If a developing country in Africa, for example, wanted to grant a compulsory license to import a low-priced generic version of an antiretroviral medicine (ARV) to treat HIV/AIDS, it could import the medicine from an Indian producer. However, India was obligated to introduce patent protection for pharmaceutical products as of January 1, 2005, when a ten-year transitional period under Article 65 of the TRIPS Agreement came to an end. In fact, it issued an executive ordinance to that effect in late December 2004.²⁶

²³ See, e.g., WHO, Report by the Secretariat, Manufacturing Antiretrovirals in Developing Countries and Challenges for the Future, UN Doc. EB114/115 (2004); Note by the WTO Secretariat, Available Information on Manufacturing Capacity for Medicines, Doc. IP/C/W/345, Annex 1 (2002); U.S. INT’L TRADE COMM’N, OFFICE OF INDUSTRIES, REVIEW OF GLOBAL COMPETITIVENESS IN THE PHARMACEUTICAL INDUSTRY, tbls. A2, A4 (Pub. No. 3172, 1999) (showing sources of U.S. imports).

²⁴ India took advantage of the transition period allowed by Article 65.4 of the TRIPS Agreement, which must be read in conjunction with Article 70.8–9. Article 65.4 permits developing members that had not previously granted patent protection for pharmaceutical products until January 1, 2005, to initiate such protection, while Article 70.8–9 provides for the establishment of a patent application “mailbox” and the availability of “exclusive marketing rights” for pharmaceutical (and agricultural chemical) products. Under Article 70.8 a member that did not provide pharmaceutical product (or agricultural chemical product) patent protection was required, commencing on January 1, 1995, to accept such patent applications for filing and store them until protection was provided. At that later point, the applications would be withdrawn from the mailbox and examined, with patentability criteria applied as if the applications were being reviewed when the applications were filed, thereby preserving patentability against acts that might otherwise be disqualifying. If the application were to result in the grant of a patent, the term of the patent would commence on the filing date of the mailbox application. For a detailed treatment of the mailbox system and exclusive marketing rights, see UNCTAD/ICTSD, *supra* note 13, at 751–82.

²⁵ See, e.g., Carsten Fink, *Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry*, 1 J. INDUSTRY, COMPETITION & TRADE 101 (2001); Jean O. Lanjouw, The Introduction of Pharmaceutical Product Patents in India: “Heartless Exploitation of the Poor and Suffering”? (Nat’l Bureau Econ. Research Working Paper No. 6366, 1998).

²⁶ Gaz. India Extraordinary pt. II, sec. 1 (2004), Patents (Amendment) Ordinance, 2004, No. 7, New Delhi, 26 Dec. 2004 [hereinafter Indian Ordinance]; see also *id.*, sec. 3(ii), Patents (Amendment) Rules, New Delhi, 28 Dec. 2004. The amendment of the Patents Act in India to fulfill TRIPS obligations with respect to patents on pharmaceutical products has been highly controversial and is worthy of treatment in a separate article. See, e.g., Frederick M. Abbott, in *TRIPS and Public Health*, 2004 PROC. INDIA CHEM 67.

On April 5, 2005, the Patents (Amendment) Act was published as law. Gaz. India Extraordinary pt. II, sec. 1 (2005), Patents (Amendment) Act, 2005, No. 15, New Delhi, 5 Apr. 2005 (An Act further to amend the Patents Act, 1970). The 2005 amendments modified the ordinance in quite a few significant ways, including by (1) defining “inventive step” to require technical advance as compared to existing knowledge, or having economic significance; (2) expressly limiting patentability of different forms of the same substance absent a showing of a significant difference in efficacy; (3) maintaining a reasonably strong form of pre-grant opposition; (4) eliminating an unnecessary hurdle to the grant of compulsory licenses under the Decision; (5) clarifying exports permitted under the general compulsory licensing provision (e.g., expressly authorizing export of the nonpredominant part of production), as well as establishing certain presumptive time frames used in that provision; (6) improving a provision intended to permit parallel importation of patented products; and (7) allowing continued production in India of generic versions of medicines already on the market (if now patented by third parties under the mailbox system), with payment of a reasonable royalty—a form of “prior user right” adapted to India’s unique situation. See India Press Information Bureau, Fact Sheet: Important Changes Incorporated in the Patents (Amendments) Bill, 2005, as Compared to the Patents (Amendments) Bill, 2003 (Mar. 23, 2005), available at <http://commerce.nic.in/Mar05_release.htm#h33>.

What are the consequences of the introduction of patent protection for pharmaceutical products in India? There are two. First, newly developed medicines (post-January 1, 2005) will be subject to patenting.²⁷ If new ARVs are developed to address, for example, resistance to existing ARVs, these drugs will not be available in low-priced generic versions (i.e., from a person other than the patent holder/originator)²⁸ unless India (or another country) issues compulsory licenses.²⁹ As long-term ARV treatment is provided, resistance to at least some regimens will emerge and new medicines will be needed. Second, India will process the patent applications that have collected in its “mailbox” since January 1, 1995.³⁰ The drugs that are the subject of “approved” mailbox applications will be patented for the remainder of the twenty-year term from the filing of their mailbox application.³¹ This two-fold nature of the end of the transitional period should be borne in mind. After January 1, 2005, “new” medicines had to be offered patent protection in all developed and developing (though not least-developed)³² countries and “old” medicines sitting in India’s mailbox could be patented.

A large number of applications regarding pharmaceutical products collected in India’s mailbox from January 1, 1995, through December 31, 2004.³³ When this article was completed, the precise contents and potential effect of these applications had not yet been determined (and India had not yet formally codified amendments to its patent legislation). The large number of applications suggested that many older established medicines would come under patent, which may present an immediate problem because it would restrict the world supply of generic medicines. However, at least with respect to HIV/AIDS treatment, most of the first-line ARV regimens used around the world are based on medicines patented before January 1, 1995.³⁴ Consequently, India’s existing supply of generic ARVs may not be substantially affected by mailbox applications. Yet this is not a foregone conclusion, as pharmaceutical research companies typically file multiple patents on medicines and they can reasonably be assumed to have done so in India. They may patent formulations that represent improvements on patents first granted on “new chemical entities,” and they may patent combinations of previously known compounds.³⁵ Not uncommonly,

²⁷ This presumes that patent applications describe inventions that meet the criteria of patentability. Patents are not required to be granted with respect to all applications.

²⁸ “Originator” is a term of art in the medicines field used to refer to the person that first submits a successful application for regulatory approval of a new medicine. There is not a strict correlation between “patent holder” and “originator” since, in theory, a new medicine need not be patented. However, as a practical matter it is unusual for the patent holder and the originator to be different parties. See WORLD BANK, *BATTLING HIV/AIDS: A DECISION MAKER’S GUIDE TO THE PROCUREMENT OF MEDICINES AND RELATED SUPPLIES* 142 (Yolanda Tayler ed., 2004).

²⁹ Or if patents on the medicines are not sought or granted.

³⁰ See note 24 *supra*.

³¹ *Id.*

³² Pursuant to paragraph 7 of the Doha Declaration, *supra* note 1, the transitional period on pharmaceutical patents and data protection for least-developed WTO members was extended to January 1, 2016. Perhaps more important, least-developed countries may choose not to enforce existing patents or data protection rules until that date. See WORLD BANK, *supra* note 28, ch. 2 & Annex B.

³³ Approximately seven thousand pharmaceutical patent mailbox applications were filed by foreign applicants. See D. G. Shah, *The New Indian Patent Law and August 30 Decision: The Response of the Generic Industry*, presentation to WHO-CIPIH Commission on Intellectual Property Rights, Innovation and Public Health, Geneva (Mar. 1, 2005).

³⁴ See MÉDECINS SANS FRONTIÈRES [MSF], *DRUG PATENTS UNDER THE SPOTLIGHT: SHARING PRACTICAL KNOWLEDGE ABOUT PHARMACEUTICAL PATENTS*, Annex A (2003), available at <<http://www.accessmed-msf.org>>. Certain formulations and combinations, including Viramune syrup (Boehringer), Kaletra (Abbott Laboratories), Combivir tablets and Trizivir (Glaxo), show priority dates after January 1, 1995. Combivir, which is a combination of zidovudine (AZT) and lamivudine (3TC), is particularly important as a widely used treatment in Africa and elsewhere. HIV/AIDS treatment experts are quite concerned that patenting of Combivir in India might provide the basis for blocking the production and export of certain generic combination treatments. Trizivir is a combination that adds abacavir to the elements of Combivir. See MÉDECINS SANS FRONTIÈRES, *supra*; Interview with Dr. Wilbert Bannenberg, formerly WHO consultant to government of South Africa (Aug. 26, 2004).

³⁵ See, e.g., MÉDECINS SANS FRONTIÈRES, *supra* note 34. To illustrate how complex this question is, consider that four patents on Combivir (Glaxo) expire in the United States on September 15, 2005, but an additional eight patents are listed for this medicine, extending to November 17, 2019. *200 Best-Selling Prescription Drugs, Patent Expirations*, tpls. 1–3, MEDAD NEWS (May 2004), at <<http://www.pharmalive.com>>. The first listed patent for Kaletra (Abbott) shows an expiration date of December 13, 2005, but there are a total of twenty-one patents listed for

patents on formulations and combinations are controversial, and the Indian controller of patents may take a different view of the validity of subject matter claimed in certain applications from that of the U.S. Patent and Trademark Office or the European Patent Office.³⁶ There is some indication that Indian generic producers and Pharma companies have different expectations regarding the extent to which patents will be granted on mailbox applications.³⁷

For these reasons, one cannot precisely foretell the extent to which countries importing generic ARVs from India after the 2005 transition will face problems resulting from the granting of mailbox-based patents. It seems likely that some (if not most) existing first-line treatments, at least in noncombination form, will remain available off patent. The terms of India's new patent legislation will be critical to determining other effects. The potential for ongoing production of generic ARVs in India was one subject matter the paragraph 6 negotiations were attempting to address. Nevertheless, no matter exactly how much the end of the transitional period affects current generic production of ARVs in India, dealing with that situation was only one objective of the negotiations.

Other countries with manufacturing capacity in the pharmaceutical sector, including developing countries such as Argentina, Brazil, and China, may choose to offer supplies of medicines under compulsory license to countries with public health needs, and in these countries the relevant patent protection has been in force for some time.³⁸ South Africa, among others, may elect to increase its local manufacturing of medicines.³⁹ As it turned out, the first countries to implement the Decision were developed countries—Canada and Norway.⁴⁰

In addition, while the medicines controversy at the WTO arose out of events surrounding the HIV/AIDS pandemic, the problem of the supply of lower-priced “new” generic medicines is not limited to HIV/AIDS.⁴¹ Most of the medicines on the “essential medicines list” of the World Health Organization are not under patent—though ARVs most notably are⁴²—and for a range of medical conditions affecting the poor in developing countries, patent protection is not the

Kaletra in two formulations, and the last patent is shown to expire on November 7, 2017. *Id.* These data are also reported in the Orange Book of the U.S. Food and Drug Administration (FDA), *infra* note 47.

³⁶ India's Patents Act (1970, as amended through 1999) expressly disallowed patents on new uses of known substances and mere combinations of known substances. *see* sec. 3(d) & (e). The executive ordinance refers to “mere” new uses, which, if adopted into law by Parliament, would introduce a significant element of uncertainty with regard to the disallowance of new use patents. Patents (Amendment) Ordinance, 2004, *supra* note 26, para. 3.

³⁷ Remarks of Nazmul Hassan, CEO, Bexcimco Chemical Division, Dhaka, Bangladesh, at May 21–23, 2004 QUNO meeting in Jongny-sur-vevey, Switzerland, *infra* note 173, regarding information presented by various pharmaceutical industry representatives.

³⁸ The executive in Argentina issued a decree in 1996 providing for the grant of patents with respect to pharmaceutical products commencing in 2000. U.S. DEP'T OF STATE, 2001 COUNTRY REPORTS ON ECONOMIC POLICY AND TRADE PRACTICES, Argentina, *available at* < <http://www.state.gov> > . China adopted patent protection for pharmaceutical products as a consequence of bilateral intellectual property negotiations with the United States. Protection for pharmaceuticals became available in 1994. Gao Lulin, *China's Intellectual Property Protection System in Progress*, in CHINA IN THE WORLD TRADING SYSTEM 127, 129 (Frederick M. Abbott ed., 1998). Brazil adopted patent protection for pharmaceutical products in 1996. Amendments to Brazil's patent law became effective on May 15, 1997. Law No. 9.279, 14 May 1996, Regulating Rights and Obligations Regarding Industrial Property, D.O., 15.05.96, notified to WTO Council on Trade-Related Aspects of Intellectual Property Rights, WTO Doc. IP/N/1/BRA/I/1 (Sept. 19, 2000).

³⁹ As discussed *infra* in text at note 202, countries in Africa receive special treatment under the Decision, which may provide additional impetus for increasing production on the continent. Even prior to the Decision, the South African government was promoting the development of capacity to produce medicines locally.

⁴⁰ *See* text at notes 106–10 *infra*.

⁴¹ Note also that HIV/AIDS is an immune deficiency syndrome that may lead to a wide range of opportunistic infections and disease conditions (such as cancer), which may be better treated by patented drugs (such as newer antibiotics). For example, Azithromycin formulation (crystalline dehydrate) is under patent in South Africa until July 2008. MÉDECINS SANS FRONTIÈRES, *supra* note 34, Annex A. A solution for HIV/AIDS limited to ARVs would be overly restrictive since it would not address the effects of the condition when treatment is not provided or fails.

⁴² References to medicines under patent on the essential medicines list are difficult to quantify. To illustrate: recognizing the importance of preventing cardiovascular disease, the authors of the list make reference to the statin class of therapies, noting that these drugs are under patent and expensive. However, the statin class, which includes Pfizer's Lipitor, was not specifically recommended when this article was written. *See* WHO, Essential Medicines Library (EMLib), *available at* < <http://mednet3.who.int/eml/> > .

principal obstacle to treatment.⁴³ On the other hand, individuals in developing countries are by no means afflicted only by a limited range of “diseases of the poor” (such as malaria and tuberculosis).⁴⁴ The statistical tables prepared by the WHO indicate that cardiovascular disease, cancer, diabetes,⁴⁵ and respiratory disease (including asthma) are major causes of morbidity and mortality in developing countries,⁴⁶ and newer, more effective treatments for these conditions are often patented and will be patented in the future.⁴⁷ One of the principal issues addressed in the negotiations was whether the solution should be a short-term means to deal with an immediate public health crisis, or whether it should provide a long-term mechanism for dealing with a broad range of present and future (and possibly unforeseeable) public health problems requiring pharmaceutical intervention. In considering this issue, the broad scope of the change that took place on January 1, 2005, must not be overlooked. The mandatory requirement of patent protection for pharmaceutical products is not directed to a narrow range or class of medicines. It will affect the world pharmaceuticals market generally and reshape the economy of supply.

New public health challenges requiring low-cost access to newer medicines are almost certain to arise.⁴⁸ The SARS outbreak gave notice that the TRIPS Agreement should provide the flexibility for responding to such challenges without the need for multiyear negotiations at the WTO.

Broadly Shared Interests

As a general proposition, developing countries at the WTO shared strong interests in the subject matter of the Decision despite substantial differences in their economic circumstances and immediate public health needs. Pharmaceutical companies based in a handful of industrialized countries own or control the vast preponderance of pharmaceutical patents.⁴⁹ Because of the concentrated structure of the industry, this situation is likely to persist for some time. India, China, and other developing countries will increasingly compete in the development and introduction of new patented medicines, but this will not necessarily make matters better for other developing countries. Instead, it may mean that patterns of “country concentration” will shift. Developing countries on the whole have shared interests in assuring that there will be alternative

⁴³ See Abbott, *supra* note 12.

⁴⁴ Note, however, that new drugs for the treatment of malaria are patented, such as artemisone-based drugs for which Bayer holds patent, see News File: Cooperation with WHO Initiative; Bayer Develops New Malaria Medicine; Plans to Help Developing Countries (May 14, 2002), at < <http://www.bayer.com> >, and that new drugs under development for the treatment of tuberculosis are likely to be patented, see, e.g., TB Alliance, at < <http://www.tballiance.org> > (reporting on developments in research as of early 2005).

⁴⁵ On cardiovascular disease, see, for example, Emma Ross, *Causes of Heart Attacks the Same All over Globe*, CHI. SUN-TIMES, Aug. 30, 2004, at 29, available in LEXIS, News Library, Major World Newspapers File, noting that “the globe’s No. 1 killer [is] now taking over the developing world” and that “80 percent of the heart disease in the world is in developing countries.” As for diabetes, it is referred to by the WHO as an “epidemic.” See, e.g., WHO, *Combating the Diabetes Epidemic (1999–2000)*, at < <http://www.who.int/diabetes/en/> >.

⁴⁶ See WHO, *WORLD HEALTH REPORT 2002*, Annex, tbl. 3; text at note 41 *supra*.

⁴⁷ There are a number of important new medicines for the treatment of diseases affecting individuals in developing countries. See, e.g., MED AD NEWS, *supra* note 35. For example, Gleevec, an important treatment for leukemia, shows a patent expiration date of March 28, 2013. Bayer’s well-known Cipro antibiotic shows an initial patent expiration date of December 8, 2003, but additional patents extend to June 9, 2015. Cardiovascular disease is a major problem in developing countries. The leading cholesterol-lowering drug, Lipitor, is under patent in the United States at least until September 2009.

At present, the U.S. FDA Orange Book, available at < <http://www.fda.gov> >, in which the pharmaceutical industry lists patents, identifies over four thousand patents. Only a portion of those patents protect medicines that have received regulatory approval, so that further applications can be expected. The operation of the Orange Book-based system for challenging accelerated new drug applications is described in U.S. FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002)*, available at < <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> >.

⁴⁸ For example, very recent reports express growing concern that the avian flu viruses sweeping Asia might migrate to humans and that adequate supplies of new medicines might not be available for a response. See Lawrence K. Altman, *U.S. Issues Its First Plan for Responding to a Flu Pandemic*, N.Y. TIMES, Aug. 26, 2004, at A17.

⁴⁹ Data on the concentration of the pharmaceutical industry are presented and referenced in Frederick M. Abbott, *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries*, prepared for the British Commission on Intellectual Property Rights (Study Paper 2a, Feb. 2002).

production of medicines not under the control of patent holders and that they will have access to newer products, wherever produced.

Developed countries at the WTO also shared interests, but a disparity separated the stakeholders. The major patent-holding pharmaceutical companies are concentrated in a few countries, including the United States, Great Britain, Germany, Japan, and Switzerland.⁵⁰ These countries earn substantial rents from the exploitation of pharmaceutical patents.⁵¹ The pursuit of patent rents, among other things, promotes future research and development. The United States is home to the largest concentration of pharmaceutical patent holders and generates the most revenue from this sector. It was not surprising that the United States was the leading advocate of patent holder interests, or that Britain, Germany, Japan, and Switzerland generally supported it.

Some developed countries, however, also expressed substantial interest in access to lower-priced patented medicines. For developed countries that are not the base of the major Pharma companies, the incentives to support the United States and similarly situated countries were not so compelling. That is, consumer interests strongly offset producer interests.⁵² Members of the European Union struggled to form common positions on the Decision, as Britain and Germany made different demands from those of the Netherlands,⁵³ and government agencies with responsibility in different policy areas advocated divergent approaches.⁵⁴ As a result of this internal competition, the European Union took a less aggressive position in support of patent holders than the United States.⁵⁵

Impact on Pharmaceutical Development

Estimating the potential impact of the Decision would be facilitated by objectively assessing the validity of claims that incremental declines in future patent rents from developing countries would undermine Pharma's mission to develop new medicines.⁵⁶ Such an assessment is difficult.

From the standpoint of developing countries, the value of increasing patent rent payments to Pharma companies can be questioned on several grounds.⁵⁷ Until now, these companies have

⁵⁰ *Id.*

⁵¹ Regarding patent rent flows from TRIPS implementation generally, see WORLD BANK, GLOBAL ECONOMIC PROSPECTS AND THE DEVELOPING COUNTRIES 2002, ch. 5 & tbl. 5.1. See also J. MICHAEL FINGER, THE DOHA AGENDA AND DEVELOPMENT: A VIEW FROM THE URUGUAY ROUND 13–19, 25 (Asian Development Bank, 2002). For estimates of patent rents from developing countries with respect to pharmaceuticals, see Abbott, *supra* note 49. Trade negotiators typically act on behalf of producer interests, see, e.g., Ernst-Ulrich Petersmann, *Challenges to the Legitimacy of the World Trading System: Democratic Governance and Competition Culture at the WTO*, 7 J. INT'L ECON. L. 585, 603 (2004), and in these negotiations would see their objective as maximizing future rents on behalf of their industrial patent holders.

⁵² This perspective is reflected in the common practice of regulating pharmaceutical prices in OECD countries other than the United States. See Organisation for Economic Co-operation and Development [OECD], Directorate for Financial, Fiscal and Enterprise Affairs, Committee on Competition Law and Policy, Competition and Regulation Issues in the Pharmaceutical Industry, Doc. DAFFE/CLP(2000)29, tbls. A-7 through A-9 (Feb. 6, 2001). See also discussion of formulation and execution of EU policy in text at notes 53–54 *infra*. Consumers benefit from pharmaceutical research and development as well as from lower prices. However, the interests of pharmaceutical producers and consumers are not coextensive. Producers seek to maximize profits, and approach the development and sale of pharmaceuticals with this objective. This modus operandi leads to distortions from a public health standpoint, such as focusing on treatments for erectile dysfunction and advertising such treatments widely.

⁵³ This division was particularly evident as the Council formulated a common position for the June 2002 TRIPS Council meeting. The Netherlands, for example, strongly supported an Article 30 approach, while Britain and Germany did not. Author's discussions with interested officials and EC documents in author's files (Apr.–June 2000).

⁵⁴ Development agencies in the EU member states took different positions from those of industrial policy agencies.

⁵⁵ See, for example, the European Union's lack of support for the U.S. position on scope of diseases, text at notes 95–105 *infra*.

⁵⁶ See, for example, Henry A. McKinnell, CEO of Pfizer, presentation at XV International AIDS Conference, Bangkok (July 2004), *quoted in* Patent Protection Crucial for Next Generation of HIV/Aids Medicines (July 13, 2004), at <http://www.pfizer.com/are/news_releases/2004pr/mn_2004_0713.html>; and Harvey Bale, IFPMA director-general, presentation at the same conference.

⁵⁷ See KEITH MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 160 (Inst. for Int'l Econ., 2000) (concluding that increased patent rent payments are probably the predominant impact on developing countries).

not relied on developing countries' patent rents for their research budgets.⁵⁸ There is reason to doubt that the Pharma companies are underfunded from lack of patent rents from those countries. In addition, developing countries have little voice in the direction of Pharma research, which tends to focus on diseases prevalent in the developed countries.⁵⁹ Pharma companies spend about 15 percent of their revenues on research and development, but a much larger portion of expenditures goes to administration, advertising, and promotion, which are also covered by patent rents.⁶⁰ In effect, higher prices for medicines in developing countries will be used to finance advertising campaigns in the member countries of the Organisation for Economic Cooperation and Development (OECD). Of some importance in this context, new drug pipelines have been fairly fallow in recent years.⁶¹ At the same time, patent protection almost certainly results in higher prices for new medicines. All other things being equal, higher prices will impose burdens on public health budgets in developing countries.⁶²

From the Pharma home-country standpoint, incremental patent revenues are used for research that results in new medicines. Stronger patent protection in developing countries will increase total research and development.⁶³ No one denies that new medicines are necessary. The Pharma companies consider themselves the best suited to develop them. Moreover, the price of newer patented medicines is only one factor in the total health care package of developing countries, and new treatments may help to reduce nonpharmaceutical costs and perhaps overall health care costs.⁶⁴ Action that would reduce patent revenues to Pharma would have the negative effect of reducing the pool of funds for research and development, and inhibiting the development of new medicines that benefit all countries and individuals.

This article cannot resolve the debate about the role of patents in pharmaceutical development and pricing. Because of limitations associated with objective analysis, any judgment concerning the prospective impact of the Decision, including alternative approaches, will necessarily be subjective. It must take into account a wide array of factors, including a substantial number of unknowables.⁶⁵ To this author, it seems unlikely that providing a mechanism by which developing countries could secure alternative, lower-priced sources of supply would materially affect the

See generally British Comm'n on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, ch. 2, Health (Sept. 2002).

⁵⁸ *See* Abbott, *supra* note 49, sec. II.C. Order-of-magnitude estimates suggest that \$1–2 billion per year of pharmaceutical research budgets of companies based in the OECD may be dependent on developing country patent rents, while research and development expenditures by those companies in 1995 were in the \$25 billion range, and are substantially higher today. The \$28 billion per year public budget of the U.S. National Institutes of Health and its contributions to medicines research swamp patent rent contributions by developing countries. Dr. Elias Zerhouni, NIH director, said: "There's no doubt that NIH has been a terrific federal investment. It has been at the basis, if you will, of most of the discoveries made in the past 50 years that have advanced our health." National Press Club Luncheon with Dr. Elias Zerhouni, Director, National Institutes of Health (Mar. 6, 2003), *available in* LEXIS, Legal Library, Fed. News. Serv. File.

⁵⁹ *See* British Comm'n on Intellectual Property Rights, *supra* note 57; Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, LANCET, June 22, 2002, at 2188, *available at* <<http://www.accessmed-msf.org>>.

⁶⁰ For a critical perspective on the research contribution of the Pharma companies by the former editor in chief of the *New England Journal of Medicine*, see MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (2004). *See also* Abbott, *supra* note 49.

⁶¹ *See* NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT FOUNDATION, *CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION* (2002), relied on by the U.S. Federal Trade Commission in its report on patents and competition, U.S. FTC, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY*, ch. 3, pt. II (2003).

⁶² As noted in the next paragraph of the text, new medicines may reduce total health care costs. Nonetheless, less expensive new medicines would further reduce costs.

⁶³ *See* Harvey E. Bale Jr., *The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, 1 J. INT'L ECON. L. 637, 640 (1998); J. A. DiMasi, R. W. Hansen, & H. G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003); Alan O. Sykes, *Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47 (2002).

⁶⁴ To the extent that patented medicines treat disease, they obviate the need for doctor and hospital visits, surgery, and so forth. Thus, even if a patented medicine has a high price in relation to a generic medicine, it may well be less costly than the alternatives.

⁶⁵ For example, the number of new medicines that will be developed with and without the system in place, the market demand for such medicines in developed and developing countries, and what new disease burdens will arise.

Pharma research mission. The negotiations on the Decision were not directed to the question whether developing countries should provide patent protection for pharmaceutical products. To the contrary, since January 1, 2005, all developing countries have been obligated to provide such protection. *The patent pendulum is shifting in a major way in favor of Pharma interests.* The question, instead, was whether a safeguard mechanism that allows countries to ameliorate the potential adverse effects of patents would be improved to take account of the interests of countries without adequate manufacturing capacity.

Compulsory licensing of patents has been a feature of the international patent system virtually since its inception.⁶⁶ The availability of this safeguard has not undermined the system. For a decision directed to one element of that system to have such an impact would require a substantial break from past experience. To repeat: the subject matter of the negotiations on the Decision was not whether governments may issue compulsory licenses with respect to pharmaceutical products. Under Article 31 of the TRIPS Agreement, any country, whether developed or developing, can issue such licenses. These negotiations were limited to one aspect of compulsory licensing, the extent to which supplies could be made available to countries without manufacturing capacity.

II. THE NEGOTIATIONS

The problem posed by Article 31(f) of the TRIPS Agreement regarding the domestic market was recognized by developing countries and NGOs well before the 2001 ministerial meeting, and a proposal to address it was incorporated in a draft for the Doha Declaration prepared by the developing countries.⁶⁷ However, while the United States and the European Union were willing to accommodate most of the developing countries' demands at Doha, they were not prepared to accept those countries' proposals to resolve the Article 31(f) problem.⁶⁸ Instead, as noted above, the issue was put over for further negotiations under paragraph 6 of the Doha Declaration.

Paragraph 6 of the declaration directed the TRIPS Council to recommend a solution to the WTO General Council before the end of December 2002. The negotiations essentially proceeded in two sets. The first resulted in the text of December 16, 2002 (commonly referred to as the "Motta" text for Ambassador Eduardo Pérez Motta of Mexico, who chaired the TRIPS Council during its negotiation).⁶⁹ The United States blocked a consensus at the meeting of the TRIPS Council convened on December 20, 2002, to consider approval of the Motta text.⁷⁰ The second set of negotiations, chaired by Ambassador Vanu Gopala Menon of Singapore, who succeeded

⁶⁶ See JEROME H. REICHMAN WITH CATHERINE HASENZAH, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA 10-13 (UNCTAD/ICTSD Issue Paper No. 5, 2003), available at < <http://www.iprsonline.org> > .

⁶⁷ That proposal relied on two legal avenues in the TRIPS Agreement: first, acknowledging the possibility for a comity-based recognition procedure under which an exporting country could give effect to a license issued by an importing country, and, second, expressly acknowledging that Article 30 (concerning exceptions to patent rights) could be used for the purposes of meeting public health needs through third-party export of medicines under patent. See Paragraphs 5 and 7 Ministerial Declaration on the TRIPS Agreement and Public Health, Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela of Sept. 12, 2001, WTO Docs. IP/C/W/312 & WT/GC/W/450 (Oct. 4, 2001), discussed in ABBOTT, *supra* note 13, at 8-11. The problem posed by Article 31(f) had been identified by the European Commission as early as October 2000, in a text dealing with compulsory licensing posted on the Commission's Web site. E-mail from Jean Charles Van Eeckhaute to the author (Aug. 27, 2004).

⁶⁸ For example, prior to the Doha meeting the European Union floated a text based on Article 30 that proposed heavy restrictions, and was rejected by both developing countries and the United States (along with similarly minded countries) (informal proposal on file with author). See Vandoren & Van Eeckhaute, *supra* note 17, at 783 n.16.

⁶⁹ See TRIPS Council, Minutes of Meeting on 25-27 and 29 Nov., and 20 Dec. 2002, WTO Doc. IP/C/M/38 (Feb. 5, 2003). The "Motta text" of December 16, 2002, and the Decision are identical.

⁷⁰ The United States stated that it was unable to join the consensus of other members on the scope-of-diseases issue. See the statement by U.S. Amb. Deily, *infra* note 96.

Ambassador Pérez Motta, resulted in the formulation of a statement that was to be read by the chairperson of the General Council prior to the formal adoption of the Decision.⁷¹

On August 28, 2003, the TRIPS Council approved the Motta text by consensus with instructions to forward it to the General Council for adoption, together with the text of the statement to be read prior to its adoption.⁷² On August 30, the General Council met in formal session. The chair of the TRIPS Council made a recommendation to the chair of the General Council.⁷³ Members that wished to do so were given the opportunity to make statements regarding opting out of the system as importing countries.⁷⁴ The chair of the General Council then read his statement and proposed the adoption of the Decision.⁷⁵ The General Council, performing the functions of the Ministerial Conference in the interval between meetings, adopted the Decision by consensus.⁷⁶ Various delegations then made statements to the General Council.⁷⁷

When the General Council adopted the Decision, the Cancún Ministerial Conference was approaching (in September 2003). There had been considerable concern at the top level of the WTO Secretariat, as well as among the member countries, that if the public health issue was not resolved beforehand, it would overshadow all the other work there. Developing as well as developed countries had interests in items on the Cancún agenda. Developing countries, for example, were seeking major concessions in the field of agriculture. As a consequence, governmental quarters harbored little enthusiasm for a repeat of the Seattle Ministerial Conference, which ended in disarray resulting from inadequate advance preparation, combined with clashes between police and demonstrators. An agreement on public health would not ensure that the Doha Development Agenda would move forward in Cancún, but failure to reach an agreement on public health would virtually ensure a lack of progress on other matters.

Core Issues

This section focuses on three sets of issues that received preponderant attention in the negotiations: “scope of diseases,” eligible countries, and the article(s) of the TRIPS Agreement that would be addressed by the solution. The so-called scope-of-diseases issue was the most contentious.

The “scope of diseases.” In paragraph 1 of the Doha Declaration, ministers “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.” The United

⁷¹ In early August 2003, Ambassador Menon convened a group of five delegations—Brazil, India, Kenya, South Africa, and the United States—to consider a proposal for a chairperson’s statement to accompany the adoption of the text of December 16, 2002. On August 21, the chair presented the text of a proposed chairperson’s statement to the five delegations. The United States indicated that from its perspective the proposal from the chair was essentially non-negotiable. It was the bare minimum that the United States would accept. Discussions of that group were undertaken in confidence. Following certain modifications to the proposal and the concurrence of those delegations, the chair proposed to the TRIPS Council that it recommend adoption of the text of December 16, 2002, to the General Council, to be preceded by the reading of the chairperson’s statement reflecting certain “shared understandings.”

⁷² The formal record of adoption is set out in General Council Minutes, *supra* note 10. Prior to the General Council meeting, an informal meeting of the five delegations that had negotiated the chairperson’s statement and other interested delegations was convened, with the purpose of explaining and clarifying the statement. This meeting was informal, but the delegate from South Africa who had co-chaired the meeting was requested to make a general report to the chair of the General Council prior to adoption of the Decision. While some delegations were not pleased with the short time frame in which they were asked to approve the chairperson’s statement or the lack of consultations during its preparation, there was agreement to move forward. Some delegations proposed making separate statements prior to the General Council’s adoption of the Decision, but, at the insistence of the United States, it was decided that any such statements would be made following its formal adoption.

⁷³ *Id.*, para. 16. The chair made several remarks that reflected the report by the South African delegate based on the informal consultations regarding the chairperson’s statement. *Id.*, paras. 17–18.

⁷⁴ *Id.*, para. 19.

⁷⁵ *Id.*, paras. 29–30.

⁷⁶ *Id.*, para. 31.

⁷⁷ *Id.*, paras. 33–89.

States adopted as its preferred "limiting approach" to the negotiations the contention that paragraph 1 of the Doha Declaration limited the solution under paragraph 6 to identified diseases.⁷⁸

Developing country delegations, however, agreed from the outset of the negotiations that the paragraph 6 solution should broadly cover their present and future public health needs.⁷⁹ Their immediate and pressing concern was to address the HIV/AIDS pandemic, malaria, and tuberculosis, but it was also recognized that the potential problem of access to affordable medicines extended beyond a short list of enumerated diseases.⁸⁰ From the standpoint of developing countries, this issue had been resolved at Doha by the adoption of a broadly framed declaration. To them, attempts to limit the solution to particular diseases therefore amounted to an effort to rewrite the Doha Declaration.⁸¹

The Doha Declaration refers to the protection of "public health," for example in paragraph 4, in the sense of the physical and mental well-being of individuals and groups. If developing countries were facing public health problems that required access to lower-priced medicines, it was not apparent why a distinction should be made between HIV/AIDS, on the one hand, and cancer, heart disease, diabetes, or asthma, on the other. NGOs rallied an impressive array of public health officials to criticize the approach of offering to help address only a few diseases.⁸² To counter the U.S. argument that developing countries such as India and Brazil intended to use the negotiations to promote the export of lifestyle drugs such as Viagra,⁸³ developing country delegations and NGOs suggested the inclusion of negative lists to exclude such drugs, but these proposals were not taken up.

The common position of developing countries on this issue is reflected in the nonpaper on substantive and procedural elements that was presented to the TRIPS Council in early November by South Africa. This paper was supported by many developing countries.

4. *Scope of diseases.* Paragraph 1 of the Declaration does not in any manner qualify "public health" in paragraph 4; neither does it limit the scope of diseases that may be addressed when finding an expeditious solution to the problem referred to in paragraph 6. There must therefore be no *a priori* exclusions regarding diseases that may be addressed by importing and exporting Members or the products in the pharmaceutical sector used to address public

⁷⁸ The idea that the paragraph 6 solution might be limited to certain diseases surfaced in June and July of 2002. It was discussed at length at an informal meeting in July 2002 convened under the auspices of the Norwegian Ministry of Foreign Affairs and the Quaker United Nations Office at Utstein Kloster, Norway. For a summary, see QUNO Staff, Implementing Paragraph 6 of the Doha Declaration, Report on Workshop on the WTO TRIPS Agreement and the Protection of Public Health (July 20–23, 2002). Nonetheless, the scope-of-diseases issue did not become a major element of the negotiations until the TRIPS Council meeting of September 2002.

⁷⁹ From the beginning, developing countries supported a broad construction of pharmaceutical products. See, for example, Communication from Kenya on Behalf of the African Group, WTO Doc. IP/C/W/351 (June 2002), though the issue was not addressed in great detail in the early papers. *E.g.*, Communication from Brazil on Behalf of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, WTO Doc. IP/C/W/355 (June 2002); Second Communication from the United States, WTO Doc. IP/C/W/358 (July 2002).

⁸⁰ NGOs, including MSF and the Consumer Project on Technology (CPTech), played key roles in pointing out the extent of public health problems. See, *e.g.*, MSF (Dr. Mary Moran), Reneging on Doha: An MSF Analysis of Recent Attempts to Restrict Developing Countries' Use of Compulsory Licensing to a Set List of Diseases (2003). NGOs played a key role in pressuring the United States on the scope-of-diseases issue. See MSF, Oxfam, Health Action International, Third World Network, & CPTech, Joint Press Release, US Seeks Further Restrictions on Generic Medicines for Developing Countries (Aug. 25, 2003); MSF, Open Letter to the Members of the WTO (June 6, 2003); Letter from CPTech, Oxfam, MSF and HAI to WTO Delegates Regarding December 16, 2002 Chairman's Text for "Solution" to Paragraph 6 of the Doha Declaration on TRIPS and Public Health (Dec. 19, 2002); CPTech, MSF, Oxfam, & Third World Network, NGOs: Say No to Poisonous Proposals on Paragraph 6 (Nov. 25, 2002); notes 43–48 *supra*. All but the last two listed sources are available on the MSF Web site, <http://www.access-msf.org>. The last two sources are available at <http://www.cptech.org/ip/wto/p6/>.

⁸¹ See, *e.g.*, Communication from the African, Caribbean and Pacific Group of States (ACP), WTO Doc. IP/C/W/401 (May 28, 2003), *quoted in text at note 102 infra*.

⁸² See, *e.g.*, Sign-on Letter to U.S. Trade Representative Zoellick Circulated by Health GAP and Médecins sans Frontières (Dec. 16, 2002), *available at* <http://www.healthgap.org/press/press_releases.html>.

⁸³ See USTR Press Release, U.S. Announces Interim Plan to Help Poor Countries Fight HIV/AIDS and Other Health Crises in Absence of WTO Consensus (Dec. 20, 2002).

health. It is neither practicable nor desirable to predict the pharmaceutical product needs of Members desiring to protect the public health by promoting access to medicines for all.⁸⁴

From the standpoint of the United States and some other major Pharma home countries,⁸⁵ the industrial policy reason for attempting to limit the solution to an enumerated list of diseases was to limit the number of patented technologies subject to compulsory licensing for export.⁸⁶ The greater the number of patents that are subject to such licensing, the greater the risk that revenues will be eroded. From a health policy perspective, erosion of revenues reduces the pool of funds available for research and development of future medicines. The United States proposed distinguishing between infectious and noninfectious diseases. Presumably, an infectious disease would pose a greater risk of cross-border transmission and require more immediate attention. In addition to arguing that prospective exporting countries were angling to make inroads in the Viagra and diet drug markets,⁸⁷ throughout the negotiations the United States made known its view that a scope-of-diseases limitation was inherent in paragraph 1, including by objecting to an explicit statement in the Decision that it was not limited to named diseases.⁸⁸ The United States blocked approval of the Motta text and then declared a moratorium on dispute settlement actions that included a list of epidemic diseases that it believed should be covered by the Decision.⁸⁹ Given the immediacy and scale of the HIV/AIDS pandemic and its impact on sub-Saharan Africa, the United States could (and did) claim that by holding out for a broader solution on the scope of diseases, other developing countries were undermining African interests. This argument put pressure on developing country negotiators to find an accommodation.

A major obstacle to the U.S. scope-of-diseases argument was posed by the text of the Doha Declaration itself. Paragraph 1 is a preambular statement in which WTO members “recognize” the significance of “public health problems” in developing and least-developed countries, and acknowledge that special problems result from certain medical conditions. In negotiating the declaration, the United States and a group of similarly minded countries had proposed that it

⁸⁴ The nonpaper appeared in *Inside U.S. Trade* on October 25, 2002. South Africa submitted it for informal circulation to the TRIPS Council as Substantive and Procedural Elements of a Report to the General Council Under Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health, WTO Ref. Job(02)/156 (Nov. 4, 2002) [hereinafter South Africa Nonpaper]. Members speaking in support included Argentina, Bolivia, Brazil, Botswana, Cuba, Egypt, India, Indonesia, Kenya, Malaysia, Pakistan, Peru, the Philippines, Sri Lanka, and Thailand. This list is not meant to imply that only the listed members supported the positions in the paper but, rather, to identify the members that expressed their views in the meeting (from meeting notes of participant as furnished to author).

⁸⁵ A limited view of the scope of diseases was also supported by Japan, *see, e.g.*, Japan proposal for compromise (Feb. 2003) (on file with author) (containing list of diseases to be expanded on decision of TRIPS Council), Switzerland, and other members where Pharma companies are based. The Swiss moratorium adopted following the U.S. rejection of the Motta text referred to a limited scope of diseases. Switzerland, State Secretary for Economic Affairs, Press Release, On the Negotiations in WTO on Access to Drugs in Developing Countries (Dec. 22, 2002) [hereinafter Swiss Press Release] (on file with author). Although at one point the European Union made a proposal to limit use of the solution to “grave” conditions, *see* Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Elements for a Compromise Solution, *reprinted in* INSIDE U.S. TRADE as *Text: EU TRIPS Paper* (Nov. 1, 2002) [hereinafter *EU TRIPS Paper*], the European Commission takes the position that it did not intend to limit the scope of the solution; nor is it so limited. *See* Vandoren & Van Eeckhaute, *supra* note 17. The EU Draft Regulation, discussed in text at note 111 *infra*, confirms the EU perspective.

⁸⁶ The USTR’s position was taken in view of the position of the Pharma companies. *See, for example, Drug Companies Push for Limits on Disease Coverage in Drug Patent Deal*, INSIDE U.S. TRADE, Nov. 22, 2002, noting:

The leading executives of 20 U.S. research-based pharmaceutical companies this week urged U.S. Trade Representative Robert Zoellick to ensure new World Trade Organization rules allowing countries greater flexibility to import generic copies of patented drugs are limited only to medicines for serious epidemics, and do not allow the overriding of patents dealing with diseases like cancer, heart disease or diabetes.

⁸⁷ *See* USTR Press Release, *supra* note 83.

⁸⁸ As reported to the author by several TRIPS Council delegates, the United States strongly objected to distribution of the chair’s draft text of November 20, 2002, which stated that it was “understood that the reference to public health problems is not limited to the three specific diseases mentioned therein or to epidemics.” Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Draft Legal Language for General Council Decision (Nov. 20, 2002) [hereinafter Nov. 20 Draft].

⁸⁹ *See* note 95 *infra*.

be limited to addressing HIV/AIDS and other pandemics. This proposal was rejected by developing countries.⁹⁰

The core of the Doha Declaration, paragraph 4, speaks broadly and does not refer to a list of diseases or conditions. After indicating agreement that members are not prevented from acting to protect public health by the TRIPS Agreement, paragraph 4 continues: "Accordingly, while reiterating our commitment to the TRIPS Agreement, [the ministers] 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."

Paragraph 5(b) of the Doha Declaration recognizes that the TRIPS Agreement in no way limits the grounds on which members may issue compulsory licenses.⁹¹ Paragraph 5(c) recognizes that each member has the right to determine what constitutes a national emergency or circumstance of extreme urgency, and that HIV/AIDS, malaria, tuberculosis, and other epidemics could constitute such emergencies.⁹² Paragraph 7, which extends the transition period for least-developed countries, broadly refers to patent and data protection rules with respect to "pharmaceutical products"; nowhere in either the text or the subsequent implementing acts by the TRIPS Council and the General Council is it suggested that this provision is in any way restricted to pharmaceutical products used to treat a category of disease.

Paragraph 6 of the Doha Declaration, which formed the basis of the negotiations, refers broadly to "products of the pharmaceutical sector."⁹³ No language in paragraph 6 implies or even suggests a scope-of-diseases limitation. The problem lies in capacity "in the pharmaceutical sector." The solution is to be directed "to this problem." If the drafters of paragraph 6 had intended to direct the TRIPS Council to find a solution to the problem of "AIDS medicines" or "epidemics" or "emergencies," it would have been a simple matter to use limiting language. The problem was instead in "making effective use of compulsory licensing" and, in paragraph 5(b) of the Doha Declaration, members affirmed that there are no limitations on the grounds for granting compulsory licenses.

In Chairman Pérez Motta's initially distributed proposed elements of a solution, and in his first tendered draft of the definition of "pharmaceutical products," the words "public health problems referred to in paragraph 1" of the Doha Declaration were used.⁹⁴ Developing countries objected to the "referred to in" language because it might imply that only specifically identified (i.e., referenced) diseases or conditions should be addressed by the solution. After repeated objections, the language was changed to the "public health problems as recognized in paragraph 1," a formulation that focuses on the acknowledgment of public health concerns without implying that only those problems "referred to" would be addressed.

The Motta text, which was later adopted as the Decision, resolved the scope-of-diseases issue in the definition of "pharmaceutical product" in paragraph 1(a). It provides:

"pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector 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.

⁹⁰ See Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L ECON. L. 469, 485 (2002).

⁹¹ Paragraph 5(b) is directed to all compulsory licensing of medicines, and not a limited set of medicines.

⁹² In paragraph 5(c), members made clear that the fast track under Article 31(b) of the TRIPS Agreement could be used for diseases that required urgent attention.

⁹³ See text of paragraph 6, in text following note 2 *supra*.

⁹⁴ The language "as referred to in paragraph 1" appeared in the chairman's first note of October 17, 2002. The draft legal language of November 19 dropped the "as." A substantially different proposal was made on November 20, 2002, when "as referred to in" language was restored but qualified as indicated *supra* note 88. In the draft of November 24, 2002, the legal language as it appears in the Decision was first used.

The United States rejected the text of December 16, 2002, because it would not accept the consensus reached by other members on scope of diseases.⁹⁵ The grounds were reflected in the minutes of the TRIPS Council.⁹⁶ In January and February 2003, several proposals were floated to resolve the scope-of-diseases impasse between the United States and other WTO members.⁹⁷ In January the European Union suggested a mechanism that would set out a presumptive list of diseases addressed by the Decision, and would involve the WHO in determining whether a public health need was present in other cases. Although the European Union argued that its proposal was not intended to limit the scope of diseases, it was difficult to understand how shifting the burden to users to establish their right to use the solution would not act as a restriction. In any event, developing countries and the United States evinced no enthusiasm for the proposal, and it did not move forward.⁹⁸ Other proposals were floated in connection with a Tokyo mini-ministerial meeting in February 2003.⁹⁹ USTR Robert Zoellick indicated at that meeting that the United States might be willing to concede on the scope of diseases if the solution were limited to Africa.¹⁰⁰ After the Tokyo meeting, the Pharma companies floated suggestions along the lines proposed by the USTR in Tokyo, that the scope of diseases might not be limited if the list of eligible importing countries was restricted.¹⁰¹

The common view of developing countries was rearticulated by African, Caribbean, and Pacific Ministers (ACP) in May 2003, and communicated to the TRIPS Council:

The ACP position then was and still is that any text that restricts the agreement to a set list of diseases, even involving the WHO in assessing public health concerns, would constitute an unacceptable attempt to restrict ACP's use of compulsory licensing. The scope of diseases was already extensively discussed in Doha, and the consensus text included in the Doha Declaration rejected any limitations.¹⁰²

When the United States offered to conclude the negotiations on the basis of the chair's statement, the initially proposed text contained language that might have raised questions about the scope of diseases.¹⁰³ The United States agreed to modify the language so as to track the Motta text.

⁹⁵ The United States promptly declared a limited unilateral moratorium on bringing dispute settlement actions based on its own view of the desired negotiating outcome. The U.S. moratorium applied to "HIV/AIDS, malaria, tuberculosis, and other infectious epidemics of comparable gravity," including, "for example, ebola, African trypanosomiasis, cholera, dengue, typhoid, and typhus fevers." USTR Press Release, *supra* note 83. The moratorium excluded high-income developing countries as defined by the World Bank. In making its announcement, the USTR stated:

Some WTO members and advocacy organizations sought to expand the targeted "poor country epidemic" focus of Doha to allow much wealthier countries to override a wide range of drug patents, for example, Viagra. This approach could seriously undermine the WTO rules on patents that provide incentives for development of new pharmaceutical products, including those to treat diseases of a non-epidemic nature.

The European Union and Switzerland followed with their own moratoriums (the former based on the December 16 text). Letter from Pascal Lamy to WTO Trade Ministers (Jan. 7, 2003), *reprinted in* INSIDE U.S. TRADE, Jan. 10, 2003; Swiss Press Release, *supra* note 85.

⁹⁶ "The representative of the *United States* regretted its inability to join the consensus on the Chairman's draft text of 16 December . . . She [Amb. Deily] indicated that her delegation was willing to join the consensus on all parts of the draft, *except the one on the scope of diseases.*" TRIPS Council, *supra* note 69, para. 34 (emphasis added).

⁹⁷ The United States attempted to divide countries on this issue by accentuating immediate African interests in addressing HIV/AIDS, and by suggesting that prospective exporting countries were not giving those interests adequate attention while pursuing their own agendas. *See, e.g.*, Media Round Table with USTR Robert B. Zoellick, Pretoria, South Africa (Jan. 13, 2003), *available at* <http://www.usembassy.it/file2003_01/alia/a3011403.htm> (stating that despite the intention of paragraph 6 to assist countries that lacked the "capacity to produce pharmaceuticals on their own, all of a sudden everyone else wants to get it too. Okay? So, Brazil and India and people who frankly may not have Africa's best interests at heart decide, well, we need to be able to get this.").

⁹⁸ *See EU Proposal on Scope of TRIPS and Health Compromise Faces Criticism*, INSIDE U.S. TRADE, Jan. 17, 2003 (comments by Jonathan Quick, director of the WHO Essential Drugs and Medicines Division). Although the proposal was criticized by the Essential Drugs and Medicines Division, the author was advised (by EU officials) that the European Union had discussed the proposal with others at the WHO before making it and had received support.

⁹⁹ *Tokyo Meeting Fails to Dislodge Impasse on TRIPS and Health*, INSIDE U.S. TRADE, Feb. 21, 2003.

¹⁰⁰ *Id.*

¹⁰¹ *See, e.g., Pharmaceutical Companies Close to New Joint Position on TRIPS*, INSIDE U.S. TRADE, July 11, 2003.

¹⁰² Communication from the African, Caribbean and Pacific Group of States (ACP), *supra* note 81.

¹⁰³ A significant concern of developing members regarding the chair's August 21 proposal related to a subtle attempt to restrict the scope of diseases. The introduction to the draft statement provided, *inter alia*: "This Decision

The reference in the definition of “pharmaceutical product” to the “public health problems as recognized in paragraph 1 of the [Doha] Declaration” does not limit the disease conditions that may be addressed under the Decision.¹⁰⁴ It is up to each member to decide whether it faces a public health problem that should be addressed by the use of compulsory licensing, and to make a determination regarding the pharmaceutical products that are needed. The negotiating history of the Decision confirms this interpretation. In light of this negotiating history, it would be exceedingly difficult to conclude that the Decision does in fact incorporate such a limitation.¹⁰⁵

On the scope-of-diseases issue, developing countries formulated and maintained a common position with a strong foundation in policy and law. The result was a major success in the negotiations. Why was the United States unsuccessful in this regard? First, its legal arguments were not adequately grounded in the Doha Declaration. Second, the U.S. position was hard to justify from a policy standpoint. The U.S. argument that broad scope-of-disease coverage would undermine future research and development was ultimately not persuasive to the broad spectrum of WTO members. Third, the United States was unable to convince the European Union to join it in demanding that the scope of diseases be limited. In the end, the United States was isolated, which put it in the diplomatically uncomfortable posture of being the sole obstacle to a solution to the paragraph 6 problem. This isolation raised the stakes to U.S. trade diplomacy of maintaining its hard line.

The scope-of-diseases issue did not end with the adoption of the Decision. Shortly afterwards, Canada announced that it would adopt legislation to implement the Decision.¹⁰⁶ An unnamed “senior federal official” promptly said there was a lack of international consensus about the diseases that could be addressed and that Canada would need to act cautiously.¹⁰⁷ Following

is part of the wider national and international action to address problems *identified in* paragraph 1 of the [Doha] Declaration” (emphasis added). *Text: Draft Chairman’s Statement* (Aug. 21, 2003), INSIDE U.S. TRADE, Aug. 27, 2003.

Developing country members had succeeded in intensive negotiations in eliminating language in the product definition of the December 16 text as to public health problems “referred to” in paragraph 1 of the Doha Declaration. The term “identified in” might again be understood to imply a reference to the express list of diseases (and other epidemics) in paragraph 1. The United States agreed to track the “as recognized” text in the final version of the chairperson’s statement.

¹⁰⁴ Vandoren & Van Eeckhaute, *supra* note 17, at 785, state: “It is now generally recognized that the disease scope of the Doha Declaration, and hence of the Decision, is flexible, and should encompass any serious public health problem.” Correa states: “As the negotiation of the Decision made clear, it applies to pharmaceutical products for *any* disease. The three mentioned epidemics are only special cases—that certainly deserve particular attention—but the system established by the Decision is not limited to products related to them.” He also notes that “the Decision is not limited to ‘grave’ diseases, since ‘gravity’ in paragraph 1 of the Declaration is generally referred to ‘the public health problems’ and is not intended to qualify the type of diseases to be addressed.” CARLOS M. CORREA, IMPLEMENTATION OF THE WTO GENERAL COUNCIL DECISION ON PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 11 (2004), available at < <http://www.who.int> > (emphasis added). This interpretation is confirmed by the European Union in its Draft Regulation, *see infra* text at note 111.

¹⁰⁵ By the express terms of paragraph 1, the Decision covers active pharmaceutical ingredients (APIs) and diagnostic test kits, in addition to finished pharmaceutical products. The reference to APIs is important since many developing country pharmaceutical sectors are able to formulate finished products from APIs and other ingredients, which allows formulators to operate with imported APIs. By referring to products of the pharmaceutical sector, the definition of pharmaceutical product appears to encompass “vaccines.” *Accord* Vandoren & Eeckhaute, *supra* note 17, at 784; CORREA, *supra* note 104, at 10. See definitions of “pharmaceutical,” “medicinal drug,” and “sector” in 1, 2 THE NEW SHORTER OXFORD ENGLISH DICTIONARY (3d ed. rev. 1993).

¹⁰⁶ This legislation was introduced after Stephen Lewis, the UN secretary-general’s special ambassador for HIV/AIDS to Africa, suggested that Canada implement the Decision. Prime Minister Jean Chrétien promptly took up the proposal, and the first bill (C-56) was introduced on November 6, 2003. The HIV/AIDS Legal Network, a Canadian NGO, played the lead role in organizing the lobbying effort by access-oriented NGOs. Documentation concerning the legislation, including submissions from all stakeholders, is available at the Web site of the HIV/AIDS Legal Network, < <http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm> >. The Pharma industry’s lobbying effort was led by Rx&D, the organization of Canada’s research-based companies. *See, e.g.*, RX&D, PROVIDING AFFORDABLE MEDICINES TO PATIENTS IN THE DEVELOPING WORLD (Feb. 2004). The Standing Committee on Industry, Science and Technology of the House of Commons was principally responsible for reviewing the government’s proposals, holding hearings, and adopting amendments. This author was invited by the committee to testify as an independent expert and provided written submissions, as well as testimony, on March 10, 2004, all of which is available at the parliamentary Web site, < <http://www.parl.gc.ca> >.

¹⁰⁷ Steven Chase & Heather Scoffield, *Ottawa Leans Toward Limits on Cheap-Drug Distribution; Export of Generics to Poor Countries Likely to Target Only AIDS, Malaria and TB for Now*, GLOBE & MAIL, Oct. 16, 2003, at A9.

extensive dialogue in Canada,¹⁰⁸ the government dropped the argument that the Decision, as such, limited the scope of diseases. It did, however, draw up a list of products that would be subject to compulsory licensing for export, which may be expanded by the government in consultation with an expert committee.¹⁰⁹

Norway, which has also implemented the Decision, did not establish a list of diseases that may be addressed, referring to the text of the Decision.¹¹⁰

The proposed EU regulation to implement the Decision (EU Draft Regulation), issued in late October 2004, covers all pharmaceutical products and provides for the authorization of compulsory licenses for “any” medicine.¹¹¹ Such authorization includes vaccines that have the property of “preventing disease in human beings” or “restoring, correcting or modifying physiological functions.”¹¹²

The Netherlands has adopted implementing policy rules that do not limit the pharmaceutical products that may be supplied.¹¹³ These rules will be modified, as needed, to conform with the EU Draft Regulation when it is adopted.¹¹⁴ The executive ordinance adopted by India to comply with its obligation under the TRIPS Agreement to implement patent protection of pharmaceutical products generally authorizes the controller of patents to issue compulsory licenses for manufacture and export without limiting the range of products.¹¹⁵ Switzerland is proposing a formula in its implementing legislation that is consistent with the WTO texts. This proposal is intended not to introduce any limitation on the scope of diseases, as compared with the Decision.¹¹⁶ The draft that was initially proposed by the government raised some question in this

¹⁰⁸ See, e.g., Frederick M. Abbott, Canada and the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, The North-South Institute/L'Institut Nord-Sud, Ottawa (Oct. 21, 2003), available at <http://www.nsi-ins.ca/ensi/doc/implementation_of_paragraph.ppt>.

¹⁰⁹ Bill C-9, An Act to Amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), R.S.C., ch. P-4 (2004) [hereinafter Canadian Medicines Export Act]. Section 21.02 defines pharmaceutical products that may be exported under the Act by reference to schedule 1. Section 21.03 provides that the governor in council, on the recommendation of the minister (leading the council) and the minister of health, may amend schedule 1. The appointment (within three years) of an advisory committee regarding recommendations on amendments to the schedule of covered products is provided for in section 21.18.

¹¹⁰ Norway played an active role in the negotiating process of the Decision, including by providing a forum for an important meeting of stakeholders. Although Canada's Act has been more widely publicized, Norway was the first country to adopt implementing legislation. On December 19, 2003, Norway amended section 49 of its Patents Act (entered into force February 1, 2004) to add a new fifth paragraph stating: “A compulsory licence shall be issued mainly with a view to supplying the domestic market. The King may by regulations prescribe rules that deviate from this.”

The Ministry of Justice and the Police laid down regulations by Royal Decree of May 14, 2004, Regulations Amending the Patent Regulations in Accordance with the Decision of the WTO General Council of 30 August 2003, pursuant to sections 49 and 69 of the Act of 15 December 1967, No. 9 Relating to Patents [hereinafter Norway Regulations]. For the amendment to the Patent Act and the regulations, see Consultation—Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in Norwegian Law (Mar. 2, 2004), available at <<http://www.dep.no/ud/engelsk/p2500832/p30003923/032121-290003/index-doc000-n-n-a.html>> [hereinafter Norway Consultation]. Section 108(2) refers to products covered by paragraph 1(a) of the Decision.

¹¹¹ Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems, COM(2004) 737, Art. 2(a) [hereinafter EU Draft Regulation]. See also Article 2(1) of the EU Draft Regulation and the cross-reference to Article 1(2) of Council Directive 2001/83/EC, 2001 O.J. (L. 311) 67.

¹¹² This interpretation is confirmed by Article 1(4) of the 2001/83/EC directive, which includes vaccines in the definition of “immunological medicinal product.” Directive 2001/83/EC, *supra* note 111, Art. 1(2).

¹¹³ State Secretary for Economic Affairs, Policy Rules on Issuing Compulsory Licences Pursuant to WTO Decision WT/L/540 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Under Section 57, Subsection 1 of the Kingdom Act on Patents of 1995, Art. 1(c) (Dec. 17, 2004) [hereinafter Netherlands Policy Rules].

¹¹⁴ *Id.*, Explanatory Notes.

¹¹⁵ Indian Ordinance, *supra* note 26, para. 54 (adding §92A to the principal Act). The ordinance may be modified as the Indian Parliament adopts amendments to the Patents Act.

¹¹⁶ E-mail to the author from Felix Addor, chief legal officer and deputy director general, Swiss Federal Institute of Intellectual Property (Mar. 11, 2005). The initially proposed draft, Transposition into the Swiss Law of the WTO Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adding new Article 40c to the Swiss Patent Law, was available as of April 4, 2005, at <<http://www.ige.ch/E/jurinfo/documents/j10019e.pdf>> [hereinafter Swiss Transposition]. The revised draft is not yet publicly available.

regard and the government reacted favorably to comments received. Switzerland also expressly acknowledges that product coverage extends to vaccines.¹¹⁷

Eligible countries. As has been seen, paragraph 6 was intended to solve the problem of countries "with insufficient or no manufacturing capacities in the pharmaceutical sector." A second set of issues concerned the countries that would be entitled to make use of the solution. Most of the attention was devoted to whether any limitation would be placed on countries that could act as importers, although an early proposal by the United States would have limited the prospective exporting countries to developing countries.¹¹⁸

As a general proposition, developing countries saw themselves as having a common interest in preventing the limitation of the solution to a particular category or class among them. No country is immune from public health problems or insulated from the need for affordable medicines. No country is self-sufficient in the sense of producing the full range of medicines used in its health system. Each maintains an interest in acting as an importer and, at least in theory, as an exporter.

Developing countries, however, differ substantially in terms of their pharmaceutical production capacity. Only a few can produce the therapeutic components of pharmaceuticals, so-called active pharmaceutical ingredients, or APIs;¹¹⁹ but many act as "formulators" of finished pharmaceutical products.¹²⁰ Existing capacities made it more likely for some developing countries to be asked to make and export products under compulsory license than others. It was generally assumed that Argentina, Brazil, China, and India would be able to act as substantial exporters in the relatively near term. Other countries, such as South Africa, were likely to increase their capacity.

Some developing countries, especially members of the African Group, expressed strong interest in increasing local production capacity.¹²¹ This ambition gave rise to potential tension between countries with manufacturing capacity and countries desiring to develop it. The ability of India, for example, to export low-priced medicines to Africa might reduce the incentive for local investment in Africa to develop its own manufacturing capacity. Thus, there was some potential for conflict between the objectives of developing countries on the question of eligible importing and exporting countries. Some developing countries would be more likely to reap rewards as exporting countries, and their success might inhibit local development in other developing countries.

Despite this potential for conflict, developing countries did not have difficulty formulating or maintaining a common position on the wide eligibility of importing and exporting countries, for at least two reasons. First, as a practical matter the interests of prospective importing and exporting developing countries were symbiotic. For the foreseeable future, African countries are going to be importing new medicines, and Brazil, China, India, and others are needed as sources of supply. African self-sufficiency in the production of medicines will not be realized in the next few years, or even within a decade.¹²² Second, achieving negotiating success demanded wide developing country support, and no group of developing countries would accept being excluded from the solution.

¹¹⁷ Swiss Transposition, *supra* note 116, Explanatory Report.

¹¹⁸ See U.S. proposal of June 2002, note 79 *supra*.

¹¹⁹ See WHO, Report by the Secretariat to the Executive Board, *Manufacture of Antiretrovirals in Developing Countries and Challenges for the Future*, Doc. EB114/15 (2004), available at <http://www.who.int/gb/eb/e_eb114.html>; W. A. KAPLAN ET AL., IS LOCAL PRODUCTION OF PHARMACEUTICALS A WAY TO IMPROVE PHARMACEUTICAL ACCESS IN DEVELOPING AND TRANSITIONAL COUNTRIES? SETTING A RESEARCH AGENDA (2004), available at <<http://www1.worldbank.org/hnp/hsd/documents/LOCALPRODUCTION.pdf>>. The complexity of API manufacturing varies depending on the medicine. The production of the APIs used in antiretroviral medicines is complex, and only a few companies worldwide produce those APIs.

¹²⁰ This function involves combining APIs with excipients and binders; creating tablets, capsules, and other means of administration; and finally packaging the finished products for distribution. KAPLAN ET AL., *supra* note 119.

¹²¹ See, e.g., Elements of a Paragraph 6 Solution, Communication from Kenya as Coordinator of the African Group, WTO Doc. IP/C/W/389 (Nov. 14, 2002).

¹²² Whether it is desirable to increase production in Africa is a subject of intensive debate. See, e.g., James Love, Remarks, Duke University Law School Conference on International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (Apr. 4-6, 2003) (questioning local production in Africa on inefficiency grounds) (notes on file with author).

These countries therefore proposed that determinations of eligibility be based on the express language of paragraph 6: that is, that a country had insufficient or no capacity in the pharmaceutical sector and, further, that this determination should be made in the specific context of the needed pharmaceutical. Moreover, each country should be responsible for determining whether it has such capacity.¹²³

From the U.S. and EU viewpoints, interest in limiting the prospective importing countries was consistent with a general interest in limiting the use of the system. The problem involved establishing a reasonable method for defining the limitation. One possibility would be to base entitlement on national income, on the theory that a country with adequate financial capacity should not need to import low-priced medicines.¹²⁴ This approach proved impractical since prospective importing countries of major concern to the United States and the European Union, such as Brazil, China, and India, would not accept their own exclusion as importers. Another option was to develop predetermined lists of countries with and without production capacity. This approach also presented difficulties. First, data on worldwide production capacity were found not to be adequate.¹²⁵ Second, it was clear that few, if any, countries would be found to be self-sufficient in pharmaceutical production capacity. In a given case, virtually any country might have insufficient manufacturing capacity.

The European Union proposed several possible ways of determining country eligibility, including by asking whether adequate manufacturing capacity existed for specific cases. One complex EU proposal would have distinguished between API production capacity and formulation capacity, and would have limited countries with formulation capacity to imports of APIs.¹²⁶ The United States suggested looking to objective data on manufacturing capacities, and it offered to concede that all least-developed countries would automatically be determined to have insufficient manufacturing capacity. The United States consistently maintained that the solution was intended to benefit the countries of Africa confronting HIV/AIDs, and not countries like Brazil and India. Late in the negotiations, it suggested a compromise on the scope-of-disease issue on the condition that the solution be limited to Africa.¹²⁷

As adopted, the Decision gives least-developed WTO members special treatment.¹²⁸ They automatically qualify as “eligible importing Members” and are automatically determined to lack sufficient manufacturing capacity for products of the pharmaceutical sector.¹²⁹ The situation is more complex for importing countries in other stages of development.

¹²³ The developing country position on this subject was reflected in the South Africa Nonpaper, *supra* note 84, paras. 6–8.

¹²⁴ See, for example, the U.S. exclusion of high-income developing countries as defined by the World Bank in the announcement of the post-December 20, 2002 moratorium, USTR Press Release, *supra* note 83.

¹²⁵ Note by the Secretariat, Available Information on Manufacturing Capacity for Medicines, WTO Doc. IP/C/W/345 (May 24, 2002) (principally relying on studies by the United Nations Industrial Development Organization noting problems of gaps in data by country and dating of information).

¹²⁶ *EU TRIPS Paper*, *supra* note 85. The rationale for this proposal was not fully apparent. It would have mandated division of the production chain and likely increased costs.

¹²⁷ See U.S. position at Tokyo miniministerial meeting in text at note 100 *supra*.

¹²⁸ Classification of a country as developed or developing according to GATT/WTO custom and practice is a matter of self-selection by the member. See FREDERICK M. ABBOTT, CHINA IN THE WORLD TRADING SYSTEM: DEFINING THE PRINCIPLES OF ENGAGEMENT 26–28 (1998). Article XI:2 of the Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, in WTO, THE LEGAL TEXTS, *supra* note 2, at 3 [hereinafter WTO Agreement], which addresses original membership in the WTO, refers to commitments and concessions to be undertaken by least-developed countries recognized as such by the United Nations. So far, the practice under the WTO Agreement appears to be that status as a least-developed country is determined by reference to the UN list. However, it is not clear that this practice is mandated by the text of any WTO agreement.

¹²⁹ Moreover, because least-developed members are not required to enforce patents until January 1, 2016, they do not need to issue compulsory licenses to import products should they choose to exercise this right of nonenforcement. Footnote 6 to paragraph 2(a)(iii) of the Decision, *supra* note 3, provides that the requirement imposed on eligible importing members to issue compulsory licenses with respect to products under patent in their territory “is without prejudice to Article 66.1 of the TRIPS Agreement,” which is the specific provision under which the TRIPS Council authorized nonenforcement of patents by least-developed members. “[P]aragraph 7 of the [Doha] Declaration constitutes a duly motivated request by the least-developed country Members for an extension of the period under paragraph 1 of Article 66 of the TRIPS Agreement.” TRIPS Council, Decision of 27 June 2002, pmb1., available at <http://www.wto.org/english/news_e/pres02_e/pr301_e.htm>. Thus, in using the system established by the Decision, a least-developed member may elect the alternatives of nonenforcement or compulsory licensing.

First, more than forty members (mainly developed) either have wholly opted out of using the solution as importing countries, or have declared that they will use it only in cases of national emergency or circumstances of extreme urgency. Some of these opt-outs are incorporated directly in the Decision, and some were undertaken by statement to the General Council before the adoption of the Decision. As noted below, members generally have the option under the Decision to modify their status as users of the system at any time, although this option may not be open to members that opted out *ab initio*.¹³⁰

To use the system as an importer, a member (other than a least-developed country) must submit a one-time notification to the TRIPS Council of its intention to use the system in whole, or in a limited way.¹³¹ This notification may be transmitted at any time and may be modified. It is not subject to approval by any WTO body.¹³² This is a general requirement not associated with specific transactions.

When a country proposes to import under the system, it must (per paragraph 2(a)(ii)) make a determination that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the “product(s) in question” and notify the TRIPS Council. This determination is made pursuant to criteria set out in an annex to the Decision, which places the determination in the hands of importing-country authorities and provides that

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.

A key aspect of the annex-based determination is that it is addressed to the specific product, and not to the general state of the local industry, which may well be capable of producing some products, but not the ones that are needed. The production of a specific pharmaceutical product often involves unique technologies. The question of capacity is therefore multidimensional and may take into account not only physical infrastructure, but also the state of technical knowledge about specific products.

The chair’s statement includes an additional reference to transparency, stating: “To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.” The referenced provision is directed to methodology (“how the Member . . . had established”), not to facts supporting an assessment.¹³³

From the standpoint of developing countries, the outcome on eligible importing and exporting countries must be considered a success. There are no a priori exclusions, except as to those countries that have voluntarily elected to opt out as prospective importers. As a practical matter, it would have been very difficult to prevent voluntary opt-outs. The determination on adequacy of capacity is made by the importing country as to specific products, and excludes the patent

¹³⁰ The extent to which the opting-out members have relinquished that right is not entirely clear. A stronger argument might be made that countries opting out directly in the text of the Decision are not free to modify their status, as contrasted with those that merely stated their intention to the General Council.

¹³¹ Decision, *supra* note 3, para. 1(b).

¹³² There is little apparent rationale for this requirement, particularly in light of the requirement that notifications be made in connection with specific uses of the system, and it has been criticized as an attempt at politically pressuring members not to use the system.

¹³³ Vandoren & Van Eeckhaute state: “What matters is that the Member in question be able to explain how the self-assessment has been performed. The related notification requirement is for information purposes only. It cannot be reversed or rejected by any other Member or by the TRIPS Council.” Vandoren & Van Eeckhaute, *supra* note 17, at 785; accord CORREA, *supra* note 104, at 17–18.

In a statement following the adoption of the Decision, the delegate from India clarified this point on the basis of the negotiation of the chairperson’s statement, saying: “It had been clarified during the consultations that this did not involve provision of a great deal of technical or other information, but only the brief and concise indication of the methodology for determination of insufficient capacity and the conclusions that were drawn on the basis of available data.” General Council Minutes, *supra* note 10, para. 52.

holder's capacity.¹³⁴ This result nicely illustrates the value of formulating and executing a common position, even when particular interests must be suppressed. In this case, developing countries with potentially differentiated interests as importing and exporting countries put aside those differences in favor of achieving a more important common goal.

Why did the United States and the European Union concede on issues of income level and predetermined criteria of eligibility? From the U.S. standpoint, this approach may have resulted from a tactical error, which was to focus on restricting the scope of diseases as its preferred control mechanism. Perhaps the United States did not appreciate the weakness of its argument for limiting the solution to particular diseases. Through the mechanism of voluntary opt-outs and limitations, the United States and the European Union managed to protect the developed countries from using the Decision as importers. The European Union appears to have been principally concerned to protect prices in developed countries' markets from erosion by low-priced imports, and to be satisfied that the solution would adequately prevent drugs produced under the system from entering Europe or other developed countries' markets. The Decision includes the control mechanisms of Article 31, and requires importing countries to implement proportionate measures against diversion.¹³⁵ In bilateral discussions with the Philippine minister of trade, USTR Zoellick said that the Philippines would not qualify as an importing country under the system because it had adequate pharmaceutical manufacturing capacity. On the basis of this interpretation, the Philippines continues to express concern about the terms of the Decision.¹³⁶ The implementing legislation of Canada, Norway, the Netherlands, India, and Switzerland, and the EU Draft Regulation¹³⁷ all rely on the country requesting exports under the Decision to make a determination regarding whether it has insufficient or no manufacturing capacity for the pharmaceutical product in question.¹³⁸

One matter that was not given significant attention during the negotiations was the permissibility of exports to countries that are not members of the WTO. When Canada implemented the Decision, NGOs pointed out that limiting exports to WTO members alone would disenfranchise some of the poorest countries in the world, which did not make sense from a public health standpoint.¹³⁹ In drawing up implementing legislation, Canada found a way to permit importation by nonmembers, and was followed in this regard by Norway, India, and Switzerland.¹⁴⁰ The

¹³⁴ A member's eligibility to import ends when it has established adequate internal manufacturing capacity for the product in question.

¹³⁵ See discussion *infra* in text at note 198. Ultimately, entry of diverted products into the European Union is under the control of EU customs authorities, so not too much on this account is necessarily left to the authorities of beneficiary countries.

¹³⁶ The Philippine delegate said at the TRIPS Council meeting of June 4–5, 2003: "the Philippines . . . had been told in bilateral settings that, on the basis of the 16 December text, the Philippines had some manufacturing capacity that would disqualify it from availing itself of the proposed solution." TRIPS Council, Minutes of Meeting on June 4–5, 2003, WTO Doc. IP/C/M/40, para. 52 (Aug. 22, 2003).

¹³⁷ Canadian Medicines Export Act, *supra* note 109, §21.04(3)(d)(iii); Norway Regulations, *supra* note 110, §107; Netherlands Policy Rules, *supra* note 113, Art. 1(f); Indian Ordinance, *supra* note 26, §92A; Swiss Transposition, *supra* note 116, Explanatory Report, "Granting conditions"; EU Draft Regulation, *supra* note 111, Art. 6(1)(b).

¹³⁸ Also, in each case least-developed countries are automatically eligible.

¹³⁹ A prospective importing country could join the WTO to become eligible to benefit from the system. Accession to the WTO is typically a multiyear process. Currently, more than twenty-seven countries are at some stage in the accession process, including Algeria, Laos, Lebanon, the Russian Federation, Ukraine, and Vietnam, and there are several additional observer countries. Countries that are neither in the process of accession nor observers include Liberia, Syria, and Turkmenistan. WTO Web site, *supra* note 1 (last modified Feb. 1, 2005).

¹⁴⁰ Canadian Medicines Export Act, *supra* note 109, §21.03(d)(ii); Norway Regulations, *supra* note 110, §107; Indian Ordinance, *supra* note 26, §92A; Swiss Transposition, *supra* note 116, Art. 40c, & Explanatory Report, "Countries of importation." If some member were prepared to initiate a challenge to the supply of nonmember countries, this would bring Article 30 of the TRIPS Agreement into play. An Article 30 exception to supply nonmembers under the Decision would be limited in the sense that it would apply only to non-WTO members (and would include conditions, such as diplomatic acceptance of responsibilities comparable to those of importing members). Such an exception would not unreasonably interfere with the normal exploitation of the patent since it would be consistent with the waiver established by the Decision and would not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties. Third-party interests, i.e., those of the patient community, are very strong in this situation.

Netherlands allows exports to least-developed non-WTO members.¹⁴¹ Canada, Norway, the Netherlands, and Switzerland effectively require compliance with the elements of the Decision intended to prevent diversion of products.¹⁴² The initial EU Draft Regulation, however, does not make provision for exports to countries that are not members of the WTO, but there is indication that this may be changed (at least to allow such exports to least-developed non-WTO members).

The TRIPS article addressed. One of the most difficult issues in the negotiations concerned the article of the TRIPS Agreement that would be addressed by the solution. As seen, the negotiations were predicated on the existence of a limitation in Article 31(f) of the TRIPS Agreement, but whether that limitation could be overcome through an exception under Article 30 was uncertain.

Article 30 of the TRIPS Agreement allows members to adopt exceptions to patent rights, and conceptually the limitation in Article 31(f) could be addressed by the grant of an exception under Article 30. However, there was considerable debate about whether Article 30 permits third parties to export products under patent so as to address public health needs. Doubt on this point was raised by the decision of the WTO dispute settlement panel in the *Canada—Generic Pharmaceuticals* case, which involved the application of Article 30 to both a “regulatory review” and a “stockpiling” exception.¹⁴³ The regulatory review exception was found to be consistent with Article 30, while the stockpiling exception was rejected. The panel focused on the terms “limited exception” in Article 30 and said that this language implied a “narrow” exception to patent rights.¹⁴⁴ The panel also indicated that whether production for commercial sale was allowed during the patent term was important to determining whether an exception was suitably limited.¹⁴⁵ These two aspects of the decision, among others, raised concerns about how Article 30 would be interpreted by the Appellate Body. It was recognized that, strictly speaking, this panel decision did not bind WTO members,¹⁴⁶ but that by suggesting limitations, it created uncertainty. It was widely considered that if Article 30 was going to form the basis of the solution, a formal interpretation (or, if necessary, an amendment) should be adopted to dispel doubts. Companies that might want to produce and export under an exception would be reluctant to do so in the face of significant legal insecurity.

Using Article 30 as the basis for a solution would not, as both its advocates and its detractors suggested, necessarily lead to a less regulated result or the absence of remuneration. Nothing precluded the adoption of a solution based on Article 30 that would have included controls or provision for remuneration. The principal alternative to interpreting or amending Article 30 was to address the Article 31(f) problem at its source: that is, to amend, waive, or interpret Article 31(f) to permit compulsory licensing predominantly for export. There was a third option of creating a *sui generis* solution under the TRIPS Agreement that would not use one of the existing

¹⁴¹ Netherlands Policy Rules, *supra* note 113, Art. 1(f).

¹⁴² Canadian Medicines Export Act, *supra* note 109, §21.03(b) (for least-developed non-WTO members), §21.03(d)(ii) (for other non-WTO members). Least-developed nonmembers must provide Canada with a diplomatic notice in writing of agreement not to use the product for commercial purposes and to adopt measures referred to in paragraph 4 of the Decision. Other nonmembers must be on the OECD list of countries eligible for development assistance. They must provide Canada with a diplomatic notice in writing of an emergency situation and agreement not to use the product for commercial purposes and to adopt measures referred to in paragraph 4 of the Decision. *See also* Norway Regulations, *supra* note 110, §§107, 109; Netherlands Policy Rules, *supra* note 113, Arts. 1(f), 3(3)(b); Swiss Transposition, *supra* note 116, Art. 40c.

¹⁴³ Canada—Patent Protection of Pharmaceutical Products, WTO Doc. WT/DS114/R (adopted Apr. 7, 2000) [hereinafter Canada—Pharmaceuticals], *discussed in* ABBOTT, *supra* note 13; Frederick M. Abbott, *WTO Dispute Settlement Practice Relating to the Agreement on Trade-Related Aspects of Intellectual Property Rights*, in *THE WTO DISPUTE SETTLEMENT SYSTEM 1995–2003*, at 421 (F. Ortino & Ernst-Ulrich Petersmann eds., 2004); Robert L. Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*, 3 J. WORLD INTELL. PROP. 493 (2000).

¹⁴⁴ Canada—Pharmaceuticals, *supra* note 143, paras. 7.30–31.

¹⁴⁵ For example, the panel said: “In theory, the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others, and manufacturing for commercial sale is a quintessential competitive commercial activity” *Id.*, para. 7.35; *see also id.*, para. 7.45.

¹⁴⁶ *See* ABBOTT, *supra* note 13, at 22–24.

articles as a base.¹⁴⁷ This option might have allowed a more nuanced tailoring of the solution, and have helped defuse the ideological struggle between the Articles 30 and 31 camps.

From the standpoint of many developing countries, NGOs, and the WHO, a solution based on Article 30 would have the major advantage of avoiding the need for a compulsory licensing procedure in the country of export.¹⁴⁸ If there were a patent in the importing country, compulsory licensing would be needed there, so the patent holder would have its interests respected. It was suggested that if there were no patent in the importing country, the patent holder would have no material interest to protect in the exporting country. The product was not being used there, and its making and export would not unreasonably interfere with the patent right.

From the standpoint of advocates of the Article 30 solution, its advantages were to a large extent defined by the perceived disadvantages of an Article 31 approach. Although Article 31 does not limit the grounds on which a compulsory license may be issued, it prescribes procedures and conditions.¹⁴⁹ The incorporation of procedural requirements implies routine bureaucratic impediment. More important, it may open the door to patent holder legal maneuvering intended to delay. If compulsory licensing procedures are required on both the importing and the exporting country sides, the possibilities for legal impediment might present a formidable barrier.

From the standpoint of pharmaceutical patent holders, a solution based on Article 30 would not provide adequate procedural safeguards or respect for patent holder interests.¹⁵⁰ The lack of any prescribed procedure in the exporting country¹⁵¹ would leave no means to distinguish between actions taken to meet the legitimate needs of importing countries and actions undertaken to profit at the expense of patent holder research. The absence of a patent in the importing country might prevent the payment of royalties.¹⁵² Just as the advocates of an Article 30-based solution centered their arguments in large measure on the perceived drawbacks of an Article 31-based solution, so the advocates of an Article 31-based solution focused on the perceived disadvantages of an Article 30-based solution.

From the standpoint of the United States, the European Union, Japan, Switzerland, and other countries where pharmaceutical patent holders are based, a solution based on Article 31

¹⁴⁷ See Frederick M. Abbott, *Legal Options for Implementing Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health* (July 21, 2002) (suggesting such an option); Marco C. E. J. Bronckers, *Legal Options for Implementing Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health* (July 21, 2002), both available at <<http://www.quno.org>>.

¹⁴⁸ For the views of developing countries, see Communication from Brazil, *supra* note 79. Medicines-access-oriented NGOs circulated a substantial number of analytical papers throughout the negotiations. These papers addressed the Article 30/Article 31 issue. See, e.g., MSF, *Why Article 30 Will Work. Why Article 31 Will Not* (June 24, 2002); MSF, Oxfam, CPTech, Health Gap, Third World Network, & Essential Action, *Joint Letter to Members of TRIPS Council* (Jan. 28, 2002), available at <<http://www.accessmed-msf.org>>. The WHO's preference was based largely on the results of CORREA, *supra* note 13, at 25–32. At the September 2002 TRIPS Council meeting, a representative of the WHO presented its view that a solution based on authoritative interpretation of Article 30 would be most consistent with the objectives of the Doha Declaration. The U.S. delegate expressed surprise that the WHO was indicating its preference for a form of solution since, as a member of the WHO, the United States had not been consulted on that question. TRIPS Council, *Minutes of Meeting on 17–19 Sept. 2002*, WTO Doc. IP/C/M/37 (Oct. 11, 2002).

¹⁴⁹ See text at notes 13–18 *supra*.

¹⁵⁰ In June 2002, the United States referred to a “growing consensus among certain Members” in favor of Article 31(f) as the basis for a solution. The United States objected to the use of Article 30 on the grounds that it was intended to address statutory exceptions predating the TRIPS Agreement, and that action under it would unreasonably conflict with the normal exploitation of patents and would unreasonably prejudice patent holder interests. It argued that Article 30 did not provide for (1) case-by-case evaluation, (2) notice to the patent holder, (3) conditions of license and expiration, and (4) remuneration. Second Communication from the United States, *supra* note 79, paras. 17, 31.

¹⁵¹ Article 28 of the TRIPS Agreement expressly gives the patent holder the right to prevent making, using, selling, offering for sale, and importing a covered product. There is no enumerated right to prevent exporting, which allows some scope for arguing that patent holders are not entitled to prevent exports, or at least that greater flexibility may be permitted to allow exports by parties other than patent holders under Article 30. From a technical perspective, the patent confers a right to exclude others from “making” a product, so allowing production for export may interfere with a patent holder right, even if there is no enumerated “export” right.

¹⁵² The use of Article 30 does not, in fact, preclude the imposition of remuneration requirements, nor does it in fact assure that bureaucratic procedures will not be imposed. By way of illustration, the U.S. “Bolar” regulatory review exception is implemented via a bureaucratic and judicial maze. See FED. TRADE COMM'N, *supra* note 47.

would provide a greater degree of control over third-party activity. European Commission officials have suggested that they opted for an Article 31-based approach because they concluded that the United States would never accept an Article 30-based solution.¹⁵³ However, this matter was debated within the European Council,¹⁵⁴ and that may be only a partial explanation. The conclusion that the European Union in fact supported an Article 31 solution on policy grounds was supported by the terms of its initial Draft Regulation, discussed below.

The African Group in its early position papers proposed that both Articles 30 and 31 be used in the solution so as to provide the most comprehensive approach to solving the problem.¹⁵⁵ However, as negotiations proceeded, a choice of approach needed to be made. The African Group spent a great deal of time deliberating this question and ultimately opted in favor of amending or waiving Article 31(f).¹⁵⁶ The African Group may have made a strategic calculation that the United States would not, under any foreseeable circumstances, accept an Article 30 solution. Nevertheless, the members of the group were aware that this stance would put them at odds with many developing countries and with virtually all NGOs.¹⁵⁷

The Decision concerns Article 31 of the TRIPS Agreement and specifically provides for a “waiver” with respect to Article 31(f) and (h).¹⁵⁸ The waiver forms the basis of negotiations leading to an amendment.¹⁵⁹ Use of the Article 31(f) waiver provided for in paragraph 2 is conditioned on the exporting member’s compliance with certain obligations under the Decision, including having received certain assurances from the importing member.¹⁶⁰ Article 31(h) ordinarily requires adequate remuneration to the patent holder in the circumstances of the case, and the waiver, provided for in paragraph 3, limits this obligation to the exporting member when remuneration is paid there. Aside from the waivers regarding Article 31(f) and (h), the conditions for granting compulsory licenses under Article 31 of the TRIPS Agreement continue to apply to licenses granted under the Decision.¹⁶¹

Paragraph 9 of the Decision clarifies that it is without prejudice to rights that members may otherwise have under the TRIPS Agreement. Thus, members have not relinquished any rights they may have to use Article 30 as the basis for exports without the consent of the patent holder. These rights may be important, for example, in justifying exports to countries that are not WTO members, where a limited exception to rights of patent holders may need to be invoked. More generally, they may also constitute an alternative to use of the system established by the Decision.¹⁶²

The Decision does not provide express relief from the possibility that two compulsory licenses will need to be issued for a single supply situation. The process can be facilitated, however, in some important ways, particularly when dealing with a situation such as the supply of ARVs and other medicines to address HIV/AIDS. The “fast track” procedure under Article 31(b) of the TRIPS

¹⁵³ See Vandoren & Van Eeckhaute, *supra* note 17, at 783; e-mail from Van Eeckhaute to the author (Mar. 26, 2004).

¹⁵⁴ See note 53 *supra* regarding the European Council debate on establishing the June 2002 negotiating position.

¹⁵⁵ Communication from Kenya on Behalf of the African Group, *supra* note 79.

¹⁵⁶ See Communication from Kenya as Coordinator of the African Group, *supra* note 121. The African Group benefits from incremental flexibility for regional arrangements, *see* text at note 202 *infra*, which may assist it in dealing with an Article 31 approach.

¹⁵⁷ See, e.g., *Zoellick Pushes for Limits in TRIPS Deal, But Supports Compromise*, INSIDE U.S. TRADE, Nov. 22, 2002.

¹⁵⁸ Vandoren and Van Eeckhaute count a total of three waivers: for Article 31(f), relating first to exporting members in general (para. 2), and second to regional groups (para. 6); and third for Article 31(h) (para. 3). Vandoren & Van Eeckhaute, *supra* note 17, at 782.

¹⁵⁹ The negotiations are discussed in text at notes 214–22 *infra*.

¹⁶⁰ These obligations and assurances are described in text at notes 196–201 *infra*.

¹⁶¹ Decision, *supra* note 3, para. 9, and general structure as limited waiver of identified provisions.

¹⁶² While the waiver option is directed at Article 31(f) and (h), there are elements of the Decision that arguably affect other provisions and obligations of the TRIPS Agreement. For example, paragraph 4 of the Decision requires importing members to take measures proportional to their means to prevent diversion of products. This requirement is in the nature of an enforcement obligation (which might involve providing the basis for remedial action to private patent holders). It may implicate part III of the TRIPS Agreement (regarding enforcement). The question of which articles of the TRIPS Agreement may be affected by the Decision becomes important in considering the best means for amending the Agreement.

Agreement permits waiver of the requirement of prior negotiation (and notification) of the patent holder. Therefore, authorities on both sides of the transaction can issue licenses immediately, and the exporting member may determine remuneration after the license is granted.¹⁶³

In addition, the TRIPS Agreement does not prevent a member from recognizing and giving effect to a compulsory license granted by another member under the Decision. Article 31(a) provides that a license shall be considered on its individual merits but does not mean that a government cannot base its determination of the merits of granting a license on another member's decision. Although the patent holder is entitled to administrative or judicial review of the grant under Article 31(i), this proceeding may take place after the grant has been made.¹⁶⁴ In the United States, when the government uses a patent without consent, the only remedy for the patent holder is to seek compensation in a proceeding before the Court of Claims.¹⁶⁵

As suggested by the varying views noted above, the developing countries were unable to formulate a common position on the selection of the proper article in which to situate the solution. Might a united developing country position in favor of an Article 30 approach have succeeded? Its acceptance would have required a major retrenchment by the United States.¹⁶⁶ Instead, the United States, confronted with an open-ended solution on the scope of diseases and a procedural mechanism it regarded as inadequately protective, might plausibly have allowed the negotiations to collapse. This author considers it doubtful that the United States could have been persuaded under the then-prevailing circumstances to accept an Article 30 approach, absent some other material limitations on the Decision. The alignment of the European Union with the United States in refusing to accept an Article 30 solution caused a large number of developing countries to yield on their Article 30 demand.

Had developing countries as a group managed to agree on a common approach to the mechanism of the solution—whether based on Article 30 or Article 31—they might have been able to exercise additional leverage regarding the conditions associated with its use. In particular, a stronger bargaining position might have allowed for the explicit streamlining of dual licensing procedures, as to which several draft alternatives were formulated.¹⁶⁷

The implementing legislation of WTO members approached the Article 31 solution in various ways. The initial proposal of the Canadian government dispensed with the prior negotiation conditions of Article 31 in favor of a “right of first refusal” for patent holders.¹⁶⁸ Before a generic producer could obtain a license to export, it would have had to offer any supply contract it had negotiated to the patent holder, which could elect to take it over on the same terms.¹⁶⁹ Under the government's proposal, patent holders were not obligated to compensate generic producers for their efforts in securing contracts.¹⁷⁰

This initial proposal seemed unlikely to result in exports by generic producers or in lower prices.¹⁷¹ The government was ultimately persuaded that the right of first refusal was a poor

¹⁶³ See Vandoren & Van Eeckhaute, *supra* note 17, at 783.

¹⁶⁴ This procedure is consistent with the text of Article 31, and is reflected in the practice of many countries that provide for determination of compensation after a license is granted, including the United States with respect to governmental use of patents. See UNCTAD/ICTSD, *supra* note 13, at 468, 477–79.

¹⁶⁵ *Id.* at 468.

¹⁶⁶ The initial U.S. position in the paragraph 6 negotiations was that a dispute settlement moratorium would be adequate to address the issue. Communication from the United States, WTO Doc. IP/C/W/340 (Mar. 14, 2002).

¹⁶⁷ Drafts on file with author.

¹⁶⁸ Bill C–56, section 21.04(6)–(7); and Bill C–9, section 21.04(6)–(7), as initially introduced February 12, 2004 (ultimately the Canadian Medicines Export Act, *supra* note 109).

¹⁶⁹ Bill C–56, §21.04(6)–(7); Bill C–9, §21.04(6)–(7).

¹⁷⁰ Negotiation of a medicines supply agreement is a costly and time-consuming endeavor. If patent holders could simply take contracts without paying compensation, it is doubtful that many generic producers would be willing to spend the time and effort to conclude them. After a few takeover incidents, generic producers would give up.

¹⁷¹ See Frederick M. Abbott, Prepared Remarks for Standing Committee on Industry, Science and Technology, *supra* note 106. Patent holders do not want generic producers to enter their markets, and there is a large spread between the marginal cost of producing drugs and the prices charged for them. Patent holders would have an incentive to take over contracts successfully negotiated by generic producers (and could probably do so profitably), if for no other reason than to prevent the emergence of competition.

idea. After considering various alternative proposals, it settled on the procedure of Article 31(b) of the TRIPS Agreement, requiring that the applicant for a compulsory license first seek a voluntary license from the patent holder.¹⁷² The legislation does not make any provision for use of the fast track for emergencies and public noncommercial use, but it does provide that thirty days are an adequate period for seeking a voluntary license. There was some suggestion in the discussion of Canada's implementation that the exporting country could not take advantage of the fast-track procedure because an emergency (or public noncommercial use) would exist in the importing country, but not in Canada.¹⁷³ The argument that the procedure in the exporting country should be based on its domestic situation turns the object and purpose of the Decision on its head. If Canada is going to export ARVs to Africa, this is not because there is a public health crisis in Canada but, rather, because there is a public health crisis in Africa.

Governments wishing to act expeditiously to address public health problems should not have to depend on the goodwill of patent holders. In United States law, the government may use patents without notice to the patent holder and without the obligation of prior negotiation.¹⁷⁴ The patent holder may *not* obtain an injunction; this U.S. rule is accommodated in the TRIPS Agreement.¹⁷⁵

The Norwegian legislation and regulations permit use of the fast-track licensing procedure on both sides of the export-import transaction.¹⁷⁶

The explanatory memorandum on the initial EU Draft Regulation acknowledged that prior negotiation with the patent holder is not a prerequisite to making use of the Decision, but stated that the regulation nevertheless required it because of the desirability of voluntary licensing.¹⁷⁷ An application for a compulsory license under the initial Draft Regulation must include satisfactory evidence that the applicant engaged in prior negotiations with the patent holder for a license on reasonable commercial terms and conditions, and that they did not succeed within a reasonable period of time. The regulation also specified that the determination of a reasonable period of time shall take into account a "declared" national emergency or other situation of extreme urgency.¹⁷⁸

From the policy standpoint, this proposed condition was particularly disappointing coming from the European Commission, because the Commission's TRIPS negotiators expressly highlighted the possibility of using the fast-track provisions of Article 31(b) as a way to ameliorate the bureaucratic obstacles facing applicants for compulsory licenses.¹⁷⁹ As this article goes to press, it appears that the European Union is seriously rethinking its position and may, in fact, permit use of the fast-track procedure for exports.

Beyond the general policy concern that the Commission backed away from providing an important mechanism for facilitating licensing, the initial drafting of Article 7 of the regulation raised other problems. First, the objective of the Decision is to meet public health needs in countries without manufacturing capacity, and in many cases licenses would presumably be sought to supply the needs of low-income populations. However, Article 7 required that efforts be directed to voluntary licensing on "commercial" terms and conditions, offering no hint that

¹⁷² Canadian Medicines Export Act, *supra* note 109, §21.04(3)(c).

¹⁷³ This viewpoint was reiterated by the Canadian representative to the QUNO meeting Implementing the Paragraph 6 Decision and Doha Declaration: Solving Practical Problems to Make the System Work, Jongny-sur-vevey, Switzerland (May 21–23, 2004).

¹⁷⁴ See *supra* notes 164–65 and corresponding text.

¹⁷⁵ TRIPS Agreement, *supra* note 2, Art. 44.2.

¹⁷⁶ Section 108(1) provides that the applicant shall have attempted to obtain a voluntary license to the extent required by section 49 of the Patents Act. In explaining this provision, the government said:

One condition for obtaining a compulsory licence is that the producer has first unsuccessfully tried to obtain a voluntary licence, cf. Article 31(b) of the TRIPS Agreement. This is not necessary in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

Norway Consultation, *supra* note 110.

¹⁷⁷ EU Draft Regulation, *supra* note 111, Explanatory Memorandum, para. 3.

¹⁷⁸ EU Draft Regulation, *supra* note 111, Art. 7.

¹⁷⁹ See Vandoren & Van Eeckhaute, *supra* note 17.

the license for export may be used for purposes that are not market based, including public noncommercial use.¹⁸⁰ Second, the reference to “declared” national emergency or other circumstances of extreme urgency unduly limited the circumstances in which special consideration would be given regarding a “reasonable period of time.” National law in the importing country may set conditions on formal declarations of emergency that make that option procedurally difficult, or national law may allow the government to take steps in declared emergency situations (such as suspending constitutional rights) that make such a declaration undesirable from a policy standpoint. The European Union initially proposed implementing the procedural requirements of the Decision in a way that raised concern that its use will be impeded by the intervention of patent holders. This reinforced the earlier observation that the European Union may not have given up on an Article 30 approach because of assumptions about what the United States would accept but, rather, because of a preference for a more tightly controlled process that gave relatively strong protection to patent holders.

The Netherlands permits the minister of economic affairs to waive the condition of prior negotiation with the patent holder in urgent cases.¹⁸¹ India does not limit the options for seeking compulsory licenses for export.¹⁸² The Swiss draft law proposes that licenses may be granted without prior negotiation with the patent holder in situations of national emergency or other circumstances of extreme urgency.¹⁸³

Lessons from the Core Issues

Although not without its faults, the Decision represents a success for developing countries in the pursuit of their public health agenda at the WTO. While the scale of this success can be debated, the important goal of increasing flexibility for trade in low-priced medicines in both the short and longer terms was achieved. Pharmaceutical trade is heavily regulated in general, and generic industry participants and bureaucrats alike should be able to work within the conditions of the Decision. Importantly, the subject matter of the Decision—compulsory licensing—has a broader purpose than enabling specific transactions: it forms part of the critical background to pricing decisions by patent holders, offering marketing options to the government that the patent holder must factor into its conduct. The Decision makes possible the better functioning of this “safeguard” or “market protection” mechanism.

Developing countries’ success in negotiating the Decision at the WTO may be attributed to two factors. First, developing country trade negotiators identified shared subject matter interests, developed common policy positions, and coordinated their negotiating strategy.¹⁸⁴ In doing so, they effectively employed an approach to trade negotiations used by the United States, the European Union, and Japan during the era of the original General Agreement on Tariffs and Trade (GATT).¹⁸⁵ Second, developing countries took advantage of policy space between the United States and the European Union. The Europeans distanced themselves from the Americans on subject matter the latter considered fairly important.¹⁸⁶

¹⁸⁰ Yet the provision on payment of royalties in the exporting country recognizes that the level of remuneration should take into account the economic value of the authorization to the importing country. EU Draft Regulation, *supra* note 111, Art. 8(9).

¹⁸¹ Netherlands Policy Rules, *supra* note 113, Explanatory Notes, pt. II, Art. 2.

¹⁸² Indian Ordinance, *supra* note 26, §92A.

¹⁸³ Swiss Transposition, *supra* note 116, Art. 40d.

¹⁸⁴ The strategies and tactics that developing countries used in pursuit of the public health agenda at the WTO have been further built upon in the formation of the G20+ and Group of 90, and have yielded positive results in the field of agriculture. See, e.g., *G20 Defends Agriculture Proposal from U.S.*, *EU Criticism*, INSIDE U.S. TRADE, June 4, 2004.

¹⁸⁵ See, e.g., SUSAN SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 96–108 (2003) (discussing formation of trilateral coalition on TRIPS for Uruguay Round).

¹⁸⁶ This suggests that in the post-Cold War era the two major trading powers may be more willing to adopt a heightened competitive approach to trade relations with developing countries than they were earlier when faced with common political and economic threats.

These negotiations demonstrated that developing countries can improve their favored outcomes at the WTO by formulating common positions and establishing coalitions committed to cohesion.¹⁸⁷ The formation and execution of common strategies may require each member of a coalition to deemphasize some of its individual interests.¹⁸⁸ Members will confront efforts to divide them, including offers of special treatment as inducement to break ranks. The coalition's success will depend on the ability to remain steadfast in the face of counterpressure.¹⁸⁹ Yet the negotiations also suggested the existence of limitations. When the United States and the European Union adopted a common position on one core issue, and developing countries were unable to formulate their own common position, the United States and the European Union prevailed.¹⁹⁰ In future negotiations it may be important for developing countries not only to formulate common positions, but also to work on creating and/or exploiting policy space between the United States, the European Union, and other developed countries. To create policy space, developing countries must identify common interests with the countries they are seeking as allies. There will be differences in the benefits and costs to particular countries in trade negotiations, and the strategy of coalition building may be more suited to some subjects than others.¹⁹¹ In the public health negotiations, a wide group of countries enjoyed strongly shared interests, even though those countries would have different roles in implementing the result.

Negotiating power at the WTO—defined as the ability of a country or group of countries to obtain a desired outcome or to block an unwanted outcome—is probably being diffused from the U.S.-EU-Japan relationship to a group of emerging developing country powers, including Brazil, China, India, South Africa, and perhaps soon Russia. China holds a growing share of world trade and is a major recipient of foreign direct investment.¹⁹² Brazil and India, both with large domestic markets, are improving their economic performance, attracting investment, and making gains in export markets.¹⁹³ South Africa, by far the leading African exporter,¹⁹⁴ is making strides in transforming its economy and is playing a leadership role in African politics. To the extent that these emerging developing country powers share interests in trade policy matters, and are able to act on these interests, their future negotiating strength at the WTO may prove substantial. Within the next ten to fifteen years, the coalition-building strategies of these emerging developing countries may be less dependent on identifying shared interests with the United States and the European Union.

The negotiating history indicates that developing countries enhance their prospects for success in WTO negotiations not only if they can agree on and maintain a common negotiating

¹⁸⁷ Accord Keith Maskus & Jerome Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. INT'L ECON. L. 279, 314–16 (2004).

¹⁸⁸ This lesson was also learned earlier by the United States, the European Union, and Japan. During the Uruguay Round TRIPS negotiations, the United States and the European Union differed significantly on various technical intellectual property rights issues, such as a first-to-invent or first-to-file patent priority, and the publication of patent applications. Yet those differences took a back seat to the core industrial policy matters, such as extending a broad requirement of product patent protection throughout the developing countries. See, e.g., SELL, *supra* note 185, at 96–120.

¹⁸⁹ NGO activity has been essential to building support for policies and to resisting counterpressures. *Accord id.* at 146–62.

¹⁹⁰ Developing country inability to reach agreement on this issue was due at least in part to a belief that the United States and the European Union would not compromise on it. See *supra* text at note 157.

¹⁹¹ See Frederick M. Abbott, *The Future of IPRs in the Multilateral Trading System*, in *TRADING IN KNOWLEDGE* 36 (C. Bellman, G. Dufield, & R. Melendez-Ortiz eds., 2003); Maskus & Reichman, *supra* note 187, at 316.

¹⁹² See WTO Committee on Trade and Development, *Participation of the Developing Economies in the Global Trading System*, Doc. WT/COMTD/W/1, paras. 3, 25, 29, & tbl. 1 (2004). Regarding the growing importance of China in world markets, including as an importer of raw materials and destination of foreign direct investment, see Larry Rohter, *China Widens Economic Role in Latin America*, N.Y. TIMES, Nov. 20, 2004, at A1.

¹⁹³ Regarding India, see WTO Committee on Trade and Development, *supra* note 192. Regarding Brazil, see, for example, *Brazil Posts Respectable \$3.172bn Trade Surplus Sep*, AE-BRAZIL, Oct. 1, 2004 (noting that “[t]he country accumulated a \$32.125 billion trade surplus in the 12 months ended September, resulting from exports of \$90.542 billion and imports of \$58.447 billion”).

¹⁹⁴ WTO Committee on Trade and Development, *supra* note 192, app., tbl. 2.

position, but also if they are opposed by no more than one of the major trading powers. Failure to adopt a common position and/or opposition by more than one major trading power diminishes the prospects for success. The formation and maintenance by developing countries of common positions may not be easy in practice. They will not always share interests. However, if they focus on identifying the most important shared interests and are willing to deemphasize less critical individualized interests, they may increase their opportunities to pursue shared objectives.

Other Conditions of the Decision

The Decision consists of a preamble and eleven paragraphs.¹⁹⁵ The first seven paragraphs (1–7) address substantive matters, and the final four paragraphs (8–11) are principally concerned with WTO institutional matters.

The Decision places transactional conditions on both importing countries and exporting countries. Importing countries must notify the TRIPS Council of the names and quantities of products they expect to import, and they must indicate (when necessary) that they have issued or will issue a compulsory license authorizing importation.¹⁹⁶ These notifications are to be made solely for transparency and are not part of a WTO approval process.¹⁹⁷ Importing countries are also expected to take measures proportional to their means and the level of risk to prevent diversion of the imported products.¹⁹⁸ Prior to supplying products, exporting countries must notify the TRIPS Council of the issuance of a compulsory license and the relevant terms, including the quantities and destinations of products.¹⁹⁹ Products supplied under the Decision must be identified as such through product packaging, labeling, and/or distinctive marking/coloration.²⁰⁰ Information concerning the transaction must be posted on a publicly accessible Web site.²⁰¹

The Decision provides additional flexibility for regional arrangements in Africa, allowing the reexport of products within such arrangements without additional export licensing.²⁰² This flexibility encompasses authority to import active pharmaceutical ingredients, formulate end-products, and reexport to members of the regional arrangements. However, the Decision does not free importing members of the arrangements of the requirement to issue compulsory licenses for importation (where applicable), so that relief from bureaucratic obstacles is limited.²⁰³

¹⁹⁵ Two useful analyses of the Decision are Vandoren & Van Eeckhaute, *supra* note 17, which reflects the views of the European Commission's delegation to the negotiations, and CORREA, *supra* note 104.

¹⁹⁶ Decision, *supra* note 3, para. 2(a)(i) & (iii).

¹⁹⁷ *Accord* Vandoren & Van Eeckhaute, *supra* note 17, at 789.

¹⁹⁸ Decision, *supra* note 3, para. 4. The text of paragraph 4 does not mandate a particular form of measure to prevent diversion. Since governments do not maintain standing bodies of patent "police," it would not generally be consistent with the notion of proportionality to create a new public enforcement arm to implement the Decision. In the general context of public health, governments typically require that controls be exercised over medicine supply chains, and it is through such generally accepted public health controls that governments may exercise vigilance over the movement of medicines supplied under the system. *See also* Vandoren & Van Eeckhaute, *supra* note 17, at 787. The Decision also imposes a general obligation on members to provide means to prevent diversion of medicines supplied under the system into their territories, "using the means already required to be available under the TRIPS Agreement." Decision, *supra*, para. 5.

¹⁹⁹ Decision, *supra* note 3, para. 2(b)–(c).

²⁰⁰ *Id.*, para. 2(b)(ii); *see also* General Council Minutes, *supra* note 10, para. 29 (chairperson's statement).

²⁰¹ The information is to be posted by the licensee, and the exporting member must notify the TRIPS Council of the address of the relevant Web site. Decision, *supra* note 3, para. 2(b)(iii) & (c).

²⁰² *Id.*, para. 6. The provision limits its territorial scope by reference to regional arrangements that are made up at least half by least-developed countries, which was understood to capture only regional arrangements in Africa. The restriction of regional flexibility to Africa is not easy to explain from the standpoint of regions such as the Caribbean, Central America, and East Asia, where there are very serious public health problems and limited pharmaceutical-manufacturing capacity.

²⁰³ Paragraph 6 of the Decision expressly refers to the "territorial nature" of patent rights, implying that importing countries should grant compulsory licenses where patents are present (unless the importing country is a least-developed country electing not to enforce patents), though the extent to which this step is necessary will depend on (1) whether a rule of regional exhaustion based on an export license is recognized, and (2) whether a region develops a joint compulsory licensing or recognition system.

The Decision waives the obligation of importing countries to provide remuneration to the patent holder when it is paid in the exporting member.²⁰⁴ In the exporting member, the level of remuneration should take into account the situation of the importing member.²⁰⁵

The chairperson's statement provides that "the system . . . should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives."²⁰⁶ Because the system is essentially "demand driven" in the sense that exporting countries will act on the basis of requests from importing countries to meet public health needs, the principle of good faith use does not appear to constitute an impediment to the effective implementation of the Decision. Also, "industrial or commercial policy objectives" do not refer to whether an export is undertaken by a private or public enterprise, or whether for profit or not for profit.²⁰⁷ Most medicines production and export under the Decision is expected to be pursued for profit by commercial enterprises. The pursuit of "industrial or commercial policy objectives" refers to steps taken by governments with the predominant aim of promoting national industrial development, in contrast with helping to address legitimate public health needs.

The Decision appears to offer a "transaction-by-transaction" solution to the problem of low-cost supplies of generic medicines. Understood in this way, the system may prove difficult to use in practice since a pharmaceutical producer might have difficulty justifying the time and expense needed to develop and produce a generic version of a patented medicine when there is only one customer, even if that customer might be fairly substantial. If the system is going to work effectively, it may well be necessary for a sufficient pool of prospective purchasers to be assembled. However, the Decision does not restrict the opportunities for multiple purchasers under an export license, or for the multiple issuing of compulsory licenses on the import side. Effective use of the solution may require coordination between exporters and importers.

Institutional Matters

The Decision does not require or envision advance authorization of its use by any WTO body. Notifications are provided to the TRIPS Council for purposes of transparency. The Decision does not preclude members from initiating dispute settlement regarding actions they consider inconsistent with it, but this is the ordinary mechanism of recourse at the WTO. While use of the Decision is generally subject to WTO dispute settlement,²⁰⁸ the Decision excludes so-called nonviolation nullification or impairment actions.²⁰⁹ The chairperson's statement refers

²⁰⁴ Decision, *supra* note 3, para. 3.

²⁰⁵ In its implementation of the Decision, Canada has prescribed royalties depending on the level of development of the importing country ranging from less than 1 to 4%. Canadian Medicines Export Act, *supra* note 109, §21.01(1) & (2), to be supplemented by regulations. The regulations are in draft form; they apply the UN Human Development Programme's Human Development Index to establish the development level. The level of remuneration under the Norwegian regulations is to be determined on a case-by-case basis. Norway Regulations, *supra* note 110, §108. The level of remuneration is likewise to be determined on a case-by-case basis under the EU Draft Regulation, *supra* note 111, Art. 8(9).

²⁰⁶ The first proposal by the chair of the TRIPS Council was based on an outline presented by U.S. Ambassador Deily, dated August 12, 2003. The central element of this proposal was the statement: "2. Purpose. That the solution is for humanitarian purposes, to be undertaken in good faith by governments, not as a part of industrial or commercial policy and hence not for commercial gain" (on file with author). Following objections by the developing country negotiators, the statement of good faith was revised to provide: "First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives." General Council Minutes, *supra* note 10, para. 29.

²⁰⁷ The initial U.S. proposal for the chairperson's statement would have limited resort to the Decision to situations "not for commercial gain." *See id.* This condition was rejected.

²⁰⁸ Under the Understanding on Rules and Procedures Governing the Settlement of Disputes, WTO Agreement, *supra* note 128, Annex 2, *in THE LEGAL TEXTS*, *supra* note 2, at 354. The point at which an action under the Dispute Settlement Understanding can be commenced and prosecuted depends not on the notification, but on the jurisprudence of the Appellate Body regarding "ripeness"; that is, when an action by a member has become actionable.

²⁰⁹ Decision, *supra* note 3, para. 10. In a nonviolation nullification or impairment action, a member does not seek to challenge the conformity of another member's measures or actions with the terms of the relevant agreement (e.g., GATT 1994), but contends that the measures or actions adversely affect the benefits it expected to

to the potential use of the good offices of the director general to address conflicts, which essentially restates WTO practice. It also refers to the right of members to bring a matter to the attention of the TRIPS Council for expeditious review, with a view to taking “appropriate action,”²¹⁰ but the types of actions the TRIPS Council is authorized to take are very limited.²¹¹ Since it acts only by consensus, there is little risk that this provision could be used to block effective use of the Decision.²¹²

The waiver. The Decision includes a waiver of certain obligations of WTO members.²¹³ Pursuant to paragraph 11, the waiver will terminate “for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member.” Paragraph 11 calls for further negotiations on an amendment to the TRIPS Agreement, based where appropriate on the Decision, to commence in the TRIPS Council before the end of 2003, with a view to its adoption within six months.²¹⁴ In June 2004, the TRIPS Council extended the period for negotiating the amendment until the end of March 2005. That deadline was missed.²¹⁵

The mechanism of a “waiver leading to an amendment” is not expressly provided for in the WTO Agreement; nor has it previously been used in GATT/WTO practice. However, nothing in the WTO Agreement prevents members from using a combination of expressly prescribed legal mechanisms to achieve their objectives. The waiver constitutes a reasonably secure legal basis for the amendment of national legislation to implement the Decision.²¹⁶ Although paragraph 11 of the Decision provides for negotiations with a view toward adoption of an amendment, it does not condition the legal validity of the waiver on the successful adoption of the amendment. The waiver expires by its terms when the amendment has been adopted and accepted by

receive based on a negotiated exchange of concessions. *See, e.g.*, Frederick M. Abbott, *TRIPS in Seattle: The Not-So-Surprising Failure and the Future of the TRIPS Agreement*, 18 BERK. J. INT’L L. 165 (2000); FREDERICK M. ABBOTT, NON-VIOLATION NULLIFICATION OR IMPAIRMENT ACTIONS UNDER THE TRIPS AGREEMENT AND THE FIFTH MINISTERIAL CONFERENCE: A WARNING AND REMINDER (QUNO Occasional Paper No. 11, July 2003), available at <http://www.geneva.quno.info>.

²¹⁰ The chairperson’s statement provides: “Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.” General Council Minutes, *supra* note 10, para. 29.

²¹¹ It can make a recommendation to the Ministerial Conference for a formal interpretation of the Agreement (WTO Agreement, *supra* note 128, Art. IX:2); it may make a report regarding a waiver (*id.*, Art. IX:3); and “[i]t shall carry out such other responsibilities as assigned to it by the Members” (TRIPS Agreement, *supra* note 2, Art. 68).

²¹² The TRIPS Council makes recommendations by consensus. Rules of Procedure for Meetings of the Council for TRIPS, Rule 33, WTO Doc. IP/C/1 (1995). In default of consensus in the TRIPS Council, the matter is referred to the General Council, which ordinarily acts by consensus but may use the alternative voting rules of the WTO Agreement in the absence of consensus (although the General Council must act by consensus when so required by the applicable rule of the TRIPS Agreement). Only in extraordinary circumstances might the Ministerial Conference or the General Council act other than by consensus. For all practical purposes (under existing circumstances), decisions at the WTO are made only by consensus. *Accord* Vandoren & Van Eeckhaute, *supra* note 17, at 789–90.

²¹³ A waiver is adopted at the WTO by decision of the members and does not require further ratification or acceptance. WTO Agreement, *supra* note 128, Art. IX:3–4. An amendment is initially decided upon collectively by the members, *id.*, Art. X:1, but is thereafter subject to acceptance by each member in accordance with its national constitutional requirements, *id.*, Art. X:3. An amendment is effective only for members that have accepted it. It was foreseeable that amending the TRIPS Agreement would be a time-consuming process, particularly if it took place outside the context of the completion of a trade negotiating “round.” It was also not entirely outside the realm of possibility that some members might never accept an amendment, even if they did not block its adoption at the WTO.

²¹⁴ The target date of six months from the end of 2003 was set when the Decision was proposed for adoption on December 20, 2002. It was not adopted until August 30, 2003.

²¹⁵ See regarding the initial extension *WTO Set to Extend TRIPS Amendment Deadline by Nine Months*, INSIDE U.S. TRADE, June 18, 2004. A WTO official provided details on the missed deadline following the TRIPS Council meeting of March 31, 2005.

²¹⁶ In the course of negotiating the Decision, a question was raised whether a long-term waiver would require annual consensus renewal by the Ministerial Conference or the General Council. *See* CORREA, *supra* note 13, at 30–31. The predominant weight of opinion, based on the express text of Article IX:4 of the WTO Agreement and on GATT/WTO practice was that no such renewal was required. A study by the secretariat implicitly confirmed this interpretation. Note by the Secretariat, Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Information on Waivers, WTO Doc. IP/C/W/387 (Oct. 24, 2002) (noting that a substantial number of long-term waivers were in effect and that the “reviews under Article IX:4 that have taken place so far have been relatively brief and no delegations have questioned the waivers under review”).

all WTO members. Otherwise, it remains in force with respect to all members for which the amendment has not taken effect. If an amendment is not adopted, it will not come into effect for any member, but the waiver will continue in force unless terminated by vote of the members.²¹⁷

Amendment. Paragraph 11 of the Decision provides that the amendment will be “based, where appropriate, on this Decision.” From a textual standpoint, the term “where appropriate” provides scope for members to reopen negotiations on those aspects of the Decision they consider inappropriate. The scope of the negotiations is more a question of politics than of law. The various options for transforming the Decision into an amendment of the TRIPS Agreement include modifying individual provisions of the Agreement and incorporating the Decision, with conforming modifications, as an annex to the Agreement. An ancillary question concerns the place of the chairperson’s statement,²¹⁸ whose legal character has been the subject of some debate. Proponents of streamlining the Decision attribute a weak legal character to it. The United States contends that it is an essential element of the Decision, hence of the amendment, package.²¹⁹

On November 29, 2004, the African Group circulated a proposal for an amendment to the TRIPS Agreement, which was introduced and discussed at the TRIPS Council meeting on December 1–2, 2004.²²⁰ This proposal sought to amend Article 31 of the Agreement so as to incorporate basic elements of the waiver²²¹ and to eliminate the notification requirements. It did not refer to the chairperson’s statement. The United States and the European Union, among others, expressed concern over what they saw as an apparent attempt to renegotiate the Decision. They suggested that the amendment process should be an exercise in technical transformation. Both the United States and Japan spoke to the importance of incorporating the chairperson’s statement. In the end, the whole question of the amendment was referred to informal consultations organized by the chair of the TRIPS Council.²²²

VI. RESPONSE AND RECOMMENDATIONS

U.S. Interests and Multiforum Strategy

For negotiators to succeed at the WTO, they must build a consensus.²²³ A country that decides to block a consensus may pay a political price, and a country with limited economic power may

²¹⁷ Paragraphs 3–4 of Article IX of the WTO Agreement do not expressly address the voting requirement for termination of a continuing waiver. However, Article IX:3 expresses a preference for action on waivers by consensus, and a secondary rule providing for a three-fourths majority. These rules would logically also apply to termination of a waiver. The secretariat’s note on waivers, *supra* note 216, indicated that the procedure for terminating a waiver has never been employed. During the negotiations, the question was raised whether a waiver might impose new obligations on a member. The view of this author and others was that a waiver could be conditioned on the fulfillment of obligations not otherwise stated in the provision subject to waiver. That is, the waiver is an instrument used to relieve parties of certain obligations, but there is no reason why the relief from obligations could not be subject to conditions.

²¹⁸ The statement is not part of the Decision, and in that sense is not subject to the paragraph 11 direction on the preparation of an amendment based on the Decision. The statement may be eliminated, modified, or used again in more or less its present form.

²¹⁹ The chairperson of the General Council stated: “Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented.” General Council Minutes, *supra* note 10, para. 29; *see, e.g., U.S., EU Criticize African TRIPS and Health Proposal*, INSIDE U.S. TRADE, Dec. 3, 2004.

²²⁰ Communication from Nigeria on Behalf of the African Group, Implementation of Paragraph 11 of the 30 August 2003 Decision, WTO Doc. IP/C/W/437 (Dec. 10, 2004).

²²¹ Including the waiver of compliance with Article 31(f) and (h), the requirement of product identification, and the obligation to provide effective legal means to prevent diversion, as well as special treatment for African regional arrangements.

²²² E-mail briefing by WTO official (Mar. 21, 2005); *U.S., EU Criticize African TRIPS and Health Proposal*, *supra* note 219.

²²³ In the predecessor GATT and in today’s WTO, member countries have voted by consensus and, in accordance with customary practice, any one member could block a consensus. This customary rule is stated in Article IX:1 of the WTO Agreement as the preferred method of WTO decision making. Article IX:1 also provides voting rules that members may follow in the event they fail to reach a consensus; but despite this possibility, the WTO operates by consensus. Unlike the United Nations (with its Security Council), the WTO does not have an explicit decision-making mechanism that weights the trading power of its members.

find it problematic to do so.²²⁴ Because of the economic and political power of the United States, a threat by it to block a consensus unilaterally is credible, and it initially blocked a consensus on the Decision. Thus, the success of the developing countries in negotiations on the Decision depended on the willingness of the United States ultimately to accept a result that it had not preferred. The U.S. concession may be explained by several factors.

First, the United States did not enjoy broad developed country support for its preferred hard-line approach to the Decision, and finally found itself more or less isolated.²²⁵ Second, the United States has diverse interests at the WTO, and must make accommodations in some areas to allow it to press its agenda in others. In the current Doha Development Round of negotiations, the United States is seeking significant concessions from developing countries on industrial tariffs, trade facilitation, and improved market access for providers of services. It is applying pressure on the European Union to reduce its agricultural subsidies. Pharmaceutical patent holders are not the USTR's only constituency. Failure to reach agreement on public health would therefore limit the potential for progress in other areas. For developing countries, public health was a priority and progress in other areas could not be made without a solution in that regard.²²⁶ Third, the United States has recourse to alternative means to accomplish its objectives. Thus, the U.S. reaction to developing country success on access-to-medicines issues at the WTO has been to shift negotiations on this subject to bilateral and regional fora.²²⁷ It has succeeded in negotiating significant restrictions on the ability of generic producers to introduce medicines in bilateral and regional deals.²²⁸ Some trade negotiators in Geneva, including those from the European Union, are concerned about the extent to which the United States is pursuing intellectual property policies in bilateral and regional arrangements that differ from those agreed upon at the WTO.²²⁹ These concerns are shared by NGOs and by economists at the World Bank.²³⁰

U.S. Free Trade Agreements and "Certain Regulated Products"

Since the adoption of the Doha Declaration in November 2001, the United States has negotiated various free trade agreements (FTAs) with developing (and developed) countries that include chapters addressing intellectual property rights.²³¹ These chapters restrict the use of

²²⁴ By threatening to block a consensus at the Doha ministerial meeting, India was able to obtain substantial concessions regarding future negotiations on the so-called Singapore issues, but India is one of the leading developing countries in terms of trade power because of its large domestic market. See, e.g., *Chairman's Statement Casts Doubt on Final WTO Declaration*, INSIDE U.S. TRADE, Nov. 15, 2001. By contrast, the Philippines briefly threatened to block a consensus on the Decision in August 2003 but quickly backed away after a diplomatic exchange with the United States.

²²⁵ See text *supra* at notes 95–101.

²²⁶ Because developing countries have relatively small delegations in Geneva, they cannot simultaneously focus on the same range of trade issues that the United States can with its much larger staff.

²²⁷ See Peter Drahos, *Developing Countries and International Intellectual Property Standards-Setting*, 5 J. WORLD INTELL. PROP. 765 (2002).

²²⁸ See FREDERICK M. ABBOTT, THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH AND THE CONTRADICTION TREND IN BILATERAL AND REGIONAL FREE TRADE ARRANGEMENTS (QUINO Occasional Paper No. 14, Apr. 2004), available at < <http://www.geneva.quino.info> > .

²²⁹ See Sarah Boseley, *France Accuses US of AIDS Blackmail*, GUARDIAN, July 14, 2004 (referring to a statement of President Jacques Chirac of France read at the XV International AIDS Conference in Bangkok); see also Pascal Lamy, The TRIPS Agreement 10 Years On, Speech Before International Conference at Brussels (June 24, 2004), available at < http://europa.eu.int/comm/archives/commission_1999_2004/lamy/speeches_articles/spla234_en.htm > ; WTO Amb. Luzius Wasecha, Switzerland, Remarks, in UNCTAD/ICTSD Policy Dialogue entitled "Intellectual Property Rights Development 10 Years After Marrakech: Where Are We? Where Are We Heading?" (May 17, 2004).

²³⁰ On NGOs, see note 234 *infra*. On the World Bank, see CARSTEN FINK & PATRICK REICHENMILLER, TIGHTENING TRIPS: THE INTELLECTUAL PROPERTY PROVISIONS OF RECENT US FREE TRADE AGREEMENTS (World Bank Trade Note No. 20, 2005); WORLD BANK, GLOBAL ECONOMIC PROSPECTS 2005, ch. 5, at 98–110.

²³¹ Agreements with Australia, Chile, and Singapore are in force, while the Bahrain FTA, the Central American Free Trade Agreement (CAFTA), and Morocco FTA are signed but not yet in force. The USTR is negotiating a significant number of additional agreements, including with countries of the Andean Community, the Southern Africa Customs Union (SACU), and Thailand. For the agreements, see the Web site of the USTR, < <http://www.ustr.gov> > .

the flexibilities under the TRIPS Agreement in regulating pharmaceutical products.²³² U.S. PhRMA stands strongly behind these efforts.²³³ While the intellectual property chapters of these agreements vary in their specific terms,²³⁴ the common objectives of the United States, achieved to different degrees, are to limit the potential exclusions from patentability,²³⁵ require the grant of patents for “new uses” of known compounds,²³⁶ require the extension of patent terms under certain conditions,²³⁷ prevent parallel importation,²³⁸ limit the grounds on which compulsory licenses may be granted,²³⁹ and permit the prosecution of nonviolation nullification or impairment claims.²⁴⁰ In addition, the United States is negotiating for periods of marketing exclusivity based on the submission of data in the regulatory approval process, which eliminates flexibilities of the TRIPS Agreement²⁴¹ and covers patented and nonpatented products. These provisions provide marketing exclusivity based not only on data submitted in the country where regulatory approval is being sought, but also on data submitted in foreign countries or on the fact of

²³² Concerns about U.S. FTAs were raised by this author in ABBOTT, *supra* note 228.

²³³ See PhRMA “Special 301” Submission to USTR, Appendix B, FTAs—Challenges and Opportunities (2004) [hereinafter PhRMA] (observing that FTA negotiations are a “second best” to multilateral agreements, but that “deliberations in the TRIPS Council call into question the current value of the WTO as a venue for improving the worldwide protection of intellectual property”).

²³⁴ The World Bank has compiled tables of intellectual-property-rights-related provisions in the various bilateral agreements. See FINK & REICHENMILLER, *supra* note 230. A number of NGOs have also compiled tables showing the TRIPS-plus provisions adopted on an agreement-by-agreement basis. See, e.g., OXFAM BRIEFING NOTE, UNDERMINING ACCESS TO MEDICINES: COMPARISON OF FIVE US FTAs (June 2004), available at < http://www.oxfamamerica.org/pdfs/fta_comparison.pdf >; CPTech, Table of Selected Provisions Related to Healthcare in the Free Trade Agreement Texts That Have Been Made Public [as of Apr. 6, 2005], available at < <http://www.cptech.org/ip/health/trade> >; see also MSF BRIEFING NOTE, ACCESS TO MEDICINES AT RISK ACROSS THE GLOBE: WHAT TO WATCH OUT FOR IN FREE TRADE AGREEMENTS WITH THE UNITED STATES (May 2004), available at < <http://www.accessmed-msf.org> >. An excellent analysis of the U.S.-Chile FTA is Pedro Roffe, Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement (Quaker International Affairs Programme, Ottawa, TRIPS Issues Paper No. 4, 2004).

²³⁵ Some agreements, for example, preclude the exclusion of plants and/or animals from patentability, eliminating the flexibility in Article 27.3(b) of the TRIPS Agreement to exclude such subject matter, and to provide only a *sui generis* form of plant variety protection. See, *supra* note 231, U.S.-Bahrain FTA, Art. 14.8(2); U.S.-Chile FTA, Art. 17.9(2) (best efforts); CAFTA, Art. 15.9(2) (best efforts); U.S.-Morocco FTA, Art. 15.9(2).

²³⁶ Granting patents for “new uses” is not permitted in a number of countries. See, e.g., Andean Community, Decision 486, Art. 21 (Sept. 14, 2000), available at < <http://www.comunidadandina.org/ingles/treaties/dec/dec.htm> >. In a typical case, a pharmaceutical compound known to be effective for treating one form of disease may be found to treat another disease, and a person seeks a patent on the “new use” (sometimes referred to as a “second medical indication” patent in that context). The TRIPS Agreement is silent on whether such patents should be granted, leaving countries with flexibility to decide the question. See, *supra* note 231, U.S.-Morocco FTA, Art. 15.9(2); U.S.-Australia FTA, Art. 15.9(1); U.S.-Bahrain FTA, Art. 14.8(2).

²³⁷ The United States provides a limited patent term extension based on the period during which a product undergoes regulatory review. Country practice varies on this matter, and it is not regulated by the TRIPS Agreement. See Canada—Pharmaceuticals, *supra* note 143 (describing U.S. system and deciding that patent term extension based on regulatory review is not required by TRIPS Agreement). The terms of the U.S. FTAs base the exception on unreasonable delays in granting patents. See, *supra* note 231, U.S.-Bahrain FTA, Art. 14.8(6); U.S.-Australia FTA, Art. 15.9(8); CAFTA, Art. 15.9(6); U.S.-Chile FTA, Art. 17.9(6); U.S.-Morocco FTA, Art. 15.9(7); U.S.-Singapore FTA, Art. 16.7(7)–(8).

²³⁸ The Doha Declaration, *supra* note 1, para. 5(d), confirmed the right of each WTO member to adopt its own policy and rules with respect to parallel imports. Some FTAs preclude parallel importation of patented products, thereby eliminating this flexibility. See, *supra* note 231, U.S.-Morocco FTA, Art. 15.9(4); U.S.-Australia FTA, Art. 17.9(4).

²³⁹ Some FTAs limit the grounds for granting compulsory licenses, for example, to public noncommercial use, national emergencies, and circumstances of extreme urgency, or to remedy anticompetitive practices. See, *supra* note 231, U.S.-Australia FTA, Art. 17.9(7); U.S.-Singapore FTA, Art. 16.7(6).

²⁴⁰ See note 209 *supra*.

²⁴¹ Article 39.3 of the TRIPS Agreement requires members to provide protection against “unfair commercial use” of confidential information with respect to “new chemical entities” submitted during the regulatory review process. The provisions in the FTAs establish strict “marketing exclusivity” periods following approval based on submitted data (initially five years), do away with the limitation to “new chemical entities,” and do not allow exceptions for fair or noncommercial uses, such as use by government authorities in public health systems. See, *supra* note 231, U.S.-Australia FTA, Art. 17.10(1); U.S.-Bahrain FTA, Art. 14.9(1); CAFTA, Art. 15.10(1); U.S.-Chile FTA, Art. 17.10(1); U.S.-Morocco FTA, Art. 15.10(1); U.S.-Singapore FTA, Art. 16.8(1). Some of the agreements allow the renewal or “evergreening” of marketing exclusivity periods. See *supra*, U.S.-Australia FTA, Art. 17.10(2); U.S.-Bahrain FTA, Art. 14.9(2); U.S.-Morocco FTA, Art. 15.10(2). These provisions taken together dramatically limit TRIPS flexibilities.

marketing approval in foreign countries.²⁴² The United States links patents to the marketing approval process, precluding a country from approving a product with effect prior to the expiration of the patent term, without the “consent or acquiescence” of the patent holder.²⁴³ In the FTA with Australia, the United States negotiated a provision newly enabling pharmaceutical companies to challenge decisions by Australian regulators as to whether drugs will qualify for reimbursement under the Australian Pharmaceutical Benefits Scheme (PBS).²⁴⁴ The PBS is Australia’s principal mechanism for controlling drug prices.²⁴⁵

The terms of the FTAs applicable to pharmaceutical products, patents, and related regulatory matters raise a substantial number of concerns about the introduction of generic, off-patent products onto the market in the countries agreeing to these provisions, including the United States.²⁴⁶ These provisions may substantially reinforce the advantages of originators, even as to off-patent products, reducing the availability of alternatives and increasing prices.²⁴⁷ Limiting the TRIPS Agreement’s flexibilities with respect to pharmaceutical products will have a significantly broader impact than inhibiting the use of compulsory licensing.

As to the potential impact of the FTAs on implementation of the Decision, U.S. FTA partners have agreed that marketing approval of a medicine may not be given effect during the term of a patent without the consent or acquiescence of the patent holder.²⁴⁸ In virtually all countries, for a medicine to be placed on the market it must be approved and registered by local public health authorities.²⁴⁹ If a country grants a compulsory license to import a generic version of a patented product, in all likelihood that product (in its generic or bioequivalent form) will not have been previously registered there. The compulsory license will authorize importation of the generic version, but the patent holder may refuse to consent to its registration. If it cannot be registered, it cannot be used or sold. This prospect may effectively bar the use of compulsory licensing.²⁵⁰ In addition to the provisions mandating the patent holder’s consent to marketing

²⁴² The United States is apparently concerned about countries that do or may accept registration in the United States or other countries, or approval by the WHO prequalification program, as sufficient evidence of the safety and efficacy of medicines, extending the basis of marketing exclusivity to actions taken outside the country where exclusion is sought.

²⁴³ See U.S.-Australia FTA, Art. 17.10(5); U.S.-Bahrain FTA, Art. 14.9(4); CAFTA, Art. 15.10(2); U.S.-Chile FTA, Art. 17.10(2); U.S.-Morocco FTA, Art. 15.10(4); U.S.-Singapore FTA, Art. 16.8(4), all *supra* note 231, and discussion in text at notes 248–250 *infra*.

²⁴⁴ U.S.-Australia FTA, *supra* note 231, Annex 2–C, Pharmaceuticals, para. 2(f).

²⁴⁵ This aspect of the U.S.-Australia FTA was the subject of intense political controversy in Australia. See Kate Burton & Jacob Varghese, The PBS and the Australia-US Free Trade Agreement (Austl. Parliamentary Library Research Dep’t, Research Note No. 3, 2004); Peter Drahos et al., The FTA and the PBS: A Submission to the Senate Select Committee on the US-Australia Free Trade Agreement (2004). Prior to approving the Agreement, Parliament adopted amendments to Australian patent law intended to prevent pharmaceutical patent holders from abusing their right to challenge the registration of generic medicines. The United States has since objected to these amendments and is negotiating with Australia to modify its implementing legislation. See, e.g., *Australia Poised to Pass U.S. FTA with Controversial Drug Amendments*, INSIDE U.S. TRADE, Aug. 13, 2004.

²⁴⁶ FTA pharmaceutical regulatory provisions provide for the grant of marketing exclusivity, whether or not a medicine is on patent, based on the submission of regulatory data or evidence of prior marketing approval.

²⁴⁷ The introduction of generic pharmaceuticals results in lower prices, particularly as the number of generic competitors increases. See, e.g., Canada, Patented Medicines Price Review Board, Prices of the Top Selling Multiple Source Medicines in Canada (June 2003).

²⁴⁸ See note 243 *supra* for a list of provisions. For a detailed analysis of these provisions in the CAFTA and the U.S.-Morocco FTA, see ABBOTT, *supra* note 228.

²⁴⁹ Country practices differ widely with respect to prerequisites for the distribution of medicines. The term “marketing approval” may refer to the technical process by which the regulatory authorities determine whether the product meets relevant quality, safety, and/or efficacy standards, while “registration” may refer to the more ministerial act of placing the medicine on a register of approved products. However, the terms are often used interchangeably.

²⁵⁰ Article 28 of the TRIPS Agreement generally allows the patent holder to prevent the manufacturing and sale of pharmaceutical products during the patent term. However, Article 31 authorizes the government to grant compulsory licenses to other persons to use the patented invention. The problem is that the marketing approval provisions of the FTAs expressly require the “consent” of the patent holder. It is not linked to the compulsory licensing process, and there is no recognition in the provisions that the government may allow the marketing of the product based on the compulsory license, that is, without the patent holder’s consent. Of course, the government could argue that a compulsory license “implies” that marketing approval of the medicine may also be

approval, provisions obligating fixed terms of marketing exclusivity based on the submission of data (regardless of patent status) do not recognize situations where marketing approval may be granted during the exclusivity period. These provisions also give rise to a conflict with the prospective use of compulsory licensing. The TRIPS Agreement, by way of contrast, provides flexibility for governments to grant marketing approval and register medicines notwithstanding prior submissions of regulatory data.²⁵¹ For its part, the European Union addresses this potential conflict in its Draft Regulation to implement the Decision, by expressly providing for the manufacture and export of the medicines notwithstanding marketing exclusivity.²⁵²

The problem created by the terms of the FTAs was brought to the attention of the USTR.²⁵³ Its response was to negotiate an understanding to the Central American Free Trade Agreement (CAFTA) and side letters to the U.S.-Bahrain FTA and the U.S.-Morocco FTA (understandings). While these understandings appear intended to provide assurance that the FTAs would not prevent effective use of the Decision and the Doha Declaration, they are drafted in a substantially more restrictive way than those texts. Moreover, the USTR has questioned whether the understandings will have legal effect.²⁵⁴

The relevant portion of the CAFTA understanding states:

The obligations of Chapter Fifteen [on intellectual property] do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all, *in particular* concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.

In recognition of the commitment to access to medicines that are supplied in accordance with the Decision [and the WTO General Council chair's statement], Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution.²⁵⁵

The CAFTA understanding limits its scope by the phrase "in particular" in reference to the scope of necessary measures to protect public health. "In particular" is language of limitation,²⁵⁶ and it refers to "cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics." Here a scope-of-diseases limitation has been introduced.²⁵⁷ The understanding also refers to circumstances of national emergency or extreme urgency, qualified by "in particular," interpretively eliminating the prospect for compulsory licensing in ordinary circumstances or for "public non-

given early effect, but the text does not say that and there is no reason to believe that patent holders would not seek to take advantage of the nonlinked provisions.

²⁵¹ On Article 39.3 of the TRIPS Agreement, see note 241 *supra*. When the government grants a compulsory license under Article 31 of the TRIPS Agreement (and Decision), marketing approval and registration are not "unfair."

²⁵² The explanatory memorandum on the EU Draft Regulation, *supra* note 111, states with regard to Article 16:

As the licensee will not necessarily hold a medicinal products marketing authorisation within the EU for the product manufactured under a compulsory licence for export, the Regulation provides for licensees to ask for a scientific opinion from the European or national regulatory authorities if they should need this for export to the country concerned. Derogations from data protection and caducity rules are provided.

²⁵³ Many groups and individuals did so, including this author on a panel with a USTR representative at the 2004 annual meeting of the American Society of International Law. See Frederick M. Abbott, Remarks, 98 ASIL PROC. 95 (2004).

²⁵⁴ See discussion *infra* text at notes 260–61.

²⁵⁵ Understanding Regarding Certain Public Health Measures, Aug. 5, 2004, CAFTA, *supra* note 231 (emphasis added). The relevant portion of the U.S.-Morocco FTA, *supra* note 231, Side Letter on Public Health, June 15, 2004, is stated in nearly identical language.

²⁵⁶ According to MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (10th ed. 1993), a standard work on U.S. usage, the prepositional phrase "in particular" is defined as "*specifically*, in distinction from others" (emphasis added). Even if one were prepared to accept the U.S. view of paragraph 1 of the Doha Declaration, i.e., that it was intended to limit the scope of diseases, that paragraph uses the term "especially," which connotes a degree of preference. The adverb "especially" is defined in the dictionary that the WTO Appellate Body would use in interpreting the Doha Declaration, 1 THE NEW SHORTER OXFORD ENGLISH DICTIONARY, *supra* note 105, as "[i]n an especial manner, to an especial degree; *chiefly, more than in other cases*" (emphasis added).

²⁵⁷ Since months of negotiations at the WTO were spent wrangling over the terms "referred to in" and "as recognized in," seemingly small changes in terminology cannot be taken lightly.

commercial use.²⁵⁸ In effect, in the understandings the USTR rewrote the Decision and the Doha Declaration to reflect a U.S.-preferred outcome to WTO negotiations.

In response to an inquiry from Congressman Sander Levin regarding the U.S.-Morocco FTA, the USTR's general counsel sent a letter assuring that its side letter would allow the registration of medicines distributed under compulsory license, though without explaining the mechanism by which this would be accomplished.²⁵⁹ More recently, the USTR has taken the position that the understandings do not provide any "exception" to the marketing exclusivity rules of the intellectual property chapters.²⁶⁰ The USTR has not explained how the textual conflicts involving marketing approval and compulsory licensing are intended to be resolved.²⁶¹

The uncertainty created by the intellectual property chapters and the potential impact on developing country public health and intellectual property authorities should not be underestimated. Few governments wish to become engaged in a trade dispute with the United States and most lean toward erring on the side of caution. Ambiguous pharmaceutical-related rules raise serious problems when procurement officials try to do their work.

Despite the provisions curtailing access to pharmaceuticals, developing countries have been anxious to conclude FTAs with the United States, and this trend shows no sign of abating.²⁶² Negotiators for developing countries understand that they are giving up flexibility in the pharmaceutical sector, and accept that its relinquishment constitutes a trade concession in favor of the United States.²⁶³ The provisions are accepted because the governments believe that, on the whole, the FTAs are beneficial to the countries involved, and that compromise in the pharmaceuticals sector is necessary to achieve gains in other areas. Of course, wider political dimensions come into play as well, as governments cement friendly relations with the United States.

The problem with an analysis of FTAs using net economic gains or losses as the developing country benchmark is that gains for a developing country's textile or agricultural producers do not directly translate into higher public or private health expenditures.²⁶⁴ Salaries for part of the workforce may increase and government tax revenues may rise, which may indirectly help offset pharmaceutical price increases. But if the health sector is not to be adversely affected, there must be some sort of transfer payment, whether in the form of increased public health expenditures on pharmaceuticals, increased health insurance benefits, or other affirmative acts. In

²⁵⁸ Proposals to limit the Decision to situations of emergency and extreme urgency were rejected by developing country members at the multilateral level during the paragraph 6 negotiations. In February 2003, Amb. Pérez Motta proposed a statement of shared understandings that would have restricted the use of the solution to situations of national emergency, as follows: "Secondly, delegations have made it clear that they see the system that we are establishing under paragraph 6 of that Declaration as being essentially designed to address national emergencies or other circumstances of extreme urgency" (on file with author). This statement was initially presented to delegates of the African Group and was met with strong criticism from within and outside the African Group. See MSF, MSF Calls on WTO to Refuse 'Paragraph 6' Change, Open Letter to the Members of the WTO (Feb. 8, 2003), available at < <http://www.accessmed-msf.org> >. By February 10, members of the African Group were prepared to reject the proposal, as were other members. Thus, the proposal was not mentioned at the General Council meeting on that date, WTO General Council, Minutes of Meeting on 10 Feb. 2003, Doc. WT/GC/M/78, paras. 36-38 (Mar. 7, 2003), or at the subsequent TRIPS Council meeting of February 18, 2003.

²⁵⁹ The letter referred to the parties' common understanding in the side letter and asserted that "if circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provisions in the FTA would not stand in the way." Letter from John K. Veroneau to Representative Sander Levin (July 19, 2004), reprinted in INSIDE U.S. TRADE, July 23, 2004.

²⁶⁰ See FINK & REICHENMILLER, *supra* note 230, at 3, 10 nn.10, 11.

²⁶¹ *Id.*

²⁶² For a trend analysis with respect to the negotiation and conclusion of FTAs involving the United States, see WTO Secretariat, Trade Policy Review, United States, Doc. WT/TPR/S/126, at viii, para. 8; & at 20-27 (2003).

²⁶³ The author has had extensive conversations with developing country negotiators of these FTAs. There is no doubt that the provisions in question are adopted at the initiative and demand of the United States, and are viewed as a necessary concession by the developing country negotiators. These negotiators assume that the country will experience higher pharmaceutical payment outflows as a consequence.

²⁶⁴ This author has proposed a move toward objective assessment of the economic impact. See Frederick M. Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism*, 8 J. INT'L ECON. L. 77 (2005).

a world of economic scarcity, the prospect that governments will offset increases in the price of medicines by raising public health expenditures is uncertain.

The primary reason developing country negotiators make bilateral concessions on pharmaceuticals is presumably to gain reciprocal concessions from the United States. Yet other factors related to bilateral and regional negotiations seem to improve the U.S. bargaining position outside the WTO.²⁶⁵ At the WTO in Geneva, trade negotiators for developing countries can readily coordinate policy formulation and negotiations. In a developing country's national capital, Trade Ministry officials are relatively isolated from their foreign counterparts and local producers exercise more direct influence than in the Geneva process.²⁶⁶ NGOs concerned with access to medicines can more effectively seek to influence developing country delegates in Geneva, where many countries can easily be brought together. Although NGOs can lobby at the national capital, it is more expensive and securing media attention may be more difficult there. The international news media play a significant role in trade negotiations. The major actors such as the *Financial Times*, the *New York Times*, and the *Wall Street Journal* are generally present in Geneva.²⁶⁷ They carry stories on developments at the WTO and are not reluctant to criticize the big powers. When trade stories move to distant venues and involve limited numbers of actors, they attract less interest in the "international public," and correspondingly less attention by the international media. Finally, negotiations at the WTO are relatively transparent in the sense that draft texts are routinely made available, officially or unofficially. So far, draft texts in U.S. FTA negotiations have been released sporadically. The public first sees the agreements when they are ready for signature. These conditions make it much more difficult for NGOs and other interested parties to put pressure on governments during the negotiating phase, and the fast-track approval process in the United States makes changing the terms of signed agreements very difficult. While perhaps none of the foregoing factors is decisive in itself, together they may help to explain why the United States appears to have more success in securing concessions in FTA negotiations than at the WTO.

The United States has given little indication of plans to alter its approach with respect to the FTAs, although members of Congress have recently begun to take note that restrictive conditions in the FTAs may impede pharmaceutical policies that the government may elect to pursue.²⁶⁸ The USTR has addressed concerns about restrictions on U.S. regulatory flexibility by stating that Congress can legislate inconsistently with the FTAs, notwithstanding any adverse decisions of dispute settlement panels.²⁶⁹

Recommendations for Developing Countries

Developing countries face a substantial problem in attempting to ameliorate the trend toward the elimination of TRIPS flexibilities in the pharmaceuticals sector. Analysis of negotiations at the WTO suggests some possible counterstrategies that developing countries might pursue.

²⁶⁵ Of course, the United States has a leading voice at the International Monetary Fund and the World Bank, and in economic and financial matters more broadly, which gives it considerable implicit leverage in trade negotiations. But this implicit leverage operates in WTO negotiations as well as in bilateral negotiations.

²⁶⁶ This is less true for developed country delegates for whom producer lobbyists are a major presence at the WTO.

²⁶⁷ News services such as the BNA publications and *Inside U.S. Trade* provide information on negotiations in disparate forums but are read mainly by specialists.

²⁶⁸ See, e.g., *Opposing the Inclusion in Future Free Trade Agreements of Provisions That Would Have the Effect of Restricting, Undermining, or Discouraging the Enactment or Implementation of Legislation Authorizing the Importation of Prescription Drugs, and for Other Purposes*, H.R. 758, 108th Cong. (2004); *House Resolution Opposes Future FTAs Against Drug Importation*, WORLD TRADE ONLINE, Sept. 14, 2004.

²⁶⁹ For example, in a question-and-answer discussion it was asked whether the U.S.-Australia FTA prevents Congress from passing legislation on drug reimportation. In its reply the USTR stated that the "FTA reflects current law in the United States. Nothing in this FTA or any other trade agreement prevents Congress from changing U.S. law in the future. Even if a dispute settlement panel found the U.S. acted inconsistently with the FTA, it could not require Congress to amend the law." USTR Fact Sheet, U.S.-Australia Free Trade Agreement, Questions and Answers About Pharmaceuticals (July 8, 2004), available at <<http://www.ustr.gov>> .

A common objective for developing countries in FTA negotiations would be to preserve flexibilities to regulate pharmaceutical products in the TRIPS Agreement, the Doha Declaration, and the Decision. Preservation of regulatory flexibility has been the common objective of developing countries in WTO negotiations so far, and they presumably continue to view this objective as a “common good.”

Developing countries have already formed important political and economic alliances that may be used as fora for the adoption and maintenance of common positions. Notable among these are regional integration arrangements, which enjoy a particularly strong tradition in Latin America and are on the increase in Africa and Asia. Developing country negotiators may see advantages to dealing with the United States in larger economic blocs, and existing political institutions associated with regional arrangements may serve as attractive depositories for commitments.

The effects of U.S. negotiations on FTAs are not limited to a particular region. By obtaining concessions in East Asia, the USTR will put pressure on negotiators in South America and southern Africa, a potential transregional “domino effect.” This possibility suggests the necessity for interregional cooperation in resisting demands for concessions. And because governments in disparate regions may see less benefit in cooperation, the politics of coalition building are likely to be the most difficult in this regard. In fact, some interregional cooperative agreements have as their purpose resisting concessions in the pharmaceutical sector.²⁷⁰ It remains unclear how effective these coalitions will be as the stakes rise in bilateral negotiations. Political commitment at a high level will be needed to sustain them.

WTO negotiations have suggested the value to developing countries of forming alliances with more powerful developed countries. Prospects for “common cause” may reside in the area of pharmaceutical regulation because on some important issues the United States has taken an approach different from that of other developed countries, and it is currently pressing others to conform to the U.S. position. Price controls are the subject of the most interest to U.S. negotiators, and the United States stands effectively alone among the OECD countries in lacking price control mechanisms.²⁷¹ U.S. PhRMA is strongly pressing to redress what it characterizes as a failure of international burden sharing in pharmaceutical research and development, which results from the refusal of other OECD countries to allow PhRMA companies to price as they do in the United States. The PhRMA-proposed remedy is to restrict or remove foreign price controls.²⁷² As noted above, in the U.S.-Australia FTA the United States won the right to challenge regulatory decisions in the PBS, which is Australia’s price control mechanism.²⁷³ PhRMA has harshly criticized Canada for its price control system.²⁷⁴ In light of the pressures and trends, the United States seems likely to continue urging other OECD countries to restrict or remove pharmaceutical price controls, and to demand conformity with its position on data protection and marketing exclusivity.²⁷⁵ These circumstances may enable developing countries to find common

²⁷⁰ At the XV International AIDS Conference, *supra* note 56, six countries (Brazil, China, Nigeria, Russia, Thailand, and Ukraine) signed an agreement to increase cooperation in developing and producing generic drugs. India and South Africa are considering joining this group. *Brazil to Coordinate Six-Country Anti-AIDS Network*, BBC Monitoring, July 16, 2004, available in LEXIS, News Library, Allnews File. According to this report, “The purpose is to form a strong alliance to withstand the interests of major laboratories,” and it will be supported by the Ford Foundation.

²⁷¹ See OECD, *supra* note 52.

²⁷² See PhRMA, *supra* note 233, at i (Introduction), 2, 7–8 (Canada), 34 (New Zealand), 57–58 (Italy), 62 (Egypt), 68 (India), 84 (Saudi Arabia), 94 (Brazil), 99 (Ecuador), 104–05 (Venezuela), 121 (Russia), 143 (CAFTA, regarding Honduras, Nicaragua, and Panama), & Appendix A, Foreign Government Price Controls Are a Major Trade Issue (referring to other countries, including Australia, Japan, and Taiwan).

²⁷³ See *supra* text at note 244.

²⁷⁴ See PhRMA, *supra* note 233, at 2, 7–8. Canada was also criticized for its refusal to accept PhRMA’s views on data protection and marketing exclusivity, and it is in the process of amending its law.

²⁷⁵ The European Union has not negotiated data protection and marketing exclusivity rules in its bilateral trade agreements with developing countries. It does, however, maintain strict internal data protection and marketing exclusivity rules, and it requires adherence to those rules as a condition to EU accession.

ground with developed countries in resisting U.S. demands for restrictions on pharmaceutical regulatory authority.

Developing countries may identify common interests outside the government-to-government coalition-building context. The United States is not monolithic. U.S. agricultural exporters, service providers (e.g., in the banking, telecommunications, and financial sectors), nonagricultural exporters (e.g., of aircraft, machine tools, and computers), and others all have substantial stakes in the outcome of FTA negotiations. The interests of these other producers and exporters are not necessarily served by supporting the major pharmaceutical companies. High health care costs, based in some measure on high pharmaceutical prices, place a significant burden on U.S. domestic industry.²⁷⁶ Developing country trade negotiators may find it useful to make a case to industry representatives from other sectors of the U.S. economy that the outcome of FTA negotiations should not hinge on pharmaceutical issues.

Since NGOs draw the attention of the public to issues, which generates news coverage, and political leaders derive their authority from the public, NGOs representing affected groups may play a significant role in resisting pressures to concede flexibilities in the pharmaceutical sector. When their interests coincide, developing country negotiators should continue to engage the support of NGOs.

This author recently suggested that agreements affecting intellectual property rights be subject to objective prior impact assessment. Such evaluations would assist all stakeholders in weighing the trade-offs involved in these agreements.²⁷⁷

Today serious cross-currents are embroiling U.S. domestic politics on the subject of pharmaceuticals. Various consumer constituencies are dissatisfied with the price of prescription medicines,²⁷⁸ state governments are seeking import supplies from Canada despite FDA prohibitions,²⁷⁹ the safety of widely sold prescription drugs has been seriously questioned, and supplies of vaccines have been interrupted.²⁸⁰ Developing countries and supporters of development interests might increase their efforts to educate American consumers (including state health authorities) about the risks of reducing regulatory flexibilities through FTAs, whose rules bind the United States.²⁸¹ In the interest of preserving domestic regulatory options, American consumers might help persuade Congress to reduce regulatory pressure on foreign governments.

Reinvigorating the Multilateral System

WTO members are negotiating to transform the Decision into an amendment to the TRIPS Agreement. The relationships between the FTAs, the TRIPS Agreement, the Doha Declaration, and the Decision might be clarified in the context of transforming the Decision into an amendment. From a legal standpoint, such clarification might require WTO members to recognize the priority of TRIPS flexibilities with respect to pharmaceutical products. A hierarchy of norms would be established. "Rights" established under the TRIPS Agreement, the Doha Declaration, and the Decision would not be subject to derogation in another agreement. A breach of this obligation in the application of an FTA might give rise to a WTO-based cause of action on the part of any affected member. While such an obligation would not preclude actions by one member

²⁷⁶ It is not clear that companies such as General Motors have strong motivation to support Pfizer's position on strengthening protection for originator medicines. *See, e.g.*, Danny Hakim, *Carmakers Face Huge Retiree Health Care Costs*, N.Y. TIMES, Sept. 15, 2004, at A1 (discussing serious financial problems facing major automobile producers in paying for prescription drugs for employees and retirees).

²⁷⁷ *See* Abbott, *supra* note 264.

²⁷⁸ *See, e.g.*, Kaiser Health Poll Report, Views on Prescription Drugs and the Pharmaceutical Industry (Jan.–Feb. 2005), at < http://www.kff.org/healthpollreport/feb_2005/ > .

²⁷⁹ *See, e.g.*, Pam Belluck, *Vermont Will Sue U.S. for the Right to Import Drugs*, N.Y. TIMES, Aug. 11, 2004, at A13; Pam Belluck, *Maine and One of Its Tribes Look to Buy Canadian Drugs*, N.Y. TIMES, Oct. 1, 2004, at A12.

²⁸⁰ Gardiner Harris, *F.D.A. Failing in Drug Safety, Official Asserts*, N.Y. TIMES, Nov. 19, 2004, at A1; Jeff Nesmith, *FDA Hit on Vaccine Oversight*, ATLANTA J.-CONST., Nov. 18, 2004, at 1A.

²⁸¹ Importantly, however, the United States denies self-executing effect for the FTAs. *See, e.g.*, United States–Morocco Free Trade Agreement Implementation Act, S. 2677, 108th Cong., §102 (2004).

against another member under the terms of an FTA, an FTA action might give rise to a separate claim at the WTO.

In the Doha Declaration, WTO ministers expressly recognized the right of WTO members to protect the health of their citizens.²⁸² This right should be given effect by the members, and by the Dispute Settlement Body.²⁸³ For example, WTO members might consider whether FTA provisions regulating access to medicines may impede the right to protect public health, at least in specific contexts. This possibility has already been raised by UN human rights organs.²⁸⁴ The WTO Committee on Regional Trade Agreements might be charged with evaluating this question.²⁸⁵ Ultimately, the WTO Dispute Settlement Body might consider whether a member's right to protect public health, as acknowledged in the Doha Declaration, has been impaired by a term in an FTA or by its implementation.

Additional avenues might be explored by developing country members that would question the compatibility of the terms of FTAs applicable to pharmaceutical products with WTO rules. This approach would include review for consistency with the most-favored-nation treatment provision of the TRIPS Agreement, as to which there might be a claim of de facto discrimination against generic pharmaceutical exporters.²⁸⁶ Rules regarding the assessment of pharmaceutical products might also be reviewed for consistency with the Agreement on Technical Barriers to Trade, which is aimed at ensuring that technical regulations do not create unnecessary obstacles to international trade. Analysis of these questions is a matter of some complexity, and is best reserved for another forum.

VI. CONCLUSION

The international system for regulating pharmaceuticals must address the needs of the rich and the poor. When patented medicines are not affordable, governments must act. The principal mechanisms for intervention by governments until now have been regulation of prices, compulsory licensing, and transfer payments.²⁸⁷ The Pharma companies are asking for and obtaining stronger protection for patents and regulatory data, and the reduction or elimination

²⁸² Doha Declaration, *supra* note 1, para. 4, *quoted in text* following note 90 *supra*. Discussion in the academic literature regarding the place of human rights norms in the WTO legal system is largely predicated on the coexistence of rules developed in different fora and contexts. See Gabrielle Marceau, *WTO Dispute Settlement and Human Rights*, in INTERNATIONAL TRADE AND HUMAN RIGHTS: FOUNDATIONS AND CONCEPTUAL ISSUES (World Trade Forum Vol. 5, Frederick M. Abbott, Christine Breining-Kaufmann, & Thomas Cottier eds., forthcoming 2005).

²⁸³ It has been suggested that the statement in the Doha Declaration does not import a right to health into the WTO legal system and that in any case the nature of the "right to health" is complex and not well-settled. As to the first point, the text of the Doha Declaration speaks for itself, and the Appellate Body continually stresses that the words of WTO texts are there for a purpose. As to the second point, neither of the trade terms "national treatment" and "most-favored-nation treatment" is self-defining, but that has not prevented the WTO Appellate Body from giving them meaning.

²⁸⁴ The UN Committee on Economic, Social and Cultural Rights warned Ecuador about the potential negative impact of the CAFTA on the right to health. 3D Press Release, UN Committee Warns Ecuador that US-Andean FTA Must Not Undermine Human Rights (May 18, 2004). The UN Committee on the Rights of the Child issued a warning in reference to CAFTA negotiations including the United States and El Salvador. 3D Press Release, UN Committee Warns El Salvador That IP Rights in CAFTA Must Not Undermine Children's Rights (June 2004). Both press releases are available online at <<http://www.3dthree.org>>.

²⁸⁵ The relationship between WTO rules and the rules of regional arrangements, and the problems raised by multiple dispute settlement forums are complex. At this stage, attention is drawn to the possibility for overlap and conflict, while addressing those matters is left for future inquiry. See generally Frederick M. Abbott, *The North American Integration Regime and Its Implications for the World Trading System*, in THE EU, THE WTO AND THE NAFTA 170 (9 Collected Courses of the Academy of European Law, bk. 1, J. H. H. Weiler ed., 2000).

²⁸⁶ The WTO Appellate Body has referred to the most-favored-nation (MFN) principle (Art. 4) as a fundamental element of TRIPS, although prior to the TRIPS Agreement MFN was not a principle of the international intellectual property system. On a historical basis, there is little international precedent for applying MFN to intellectual property rights. A considerable amount of GATT/WTO and EU jurisprudence concerns the use of facially neutral measures as disguised trade barriers. It may at least be worth exploring whether some developing country generic producers may be suffering de facto MFN discrimination by importing members of FTAs as a consequence of the new FTA rules, which may effectively grant preferences to originator companies principally based in a few WTO members.

²⁸⁷ "Transfer payments" can take many different forms, including the establishment of health insurance arrangements with redistributive effect, and grants for financing the purchase of medicines, as in the case of the Global Fund.

of price controls. From this author's perspective, stronger monopolies and reduced regulatory flexibility threaten to exacerbate the already alarming disparity in medicinal treatment between rich and poor throughout the world. The Doha Declaration and the Decision at the WTO are aimed at securing a modicum of balance. However, preserving even these modest accomplishments has turned into a struggle.

There may be a better international approach than the present one to the development and distribution of new medicines. The current system involves constant tension between patent holder and consumer, mediated through a complex body of rules. The objective of this article is not to recommend a better approach, but to emphasize that the equitable functioning of the present system depends on checks and balances. The Decision may not be the first-best instrument from anybody's perspective, but it does give countries lacking adequate manufacturing capacity some flexibility to make use of compulsory licensing—one of the core balancing mechanisms. The adoption of the Decision shows that the WTO can address important issues of social concern. But adoption standing alone does not show that the WTO can do so effectively. Effective implementation of the Decision is threatened by newly negotiated bilateral and regional agreements. The WTO's effectiveness can be better assessed if, and when, developing countries actually use the Decision to address their public health needs.